



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

Report of the investigation  
into the safety, quality  
and standards of services  
provided by the Health  
Service Executive to patients  
in the Midland Regional  
Hospital, Portlaoise

8 May 2015

*Safer Better Care*



# About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive high-quality and safe care for people using our health and social care services. HIQA's role is to promote sustainable improvements, safeguard people using health and social care services, support informed decisions on how services are delivered, 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.
- **Supporting Improvement** — Supporting health and social care services to implement standards by providing education in quality improvement tools and methodologies.
- **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.

## **Note on terms and abbreviations used in this report**

A full range of terms and abbreviations used in this report is contained in a glossary at the end of this report

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## Executive summary

### Introduction and background to the investigation

This report presents the findings of the investigation by the Health Information and Quality Authority (the Authority or HIQA) into the governance and assurance arrangements that the Health Service Executive (HSE) has in place to ensure the safety, quality and standard of services provided to patients in the Midland Regional Hospital, Portlaoise (Portlaoise Hospital), Co Laois.

On 30 January 2014, the RTÉ Investigations Unit broadcast a *Prime Time* programme about the tragic deaths of newborn babies in Portlaoise Hospital and the subsequent management of patients and their families by the hospital and the HSE. Following the broadcast, the then Minister of Health asked the Chief Medical Officer of the Department of Health to conduct a preliminary assessment of perinatal deaths and related matters from 2006 up to that point in 2014 in the maternity services at Portlaoise Hospital.

Following publication on 28 February 2014 of the Chief Medical Officer's report, the Board of the Authority considered and agreed to a request from the then Minister for Health to conduct an independent investigation into the services provided by the HSE at Portlaoise Hospital. This statutory HIQA investigation, announced by the Authority on 6 March 2014, has been carried out in line with the Authority's published Terms of Reference in order to make recommendations to improve the safety, quality and standards of services provided by the HSE.

As part of this investigation, the Authority considered the effectiveness of the HSE's role in overseeing a hospital where concerns about the quality and safety of services had been raised previously on a number of occasions. The Authority also reviewed the progress that had been made in ensuring that the findings from previous investigations and reviews conducted by HIQA, the HSE, the Chief Medical Officer and others had been implemented. Essentially, this included an assessment against the hospital's service model to assure the delivery of high-quality, safe and reliable care.

Central to this HIQA investigation was the experience of a number of patients and families whose experience of care fell well below the standard expected in a modern acute hospital. The assessment of these patients and families' experience reflects their experience of care and its aftermath when they raised concerns at local and national levels of the HSE. In line with the Terms of Reference, to assess the patient safety culture at Portlaoise Hospital, the Authority used the Safety Culture Index – a survey developed by Applied Research Ltd working from Warwick University in the United Kingdom.

This investigation examined the quality and safety of clinical services, and the governance arrangements in place for the maternity and the general healthcare services at Portlaoise Hospital and how these were governed by the HSE's

relevant national directorate. This report also reflects interim governance arrangements and changes that have occurred at the Maternity Department since February 2014.

Upon publication of the Terms of Reference on 21 March 2014, the Investigation Team commenced gathering and reviewing information in line with the investigation's methodology. The review of pre due process evidence was completed by the end of October 2014. The Investigation Team then began writing a draft report with reviews and contributions from the external members of the Investigation Team and the Board of the Authority. For ease of readership all events which occurred following the end of October 2014 are reflected as footnotes throughout the report.

On 2 February 2015 relevant excerpt(s) of the draft report were circulated for the purpose of due process feedback to relevant healthcare professionals and healthcare managers who were interviewed as part of this investigation. The final submissions for due process were received by 20 April 2015.

Portlaoise Hospital opened in 1936 and is funded by the HSE. It is an acute general and maternity hospital with a mental healthcare service on site. Portlaoise Hospital has 151 beds in total; 108 adult beds (including 29 inpatient maternity beds), 29 paediatric beds and 14 day beds. The general services at Portlaoise Hospital include elective (pre-arranged care) and emergency adult and children's services on an inpatient, day and outpatient basis. The hospital employs 552 whole-time equivalent staff, equating to over 600 members of staff.

## **Investigation findings**

In his report, the Department of Health's Chief Medical Officer said two previous HSE reviews published in 2008 into breast cancer misdiagnosis cases at Portlaoise Hospital should have provided a very strong case for 'external oversight and support to Portlaoise Hospital as it dealt with the legacy of those issues'. The Authority strongly reiterates this view, particularly as throughout this investigation it found examples of weak oversight and inaction by the HSE at local, regional and national level in relation to the model of clinical services being delivered and the associated risks to patients identified at Portlaoise Hospital.

Six previous investigations into hospital care in Ireland have been carried out by the Authority between 2007 and 2013. These have made a number of important findings and recommendations which were intended to be used by all healthcare services to inform and improve practice. Had the relevance of these investigation findings been reviewed in the context of Portlaoise Hospital and the aligned recommendations been subsequently implemented, the Authority is of the opinion this could have vastly reduced the identified risks in the services being provided to patients.

Consequently, the Authority has once again recommended that prior to the hospital-group management boards being formalised, that the HSE assign responsibility and

accountability to a named person or persons for implementing recommendations and actions contained in internal and external reviews and investigation reports.

Two previous HIQA reports with particular relevance to Portlaoise Hospital were the investigation reports into Ennis and Mallow hospitals, published in 2009 and 2011 respectively. In particular, these reports identified the risks associated with treating low numbers of acutely ill patients in smaller, stand-alone hospitals without having senior clinicians on site 24 hours a day. Both reports stressed that patients with complex needs should be directed to hospitals with the necessary staffing, competencies, infrastructure and equipment for safe and effective care.

This current investigation found that the HSE – as the provider of healthcare services – failed to take decisive action on defining the role of Portlaoise Hospital and its model of care in the context of the findings of previous investigations. Corporately Portlaoise Hospital viewed itself as a model-3 hospital and was not included in the national *Smaller Hospitals Framework*. Similar to a model-3 hospital, Portlaoise provided a full range of acute services to patients presenting with all manner of injury and illness, including life support. However, at the time of this investigation, the HSE had failed to resource the hospital sufficiently and to ensure that the governance arrangements in place could safely deliver such a model of care to patients. For example, up until July 2014 the Emergency Department at the hospital – which was open 24 hours a day seven days a week – only had a consultant in emergency medicine on site for six hours four days a week.

Alongside the *Smaller Hospitals Framework*, the report, *Establishment of Hospital Groups as a transition to Independent Hospital Trusts* was published by the Department of Health in 2013. This report outlined how Ireland's acute public hospitals would be organised into seven groups of hospitals, each containing smaller and larger hospitals. It recommended that Portlaoise Hospital be part of the Health Dublin Midlands Group.\* At the time of the investigation, the formation of this hospital group, like a number of other hospital groups, was still at an early stage.

In the interim, at the time of this investigation, Portlaoise Hospital continued to operate in the absence of formal systems enabling clinical cooperation and communication between it and some of the larger training hospitals that are to be involved in the group. The Chief Medical Officer's report made a specific recommendation about ensuring the networking of senior clinical leadership between the larger Coombe Women and Infants University Hospital in Dublin and the maternity unit within the smaller Portlaoise Hospital.

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\* The Health Dublin Midlands Group contains the following hospitals: St James's Hospital, Dublin; The Adelaide and Meath Hospital, Dublin, Incorporating the National Children's Hospital; Midland Regional Hospital Tullamore; Naas General Hospital; Midland Regional Hospital, Portlaoise; and the Coombe Women and Infants University Hospital, Dublin. Its primary academic partner is Trinity College Dublin (TCD). This group has subsequently been renamed the Dublin Midlands Hospitals Group.

At the time of reporting in May 2015 – some 13 months after the publication of this recommendation by the Chief Medical Officer – these arrangements were still not in place.\*\*

## The patient experience

This investigation was initiated as a result of the very negative experiences of a number of patients and their families in receipt of services in Portlaoise Hospital. When the investigation started, the Authority was contacted by or received information in relation to 83 patients and their families, most of whom had used the maternity services at Portlaoise Hospital. Some were identified after contacting the HSE helpline set up after the airing of the RTÉ Investigations Unit *Prime Time* programme in January 2014. Members of the Investigation Team facilitated meetings with patients and or their family members to learn about the experience of 15 individual patients.

The Authority and Investigation Team wish to convey their sympathies to those affected by the events which gave rise to this investigation, and to express their gratitude to the people who contacted or who met with the Authority as part of this investigation.

While the purpose of the investigation was not to undertake a detailed examination of individual patients' care, their experiences helped to inform the investigation and give the Investigation Team a range of personal perspectives on the quality of care experienced by those individuals. The Authority acknowledges that such recollections are personal perspectives on their experiences and that the validation and or verification of each of those experiences are outside the scope of the investigation.

Those parents who spoke with the Investigation Team gave examples of poor communication with hospital staff where they were not afforded adequate explanations following an adverse event including the death of a baby or regarding their clinical condition. Some parents said they felt that they were not entitled to an explanation. Others said that unexplained medical jargon left them feeling intimidated and unclear as to what was being said. Parents found that such lack of openness in providing information and explanations compounded their feelings of fear and grief.

Parents also described significant delays in the time it took the HSE to respond to their requests for information and explanations following adverse events. The Authority is aware that such delays in the investigation of adverse events have occurred elsewhere in the health services. The current HSE review process is often protracted and leaves families with unanswered questions pending completion of a final report, thereby increasing their upset and trauma.

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\*\* On 26 March 2015, the Minister for Health announced that a memorandum of understanding was signed between The Coombe Women and Infants University Hospital and the Dublin Midlands Hospital Group/ Health Service Executive which will see the Coombe Women and Infants University Hospital assume responsibility for the governance, management and provision of maternity services at Portlaoise Hospital.

Additionally, safety issues may potentially remain unidentified and unresolved for lengthy periods of time.

The experiences described by parents highlighted an apparent lack of skill and sensitivity among some staff, including management, in communicating sensitively and empathising with people. Some parents described having very different and more positive experiences in other hospitals.

The experiences described by those patients and families who spoke to the Authority highlighted significant deficiencies in the delivery of person-centred care at the hospital. The interactions that the Authority had with patients and their families also raised significant concerns about the lack of a formal integrated national response to address their ongoing needs. This fell outside the Terms of Reference of the investigation and outside the remit of the Authority as a regulator. As a consequence, in June 2014, the Authority formally wrote to the then Minister for Health Dr James Reilly TD and raised these issues both as a concern and a risk.

Subsequently, a single contact person was identified in the HSE to assist these patients and their families. In October 2014, a HSE report indicated that a total of 176 complaints or contacts have been made by patients through a variety of channels and that these complaints were being dealt with on a phased basis. While these cases involved a number of hospitals, the vast majority of them related to the maternity services at Portlaoise Hospital.

As part of this process, the HSE committed to reviewing each person's experience on an individual basis and to facilitate an independent external clinical review of patient care where necessary.

## **Governance Health Service Executive – National**

There were many reasons why the HSE should have maintained very close oversight of the quality and safety of services at Portlaoise Hospital. These reasons included local and national HSE inquiries and clinical reviews into patient-safety incidents, significant service failures, statutory investigations of hospital services, and resultant publication of findings and recommendations. However, there was no evidence that the HSE nationally was proactively exercising meaningful oversight of the hospital and the inherent risks there. Up until the publication of the Chief Medical Officer's report in February 2014, it appeared that senior HSE managers were predominantly focused on controlling healthcare expenditure.

Another concern for the Investigation Team was that for seven years prior to the Chief Medical Officer's report, the State Claims Agency through its Clinical Indemnity Scheme knew of actual or potential risks in the maternity services at Portlaoise Hospital. The Investigation Team recognises that the State Claims Agency does not have statutory powers by which it can compel healthcare institutions, including the HSE, to engage with it or to implement any recommendations which it may make. However, the Investigation Team was concerned that the interaction between the State Claims Agency and the

HSE in relation to the sharing and use of available information did not result in effective mitigation of the identified risks. In addition, some senior HSE managers informed the Investigation Team that before the RTÉ Investigations Unit *Prime Time* programme they were unaware of safety concerns at Portlaoise Hospital.

Evidence gathered during the course of this investigation showed that up until late 2014, patient safety issues were not a standing agenda item for discussion at meetings of the Health Service Directorate, the highest level of management within the HSE. Despite the seriousness of the patient safety concerns at the hospital at the time of the *Prime Time* programme, there was no evidence that key senior HSE managers had visited the hospital in the immediate aftermath of the broadcast to assess the situation in the maternity services.

During the course of the investigation, many of the senior HSE managers interviewed placed significant weight on the organisation's future plans, particularly in the context of the patient quality and safety agenda and the development of the hospital-group structures. The Authority is of the opinion that the success of the emerging hospital-group structure depends on:

- developing formal clinical arrangements which facilitate a stronger focus on identifying and managing clinical risks and incidents
- improved clinical cooperation with robust arrangements to ensure that higher-risk patients are managed at the most appropriate clinical site within the group.

### **Clinical services at Portlaoise Hospital – national planning and oversight**

Contrary to the findings and recommendations of the Authority in 2009 and 2011 in investigation reports into acute general hospital services similar to Portlaoise Hospital, the Investigation Team found that Portlaoise Hospital continues to provide:

- undifferentiated (all manner of conditions) emergency services 24 hours a day 7 days per week (24-seven), and
- undifferentiated surgical services where there is a low number of complex surgical cases.

In addition, the Investigation Team found that Portlaoise Hospital had other major deficiencies in corporate and clinical governance arrangements including not having:

- effective corporate accountability arrangements and performance management processes
- effective clinical governance arrangements in the Emergency Department
- effective risk management structures to include dealing with adverse patient events and or complaints
- effective clinical audit arrangements
- comprehensive systems of workforce planning.

Although described as a 'model-3 hospital' by senior HSE and local hospital staff, the Investigation Team found that the hospital was neither governed, resourced nor equipped to safely deliver this level of clinical services. Furthermore, the HSE itself in 2012 and 2013 had specifically identified clinical risks associated with surgery and emergency medicine, going as far as to say that surgical services at the hospital should cease. However, at the time of publication of this report, the hospital continues to deliver these services.

It was also notable to the Investigation Team that an unpublished 2014 HSE report had reinforced its findings about performance, quality and safety issues within the hospital. Senior HSE managers reported to the Investigation Team that as a result of the findings contained in that HSE report, they had:

- assigned a senior HSE manager to work on site with the hospital management team to ensure that patient pathways of care were safe
- reinforced the paediatric trauma bypass protocol, whereby children with certain serious conditions would be taken by ambulance to another hospital
- begun the process of creating the hospital-group structure, citing examples of clinicians meeting to work towards agreeing the best possible patient pathways and service model for people attending Portlaoise Hospital.

At the time of reporting, it was too early for the Investigation Team to assess the efficacy or impact of these arrangements. The Investigation Team is of the view that these plans, which are long term, are intrinsically dependent on the formation of a hospital-group structure supported through effective clinical and corporate governance structures and arrangements.

## **Corporate and clinical governance arrangements in Portlaoise Hospital – HSE regional and local structures**

### **Regional structures**

The HSE assumed responsibility for providing health and social care services in Ireland in 2005 with Portlaoise Hospital becoming part of the HSE Dublin Mid Leinster Region, the largest of the four HSE regions which catered for a population of 1.31 million.

In 2013 following interaction with the Authority in relation to concerns about the governance arrangements in place at Portlaoise Hospital, the then HSE regional management altered the local management arrangements that were in place. The purpose of these alterations was to increase the interaction between regional and local management structures and bring decision-making powers onto the hospital site.

However, it is apparent that despite overwhelming evidence to indicate that the local management team at Portlaoise Hospital was struggling to deliver the service, there is no evidence to show that regional HSE managers took effective

control of the situation at that time. For example, although the HSE was aware of risk management deficiencies at the hospital, known risk management gaps were not actively addressed. Furthermore, in December 2012 the Authority raised with the HSE the immediate requirement to appoint an experienced and qualified risk manager to the hospital. However, this did not happen.

Following the RTÉ Investigations Unit's *Prime Time* programme in January 2014, relevant minutes from regional quality and patient safety committee meetings held during February 2014 do not detail any remedial action at regional level to either deal with the issues raised in the television programme or to support local managers in dealing with its aftermath.

### **Local management at Portlaoise Hospital**

The local management team within the hospital – which consisted of the Hospital Manager, the Director of Nursing and the Clinical Director, reporting collectively to a regionally based Assistant National Director – were responsible for all clinical services including maternity services up until the publication of the Chief Medical Officer's report in February 2014. As an immediate response to that report, the HSE revised the management structure and at the time of the investigation the maternity services were being governed separately. Management arrangements for the general services remained the same.

A Senior Hospital Management Committee was responsible for providing safe effective services through leading and directing the performance of the hospital. Only nine meetings of this Committee were recorded as taking place between April 2013 and March 2014. In the minutes of meetings reviewed by the Investigation Team, there was little evidence to show that the Committee was effective in identifying or implementing actions aimed at addressing quality and safety issues within the hospital.

A Quality and Safety Executive Committee was in place for the hospital. This Committee has approximately 20 different local committees reporting into it. In a hospital the size of Portlaoise Hospital, this committee structure was overly complicated and not effective. The same small group of people were responsible for directing the implementation of quality and patient safety at local committee level and overseeing the entire process at executive management level.

It was also evident that at this time, the hospital's senior management team did not collectively conduct formal safety walk-rounds.

There was poor connection between local and regional risk management structures. The Investigation Team found that local and regional managers had very different opinions on what constituted the most immediate and serious risks for Portlaoise Hospital.

There was no evidence to show that the Portlaoise Hospital management team used these structures to address issues of concern with more senior regional managers in order to achieve positive outcomes for the hospital.

The Investigation Team concluded there were significant ongoing problems with workforce planning relating to Portlaoise Hospital. The absence of a clear vision for the hospital coupled with the national imperative to reduce the staff headcount ensured that workforce planning was focused on counting staff rather than on the type of service the hospital should be delivering and the workforce needed to deliver that service.

Risk management structures in the Hospital were poorly developed with the result that risks were not comprehensively reviewed or addressed at a senior level in an effective and proactive manner. The risk management system did not capture all known risks in the hospital, for example risks identified following investigation of complaints and clinical incidents were not included.

It was evident at interview that not all hospital staff had confidence in the local and regional systems in place to deal with and resolve risk issues. Staff members described an endless process of escalation which did not result in informative feedback or tangible results.

The process of incident management at Portlaoise Hospital was largely a reactive process focused on recording incidents that occurred. Incident forms were not entered on to the National Incident Reporting Database at a local level. Rather they were inputted at a regional level. This process meant that there was no validation or ownership to ensure that what was entered on to the incident reporting system was accurate and timely.

A crucial step in the management of adverse incidents is the review of incidents which have occurred. The management team at Portlaoise hospital did not corporately collate, analyse, trend or use this information proactively to address risks, investigate incidents and share any resulting learning. It was evident that the deficiencies in risk management processes in the hospital contributed to the poor experiences as described by patients who met with the Investigation Team.

At the time of the investigation, Portlaoise Hospital did not have a dedicated on-site complaints manager. Complaint management was assigned, along with multiple other duties, to one individual. The Hospital did not manage complaints in line with the national HSE complaints management process. In particular, complaints were not managed within recommended time frames and patients were not updated about delays in addressing their complaints.

The Investigation Team found that there was no evidence that learning following investigations into specific complaints was put into practice for the benefit of other patients. The Investigation Team concluded that the arrangements in place to effectively manage patient complaints at Portlaoise Hospital was inadequate. In October 2014, senior managers at the hospital reported that significant changes were being made to improve the complaints management process at Portlaoise Hospital.

Although there was evidence of some clinical audits being carried out in different areas of the hospital, there was no strategic plan for clinical audit across the hospital. The regional clinical audit function in place at the time was described as 'supportive and advisory', but no dedicated staff member was in place on site with oversight of an audit programme. In addition, the hospital did not have the information technology structures necessary to support an effective system of multidisciplinary audit.

### **Patient safety culture in Portlaoise Hospital**

As part of the investigation, HIQA assessed the prevailing patient safety culture in Portlaoise Hospital using an assessment tool called the Safety Culture Index. The results, which were used to inform the lines of enquiry of this investigation, suggested that Portlaoise Hospital did not have a strong safety culture. At an organisational level, the results indicated an absence of standard monitoring and the lack of a clear vision and mission for the hospital. While there were different perceptions about safety culture between staff groups at the hospital, the results from most staff groups indicated an immediate need for management intervention or monitoring of the safety culture.

In August 2014, the Investigation Team provided the HSE with a report of the assessment of the patient safety culture at Portlaoise Hospital. The Investigation Team advised the HSE that this report should not be viewed in isolation but rather as a starting point from which action planning begins and effective safety initiatives emerge. At a final meeting in October 2014 with senior managers in Portlaoise Hospital, some senior managers at the hospital reported that they had not been provided with the results by HSE management. The Investigation Team views this as a missed opportunity, particularly as the process yielded a report that could be used to inform the development of a culture of safety.

### **Maternity services at Portlaoise Hospital**

The continued absence of a national maternity strategy as recommended by the Authority in 2013 makes it difficult to assess and compare maternity services in Ireland.\*

Furthermore, a clinical governance network linking Portlaoise Hospital's Maternity Department to the Coombe Women and Infants University Hospital, as recommended by the Institute of Obstetricians and Gynaecologists in 2006 and in the Chief Medical Officer's report, has not formally been implemented.

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\* On 30 April 2015 the Minister for Health announced the establishment of a Steering Group to advise on the development of a National Maternity Strategy and published a list of its membership.

Such a clinical network would facilitate:

- a common system of governance
- capacity for medical, midwifery and other staff to be appointed to the network and to rotate between the two sites to facilitate training and service delivery
- training of junior doctors and midwives on both sites
- risk categorisation of patients to ensure that higher risk patients are managed at the Coombe Women and Infants University Hospital.

The Investigation Team advised that the development of such a clinical network is an essential step in ensuring the quality and safety of the maternity services at Portlaoise Hospital by creating one single maternity service operating over two sites.

Increasing pressure on the maternity services at Portlaoise Hospital was highlighted as far back as 2004. Additionally, deficiencies in midwifery staffing had been identified in a review carried out by the hospital in 2006. These issues were not substantially addressed until 2014, following publication of the Chief Medical Officer's report.

Local management structures in Portlaoise Hospital were revised in early 2014 following publication of the Chief Medical Officer's report. An Interim Maternity Services Management Team was appointed. There was evidence to show that this arrangement was working well.

The pivotal appointment of a director of midwifery to a maternity department located within a general hospital is unique to Portlaoise Hospital. This role has had a very positive influence in terms of assessing and improving the standard of midwifery care, enhancing multidisciplinary working relationships, improving staff morale and re-energising a patient-centred approach to care. However, at the time of writing, a senior obstetric lead had not been appointed to the Maternity Department to provide independent senior experienced obstetric clinical leadership. This is despite a direct request by the Authority to the Director General of the HSE in September 2014 to do so because of the investigation team's concerns about the absence of adequate clinical leadership within the maternity unit and the failure to progress the development of a clinical network with the Coombe Women and Infants University Hospital.

Since the Chief Medical Officer's report, midwifery staffing levels have been significantly improved with the appointment of senior clinical midwifery managers, shift leaders, a bereavement specialist, a clinical skills coordinator and a clinical midwife specialist. One additional consultant obstetrician has also been appointed.

Clinical experts on the Investigation Team identified the current staffing arrangements for non-consultant hospital doctors (NCHDs) as a serious concern and risk for the sustainability of the maternity services at Portlaoise Hospital.

These experts considered it vital that a clinical network and system of rotation be designed between Portlaoise Hospital and a large maternity hospital such as the Coombe Women and Infants University Hospital. Setting up a clinical network incorporating Portlaoise Hospital and the Coombe Women and Infants University Hospital is an essential first step in developing such a system of rotation.

Poor standards of multidisciplinary communication were highlighted by a number of people who met with the Authority. Yet, these concerns were reported as far back as 2007 and had not been addressed. Multidisciplinary communication had also been highlighted as problematic in the safety culture assessment carried out as part of this investigation.

Before the Chief Medical Officer's report, the Maternity Department at Portlaoise Hospital did not have a midwife or a social worker in post to support bereaved patients, parents and families. At the time of reporting, a midwife had been appointed to the role of bereavement specialist and three midwives were also undertaking formal training in the care of bereaved patients. In addition local guidelines in relation to pregnancy loss and perinatal death had been developed and implemented by the Maternity Department.

Concerns in relation to the governance arrangements for ultrasound scanning services at Portlaoise Hospital were identified during the investigation. Specific issues in relation to service capacity, staff competency and clinical oversight of the ultrasound service were acknowledged by the hospital management team. However, despite awareness of these concerns at the time of the investigation, the effectiveness of ultrasound services had not been comprehensively evaluated through clinical audit to identify and address potential risks to patients.

In January 2015, the Investigation Team was informed that three obstetric registrars and one additional consultant obstetrician were in the process of completing formal training in ultrasound scanning. In addition a revised model of service had been agreed with consultant obstetricians in the hospital whereby a consultant with formal accreditation in fetal ultrasound scanning would assume a clinical lead position in relation to scanning.

While existing facilities in the Maternity Department had undergone some refurbishment and essential renovations, major inadequacies remained in its infrastructure, presenting an inherent risk to patient safety. Plans to commission and resource new maternity facilities are under consideration at the time of preparing this report but had not been agreed.

## General hospital services

### Emergency Department

Portlaoise Hospital provides a 24-seven emergency service for adult and paediatric patients with any degree of seriousness or complexity of illness or injury who present themselves at the hospital.

The clinical governance arrangements in the hospital's Emergency Department were unsatisfactory and overcomplicated. Despite the fact that both the HSE's Emergency Medicine Programme and the HSE's Acute Medicines Programme had previously identified concerns in relation to these arrangements, the inherent risks remained unaddressed.

The HSE's own Emergency Medicine Programme considered that the Emergency Department was not appropriately resourced to provide a 24-seven model of emergency care. Also, the HSE's unpublished performance review in 2014 concluded that a 24-seven emergency care service at Portlaoise Hospital was not clinically sustainable. Despite these reports, neither the HSE nor Portlaoise Hospital effectively collected nor analysed emergency department data at the hospital to best inform service delivery. This means that at the time of this investigation the clinical profile of Emergency Department patients is not being actively assessed to inform the type of service that is required to best meet the needs of those patients presenting to it.

### Intensive and critical care

The overall volume of critical care activity within the Intensive Care Unit of the hospital was low, hindering the ability of staff to maintain their clinical skills. Floor space was limited in the Intensive Care Unit, and it was not self-contained. The Intensive Care Unit does not meet the minimum requirements for critical care, patient confidentiality and privacy and was not fit for purpose. Senior clinical staff were aware of the limitations of the care that could be safely provided there. They confirmed that if necessary, patients are transferred to a more appropriately resourced hospital for care.

A report by the HSE in 2014 recommended that critical care services in the hospital should be discontinued. This HSE report acknowledged that on-site anaesthesia cover would be required for obstetric patients and that pre-hospital emergency care resources would have to be reconfigured to divert patients requiring admission to an intensive care unit to another facility. In light of this HSE review and the concerns of senior local clinicians, the Investigation Team is not assured that critical care services are sustainable in Portlaoise hospital.

## **Surgical services**

The surgical services at Portlaoise Hospital operate a 24-seven emergency service, catering for all degrees of surgical illness or injury arriving at the hospital. Most hospital inpatients using the surgical services at Portlaoise Hospital were admitted through the Emergency Department.

Two recent clinical reviews of the surgical services at Portlaoise Hospital, both concluded that the Hospital on its own was not structured to provide safe, acute and pre-planned surgical care. In particular, one of these reviews outlined serious concerns about significant surgical risks in the hospital, and advised that these risks could only be dealt with in the context of providing a rationalised surgical service within a hospital-group setting. Such a setting would help develop a clinical network approach to service delivery which would ensure that each hospital site within the group delivers care appropriate to the resources, facilities and services available on that site.

The Investigation Team found that low numbers of complex surgical procedures were being carried out at the hospital. As previously reported by the Authority, surgeons who do not have the opportunity to treat sufficient numbers of patients and or carry out a sufficient volume of procedures run the risk of becoming de-skilled. This potential risk has not been addressed in Portlaoise Hospital.

Despite the findings of the HSE reviews, Portlaoise Hospital was in the process of appointing two colorectal surgeons at the time of the investigation. Such appointments did not reflect the surgical demand, general practitioner (GP) patient referral patterns, or any clear direction for the hospital and are contrary to previous findings that the service was not set up to provide safe pre-planned surgery.

## **Medical services**

The Investigation Team found that medical services at Portlaoise Hospital required significant restructuring and resourcing in order to deliver a service aligned to the HSE's Acute Medicine Programme. Despite the recommendations of the HSE's Acute Medicine Programme, the hospital did not have a medical assessment unit or a bed management structure.

This investigation also found that the medical team was under-resourced, with local clinicians reporting that two additional medical consultants were needed for care of the elderly and endocrinology. These appointments would also help release the hospital's Clinical Director from general medical duties for 25 hours each week in order to increase time for the functions of the clinical director role. However, the model of care at the time of the investigation (and its associated risks) remained unchanged.

## Diagnostic imaging

The diagnostic imaging service at Portlaoise Hospital is significantly under-resourced with a lack of resources preventing the development of strong clinical governance arrangements to ensure the quality of service delivery. At the time of reporting, the diagnostic imaging service is overly reliant on one lead clinician. Therefore, this model of care is clearly not sustainable. A clinical network linking Portlaoise hospital with other hospitals in the group would provide support for clinicians as well as centrally agreed protocols and care pathways, and opportunities for peer review and quality assurance across hospitals.

Despite these constraints, there was evidence of regular clinical audit within the diagnostic imaging services, the recent implementation of 24-seven computerised tomography (CT) scanning, with reporting of scans being introduced since October 2013, and improved information technology systems to facilitate viewing and reporting of images.

## Conclusion

The findings of this investigation reflect an ongoing failure on the part of the HSE to evaluate the services provided at Portlaoise Hospital against the risks and recommendations identified in previous local and national reviews and investigations conducted by the Authority and the HSE.

The findings of this HIQA investigation highlight again issues and recommendations that have been identified on a number of occasions previously in both internal HSE reviews and independent HIQA investigations.

The HSE conducted a number of local and national reviews of services at Portlaoise hospital. The HSE National Clinical Programmes also reviewed the model of clinical services provided with particular reference to emergency medicine and adult and paediatric surgical services, highlighting significant patient safety concerns.

This investigation concludes that Portlaoise Hospital was allowed to struggle on despite a number of substantial governance and management issues in relation to the quality, and safety of services. Sufficient action was not taken by the HSE at a national, regional or local level to address these issues.

At the time of reporting there was still no national maternity strategy. Also, while it had been recommended in 2006 and again in 2014 that Portlaoise Hospital be formally integrated into a clinical network with the Coombe Women and Infants University Hospital, this was in the very early stages of implementation at the time of reporting. While significant progress has been made in restructuring the maternity service at Portlaoise Hospital, until the memorandum of understanding is fully implemented and operational, this service continues to function in isolation without the support of a maternity-services network of care and without an assured clinical leadership arrangement.

The establishment of formal clinical networks is a critical point in the modernisation of the Irish healthcare system. Each hospital group must prioritise the development of systems of care that embody quality and safety at all levels including managed clinical networks for maternity services.

Every healthcare system must ensure that national, regional and local systems learn from errors and strive where possible to ensure that errors are not repeated. 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, wherever possible to ensure that clinical practice and models of care are safe, effective and up to date.

The experiences outlined by patients and families during the course of this investigation were disturbing when viewed within the context of the delivery of a modern health service. These experiences highlight significant deficiencies in the delivery of person-centred care at Portlaoise Hospital. Poor experiences by patients and families were compounded by ineffective governance arrangements at all levels of the HSE with the result that the patient's voice was ignored and valuable insights and learning to inform better care was lost.

### **Moving forward**

The HSE must now address the risks and deficiencies identified within this report in order to improve the quality, safety and experience of patient care in Portlaoise Hospital. It must also ensure that where similar risks and deficiencies exist in other hospitals, these are also addressed as a matter of urgency. The HSE at a national level must oversee the necessary improvements as part of its performance management arrangements.

The HSE governance arrangements to support the implementation of the national recommendations contained in this investigation must be clear, with a named accountable person with overall delegated responsibility for their implementation. The implementation plans should include clear timelines and identified individuals with responsibility for each recommendation and action.

A national maternity strategy must be developed and published as a matter of urgency. The purpose of this strategy should be to agree and implement standard, consistent, modern-day models of maternity care in order to ensure that all pregnant women have choice and access to the right level of safe care and support on a 24-hour basis. In the interim, inherent risks identified in this report must be urgently addressed and the necessary changes implemented.

The Authority acknowledges the work that has been done to date to incorporate the maternity services at Portlaoise Hospital into a clinical network with the Coombe Women and Infants University Hospital. This process must be concluded as a matter of priority.

The Authority also acknowledges the appointment of a chief executive officer, a chief operating officer and a group director of nursing to the Dublin Midlands Hospital Group. In driving the development of this hospital-group structure, this management team has undertaken to define the services that will be delivered at Portlaoise Hospital and ensure that they are safe and resourced appropriately. Senior management of the Dublin Midlands Hospital Group must now prioritise the development of speciality-based clinical networks between Portlaoise Hospital and larger hospitals within the Dublin Midlands Hospital Group. The recently signed memorandum of understanding between the Coombe Women and Infants University Hospital and Portlaoise Hospital is a first step in this process.

The Authority welcomes the inclusion of quality and safety within the remit of the newly appointed Group Director of Nursing. This appointment should, if effective, ensure that issues of quality and safety will be managed at group executive level.

Given the significant system-wide recommendations outlined in this Report, it will be vital that there is the necessary political commitment to their managed implementation in order to drive further improvements in the quality, safety and governance of the care provided in our health system. The Authority therefore recommends that the Minister for Health should establish, as a priority, an oversight committee in the Department of Health to ensure the implementation of the recommendations in this HIQA investigation report.

The Health Information and Quality Authority – in conjunction with the relevant clinical and professional organisations and patient advocacy groups – will, in 2015 develop for public consultation, service-specific draft standards for maternity services in Ireland, which will be a sub-set of the Authority's *National Standards for Safer Better Healthcare*.

Finally, the Authority wishes to acknowledge the courage and fortitude of all patients and families who made contact with the Authority to outline their experience of care within Portlaoise Hospital. It should be acknowledged that their efforts, harnessed with the required actions of those charged with delivering services, should ensure a better experience for those availing of services at Portlaoise Hospital in the future.

# Recommendations

## Recommendation 1

The Department of Health should commence discussions with the Health Service Executive (HSE) to establish an independent patient advocacy service, with a view to having a service in place by May 2016. This service's role would be to ensure that patients' reported experiences are recorded, listened to and learned from. Such learning needs to be shared between hospitals within hospital groups; between hospital groups; nationally throughout the wider health system; and published. In the interim, the Department of Health and the HSE should provide regular updates on their websites to inform the public on the progress of establishing this service.

## Recommendation 2

The Department of Health should, in line with its published Profile Table of Priority Areas, Actions and Deliverables for the Period 2015-2017, ensure implementation of the recommendations contained in this investigation report and previous investigations undertaken by the Authority.<sup>(1)</sup>

## Recommendation 3

- A. The Department of Health must now develop a national maternity services strategy for Ireland, as specified in recommendation N7 of the Authority's October 2013 *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*.\*
- B. The Department of Health should provide regular updates on its website to inform the public of progress with developing and implementing this national maternity strategy.

\* On 30 April 2015, the Minister for Health announced the establishment of a Steering Group to advise on the development of a National Maternity Strategy and published a list of its membership.

## Recommendation 4

In line with the Department of Health's policy to develop independent hospital groups, the Department should expedite the necessary legal framework to enable the group boards of management and chief executive officers of each hospital group to comprehensively perform their governance and assurance functions.

## Recommendation 5

The Health Service Executive (HSE) should ensure the appointment of a director of midwifery, before September 2015, in all statutory and voluntary maternity units and hospitals in Ireland that currently do not have such a post.

## Recommendation 6

The Health Service Executive (HSE), along with the chief executive officers of each hospital group, must ensure that the new hospital groups prioritise the development of strong clinical networks underpinned by:

- a. a group-based system of clinical and corporate governance informed by the *National Standards for Safer Better Healthcare*.
- b. a clearly defined, agreed, resourced and published model of clinical service delivery for each hospital within the group. This must be supported by clearly defined, agreed and documented patient care pathways to ensure that patients are managed in or transferred to the most appropriate hospital.
- c. regular evaluation and audit of the quality and safety of services provided.
- d. systems to support a competent and appropriately resourced workforce
- e. a system to proactively evaluate the culture of patient safety in each hospital as a tool to drive improvement.
- f. systems in place to ensure patient feedback is welcomed and used to improve services and that patient partnership and person-centred care is promoted, as per the *National Standards for Safer Better Healthcare*.
- g. effective arrangements to ensure the timely completion of investigations and reviews of patient safety incidents and associated dissemination of learning. These arrangements must ensure that patients and service users are regularly updated and informed of findings and resultant actions.

## Recommendation 7

The Health Service Executive (HSE), in conjunction with the Chief Executive Officer of the Dublin Midlands Hospital Group should:

- A. review all of the findings of this investigation and address the patient safety concerns at the Midland Regional Hospital, Portlaoise
- B. immediately address the local clinical and corporate governance deficiencies in the maternity and general acute services in Portlaoise Hospital
- C. publish an action plan outlining the measures and timelines to address the safety concerns and risks at Portlaoise Hospital, to include both general and maternity services. This action plan should include a named person or persons with responsibility and accountability for implementation of recommendations and actions in internal and external reviews and investigation reports, and be continuously reviewed and updated in order to drive improvement and mitigate risk.

The HSE and hospital group CEOs must now ensure that every hospital undertakes a self-assessment against the findings and recommendations of this investigation report, and develop, implement and publish an action plan to ensure the quality and safety of patient services.

## Recommendation 8

The Health Service Executive (HSE), the chief executive officer of each hospital group and the State Claims Agency must immediately develop, agree and implement a memorandum of understanding between each party to ensure the timely sharing of actual and potential clinical risk information, analysis and trending data. This information must be used to inform national and hospital-group patient safety strategies.

# Chapter 1. Introduction and methodology

## 1.1 Introduction

This report presents the findings of the investigation by the Health Information and Quality Authority (the Authority or HIQA) into the safety, quality and standard of services provided by the Health Service Executive (HSE) to patients in the Midland Regional Hospital, Portlaoise, Co Laois (referred to in this report as Portlaoise Hospital).

At the onset of this investigation report, the Authority and Investigation Team wish to convey their sympathies to those affected by the events which gave rise to this investigation, and to express their gratitude to the people who contacted us as part of this investigation.

### 1.1.1 Background

An RTÉ Investigations Unit *Prime Time* television programme broadcast on 30 January 2014 raised a number of issues about the maternity services at Portlaoise Hospital<sup>(2)</sup>. Following the programme, at the request of the then Minister for Health, the Chief Medical Officer of the Department of Health prepared a report on the maternity services at Portlaoise Hospital entitled, *HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006 – date)*.

The Chief Medical Officer's report, dated 24 February 2014, was published on 28 February 2014, and focused on perinatal deaths from 2006 to early 2014. It will be referred to in this HIQA investigation report as the Chief Medical Officer's report<sup>(3)</sup>. It made 53 recommendations, including a recommendation for the then Minister for Health to request HIQA to undertake an investigation in accordance with Section 9(2) of the Health Act 2007. A copy of this request from the then Minister for Health is attached as Appendix 1.

### 1.1.2 Establishment of the HIQA investigation

The Board of the Authority met on 4 March 2014 to discuss the:

- findings and recommendations of the Chief Medical Officer's report
- the then Minister for Health's request under Section 9(2) of the Health Act 2007<sup>(4)</sup> for the Authority to undertake an investigation.

The discussion was in consideration of the Authority's previous engagement with Portlaoise Hospital, and the Authority's receipt-of-unsolicited-information programme as well as the Authority's investigations, formal reviews and assessments.

The Board of the Authority recognised that there were reasonable grounds regarding the health or welfare of a person or persons receiving services at Portlaoise Hospital and approved the commencement of an investigation under section 9 of the Health Act 2007. The Terms of Reference (see Appendix 2) for the investigation were approved by the Board of the Authority on 18 March 2014 and published on 21 March 2014.

This subsequent statutory investigation by HIQA has been conducted in accordance with its Terms of Reference, and the Authority's *National Standards for Safer Better Healthcare*<sup>(5)</sup> in order to make recommendations to improve 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 Maternity Department in the hospital following the publication of the recommendations included in the Chief Medical Officer's report. The investigation included looking at the interim governance arrangements and the changes that have occurred there since February 2014. In light of previous Health Service Executive (HSE) and Authority reports, the investigation also looked at the quality and safety of clinical services in the general hospital, and the local, regional and national HSE arrangements to ensure the delivery of safe quality services. The Investigation Team's lines of enquiry (the questions posed by the Investigation Team) were informed by the accounts outlined to members of the Investigation Team by a number of patients and or their families who had used the maternity services in Portlaoise Hospital. Lines of enquiry were also informed by a safety culture assessment conducted in the hospital as part of this investigation.

### **1.1.3 How the report is structured**

The report is divided into eight chapters, as follows:

Chapter 1. Introduction and methodology

Chapter 2. Setting the scene

Chapter 3. Patient safety culture in Portlaoise Hospital

Chapter 4. The patient experience

Chapter 5. Maternity services at Portlaoise Hospital

Chapter 6. General Hospital Services at Portlaoise Hospital

Chapter 7. Governance

Chapter 8. Conclusions and recommendations

This report is supported by a glossary of terms used (located at the start of this report) and a number of appendices to provide the reader with additional information. In addition, the report contains a number of explanatory footnotes, and contains references that are identified by a superscript number in the body of the report. These references are listed at the end of the report.

## 1.2 Methodology

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

### 1.2.1 Overall approach

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 and published on 21 March 2014, the Authority designed the investigation approach to examine the safety, quality and standards of services provided by the HSE to general and maternity patients in Portlaoise Hospital. This investigation was further to, and carried out with an awareness of, the report of the Chief Medical Officer.

The approach paid particular attention to compliance of the HSE with the Authority's *National Standards for Safer Better Healthcare* (the National Standards). This 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.

### 1.2.2 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 membership of the Investigation Team is set out in Appendix 3.

### 1.2.3 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.

The lines of enquiry reflect the:

- Authority's *National Standards for Safer Better Healthcare*
- findings and recommendations of previous reviews and investigations carried out by the Authority<sup>(6-11)</sup>

The lines of enquiry were framed around the National Standards' themes of quality and safety. These in turn were originally identified through a process of reviewing international and national evidence, engagement with international and national experts and applying the Authority's knowledge and experience of the Irish healthcare context.

These themes reflect the essential components of a high-quality, safe healthcare service and include the required capacity and capability of the service provider to deliver such services.

The dimensions of quality described in the National Standards are:

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

Delivering improvements within these quality dimensions depends on service providers having capability and capacity in four key areas. These are:

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

#### **1.2.4 Patients and relatives' experience**

The Authority was contacted directly, both in writing and by telephone, by 13 members of the public who had received care at Portlaoise Hospital, or who had accompanied family members who had received care at the hospital. The Authority was also provided with the information and details of individuals who had first contacted the HSE, the Department of Health and Patient Focus (a patient advocacy group). In total the Authority was contacted by, or received information in relation to, 83 patients and their families who had serious concerns about aspects of their care either at Portlaoise Hospital or at another maternity facility. In order to explore the provision of patient-centred care from a patient's perspective specifically, the Authority held meetings with 15 patients and or members of their families who had received care at Portlaoise Hospital.

The Authority recognises that this is a very limited sample of the experience of all the patients who receive care at Portlaoise Hospital and also acknowledges that the patients and their families who came forward were motivated by their poor experiences.

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 they received, as well as their perspective on the associated relationship and communication between them and the HSE. While the investigation did not set out to undertake a detailed examination of each of these patients' care, their experiences – outlined in Chapter 4 – helped to inform the investigation and its lines of enquiry (the questions asked by the Investigation Team).

### **1.2.5 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 and observation. In line with these processes, this report outlines the findings, conclusions and recommendations of the Authority from Chapters 2 to 8.

### **1.2.6 Review of literature**

The Authority conducted a review of the literature concerning 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. References are cited by superscript numbers in the body of the text throughout the report, and are listed in the References chapter of this report.

### **1.2.7 Culture of patient safety at Portlaoise Hospital**

An assessment of the patient safety culture was conducted at Portlaoise Hospital at the outset of the investigation to inform the lines of enquiry. The methodology of the patient safety culture assessment is contained in Chapter 3.

### **1.2.8 Documentation and data**

In accordance with section 73 of the Health Act 2007, the Authority issued formal documentation and data requirements to Portlaoise Hospital, the HSE at a national and a regional level and the Department of Health (see Appendices 4 and 5).

The Investigation Team obtained approximately 1,380 pieces of documentation and data which covered areas such as the:

- corporate and clinical governance structure and management arrangements
- patient activity and patient-outcome data
- 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 time frame of 10 working days for the return of documentation and data from the date that the information requests were issued.

### 1.2.9 Interviews

In accordance with section 73 of the Health Act 2007, the Authority obtained information through interview with 45 individuals including:

- staff working in Portlaoise Hospital at local level
- the wider hospitals management group at a regional level whose role included responsibility for aspects of governance and risk management at the hospital
- HSE staff at national level whose role related to aspects of the governance and quality and safety of services at Portlaoise Hospital
- staff of the State Claims Agency with responsibility for the Clinical Indemnity Scheme
- staff of the Department of Health.

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.

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
- inform the investigation findings.

All interviewees had the option of having their interview recorded electronically. Following the interview, individuals were provided with an audio recording of their interview on CD for their records and were requested to inform the Authority, within 10 working days, if they wished to provide further information or clarification in relation to the recorded discussions. If the option of a recording had been declined, an alternate record of the interview, in the form of a written summary, was provided for the same purpose. Where commentary was received, it was included by the Authority in the investigation findings.

### 1.2.10 Group meetings

The Investigation Team also carried out three group meetings with staff at Portlaoise Hospital. 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.

Group meetings were not recorded electronically; key items were noted on large sheets of white paper attached to flipcharts and visible to all throughout the group meeting. Key points noted on the flip-board sheets had been agreed by all attendees on completion of the meeting.

### **1.2.11 Observation**

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

- Emergency Department (ED)
- Maternity Department
- Intensive Care Unit (ICU)
- Coronary Care Unit
- Outpatients Department (OPD)
- Special Care Baby Unit (SCBU)
- General Medical Wards
- Operating Theatre
- Diagnostic Imaging and Laboratory Departments.

In addition to the scheduled observation components of the investigation, an unannounced visit to the Maternity Department and Emergency Department in accordance with section 73 of the Health Act 2007 was undertaken by members of the Investigation Team on the night of 16 June 2014.

### **1.2.12 Patient healthcare record review**

To further inform the patient experience and understand the patient pathway, the Investigation Team, in accordance with section 73 of the Act, reviewed the healthcare records of a number of public patients who were inpatients in Portlaoise Hospital at the time of the investigation.

### **1.2.13 Due process feedback**

The Authority provided a copy of the relevant excerpt(s) of the confidential draft report of the investigation findings, on an individual basis or in a representative role, to relevant healthcare professionals and senior managers in the HSE and another State body, the State Claims Agency, interviewed by the Investigation Team during the investigation. 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. The Authority provided a time frame of 10 working days for the return of any feedback and comments from the date of issue of the draft excerpt of the report.

Extended deadlines were provided. Every comment received was carefully considered by the Authority prior to the publication of this report.

#### **1.2.14 Quality assurance**

To maximise the consistency and reliability of the investigation approach, the Authority put a series of quality assurance processes in place. These included the:

- investigation methodology, and supporting quality controls, designed in line with the Terms of Reference agreed by the Board of the Authority
- Investigation Team being established based on the skills, knowledge, experience and competencies required, in line with the Terms of Reference of the Investigation
- establishment of an internal committee governing the investigation processes
- formal roll out of the Authority's challenge process at key points of the Investigation
- draft report being quality reviewed by Authority personnel, external to the Investigation Team
- healthcare professionals and healthcare managers interviewed being provided with relevant excerpt(s) of the draft report of the investigation findings for the purpose of due process feedback.

Upon publication of the Terms of Reference (see Appendix 2) in March 2014, the investigation commenced gathering information in line with the methodology outlined in this chapter. The Investigation Team began writing the report in October 2014 with reviews and contributions from the external members of the Investigation Team and the Board of the Authority. The final report was approved for publication by the Board of the Authority on 5 May 2015.

#### **1.2.15 Acknowledgements**

The Authority wishes to thank those patients and or their families who bravely shared their experiences for the future benefit of others. The Authority would also like to thank the staff of Portlaoise Hospital, patients who spoke with the Investigation Team during the site visit, the Patient Focus organisation, the Department of Health, the HSE, external members of the Investigation Team, and the staff of the Authority who contributed to this investigation.

## Chapter 2. Setting the scene

### 2.1 Introduction to setting the scene

In previous investigation reports, the Authority has identified the need for ownership of actions to ensure accountability and responsibility at senior level within the health service's national, regional and local structures for implementing recommendations and actions listed in various expert reports.

Previous investigations by the Authority have also highlighted serious deficiencies within the healthcare service in relation to its ability to learn from adverse findings. This is particularly the case in relation to lessons learned from adverse events which happen in one healthcare setting being universally applied elsewhere.

Sharing of learning arising from when things go wrong for patients is vital to minimise and reduce avoidable clinical risk to all patients, and helps prevent the reoccurrence of preventable events that may cause harm to future patients. This investigation highlights further these previously reported deficiencies.

In his report<sup>(3)</sup>, the Department of Health's Chief Medical Officer said two previous Health Service Executive (HSE) reviews<sup>(12,13)</sup> published in 2008 into the breast cancer misdiagnosis cases at Portlaoise Hospital should have provided a very strong case for 'external oversight and support to Portlaoise Hospital as it dealt with the legacy of those issues'. The Authority strongly supports this view, and will throughout this report provide examples of weak oversight – at local, regional and national HSE level – of risks to patients identified at Portlaoise Hospital.

It is important that the findings of this investigation are placed and understood within the context of critical events which happened at Portlaoise Hospital over a number of years, and the national, regional and local context within which the risks arising from these events developed. The context covers both risks in the maternity services and other general hospital services in Portlaoise Hospital. To that end, this section sets out a number of key structural, regulatory and policy developments that, taken together, significantly underpin the findings of this investigation into Portlaoise Hospital and provide the context within which those findings can be understood.

## 2.2 Transition from previous health board structures to the Health Service Executive (HSE) and the impact on Portlaoise Hospital (2004–2005)

Before the HSE was set up in 2005, Ireland's health services for public patients were delivered by 11 regional health organisations. The Midland Health Board covered counties Laois, Offaly, Longford and Westmeath, and therefore Portlaoise Hospital was under its remit. The Midland Health Board's final Service Plan in 2004 reported that an increase in population, and corresponding increased pressure on its maternity services due to an increasing birth rate, was a key issue for the year ahead. Its final annual report produced in 2004, prior to the transfer of services to the HSE, also highlighted that the region continued to have a higher birth rate than the national average.

On 1 January 2005, the HSE took over health and social care services from the 11 regional health organisations and their funded agencies. These services were then managed within four new HSE regions: Dublin Mid Leinster, Dublin North East, South and West. Portlaoise Hospital was part of the Dublin Mid Leinster HSE region. In February 2006, a review was published into midwifery staffing at the Maternity Department in Portlaoise Hospital, initiated by the hospital's Director of Nursing and supported by the Dublin Mid Leinster region's Director of Nursing Planning and Development Unit (see also Chapter 5)<sup>(14)</sup>. It made a number of recommendations including the need for:

- a maternity assessment unit to be developed
- the high rate of staff absenteeism to be addressed
- the midwife in charge to have protected time for management duties
- additional clinical midwifery manager IIs (CMMIIs) to act as shift leaders on each shift
- the appointment of an additional clinical midwifery manager 1 (CMMI) and additional healthcare assistants.

A maternity assessment unit was established by the end of 2007. However, the issues raised regarding midwifery leadership and the need for midwife shift leaders were not fully addressed until 2014, after media and political attention focused on the services following serious adverse events – almost eight years after the recommendations had first been made.

### 2.2.1 Establishment of HIQA in 2007: the role of the regulator

The Health Information and Quality Authority (the Authority or HIQA) is an independent Authority established in May 2007 and has the national statutory role to set and monitor compliance with standards for the quality and safety of health and social care services in Ireland. The *National Standards for Safer Better Healthcare* were mandated in 2012 and set out the standards necessary to ensure effective systems of governance. These standards define a well-governed service as one that is clear about what it does, how it does it and is accountable to its stakeholders including the people who use the services. These standards are applicable both to the HSE provider and the HSE commissioner of services and should therefore transition across local, regional and national health services executive structures.

The Authority receives information on healthcare service providers through a number of its functions including:

- scheduled regulatory activity which includes the national programme of monitoring against the *National Standards for the Prevention and Control of Healthcare Associated Infections* (referred to in this report as the Infection Prevention and Control Standards)
- statutory investigations and formal reviews
- receipt-of-unsolicited-information programme.

The Authority does not have a remit to address or investigate individual complaints in relation to health and social care services. The Authority advises all persons with individual complaints to contact the HSE National Information Line and or the Office of the Ombudsman as appropriate. However, the Authority reviews all information received about the safety, quality and standards of services as it could indicate that a service provider may not be complying with national standards. The purpose of this is to establish if:

- the information indicates non-compliance with the National Standards and if that non-compliance poses a serious risk to the health and welfare of persons receiving those services
- there are reasonable grounds for the Authority to believe that there is a serious risk to the health and welfare of persons receiving those services.

When concerns regarding the quality and safety of services provided to patients are identified, depending on the nature of the information and the level of assessed risk to patients, the Authority may initiate a range of interventions that includes seeking assurances from service providers to ensure any identified risks are mitigated and managed.

## 2.2.2 HIQA's investigations 2007–2013

The Authority, under Section 9(1) or (2) of the Health Act, may undertake an investigation into the safety, quality and standards of healthcare services if the Authority believes on reasonable grounds that there is a serious risk to the health or welfare of patients receiving those services or if requested by the Minister for Health. These investigations are not forensic investigations of an individual patient's care.

The majority of the resources allocated to healthcare regulation within the Authority were, between 2007 and 2013, involved in conducting and reporting on a series of separate investigations into patient care at HSE or HSE-funded hospitals around the country. During this time period, the Authority conducted and published six investigations into healthcare organisations, as detailed in Table 1.

**Table 1.** Schedule of investigations and resulting reports by the Health Information and Quality Authority, 2008 – 2013

Year report published	HIQA report
<b>2008</b>	Report of the Investigation into the circumstances surrounding the provision of care to Rebecca O'Malley, in relation to her symptomatic breast disease, the Pathology Services at Cork University Hospital and Symptomatic Breast Disease Services at the Mid Western Regional Hospital, Limerick <sup>(9)</sup> .
<b>2008</b>	Report of the investigation into the provision of services to Ms A by the Health Service Executive at University Hospital Galway in relation to her symptomatic breast disease, and the provision of Pathology and Symptomatic Breast Disease Services by the Executive at the Hospital <sup>(10)</sup> .
<b>2009</b>	Report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at the Mid-Western Regional Hospital Ennis <sup>(8)</sup> (referred to in this report as the Ennis Report).
<b>2010</b>	Report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at Mallow General Hospital <sup>(7)</sup> (referred to in this report as the Mallow Report).

<p><b>2012</b></p>	<p>Report of the investigation into the quality, safety and governance of the care provided by the Adelaide and Meath Hospital, Dublin incorporating the National Children’s Hospital (AMNCH) for patients who require acute admission<sup>(6)</sup> (referred to in this report as the Tallaght report).</p>
<p><b>2013</b></p>	<p><i>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<sup>(11)</sup> (referred to in this report as HIQA’s 2013 Galway report)</i></p>

These HIQA investigation reports made a number of findings and recommendations for the relevant hospitals and the HSE nationally which should have been used by all healthcare services as a learning tool to inform, improve practice and drive service quality and safety.

Had the relevance of the findings from these investigation been reviewed in the context of Portlaoise Hospital and the aligned recommendations been subsequently implemented, the Authority is of the opinion this could have vastly reduced the identified risks in the services being provided to patients. A brief overview of a selection of the risks and recommendations is provided in the following paragraphs and will be explored in more depth in subsequent chapters of this report.

### 2.2.3 Specific HIQA recommendations relevant to Portlaoise

Of particular relevance to the HSE nationally and the management of Portlaoise Hospital were the Ennis and Mallow investigation reports published in 2009 and 2011 respectively. A key finding from these reports was the risk associated with treating low numbers of acutely ill patients in smaller, stand-alone hospitals without senior clinicians being on site 24 hours a day. They also highlighted that there was a need to ensure that patients with complex needs are directed to hospitals with the necessary staffing, competencies, infrastructure and equipment for safe and effective care. These reports advised that the HSE should universally apply the recommendations for Ennis and Mallow hospitals to general hospitals of similar activity profiles.

The two reports described the potential risks to acutely ill patients in hospitals that did not have a clearly defined model of service outlining what could (and what could not) be safely provided to patients. The reports made recommendations concerning the national provision of safe and sustainable critical care, anaesthesia and surgical services.

The reports recommended that the HSE carry out a systematic assessment of potential risks to acutely ill patients in hospitals similar to Ennis and Mallow and take appropriate steps to mitigate any immediate risks for such patients.

In addition, the Ennis and Mallow reports also recommended that the HSE undertake a strategic review of how local emergency care services are organised, with the aim of consolidating emergency services in regional centres. This was to include prompt action to ensure that any hospital providing 24-hour, seven-days-a-week (24-seven) emergency care had immediate access to clinical triage, resuscitation and diagnostic support and full-time on-site competent senior clinical decision makers. This recommendation was linked to the need to establish emergency care networks and associated national ambulance bypass protocols, whereby patients with certain conditions may be transported by ambulance to a more distant, yet more appropriate hospital.

The findings and recommendations from both Ennis and Mallow informed the national development of a *smaller hospitals framework*, published by the Department of Health and the HSE in 2013<sup>(15)</sup>. This framework set out a plan and model of care for the provision of services at smaller acute hospitals throughout Ireland.

Following on from the Ennis and Mallow reports, the Authority's Tallaght Report in 2012 made further recommendations regarding the provision of emergency services nationally. It also re-emphasised the need for the HSE to review the working hours and availability of emergency medicine consultants and senior clinical decision makers.

Throughout all of the Authority's six previous investigation reports, the need to respond effectively to concerns and learn from adverse incidents has been reiterated. Furthermore, repeated recommendations identify the need for clearer governance and accountability arrangements within hospitals and the wider HSE, including the provision of performance monitoring systems to assess the safety and effectiveness of hospital services.

#### **2.2.4 Specific recommendations relevant to the national maternity services**

Also of relevance to this investigation were previous recommendations specific to the national maternity services. In line with the Terms of Reference of this investigation, the Investigation Team reviewed the progress to date on implementing national recommendations from previous reviews of the maternity services, specifically HIQA's 2013 Galway report and the Chief Medical Officer's February 2014 report.

This section will focus on the implementation of recommendations at a national level\* including:

- the development and implementation of a national maternity strategy
- implementation of quality assurance mechanisms
- publication of national guidelines
- reporting and management of serious untoward incidents
- national laboratory alert system.

The requirement for a national maternity strategy was first recommended as far back as 2001 when the National Health Strategy committed to producing a plan to provide responsive, high-quality maternity care<sup>(16)</sup>. More recently a key recommendation of HIQA's 2013 Galway report was that the Department of Health and the HSE should work together to develop and implement a National Maternity Services Strategy<sup>(11)</sup>.

In February 2014, at the publication of the Chief Medical Officer's Report on Portlaoise Hospital, the then Minister for Health stated that the national maternity strategy would be developed and published by December 2014. The Chief Medical Officer's report details that the Department of Health will oversee the development of this strategy. However, at the time of writing this report, this essential strategy had not been developed or implemented.\*\*

As detailed at the outset of this chapter, the pressures caused by an increasing birth rate on the delivery of maternity services at Portlaoise Hospital were identified at a local and regional level over 10 years ago. However, without a national maternity strategy, nationally mandated maternity standards and advice on appropriate models of maternity care, it was challenging for a small maternity department such as in Portlaoise Hospital to develop local initiatives to address these pressures.

HIQA's 2013 Galway report made several recommendations designed to improve the quality and safety of the national maternity services. The Investigation Team reviewed documentation submitted by the HSE which reported that all hospitals had undertaken a self-assessment against the recommendations in the above 2013 investigation report. As a result of this process of self-assessment, the HSE required each hospital to develop action plans to address identified gaps. The HSE also reported that hospitals were also in the process of completing a self-assessment against the Authority's *National Standards for Safer Better Healthcare*.

A key finding of HIQA's 2013 Galway report was the absence of comprehensive national data relevant to the maternity services which would allow the HSE to

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\* The implementation of recommendations from these two reports at Portlaoise Hospital will be covered in the maternity chapter (Chapter 5) of this report.

\*\* On 30 April 2015 the Minister for Health announced the establishment of a Steering Group to advise on the development of a National Maternity Strategy and published a list of its membership.

evaluate the quality and safety of the maternity services provided nationally. The Investigation Team acknowledges the progress achieved in implementing the recommendation to define and agree a dataset of quality metrics. This recommendation is designed to support monitoring and evaluation of performance and management of crucial patient outcome and experience indicators. This dataset was shared with all 19 public maternity hospitals or units for implementation in July 2014.

The Investigation Team noted the publication of a number of national guidelines by the National Clinical Effectiveness Committee and the HSE's Clinical Programmes, as follows:

- National Clinical Effectiveness Committee:
  - Irish Maternity Early Warning System (IMEWS)<sup>(17)</sup>
  - Communication (Clinical Handover) in Maternity Services<sup>(18)</sup>
  - Sepsis Management<sup>(19)</sup>
- HSE's Clinical Programmes:
  - The Management of Second trimester miscarriage<sup>(20)</sup>
  - The care of the critically ill woman in obstetrics<sup>(21)</sup>
  - Resuscitation for the Pregnant Woman<sup>(22)</sup>
  - The Diagnosis and Management of Ectopic Pregnancy<sup>(23)</sup>
  - Bacterial Infections Specific to Pregnancy<sup>(24)</sup>.

In addition, the Investigation Team welcomed the reported progress with regards to the national implementation of the National Early Warning Score (NEWS) and the Irish Maternity Early Warning Score (IMEWS). In a self-assessment in January 2014, all hospitals indicated that they had implemented NEWS and IMEWS and that on average between 70% and 90% of staff had received training on their use.

The Chief Medical Officer's report made several recommendations which were relevant to the reporting and management of serious untoward incidents. The Investigation Team acknowledges the progress to date in the implementation of these recommendations including:

- setting up a serious reportable event governance group chaired by the then HSE's Director of Quality and Patient Safety
- publishing a Safety Incident Management policy which sets out the HSE's policy for managing safety incidents<sup>(25)</sup>. This policy replaces six previous HSE documents related to incident management in order to ensure consistency of adverse-event terminology across documentation and guidance
- publishing a summary list of Serious Reportable Events and an implementation guidance document

- issuing a directive to all providers to require them to notify 'serious reportable events' to the National Director responsible for their service
- educating staff and training them in relation to safety incident management.

The HSE reported that all clinical directors had received training, with training of hospital management teams and relevant staff due for completion within the first three months of 2015.

HIQA's 2013 Galway report recommended that 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. This was to allow for timely recognition of emerging national microbial threats including antimicrobial resistance. The HSE reported that a national Infection Prevention and Control Information System is in the process of being developed and has received approval from the Department of Finance.

### **2.2.5. The Authority's previous engagement with Portlaoise Hospital**

Between 2008 and 2012, the Authority received seven pieces of unsolicited information regarding individual patients' experiences of their care across a number of services including maternity, acute and emergency services, and hygiene practice at Portlaoise Hospital. All patients were provided with advice on the most appropriate organisation to manage their complaint and or internal incident review. Each information piece was considered in terms of the potential risks to patients' safety. The HSE conducted an internal incident review of two cases. The Authority requested a copy of the final review reports once complete as well as actions taken to mitigate risks. On analysis of one report it was identified that the substantive issue related to the availability of senior clinical decision-making in the emergency services.

In December 2012 the Authority conducted a full announced monitoring assessment of Portlaoise Hospital to assess the hospital's compliance with the Infection Prevention and Control Standards which included a review of its governance structures<sup>(26)</sup>.

The Authority found that the hospital had inadequate corporate and clinical governance arrangements in place which contributed to serious risks to patient safety.

These risks were formally escalated to the hospital and the HSE regionally on 7 December 2012. This letter gave formal notification of the risks identified during the announced inspection.

The identified risks included:

- that Portlaoise Hospital was providing 24-seven undifferentiated patient care through its emergency department in the absence of appropriate access to imaging diagnostics, particularly CT\* scans
- a backlog in radiology reporting
- deficiencies in the corporate and clinical governance structures. These were reflected in the:
  - underdeveloped corporate and clinical group governance structure
  - absence of a formal lead clinician at division level
  - reported prevalence and culture of informal communication as opposed to formal communication structures
  - absence of a dedicated risk manager.

Accordingly, the Authority made recommendations to:

- strengthen the hospital's clinical and corporate governance arrangements
- put in place a local dedicated risk manager at the hospital
- improve processes for prevention and control of Healthcare Associated Infections.

The HSE responded with details of actions taken to reduce and or eliminate the risks that had been identified. In January 2013, the Authority acknowledged that the quality improvement plans relating to the hospital's governance arrangements would require a period for implementation and requested an update on progress by May 2013. The progress update received did not assure the Authority that all the risks identified had been addressed in full.

In addition, the Authority received two further pieces of unsolicited information in June and August 2013 that suggested that the care provided to maternity patients at Portlaoise Hospital may not be compliant with Standards 2.2,\*\* 2.6\*\*\* and 3.1\*\*\*\* of the *National Standards for Safer Better Healthcare*. Accordingly, the Authority sought further assurance regarding maternity services at Portlaoise Hospital from the HSE at a regional level. Again, the replies received in response to this request did not assure the Authority that mitigating actions had been implemented to address local risks identified, which included the implementation of recommendations from an HSE external incident review.

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\* A computed tomography (CT) uses X-rays to create cross-section images of the body.

\*\* Standard 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.

\*\*\* Standard 2.6: Care is provided through a model of service designed to deliver high-quality, safe and reliable healthcare.

\*\*\*\* Standard 3.1: Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.

While the Authority recognised that a number of the risks were being managed on an individual basis, and while an initiative to enhance governance arrangements at the hospital was described, the Authority was not assured of the strength and reliability of the improvements implemented to support the sustainability of these processes.

Accordingly, in September 2013, the Authority wrote to the HSE Office for Acute Services with a request for any other information that would provide assurances that risks described were being effectively and safely managed to minimise risks to current and future patients, specifically in the care of clinically deteriorating patients, both general and maternity patients. Its response, received by the Authority in October 2013, reconfirmed details of actions undertaken by the HSE in relation to corporate and clinical governance, computed tomography (CT) scanning services and maternity services.

Notwithstanding these assurances, the Authority decided, as part of its regulatory programme for acute hospital services for 2014, to schedule a governance review of Portlaoise Hospital in early 2014<sup>(27)</sup>. This decision was communicated to members of the HSE Leadership Team at a briefing session on the Authority's assurance programme on 28 January 2014, with the governance review scheduled to commence in March 2014.

### **2.2.6 HSE reviews and recommendations in Portlaoise Hospital**

In June 2007, staff at Portlaoise Hospital expressed a number of serious concerns about the quality and safety of breast disease services in the hospital to the Director of Nursing<sup>(12)</sup>. These concerns were brought to the attention of the HSE regional network manager in August 2007 and a decision to suspend breast radiology services at the hospital was made. At this time cancer services throughout Ireland were beginning to be centralised.

In response to the concerns raised regarding the breast disease services, two clinical reviews of the mammography and ultrasound services were completed which reviewed mammograms and ultrasounds of patients who had received treatment at the hospital between August 2005 and August 2007<sup>(28,29)</sup>. These reviews were both published by the HSE in 2008. The review of the mammography services concluded that best practice in breast imaging services was not adhered to at Portlaoise Hospital<sup>(28)</sup>. As a result, the safety, quality and standards of many aspects of the breast imaging service fell well below achievable best practice and resulted in a significant and avoidable delay in the diagnosis of breast cancer. At the same time that these clinical reviews were being conducted, the Department of Health requested the HSE to carry out two reviews into the processes that led to the decision to suspend breast radiology services at the hospital and the overall process that had been followed in carrying out the review of breast radiology services.

The first of these reports (referred to as the Doherty report)<sup>(13)</sup> aimed to establish factually all the matters that led to the following decisions being taken:

- suspend breast radiology services
- initiate a clinical review of the symptomatic breast radiology service
- place a consultant radiologist on administrative leave
- The Doherty report outlined a chronology for these events. It also made the following general findings in relation to Portlaoise Hospital, including but not limited to:
  - The role of the lead clinician as envisaged seven years previously in the Development of Services for Symptomatic Breast Disease (2000) was not in place at the hospital.
  - There was significant investment within the HSE Midland area in the functions of quality and risk. However, there was no formal reporting relationship between the quality and risk functions and hospital management.
  - Local recommendations made in January 2007 following an incident that occurred in 2006 remained outstanding as of 28 August 2007.
  - There was a difference of opinion among local senior management at the hospital regarding their formal reporting relationships at a local and regional level.

The second of these reports (referred to as the Fitzgerald report) examined the HSE's management, governance and communication of the breast review process between the end of August and end of November 2007. This report found fundamental weaknesses in the management and governance of the process from the outset<sup>(12)</sup>. The Fitzgerald report identified that the review facilitation group set up by the HSE did not work effectively and did not exert control over the integrity of the communications process either with patients, with the Department of Health and Children, or internally. This meant that communication throughout the period was inconsistent and sometimes contradictory. Related to this risk was the fact that too many people were involved from different levels in the HSE without clarity about their roles, responsibilities and status within the process and with significant competing pressures on their time.

The report also identified an overall lack of urgency in the response from both central management in the HSE and HSE regional management to the review process. This was evident by the fact that the Review Facilitation Group met on only three occasions and that inadequate resources were allocated to the review process, especially in the early stages<sup>(12)</sup>. The Fitzgerald report identified the need for critical incidents, such as had occurred at Portlaoise Hospital, to be managed as a priority with dedicated resources devoted exclusively to their management.

The Fitzgerald report concluded that fundamentally the problems in the review process had arisen from systematic weaknesses of governance, management and communication within the HSE for dealing with critical incidents such as had arisen with the breast disease services at Portlaoise Hospital in 2007. In response to the Fitzgerald report, the HSE stated that important lessons would be learnt from these findings and that in future it would ensure that investigations would be conducted efficiently. To ensure this, the HSE developed a national serious incident management protocol to guide the effective response to such adverse events.

As previously cited in this section of the report, the Chief Medical Officer's report identified in 2014 that the Doherty and Fitzgerald reports – along with the response of the HSE Board and senior management at the time – should have provided a very strong case for 'external oversight and support to Portlaoise Hospital as it dealt with the legacy of those issues'.

### **2.3 Portlaoise Hospital in the context of national health service reform**

In 2010, the HSE's National Acute Medicine Programme described four generic acute hospital models (model 1, 2, 3 and 4)<sup>(30)</sup>. The purpose of these models was to define the level of service that can be safely provided at acute hospitals according to the available facilities, staff, resources and local factors at each hospital. The role and functions of these hospital models as described in *Securing the Future of Smaller Hospitals: A Framework for Development* (hereafter referred to as the *Smaller Hospitals Framework*) are provided in Table 2<sup>(15)</sup>.

**Table 2.** How hospitals are structured in Ireland under 2010 HSE models\*

<b>Role and function of hospital models</b>
Model-1 hospitals are community and or district hospitals and do not have surgery, emergency care, acute medicine (other than a select group of low-risk patients) or critical care.
Model-2 hospitals can provide the majority of hospital activity including extended day surgery, selected acute medicine, local injuries, a large range of diagnostic services, including endoscopy, laboratory medicine, point-of-care testing, and radiology – computed tomography (CT), ultrasound and plain-film X-ray – specialist rehabilitation medicine and palliative care.
Model-3 hospitals admit undifferentiated acute medical patients,** provide 24-seven acute surgery, acute medicine, and critical care.
Model-4 hospitals are tertiary hospitals and are similar to model 3 hospitals but also provide tertiary care and, in certain locations, supra-regional care.**

Also in September 2010, the Authority received correspondence from the HSE outlining the status of implementation of recommendations from the Ennis Report<sup>(8)</sup> as they related to the delivery of acute clinical services in 10 similarly sized hospitals. As stated earlier, the Ennis Report had recommended that the HSE carry out a systematic assessment of potential risks to acutely ill patients in hospitals similar to Ennis Hospital (2009), and take appropriate steps to mitigate any immediate risks for such patients. The Mallow Report (2010) reiterated the need for this to happen. Those 10 hospitals identified by the HSE as a result of this recommendation were the hospitals initially chosen by the HSE to become model-2 hospitals.

As illustrated in Table 3, Portlaoise Hospital was one of 10 hospitals initially identified by the HSE with risks similar to those identified in the Ennis Hospital Report.

\* Definitions of the four hospital models from *Securing the Future of Smaller Hospitals: A Framework for Development (2013)*.

\*\* Undifferentiated patients includes all types of patients with any degree of seriousness or severity of illness

**Table 3.** The 10 hospitals initially identified by the HSE with risks similar to those identified in the Ennis Hospital Report and which were initially chosen by the HSE to become model-2 hospitals.

Mid-Western Regional Hospital Ennis	The 10 hospitals initially identified by the HSE with risks similar to those identified in the Ennis Hospital Report and which were initially chosen by the HSE to become model-2 hospitals.
<b>Midland Regional Hospital, Portlaoise</b>	
Our Lady’s Hospital, Navan	
Louth County Hospital	
St Columcille’s Hospital, Loughlinstown	
Mid-Western Regional Hospital Nenagh	
St John’s Hospital, Limerick	
Roscommon County Hospital	
Mallow General Hospital	
Bantry General Hospital.	

The HSE actively progressed implementing recommendations of the Ennis and Mallow reports in these smaller hospitals. However, in July 2011, the Oireachtas Joint Committee on Health and Children was told that it was Government policy that Portlaoise Hospital is a model-3 hospital in the context that the hospital provided maternity and paediatric services<sup>(31)</sup>. In May 2013, the Department of Health and the HSE published the *Smaller Hospitals Framework*<sup>(15)</sup>. This framework outlined in detail the clinical services that would be delivered in smaller (model-2) hospitals. However, this framework document reported that it had focused on the role of nine smaller hospitals which had been the subject of particular attention from the Authority. This list did not include Portlaoise Hospital.

Whatever the rationale for any decisions underpinning the model of care to be delivered at Portlaoise Hospital, it would be expected that the HSE would ensure that the hospital was safely structured and resourced to provide the care it was delivering (that is to say, to admit undifferentiated acute medical patients,\* provide 24-hour, seven-days-a-week [24-seven] acute surgery, acute medicine, and critical care).

Alongside the *Smaller Hospitals Framework*, the report, *Establishment of Hospital Groups as a transition to Independent Hospital Trusts*<sup>(57)</sup>, chaired by Professor John Higgins (hereafter referred to as the Higgins’ report) was published by the Department of Health in 2013. The Higgins’ report outlined how Ireland’s acute public hospitals would be organised into seven groups of hospitals, each

\* Undifferentiated patients includes all types of patients with any degree of seriousness or severity of illness.

containing smaller and larger hospitals. It detailed how each of these groups would work together as a single cohesive entity, while managed as one, to provide acute care for patients in their area, integrating with community and primary care. It described the need for the smaller hospital to be supported within the hospital group in terms of:

- education and training
- continuous professional development
- the sustainable recruitment of high-quality clinical staff
- the safe management of deteriorating and complex patients.

The Higgins' report recommended that Portlaoise Hospital be part of the Health Dublin Midlands Group.\*\* However, at the time of this HIQA investigation report, the formation of this hospital group, like a number of other hospital groups, is still at an early stage. In the interim, Portlaoise Hospital continues to engage in the provision of a stand-alone single-hospital model of care. As a result, the Investigation Team determined that at the time of this investigation, Portlaoise Hospital lacked formal systems to ensure close clinical cooperation, communication and integrated systems of clinical governance between it and a larger training hospital.

The Investigation Team was informed at interview by local senior managers and senior clinicians that the model of care underpinning the general services at Portlaoise Hospital had been the subject of discussion and speculation for a number of years. Senior national and regional HSE managers and the hospital reported that it was a model-3 hospital. This means that it admits undifferentiated acutely ill patients, has an on-site emergency department and a category 2 intensive care unit. Accordingly, it was through this lens that the Authority conducted this investigation. The Authority's investigation found a number of examples of how the hospital was not resourced to safely provide services at a level that would be expected of a model-3 hospital.

In summary, at the time of the investigation, Portlaoise Hospital was not resourced as a model 3 hospital, was excluded from the *Smaller Hospitals Framework* and was awaiting its role within the hospital groups set out by the Higgins report. In the interim, there was no clear vision of the services that Portlaoise Hospital could and would safely provide into the future. While the Authority supports the positive development of hospital groups, it is important that as smaller hospitals await full integration into the new hospital group structures, robust interim arrangements are necessary to ensure that the risks identified in Portlaoise are not replicated in other hospitals.

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\*\* The Health Dublin Midlands Group contains the following hospitals: St James's Hospital, Dublin; The Adelaide and Meath Hospital, Dublin, Incorporating the National Children's Hospital; Midland Regional Hospital Tullamore; Naas General Hospital; Midland Regional Hospital, Portlaoise; and the Coombe Women and Infants University Hospital, Dublin. Its primary academic partner is Trinity College Dublin (TCD). This group has subsequently been renamed the Dublin Midlands Hospitals Group.

### 2.3.1 Clinicians in management

The Clinicians in Management (CIM) initiative was launched in Ireland in 1998. The aim of this initiative was to give health professionals a greater say in the planning and management of health services by involving doctors, nurses and allied health professionals in decision-making and decentralising the responsibility for managing resources down to local units<sup>(32)</sup>. In order to achieve this aim, the concept of clinical directorates was also introduced to the health service. A clinical directorate is defined as a team of healthcare professionals within a specialty, or group of specialties, which is responsible for the provision of patient care within allocated resources.

In 2007, a job description for clinical directors was published and in 2008 a new hospital consultant contract which facilitated these new senior management positions across the health service was agreed<sup>(33,34)</sup>. 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
- influence and respond to organisational priorities.

The HSE published national guidance with regards to the appointment of clinical directors in June 2012 that stipulates that clinical directors should be afforded 50% protected time for the directorate and or managerial business and a 50% backfill arrangement in place to maintain clinical service provision. Similar to previous investigations conducted by the Authority, this investigation identified deficiencies in respect of adequately supporting and resourcing clinical directors to achieve these roles<sup>(6,7,11)</sup>.

### 2.3.2 Clinical programmes visits to Portlaoise Hospital

The HSE's National Clinical Programmes were established in 2010. They 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. The National Clinical Programmes are tasked with developing evidence-based practice within each programme, and producing guidelines and integrated care pathways for patients in specific areas. Implementing the recommendations from various Department of Health, HIQA and HSE reports was to be set within the context of the roll-out of a series of National Clinical Programmes.

These national programmes have an important role which is identified in the Department of Health's publication entitled Department of Health Statement of Strategy 2011–2014. This document identifies the requirement to reform the acute hospitals and highlights the development of the National Clinical 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*<sup>(57)</sup> (2013) identifies that the hospital groups will adhere to the principles of the National Clinical Programmes.

Members of these programmes conduct on-site review visits at hospitals in order to assess their suitability for the services they provide and the progress to date in implementing programme recommendations. With this objective, the acute medicine, emergency medicine, surgical care and paediatric programmes all separately visited Portlaoise Hospital between February 2012 and July 2013. The investigation team found, through documentation reviewed, that the clinical programmes had expressed concerns and had identified risks in various aspects of the services they reviewed. Despite the fact that these issues were escalated in March 2014, to a national level both within the Department of Health and the HSE, at the time of this investigation, many of the risks identified by the National Clinical Programme teams were still evident.

### **2.3.3 The State Claims Agency and the Clinical Indemnity Scheme**

The State Claims Agency is the state body responsible for claims and risk management functions under the National Treasury Management Agency (Amendment) Act 2000. The Clinical Indemnity Scheme is the main scheme under which the State Claims Agency manages clinical negligence claims taken against hospitals and clinical, nursing and allied healthcare practitioners covered under this scheme.

The State Claims Agency, through its Clinical Indemnity Scheme, is responsible for managing on behalf of the Department of Health clinical negligence claims and associated risks in public healthcare services. One of its objectives is to provide risk management advisory services to State authorities, including the HSE, with the aim of reducing the frequency, severity and repetition of adverse events and in so doing, also reducing subsequent claims and the cost of claims. The State Claims Agency does not have statutory powers by which it can compel healthcare institutions, including the HSE, to engage with it or to implement any recommendations which it may make.

In 2004, the introduction of the STARSWeb system (a national database to record adverse clinical incidents and 'near misses' reported by hospitals) provided organisations with a central point for the recording of non-clinical and clinical incidents and near misses. The system links hospitals and other healthcare enterprises to the State Claims Agency's core database. Each enterprise only has access to its own data, however, the State Claims Agency can access all data in order to identify emerging trends.

The HIQA 2013 Galway report<sup>(11)</sup> on the safety of maternity services reported that the HSE's National Clinical Programmes, at both director and clinical lead level, did not have formal links with the Clinical Indemnity Scheme. The Authority identified 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. To address this deficiency, the Authority recommended that the HSE should develop better communication with the Clinical Indemnity Scheme in order to share information and learning on safety incidents within healthcare services. It was expected that this would lead to the development of tailored quality and safety programmes across services nationally. This learning should actively inform the respective National Clinical Programmes and relevant guidelines. However, the interaction between the HSE and the State Claims Agency in relation to the sharing and use of available information did not result in effective mitigation of the identified risks at Portlaoise Hospital.

The State Claims Agency, as far back as 2007, had identified concerns in relation to the quality of maternity services at Portlaoise Hospital. However, up to the time of this HIQA investigation, no formal engagement process was in place between the State Claims Agency and the HSE. As a result, there was limited proactive and meaningful engagement between the State Claims Agency and the HSE in relation to reported adverse events at Portlaoise Hospital.

## 2.4 Conclusions in relation to setting the scene

In the period from 2007 to date, the Authority's resources have been deployed in conducting seven national investigations, resulting in the publication of over 200 recommendations.

These investigation reports had a number of recommendations for the relevant hospitals and the HSE nationally which should have been used by all healthcare services as a learning tool to inform, improve practice and drive service quality and safety. Had the relevance of investigation findings been reviewed in the context of Portlaoise Hospital, and the aligned recommendations been subsequently implemented, the Authority is of the opinion this could have vastly reduced the number of adverse findings as identified throughout this investigation.

In addition, this section has presented a timeline of significant and related national events and reports that show that risks in both general hospital services and maternity services at Portlaoise Hospital were already identified and known about at all levels of health service management.

The Authority will continue to highlight patient safety concerns as they arise. However, without commitment to and evidence of action in respect of the implementation of recommendations from those charged with managing and leading our hospital services, we face the continued potential of circumstances such as those the Authority has had to investigate over the last eight years.

## Chapter 3. Patient safety culture in Portlaoise Hospital

### 3.1 Introduction to findings in relation to the culture of patient safety in Portlaoise Hospital

The HSE Midland Regional Hospital, Portlaoise, Perinatal Deaths (2006–date) report (referred to in this report as the Chief Medical Officer’s report)<sup>(3)</sup> recommended that the Health Information and Quality Authority carry out an immediate assessment of the patient safety culture at Portlaoise Hospital. As a result, this task was included in the Terms of Reference of this investigation.

Patient safety culture is a complex phenomenon and a number of significant studies have shown that senior leadership accountability is crucial to an organisation-wide culture of safety<sup>(35)</sup>.

Culture in general has been defined in a number of ways, but most simply it means the learned and shared behaviour of a community of interacting human beings<sup>(36)</sup>.

In Ireland in 2008, *Building a Culture of Patient Safety – Report of the Commission on Patient Safety and Quality Assurance* identified leadership and accountability as fundamentally important criteria for the delivery of a safe system. It reinforced open communication, mutual trust and shared perceptions of the importance of safety and confidence in the usefulness of preventative measures<sup>(37)</sup>.

A strong patient safety culture is always characterised by effective governance arrangements which place patient safety at the top of the organisation’s agenda. It includes routine checking of clinical practice, open discussion on quality and safety issues, effective teamwork and the reporting of and learning from adverse incidents. Managing risk must entail an understanding of how the safety culture impacts upon staff performance. As a consequence, organisations that evaluate and understand their current culture can then proactively develop ways to facilitate a culture of patient safety and reduce patient risk<sup>(38)</sup>.

This chapter outlines the tool used by the Investigation Team to assess the culture of patient safety in place in Portlaoise Hospital and how the findings were used to inform the lines of enquiry (the questions asked by the Investigation Team) of this investigation.

### 3.2 Background assessment of safety culture

Although patient safety culture is an important concept for making safe care a reality, the strategy on how to create a safety culture and how to evaluate resulting improvements is less evident.

Internationally, there is a major effort by healthcare organisations to improve patient safety in addition to a new global initiative launched by the World Health Organization<sup>(39)</sup>. In healthcare, over the past two decades, messages about building a positive safety culture have been reinforced in policy documents, guidelines and national priorities in the UK, Europe, North America, Australia and some parts of Asia<sup>(40,41)</sup>.

One such example is that of measuring organisational safety culture. Healthcare providers have been encouraged to assess the current state of their safety culture with a view to designing interventions to improve it, and thereby improve safety in their organisations<sup>(42)</sup>. Safety culture assessments have two critical purposes. They can be used to measure organisational conditions that can potentially contribute and or lead to adverse events and patient harm, and they can be used for developing and evaluating safety improvement interventions in healthcare organisations.

The usefulness of safety-culture-assessment data depends on:

- involving key interested and informed parties
- selecting a suitable safety culture assessment tool
- using effective data collection procedures
- implementing action planning and initiating change<sup>(43)</sup>.

In the hospital setting, assessment of safety culture has primarily been approached using quantitative methods (counting or considering amounts or a number of responses). Quantitative surveys have been useful in eliciting snapshots of individual's shared beliefs, values and norms concerning a wide range of safety issues<sup>(43)</sup>. The reason for this is that questionnaires can be distributed to large samples relatively easily and economically, and the cultural mindset of the organisation can thereby be represented comprehensively and relatively quickly<sup>(44,45)</sup>.

Recognising that every research method has advantages and disadvantages, researchers have suggested that mixed-method approaches could provide superior data relating to the assessment of safety culture. For instance, personal interviews and focus groups can be used to interpret and deepen self-administered questionnaire findings<sup>(46)</sup>.

Consequently, it was critical that the Investigation Team selected a tool to measure the status of a patient safety culture in the hospital that would comprehensively assess the safety culture and inform the lines of enquiry, particularly in relation to the areas to be explored with staff working in (and people who use) the service. In addition, it was critical that the chosen tool would also provide a platform for the HSE to implement an informed improvement programme in Portlaoise Hospital.

### 3.3 Choosing a patient-safety-culture measurement tool

The Investigation Team was informed by the HSE that a safety culture assessment had been conducted as part of a national pilot programme in Portlaoise Hospital. The draft HSE report, 'Patient Safety Culture Survey of Staff in Acute Hospitals, February 2014'<sup>(47)</sup> indicated that the survey tool\* used had been made available to staff at the hospital for six weeks.

However, there was a very poor response rate of 14% with only 92 of the 649 staff members employed at the hospital at the time of the survey completing the survey. The report identified six areas for improvement including a requirement for improved support from management and more resources appropriate to workload and patient care. How incidents are reported and prevented was also identified as requiring improvement. At the time of publication of this HIQA investigation report, the Authority is not aware of any actions or initiatives instituted at Portlaoise Hospital as a result of this particular HSE survey.

The Investigation Team was informed during interview that following completion of the initial pilot study, the survey had been conducted in all public acute hospitals and a composite report would be available in due course. At the time of this HIQA investigation report, that composite report is not yet available. Surprisingly, during this investigation, the Authority was also told that a different assessment tool of a culture of patient safety – Caring Behaviours Assurance System (CBAS) – was being piloted by another office of the HSE. The Investigation Team is unclear as to why the HSE at a senior level did not coordinate and agree the use of one tool to assess and then address the culture of safety across all public healthcare services.

At the outset, the Authority identified the Safety Culture Index© (SCI©) developed by Applied Research Ltd working from Warwick University in the United Kingdom as an effective tool, for the purpose of this investigation, to assess the safety culture at the hospital.

This decision was based on several factors including the:

- necessity to ensure the assessment was guided by appropriate expertise and experience in a very specialised area of practice
- requirement for an assessment tool that had been validated in a comparable test population
- requirement for the process to yield a report with recommendations and methods for improvement in a timely manner.

The chosen provider had the required expertise and experience as its assessment tool has been used in the healthcare setting in the United Kingdom, with 3,000 responses on record which can be used for comparison. In addition, it had the expertise to make any necessary changes to the survey questionnaire for the Irish setting as well as collating the results and providing analysis in report form to the Authority.

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\* Adapted version of the "Hospital Survey on Patient Safety Culture" by the US Agency for Health Care Research

Also influencing the Authority’s choice of assessment tool was the fact that this tool could – if the HSE wished – be repeated in the hospital. It could also be used in tandem with other assessments to monitor how successful interventions and initiatives had been to improve the safety culture in Portlaoise Hospital, such as initiatives started as a result of the risks previously identified by the Chief Medical Officer and the HSE, and the findings of this investigation.

### 3.4 Tool description

The Safety Culture Index© is informed by a 60-item survey questionnaire to assess the cultural roots of poor organisational performance in healthcare organisations. The factors which appear to have the capacity to significantly influence safety can be grouped into individual, team and organisational influences<sup>(47)</sup>.

Responses to the 60 questions are tabulated to give 12 reliable and valid measurements which are called scales (see Table 4). These scales describe staff perceptions of various aspects of a patient safety culture.

**Table 4.<sup>(47)</sup> Scales describing staff perceptions of patient safety culture**

	Task Focus	People Focus	Control Focus	Change Focus
INDIVIDUAL (‘Maintain safety competence’)	Scale a1) Coping with work demands	Scale b1) Participation in decision-making	Scale c1) Checking and accountability	Scale d1) Commitment to learning
TEAM (‘Enhance safety and productivity’)	Scale a2) Purpose and direction	Scale b2) Working in collaboration	Scale c2) Sharing information	Scale d2) Blame-free climate
ORGANISATIONAL (‘Provide safety leadership’)	Scale a3) Role clarity	Scale b3) Staff motivation	Scale c3) Standards monitoring	Scale d3) Vision and mission

The 12 scales differentiate distinct cultural profiles between and within staff groups at a level of detail that can usefully increase management understanding of the causes and consequences of unsafe working practices.

The results from the survey questionnaire were used to compare units within the hospital (internal) and to examine differences in safety culture perceptions across other organisations or systems (external). This was done through comparing the results with other established norms. This external benchmarking system uses norms for the Safety Culture Index© that comprises the views and beliefs of 3,000 healthcare staff from outside of Ireland.

Of the 653 staff working in Portlaoise Hospital when this survey was carried out, a total of 282 completed and returned a survey questionnaire (a 43% response rate). This was considered a sufficient representation to permit reliable conclusions.

### 3.5 Findings

The findings of the report on patient safety culture are based on the opinions held by Portlaoise Hospital staff who took part in the survey and therefore relied on these hospital staff to complete the survey questionnaire honestly in order to produce accurate results. A briefing document was distributed to all staff to explain the importance and significant opportunity available to improve patient safety through honest responses. Following completion of the survey, the Authority facilitated an information session in which the provider (Applied Research Ltd) explained to local and national HSE staff how the findings could be used in the context of planned actions. The external provider collated and evaluated the results in a report<sup>(47)</sup> which the Authority subsequently provided to the HSE on 18 August 2014.

Overall, the safety culture assessment found different perceptions about safety culture between staff groups.\* This was particularly evident from the results for doctors. As a staff group, doctors had a positive overall result across the 12 scales. Worryingly, this was in stark contrast to all other staff groups (allied health professionals, general nurses, managers, midwives, administrative staff, care assistants, portering staff, household staff and a 'Not stated' category) whose scores reflected a negative perception of a safety culture in the hospital.

Key areas that had a negative score for the majority of staff groups included:

- participation in decision-making
- role clarity
- monitoring of standards with a particular emphasis on quality and safety
- coping with work demands.

In Portlaoise Hospital, the results of most staff groups indicated a need for intervention or monitoring of the safety culture in the hospital. On a positive note, all staff at individual levels reported a commitment to learning. However, at a team level they reported that they were not working in a blame-free environment. At an organisational level, they reported an absence of standard monitoring and lack of a clear vision and mission for the hospital.

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\* The nine staff groups represented management, doctors, midwives, general nurses, allied health professionals, administrative, care assistants, porters and household staff.

The following are specific examples of how the staff and or group responses suggest a challenged safety culture requiring the leadership team at a local and national level to monitor and or intervene.

Four staff groups had a negative result for the 'Coping with work demands' scale. This result indicates that safety may not be given the priority it requires and this focus is influenced by job pressure and workload.

General nurses and midwives felt that safety was not treated sufficiently seriously by the hospital. The results suggested that they would like to receive more useful feedback about the quality and safety of their performance at work. The returns also suggested that these two staff groups tend to think that it is likely that they will be unfairly blamed for mistakes and as a result may not report them.

General nurses reported a low score for participation in decision-making, while midwives reported a low score in quality and safety standards monitoring, sharing information and having a clear vision and mission.

The result for 'Staff Motivation' and 'Standards Monitoring' for the majority of staff groups (including managers) was negative. The scales revealed that many staff felt that management was not especially supportive and does not actively monitor or motivate staff to adopt safer working practices and procedures.

Individually, hospital managers reported a low score for participation in decision-making and as a management team reported a lack of purpose and direction. At an organisation level, they reported poor role clarity and motivation.

Administrative staff reported at individual and team levels low participation in decision-making, low participation of working in collaboration, lack of role clarity, purpose and direction.

It is clear that a positive safety culture has a crucial role in supporting and facilitating effective safety management. Although the behaviour of an individual is still considered to be a possible prerequisite of safe or unsafe behaviour in the workplace, safety culture has assumed a considerable importance in patient safety.

The completed 'Assessment of Safety Culture in Midland Regional Hospital Portlaoise using the Safety Culture Index®' suggests the immediate need for a management intervention. This should include communicating a compelling vision of a new safety culture to all staff, which should consist of priority interventions such as:

- increasing management 'safety rounds'
- streamlining incident reporting procedures
- linking safety initiatives to actual incidents and issues
- providing incentives to empower staff about safety.

Following the Chief Medical Officer's report in February 2014 and the HSE's own performance review of June 2014, the Investigation Team provided the patient safety assessment report to the HSE in August 2014. The Authority advised that it should not be viewed in isolation but rather as a starting point from which action planning begins and effective safety initiatives emerge. However, it was evident at the final meeting in October 2014 with senior managers in Portlaoise Hospital, that some senior staff had not received a copy of the final report of the safety culture assessment. The Investigation Team views this as a significant missed opportunity, particularly as the process did yield a report with recommendations and methods for tangible improvement to assist in the development of a culture of safety.

### **3.6 Conclusions on patient safety culture**

A good safety culture is certainly an important foundation of a safe organisation and is founded on the individual attitudes and values of everyone in the organisation. A strong organisation and management commitment is also implicit. It is noteworthy that safety culture assessments are not infallible markers of safety and should only be used in conjunction with other safety initiatives. Multiple factors potentially affect the safety and quality of care delivered to and experienced by patients and people using healthcare services. The findings of this assessment suggest that at the time of this investigation, a strong safety culture did not exist in Portlaoise Hospital.

An assessment of the patient safety culture at Portlaoise Hospital was conducted in line with the terms of reference for this investigation. It is regrettable that at the final meeting in October 2014 with senior managers in Portlaoise Hospital that some senior staff at the hospital had not yet received a copy of the assessment report that the Authority had provided to the HSE some two months' earlier. Some of the findings of this report were subsequently explored by the Investigation Team, and are reported on in the following sections of this report.

## Chapter 4. The patient experience

### 4.1 Introduction to the patient experience

When a person seeks treatment from their health services, it is expected that the service provider, such as a hospital, will meet their needs. These needs do not only include patient care and safety. Their experience of the service should also be characterised by the core principles of dignity, respect and good communication. Person-centred care and support endorses such expectations by placing patients at the centre of all that the service does, thereby promoting kindness, consideration and respect for patients' dignity, privacy and autonomy<sup>(5)</sup>.

This can be done through a variety of different means including by advocating for the needs of patients, protecting their rights, respecting their values, preferences and diversity and actively involving them in the provision of care. Good patient experiences are a key indicator of quality and an important outcome for all healthcare services. In addition, feedback provided by patients can also assist to continuously improve the patient experience for everyone else using the service<sup>(5)</sup>.

Things can and do go wrong in healthcare; the critical question for any healthcare organisation is how it reacts when things go wrong. Portlaoise Hospital provided examples of where patients and families were satisfied with the care they had received and had been complimentary about the staff who had cared for them. However, for the patients or families met by the Investigation Team who had raised concerns about care they had received, the hospital and the HSE as an organisation failed to respond appropriately.

In raising their concerns, the patients and families met by the Investigation Team gave the hospital and the HSE the opportunity to correct the immediate problem and restore faith in the service that they are providing. These patients and families were focused on ensuring that the system of healthcare learned from what had occurred in order to prevent another patient or family having the same experience. These concerns should have alerted the service to problems that required prompt attention and correction.

Throughout an organisation, all levels of staff have a responsibility to promote a culture of compassionate care and openness. In particular, senior members of staff in healthcare services should lead by example. For example, it is the supervisor's responsibility to ensure that an appropriate level of care is provided to the patient and that their expectations have been met, managed and delivered. At an organisational level, appropriate procedures and controls (for example, patient safety walk-rounds) must also be put in place to ensure such delivery of care.

A culture that lacks the promotion of compassionate care and honesty at an individual and organisational level can result in negative patient experiences. For instance, the death of a baby is an extremely traumatic experience for a patient and their family to endure. Failure to display understanding of a patient's loss, or mistreatment by healthcare staff, only serves to compound their distress<sup>(48,49)</sup>.

## 4.2 Communication with patients and their relatives

Following an RTÉ Investigations Unit *Prime Time* programme on 30 January 2014 into the deaths of babies in Portlaoise Hospital and the subsequent treatment of patients and their families by the hospital and the Health Service Executive (HSE)<sup>(2)</sup>, the hospital set up a helpline. This helpline was established to deal with significant concerns arising from the experience of patients and their families using services in the hospital's Maternity Department. Another RTÉ Investigations Unit *Prime Time* broadcast on 3 April 2014 outlined further concerns about the quality and safety of care in the hospital's Maternity Department<sup>(50)</sup>.

The RTÉ Investigations Unit *Prime Time* programme on 30 January 2014 was the catalyst for the initiation of this investigation. As outlined in Chapter 1, it is important to note that the scope of the investigation did not include a review of any individual experiences, including those of the families involved in these *Prime Time* programmes, as the Health Act 2007 does not provide the Authority with the legal remit to do so. This investigation report is not a resolution of their cases. It instead aims to inform both the local and wider healthcare system of the lessons learned, the actions now needed to prevent as far as possible further avoidable harm and anguish to patients and their families, and to support healthcare staff providing care.

Following the start of the investigation, the Authority was contacted by or received information in relation to 83 patients and their families who had similar concerns, most of whom had used the maternity services at Portlaoise Hospital. Some of these individuals were identified after contacting the helpline set up after the airing of the *Prime Time* programmes. Patients and their families who did not contact the Authority directly had agreed to their contact details being forwarded to the Authority by the Department of Health, Patient Focus or the HSE.

As previously stated in Chapter 1, the Authority recognises that the patients and families who contacted the Authority or the HSE did so because they had serious concerns about aspects of the care they had received in Portlaoise Hospital. The Authority acknowledges that the number of patients and families who contacted the Authority or the HSE is small relative to the total number of patients who attend the hospital every year. Other parents and patients may have offered a different perspective on the care provided at the hospital. Nonetheless, the feedback provided by these patients and their families must be acknowledged as a valuable resource for learning, and used to inform and improve the healthcare services.

Members of the Investigation Team met with 15 patients and or members of their families to learn about their experience of the care they received at Portlaoise Hospital. While the investigation did not set out to undertake a detailed examination of each of these patients' care, their experiences helped to inform the investigation process.

In line with the Terms of Reference of this investigation, the purpose of these meetings was to hear what patients and their families had experienced and to understand their associated relationship and communications with the HSE. Although the number of patients who met directly with the Investigation Team represents a limited sub-set of patients using services at the hospital, the meetings were immensely helpful in gaining an in-depth understanding of their own personal experience.

### **4.3 Experience of care as expressed by parents**

The experience of care was recounted to the Investigation Team during the 15 meetings held with a number of patients and or their families. At that time, the Investigation Team witnessed the emotional and physical effect that revisiting their experiences had on these women and men. Despite this, the overriding assertion of those interviewed was that their motivation in coming forward stemmed from a wish to help prevent similar occurrences in the future.

The Authority acknowledges that such recollections are personal perspectives on their experiences and that the validation and or verification of each of those experiences is outside the scope of the investigation. For instance, other parents and patients using the maternity service, who did not come forward, may have offered a different perspective. In this section of report, those patients who provided the Authority with details of their experience have been referred to as parents. An overview of the parents' experiences is set out below.

#### **4.3.1 Listening and communication**

Most parents who met with the Investigation Team recounted difficulties in getting information from the hospital. Particularly, when they contacted the hospital for information and clarity on issues, they believed their questions were either ignored or side-stepped and requests for meetings or information were avoided or refused. Many parents stated that they were afraid to ask questions. Some parents said that they still await answers to their questions while another set of parents said that they experienced significant delays from the HSE when seeking a response to their correspondence, with no response being received to calls, emails and letters.

Parents also mentioned feeling that some staff were difficult to understand and possessed poor communication and language skills. Parents also said that unexplained medical jargon was used during very sensitive and important situations. This left parents feeling intimidated and unclear as to what was being said to them and some of them felt inadequate and uncomfortable about asking for a clearer explanation.

Women described how when, for example, they were being given intravenous oxytocin – a medication used to induce labour – they were not given adequate explanations regarding the use and side-effects of this medication. The Investigation Team was also advised by some women that the volume of the alarms on their cardiotocograph (CTG) machine (a machine used to record baby's heart rate while the baby is still in the womb) were turned down or silenced. Two of these women told the Investigation Team that some staff had shown them how to silence the alarm. They also said that explanations as to why the alarm needed to be reduced or silenced were not given, or indeed what the alarm going off indicated.

Most parents who met with the Authority during this investigation explicitly expressed the opinion that some staff who were involved in their care were uncaring and did not listen to what they were saying. This was a common theme running through the meetings with those met with by the Authority with parents saying they felt they were being talked about, were being ignored, and that they felt invisible.

As a result, some women described how they were afraid to seek help and assistance, while some men felt they were ignored when expressing their concerns. Furthermore, some women said they felt they were not listened to when they raised their concerns regarding the wellbeing of their babies. Some women felt that when they believed that something was not right with their pregnancy their worries were not addressed. Some women said that they were not given explanations during and or following a traumatic labour or emergency Caesarean section. Women reported feeling terrified during these experiences, and the degree of communication from staff added to their fears. Parents, who had been transferred to other facilities with their babies, and those who had subsequent deliveries in other maternity units, spoke about how those later experiences were in marked contrast to their earlier experience in Portlaoise Hospital.

Following an RTÉ News story on 28 February 2014 on the publication of the Chief Medical Officer's report entitled *HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006 – date)*, some women called the advertised HSE helpline and arranged for meetings with the hospital. However, some women recounted how they felt that these meetings were unhelpful and had not given them an opportunity to describe their experience.

### **4.3.2 Dignity and respect**

The Investigation Team met a woman whose reported experiences reflected a lack of compassion, humanity, dignity and respect during her care. Another woman recounted that some staff made her feel like a naughty child or that she was a troublemaker when she questioned her care and treatment. Another believed she was made to feel guilty for her tragic outcome and consequently this made her fearful of conceiving again. This fear of further pregnancy was a recurring theme among those parents who met with the Investigation Team.

One set of parents also said they felt that they were not entitled to an explanation as to what happened when their baby had tragically died. Others described being told their baby did not survive, or being given other sensitive information, in an unsuitable environment such as the hospital corridor.

Some women stated that during their clinical examination, doctors did not address them directly and only spoke to the midwives present. This reported approach made them feel inadequate and upset.

Although some parents told the Investigation Team of instances where a single member of staff had shown kindness, they felt that this compassionate approach was not the norm during their care. Instead, parents said that overall they had been shown a lack of empathy, sensitivity and advocacy. Another woman mentioned that staff she had encountered seemed to lack a human touch.

### **4.3.3 Care of bereaved parents**

During the course of the meetings with 15 patients and or members of their families, the Investigation Team met with eight mothers whose babies had died while in the care of Portlaoise Hospital. The Investigation Team also spoke with most of the fathers during these meetings.

Parents told the Investigation Team how they felt that the care offered in the midst of their grief was poor and did not reflect good practice. For example, some parents spoke of being advised of their babies' deaths separately and where their first sight of their baby was when being ushered alone into a room where the deceased baby lay on a table. Parents who spoke with the Investigation Team also stated how little or no psychological support was given to them and no information was given regarding support groups.

Some women told the Investigation Team of the loneliness they felt after losing their baby. One woman said how she felt that staff avoided going into her room after her baby had died, while another woman said she was reprimanded for crying as it would upset other mothers who had delivered healthy babies. One woman reflected on the lack of compassion she had experienced following the loss of her baby recounting that any small simple act of humanity would have provided much needed comfort during that moment.

Some parents spoke of their acute distress about how they had been treated by some of the staff locally in Portlaoise Hospital and due to what they believed was inaction nationally in the HSE. Some parents also expressed a real frustration and anger that lessons had emerged from preceding investigations and reviews but that improvements had not happened to benefit them and their children.

Some parents reported that they were told that their baby had been stillborn or that their baby had died instantly at birth. However, by obtaining documentation or reports after the birth of their baby they subsequently discovered conflicting information about when their baby had died. This discrepancy in the facts surrounding the death of their baby was a source of great distress for these parents and caused a breakdown of trust.

Two sets of parents also reported being unprepared for seeing their deceased babies. The manner in which these parents received their babies was recounted by them as being grossly inappropriate and extremely traumatising. For example, they stated how their baby was brought to them in a metal box on a wheelchair covered with a sheet and pushed by mortuary staff. One mother described how the box was not of sufficient size and their baby was squeezed in to fit. She said she did not remove or hold her baby for fear of being unable to return him to the box. One woman stated that she had been told that this arrangement was intended to prevent upsetting the other mothers.

Some women also said how some keepsakes of their baby were either not given back to them or if they were returned, they were incomplete.

Some parents articulated that there was no liaison person allocated to accompany them to the mortuary and that the directions that they were given were inadequate. They described walking around unable to find the mortuary.

One set of parents described being further traumatised when contacted by telephone years later with the query as to how they wished the disposal of their baby's retained tissue be carried out. They said informed consent had not been given by them to retain the tissue, or stated that they had no knowledge of any such retention.

#### **4.3.4 Parents' contact with the hospital**

Some parents who had lost their babies said they were given the impression that they were isolated cases and that such events were not regular occurrences. Following the airing of the RTÉ Investigations Unit *Prime Time* programme, parents reported that they felt betrayed when they subsequently discovered that other parents had had similar experiences.

The interactions between parents and the hospital at local level were reported as unsatisfactory. Parents said they sought answers but had encountered defensiveness and felt that there had been a cover-up. Over time, they came to realise that some internal investigations had been carried out and found it

unacceptable that they – as the parents involved – had not been informed. Others said they had been assured that investigations were about to start or were in progress but had found out that this was not the case. The reported unfulfilled initial assurances served only to increase the levels of frustration and lack of trust. They felt strongly that there was an attempt to both play down and contain the seriousness of the situation.

#### **4.3.5 Parents' contact with the HSE at regional level**

Several parents advised that they had been contacted by a senior staff member of the HSE following the airing of the *Prime Time* programme and prior to meeting with the Authority, in order to arrange meetings between parents and the HSE. Some parents described these meetings with the HSE as positive and beneficial and this contact has also resulted in arrangements of independent reviews and counselling.

#### **4.3.6 Summary of patients' experiences**

All of the parents who bravely contributed to this investigation must be commended for allowing their private and painful experiences to be shared.

These experiences show on a human level how an absence of simple actions (for example, listening, caring and giving compassion) during a hugely traumatic experience in a person's life can make a harrowing event even worse for a parent. It is difficult to understand how some members of staff left these parents with a sense of not receiving these basic acts of humanity. As a means of helping to deal with their experiences, some parents have called for an appropriate advocacy service so that they may feel supported during such a traumatic event. If complications arise and if something does go wrong, open disclosure and a timely response to complaints are essential.

Specific needs of bereaved parents must be taken into account by hospital staff so that parents do not experience any further unnecessary trauma. No parent should ever have to endure the pain of receiving their deceased baby in the manner in which some of these parents described to the Investigation Team. The parents who had experienced some kindness and compassion remarked at how supported they felt by this and how this approach had helped them get through a difficult time. Some examples of such kindness and compassion were given by patients who told the Investigation Team of staff who had stayed with them beyond their shift just to provide them with support when needed, or who made home visits to them outside of their working hours. Person-centred care such as this can make an enormous difference to those dealing with a traumatic experience.

### **4.3.7 Acknowledgment**

The Authority wishes to acknowledge the time and energy given by the parents who contributed to this investigation and thank them for their involvement. It took great courage for these parents to attend meetings with the Authority and to relive very distressing experiences. Relating their experiences was very stressful for all of the parents. Many described their experiences as having overwhelmed their lives and as having an ongoing traumatic effect on them. All of the parents interviewed stated that the reason why they had attended the meetings and told their accounts was that they hoped to prevent other parents having such stressful experiences. Many voiced the hope that their contribution would help to improve the service in the hospital.

### **4.3.8 An untapped resource**

The Authority believes that these parents have acquired a range of insights, have conducted extensive research and have a valuable perspective to offer because they see maternity services through a different lens. The healthcare system would be well advised to embrace them as a resource and recognise them in the future as potential co-partners in the delivery of safer care.

## **4.4 Risks highlighted**

### **4.4.1 Addressing the needs of patients with the HSE**

In addition to the families met by the Investigation Team, the Authority also received a large volume of correspondence and phone calls in February and March 2014 from women who had attended the Portlaoise Maternity Department and other maternity hospitals in Ireland. In many cases, the information reviewed by the Investigation Team included a comprehensive narrative of their experiences. The correspondence and phone calls, together with the experiences described to the Investigation Team engaged in the patient interviews, were identified as a significant cause for concern. This was because many of the patients interviewed had described themselves as damaged and traumatised from their experiences in the aftermath of incidents.

Each contact that the Authority had with patients regarding their experiences – including the narratives reviewed, the meetings held and the phone calls taken – raised significant concerns about the lack of a formal integrated national response. Such a response would include clinical review, psychological support and counselling, as well as assisting bereaved parents with their choices about seeing and holding their baby. It would also include options for creating mementos such as footprints and photos for the parents to keep.

Such issues fell outside the Terms of Reference of the investigation and outside the remit of the Authority as a regulator. Therefore, in June 2014, the Authority formally wrote to the then Minister for Health Dr James Reilly TD and raised these

issues both as a concern and a risk (see Appendix 6). The Authority was concerned that the personal accounts given by the patients and their families indicated that the interventions of the HSE up to that point were not adequately addressing the hurt and damage caused to parents arising from their experiences.

In light of the described shortcomings in the HSE response to these patients at that time, the Authority wrote to the then Minister for Health and requested that a national alternative approach needed to be created as a priority which would be separate to this investigation process and which would provide:

- a trusted and single point of access
- a rigorous consideration of individual and family experiences
- a review of clinical outcomes (as necessary)
- relevant psychological support for the patients and their families.

The Minister for Health responded that the matter had been referred to the HSE. Subsequently, a single contact person was identified in the HSE to address the needs of these patients and their families. The Authority then wrote to 83 patients who had been in direct contact or had been referred to the Authority and informed them in writing about the availability of this resource. The Authority also advised these patients that the HSE would be in contact with them in due course and permission was sought to send on their details where appropriate. When permission was received by the Authority, their details were then transferred to be managed by the appointed contact person in the HSE.

However, during the course of the investigation, the Investigation Team determined that the case-review process set up by the HSE was potentially not structured to ensure risks were identified, trended and addressed. HSE management subsequently outlined to the Investigation Team additional arrangements that were put in place. These included an incident management team, specifically to manage the group of cases where concerns were raised by families following the RTÉ Investigations Unit *Prime Time* programme on 30 January 2014 regarding the care delivered by the Maternity Department. The Incident Management Team includes representatives from Portlaoise Hospital, the HSE and the patient advocacy group, Patient Focus. In addition, a clinical review team had also been convened. At the time of this report, this team comprises an external independent chairperson with a team of six external independent consultant obstetricians and two externally appointed midwives.

The Investigation Team received a report from the HSE in October 2014 that indicated that a total of 176 complaints or contacts have been made by patients through a variety of channels and that these complaints were being dealt with on a phased basis. These cases involved a number of hospitals, however, the vast majority of these relate to the maternity services at Portlaoise Hospital. In addition, it was reported that the Royal College of Physicians of Ireland (RCPI) is working with the HSE to support the methodology of the process.

It was also reported that the HSE has engaged with patients who have requested additional assistance or support which included:

- access to counselling
- fast-tracking of certain clinical treatments
- support in linking with employers where appropriate.

The HSE has reported that this assistance has been provided where possible, although it has stated some requests have been difficult to successfully address. A commitment to continue to address any further requests that are received in the future from the patients has been provided by the HSE.

During the Authority's follow-up meeting with senior managers in the Maternity Department of Portlaoise Hospital in October 2014, senior managers reported that improvements were being made to the complaints management process. For example, maternity staff were proactively seeking to improve the experience of patients who were returning to Portlaoise Hospital whose previous experience had been poor. These managers also reported that since March 2014, the Maternity Department had received 200 compliments. Twenty complaints which had been received during the same time frame were all resolved within the HSE's 30-day target response time policy.

It is important, however, that information supplied in relation to the above interventions, together with commitments for the future, are first of all validated and then monitored and evaluated. This is a necessary first step in the restoration of public confidence in the maternity services being provided at Portlaoise Hospital, as well as an exercise in preventing future anguish for women and their families, and the need for future investigations such as this one.

#### **4.5 Conclusions in relation to patients' experiences**

The Authority acknowledges that the total number of patients and families who contacted the Authority or the HSE with concerns about the care they had received in Portlaoise Hospital is small. The Authority also acknowledges that the patients and families who contacted the Authority or the HSE were motivated by their poor experiences.

The Authority greatly recognises the importance of the narratives generously given by those affected by their experiences in the Maternity Department of Portlaoise Hospital. This has been demonstrated by ensuring that the first interviews during this investigation, which were held following the patient safety culture assessment, were with the patients and their families. These accounts have played a fundamental role in guiding the direction of this investigation and in particular they have greatly informed the Investigation Team's lines of enquiry (the questions posed by the Investigation Team).

The narratives provided by patients and families who contacted the Authority or the HSE with concerns about the care they had received in Portlaoise Hospital demonstrated how the absence of a culture of compassionate care and openness within a healthcare service could result in devastating consequences for patients and their families. This is particularly the case in the circumstances when families experienced the death of their baby.

The communication and interactions of the healthcare service with patients, as described to the Authority during the course of this investigation, has shown a significant disengagement between patients and healthcare services at individual, local and national levels.

These events have highlighted that this disengagement runs much deeper than an adverse systemic response; rather it appears to originate from the individual. Individuals working within a healthcare service must ensure to take personal and professional accountability for their actions.

It is for these reasons it is important to look at and evaluate the culture within such an environment, so that positive changes may be made. Such positive changes must include the inherent qualities of compassion and openness during the care of a patient, particularly when a devastating life experience has happened.

## Chapter 5. Maternity services at Portlaoise Hospital

### 5.1 Introduction to maternity services at Portlaoise Hospital

This section of the report presents the Investigation Team's findings in relation to the quality and safety of maternity services currently provided at Portlaoise Hospital.

These findings focus predominantly on the status of the maternity service and the immediate controls put in place within the Maternity Department by the Health Service Executive (HSE) in the aftermath of the publication of the Chief Medical Officer's report<sup>(3)</sup> and its recommendations. In reporting these findings, the Investigation Team considered the implementation status of relevant national recommendations previously made by the Authority<sup>(6-8,11)</sup>, professional bodies and other investigations in relation to the delivery of safe and effective public maternity services in Ireland. The Investigation Team – in line with the Terms of Reference of this investigation – did not investigate or comment on individual cases.

In conducting this investigation, the Investigation Team was mindful of the circumstances that gave rise to increasing concerns about the quality and safety of services at Portlaoise Hospital – and in particular its maternity services. Chief among these concerns were consistent reports from many service users describing unacceptable standards of care (Chapter 4), the Authority's previous engagement with the HSE in relation to unresolved risks at Portlaoise Hospital (Chapter 2), and the contents of the Chief Medical Officer's report published in February 2014.

The Investigation Team visited the Maternity Department at Portlaoise Hospital in June 2014 and spoke to women using the service at the time. Women who had previous experience of the service reported notable improvements in terms of the service they received, their interactions with staff and the increased visibility of the management team. People who were using the service for the first time also reported satisfaction with the care received.

### 5.2 HSE governance of maternity services

The HSE is the national agency accountable for the planning and delivery of the national health services including the 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 and midwives working within the maternity services. At the time of this investigation, the public maternity services are part of the Acute Hospitals Division. The HSE's National Director of Acute Services is the senior HSE manager with responsibility for this division.

The National Director of Acute Services is a member of the HSE Directorate and reports directly to the Director General of the HSE.

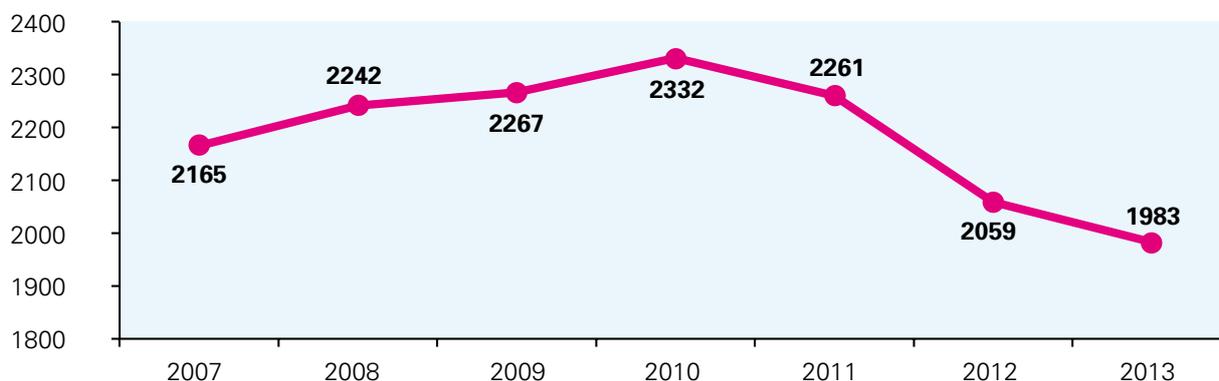
Maternity services are provided in 19 maternity units around the country. The birth rate in Ireland increased by approximately 30% from 2000 to 2012, with the greatest rate of increase recorded between 2005 and 2007 and the greatest number of births recorded in 2009<sup>(3,51)</sup>.

### 5.2.1 Profile of the maternity services at Portlaoise Hospital

The Maternity Department at Portlaoise Hospital primarily serves the population of counties Laois, Offaly, Tipperary, Kildare, and Carlow. The Chief Medical Officer's report cited a 100% increase in the number of births at the Portlaoise Hospital Maternity Department from the year 2000 to 2012. This equated to 1,047 births in the year 2000 compared with 2,059 births in 2012.

Figure 1 illustrates the total number of births per year (both live and stillbirths) at the Portlaoise Maternity Department from 2007 to 2013.

**Figure 1.** Births each year at Portlaoise Hospital, 2007 – 2013\*



\*Data source: HSE Performance Reports. Note: total births are inclusive of stillbirths.

The increasing trend in the number of births in Portlaoise Hospital up to 2010 mirrors the national trend in Ireland. The Department of Health's National Healthcare Quality reporting system reported a rate of 30 Caesarean sections per 100 live births for Portlaoise Hospital in 2013<sup>(52)</sup>. This is similar to the national reported rate of 28.8 Caesarean sections per 100 live births for the same year. In addition, perinatal mortality rates for Portlaoise Hospital reviewed by the Investigation Team also compare favourably with national average rates<sup>(53)</sup>.

The HSE was set up under the Health Act 2004 as the single body with statutory responsibility for the management and delivery of health and personal social services in Ireland<sup>(54)</sup>. Before the establishment of the HSE, Portlaoise Hospital had been governed by the former Midland Health Board, which met for the final time in May 2004.

It is notable that the Midland Health Board's final annual report<sup>(55)</sup> – produced in 2004 prior to the transfer of service delivery responsibilities to the HSE – highlighted that the area continued to have a higher birth rate than the national average and that this had implications for the management of regional maternity services.

As reported in Chapter 2 of this report, in February 2006, a review was published into midwifery staffing at the Maternity Department in Portlaoise Hospital, initiated by the hospital's Director of Nursing and supported by the HSE Dublin Mid Leinster region's Director of Nursing Planning and Development Unit<sup>(14)</sup>. It made a number of recommendations, including additional clinical midwifery manager IIs (CMMIIs) to act as shift leaders on each shift, which were not fully addressed until 2014. This followed the media and political attention on the services following a series of reported serious adverse events, almost eight years after the recommendations had first been made.

### **5.2.2 Model of maternity care**

Maternity services at Portlaoise Hospital are hospital consultant-led, with pregnant women and mothers attending the hospital for antenatal, delivery and postnatal care. General practitioners (GPs) also provide antenatal and postnatal care in the community. This model of maternity service is in keeping with the predominantly medical model of maternity care that, at the time of the investigation, has been in place for over 60 years throughout Ireland.

In 2013, the Authority recommended that the Department of Health and the HSE should work together to conduct a review of the national maternity services and develop and implement a National Maternity Services Strategy<sup>(11)</sup>. The purpose of this strategy was to agree and implement standard, consistent, modern-day models of maternity care for the delivery of maternity services nationally in order to ensure that all pregnant women have choice and access to the right level of safe care and support on a 24-hour basis.

At the time of finalising this report 19 months since the Authority published this recommendation, a national maternity strategy had not been developed or significantly progressed.\* The Authority considers the delay in developing and publishing a national maternity strategy unacceptable.

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\* On 30 April 2015 the Minister for Health announced the establishment of a Steering Group to advise on the development of a National Maternity Strategy and published a list of its membership.

## 5.3 Corporate and clinical governance

### 5.3.1 Introduction

Safe, effective and sustainable healthcare services are dependent on good corporate and clinical governance arrangements, efficient workforce planning and the effective use of information and resources.

In a complex healthcare system, clear lines of accountability and levels of authority are essential for an effective system of governance. Previously published Authority investigation reports identified the requirement for service providers to have strong integrated clinical and corporate governance structures with clear accountability arrangements in place<sup>(6-8,11)</sup>.

The Investigation Team reviewed clinical and corporate governance arrangements in place for the maternity services at Portlaoise Hospital. It identified that, although progress had been made following publication of the Chief Medical Officer's report in February 2014, there were still significant deficiencies in the governance of the service. In particular, this section will focus on systems of management and leadership for the maternity services, workforce issues, clinical audit (ongoing review and evaluation of clinical practice) use of information and education and training.

### 5.3.2 Interim Management Team for the maternity services

On 28 February 2014 following publication of the Chief Medical Officer's report, local corporate governance structures for the maternity services were reviewed and supplemented. An Interim Management Team consisting of a general manager, director of midwifery and a quality and patient safety manager was appointed by the HSE's Regional Director of Performance and Integration. In addition, one of the consultant obstetricians working in the maternity unit assumed the role of Clinical Lead and joined the Interim Management Team.

The Interim Management Team reported that it had delegated authority from the HSE to make whatever changes were necessary to improve the service. The General Manager had accountability and authority for the day-to-day operational management of the Maternity Department with a direct reporting line to the Regional Director of Performance and Integration.

At the time of the investigation, the members of the Interim Management Team had only recently been redeployed from within the HSE and from the Coombe Women and Infants University Hospital in Dublin to work in the Maternity Department in Portlaoise Hospital. It was apparent that the team was working well and had begun to develop a clear vision of what it wanted to achieve.

Structures have been put in place that included:

- a formal leadership team
- the appointment of a dedicated quality and patient safety manager
- a staff communication forum
- timely reporting of incidents and staff feedback processes
- and a visible management presence on the maternity unit floor working with staff and meeting patients.

Staff who participated in group meetings with the Investigation Team reported that they were optimistic that positive changes were happening.

While the HSE had put in an Interim Management Team in the maternity section of Portlaoise Hospital, the governance of the general hospital remained unchanged. This meant that shared clinical and general services, for example, paediatrics, anaesthetists, diagnostic and outpatient services reported to and were managed within the corporate structures of the general hospital. It was too early at that stage for the Investigation Team to assess how this arrangement would work. However, senior managers in the Maternity Department were confident that given time, all the necessary arrangements would be agreed.

This area will be further discussed in Chapter 6 of this report.

### 5.3.3 Clinical network

In December 2006, the Institute of Obstetricians and Gynaecologists in its report on the future of maternity and gynaecology services in Ireland<sup>(56)</sup> recommended that clinical maternity networks should be established in Ireland. It recommended that the Maternity Department in Portlaoise Hospital be linked with the Coombe Women and Infants University Hospital in Dublin. This recommendation to establish clinical maternity networks was not progressed at a national level.

Eight years later, in 2014 and in light of the range of adverse incidents highlighted earlier in this report, the Chief Medical Officer's report<sup>(3)</sup> repeated the same recommendation that Portlaoise Hospital should be included under the clinical governance, direction and authority of the Master\* of the Coombe Women and Infants University Hospital.

In essence, this was aimed at creating one single maternity service operating over two sites which would in turn facilitate:

- a common system of governance
- capacity for medical, midwifery and other staff to be appointed to the network and to rotate between the two sites to facilitate training and service delivery

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\* The Master is a term from the 19th Century when the Rotunda, the Coombe and National Maternity hospitals were each granted the power to appoint a lead doctor to take control of all aspects of the hospitals' clinical and administrative areas.

- training of junior doctors and midwives on both sites
- risk categorisation of patients to ensure that higher risk patients are managed at the Coombe Women and Infants University Hospital.

This recommendation of the Chief Medical Officer is in keeping with current national policy to create hospital groups<sup>(57)</sup> and is supported by the Investigation Team. Furthermore, the Investigation Team is of the opinion that the proposed hospital group structures will only work if they incorporate the elements of a clinical network that are outlined above across all services that are provided (for example medical, surgical, paediatrics and so on).

However, at the time of the investigation this had not happened, and therefore the maternity services at Portlaoise Hospital continued to function in isolation without the support of a maternity service network of care.\*

### 5.3.4 Clinical leadership

In light of the Chief Medical Officer's report and the factors that led to this investigation, the Investigation Team was concerned to find at the time of this investigation, a clinical network had not formally been established. It was also of concern that a senior obstetrician had not been seconded to provide independent senior experienced clinical leadership. Such an appointment would help to ensure a safe quality service for people using the maternity services including reviewing and overseeing current practices and the aligned clinical quality and audit arrangements in the Maternity Department of Portlaoise Hospital.

These concerns were subsequently raised formally with senior HSE management who reported that negotiations were underway at that time with the Board of the Coombe Women and Infants University Hospital to take over the governance of Portlaoise Hospital maternity services. The Authority recognised the need to agree a memorandum of understanding and the funding arrangements required for the Coombe to assume governance of the service. However, the Authority was concerned that following the range of clinical incidents and reports of adverse patient experience within the Maternity Department that, at the time of the investigation, the Interim Management team was not resourced to provide independent obstetric clinical expertise to ensure a consistently safe service.

The Authority wrote to the Director General of the HSE in September 2014 outlining its concerns about the continued absence of experienced senior clinical leadership within the maternity unit. However, until the recently signed memorandum of understanding between the Coombe Women and Infants University Hospital and Portlaoise Hospital is implemented and operational, a clinical network linking the Maternity Department in Portlaoise Hospital with the

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\* On 26 March 2015, the Minister for Health announced that a memorandum of understanding was signed between The Coombe Women and Infant University Hospital and the Dublin Midlands Hospital Group/ Health Service Executive which will see the Coombe Women and Infant University Hospital assume responsibility for the governance, management and provision of maternity services at Portlaoise Hospital.

Coombe Women and Infants University Hospital will not become a reality. The failure of the HSE to put in place adequate and comprehensive interim clinical leadership arrangements within the obstetric services at Portlaoise Hospital from February 2014 until March 2015 is not acceptable, and represents a failure to accept and address some of the clinical governance issues and risks identified in the Chief Medical Officer's report.

### **5.3.5 Clinical audit**

Clinical audit, an integral and important component of clinical governance, involves checking the safety, reliability and effectiveness of outcomes of clinical practice. It is an important means of understanding and assuring the quality of care provided to patients. Clinical audit, integrated into systems of care, facilitates the identification of incidents where care was substandard, thereby highlighting opportunities for improvement. All clinicians are required to actively participate in clinical audit in compliance with national standards.

The Chief Medical Officer's report addressed the issue of clinical audit indirectly when discussing the practice of transferring high-risk pregnant women and premature babies to other hospitals better equipped to care for them, pointing to a failure at hospital level to collate and analyse data for the purpose of informing practice. More specifically, the Chief Medical Officer's report says that 'the fact that data on changing Maternity Department activity was easily available and had not been examined is an important observation'. The Investigation Team agreed that audit processes that collate and analyse data help to facilitate a service in recognising changing stresses on the system and associated risks, and the need for actions to alleviate them.

The Investigation Team established that there is an evolving system in place to coordinate clinical audit activity at Portlaoise Hospital. However, audit activity as reviewed was predominantly midwifery focused. Following a review of documentation and data and an exploration of clinical audit, the Investigation Team shares the concerns of the Chief Medical Officer. Of particular concern is the maturity of the system to collate and analyse clinical data and respond appropriately.

The Investigation Team further reviewed the system of clinical audit through the lens of two specific areas of clinical practice; the practice of transferring high-risk pregnant women and premature babies and the incidence of postpartum haemorrhage.

### **5.3.6 The practice of transferring high-risk pregnant women and premature babies**

The Chief Medical Officer's report identified an increasing trend in transfers out of Portlaoise Hospital for high-risk pregnant women and premature babies

The CMO's report suggests that the service was unaware of these trends and as a consequence had not assessed the cause or appropriateness of the increase. Local clinicians interviewed by the Investigation Team were of the opinion that this increased rate of transfers was a sign of good practice in that they were redirecting high-risk pregnant women and premature babies to the appropriate care setting. However, there was no evidence in October 2014 – 10 months since the publication of the Chief Medical Officer's report – that any formal arrangements has been introduced to assure the service that (a) all transfers were clinically appropriate and (b) that all appropriate cases to include high-risk babies were always transferred in a timely manner to an appropriate setting.

This further reinforces the need for robust audit arrangements to assure good practice or to identify areas of improvement.

### **5.3.7 Monitoring the incidence of postpartum haemorrhage**

The HSE's Clinical Programme in Obstetricians and Gynaecology's guidelines on the prevention and management of postpartum haemorrhage define primary postpartum haemorrhage as the loss of 500 mls or more of blood from the genital tract within 24 hours of the birth of a baby<sup>(58)</sup>. They further categorise a blood loss of 500 to 1,000 mls as minor and more than 1,000 mls as major.\*

In the course of the investigation, the Investigation Team identified a potential area of concern at the level of clinical oversight of the calculated rate of postpartum haemorrhage at Portlaoise Hospital. By way of example, the hospital provided the annual postpartum haemorrhage data for January to December 2014 and reported an overall increase in the rate of postpartum haemorrhage ranging from 15.2 to 26.8 per 100 maternities. In the same report, the hospital identified that six cases of severe post partum haemorrhage had occurred during the three-month period of March to May 2014.

How units manage postpartum haemorrhage can be an indicator of effective team work and supervision in the delivery suite, since effective clinical management requires good working relationships between the midwives and doctors, formal escalation protocols and effective senior clinical supervision.

The Investigation Team acknowledges that the issue of post partum haemorrhage was reviewed and discussed at the Quality and Patient Safety Committee level in July 2014. As a result of this review, a local guideline was developed and implemented and infusion pumps for the delivery of a drug called Oxytocin were provided in the theatre. While the Investigation Team acknowledges the development of this general guidance, it is not assured that this review included a full review of these cases with causation and management assessment, lessons learnt and recommendations given.

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\* Major postpartum haemorrhage is further subdivided into moderate (1,000 – 2,000 mls) and severe (more than 2,000 mls).

It is important that the management of postpartum haemorrhage is regularly audited to assess current practice against expected standards of care and actions agreed and implemented to address any deficiencies observed. Only then can the hospital be assured that the risk of postpartum haemorrhage is being effectively managed. The Authority recommends that the hospital continues to closely monitor the rate of postpartum haemorrhage and regularly audit its management in order to assess the effectiveness of the steps taken to date

## 5.4 Workforce

A service's workforce is one of its most important resources in delivering safe, high-quality care. The Chief Medical Officer's report highlighted serious concerns in relation to the staffing arrangements in the Maternity Department including an over-reliance on the use of agency and or locum clinical staff, absence of senior midwifery leadership and effective workforce planning. Clinical staff throughout the general and maternity departments of the hospital reiterated at interview, and in group meetings, a long-standing issue in relation to the inadequacy of the staffing levels in all areas of the hospital.

At a local level, hospital management produced large amounts of reports and correspondence that it had sent to regional and national HSE managers requesting additional staff. Reciprocally, HSE staff at a national level produced equal amounts of correspondence showing their responses to these requests. Irrespective of the amount and frequency of communication on this matter, up to the time of the Chief Medical Officer's report there were insufficient numbers of front-line clinical staff, a reliance on agency staff and a complete deficit in senior midwifery management support in the hospital, as detailed below.

One of the key priorities that the Interim Management Team identified at interview was the need to address the staffing deficiencies and ensure 24-hour, seven-days-a-week (24-seven) senior midwifery availability to monitor and support staff in the delivery of a safe and high-quality maternity service.

This following section of the report will discuss the findings of the Investigation Team since the publication of the Chief Medical Officer's report in respect of the following key staffing areas:

- midwifery services
- consultant obstetricians
- obstetric anaesthetic care
- non-consultant hospital doctor staffing.

### 5.4.1 Midwifery services

Midwifery staff at Portlaoise Hospital provide antenatal care, care during labour, and postnatal care as well as pregnancy assessment, health promotion, screening, clinical skills training, bereavement support and lactation advice and support. Specific to this workforce, the Chief Medical Officer's report<sup>(3)</sup> identified large gaps in terms of midwifery leadership positions, and extensive and increasing use of agency staff.

Members of the Interim Management Team of the Maternity Department in the hospital were unable to provide the Investigation Team with a validated picture of the actual number of midwifery staff employed or contracted to work in the hospital prior to the Chief Medical Officer's report. This is because prior to publication of the Chief Medical Officer's report, the whole-time equivalent numbers for the maternity services were combined with the general staffing numbers. The newly appointed Director of Midwifery reported at interview that she estimated 72 whole-time equivalent midwifery staff\* were required to safely provide the midwifery services at the hospital.

At the time of the investigation, significant progress had been made increasing the midwifery numbers, introducing senior clinical midwifery managers, shift midwifery leaders, a bereavement specialist, clinical skills coordinator and clinical midwife specialist.

The pivotal appointment of a director of midwifery with relevant current clinical and managerial experience and close ties to the Coombe Women and Infants University Hospital was a crucial factor underpinning many of the improvements that were in progress when the Investigation Team visited the hospital. This appointment of a director of midwifery to a maternity department located within a larger hospital is unique to Portlaoise Hospital and not reflected anywhere else in the country. It was evident to the Investigation Team through interview, in group interviews and on-site observation that the director of midwifery role has had a very positive influence in terms of assessing and improving the standard of midwifery care. It was noted that the role appeared to be enhancing multidisciplinary working relationships, improving staff morale and re-energising a patient-centred approach to care.

At the time of reporting there is no national standard for midwifery staffing levels for women in labour – a key standard available in other jurisdictions. The Authority views this as an essential component of a National Maternity Strategy.

### 5.4.2 Consultant obstetricians

Obstetrics and gynaecology at Portlaoise Hospital are delivered through a consultant-led model of care.

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\* Information provided by the HSE in April 2015 advised that the required number of midwives had been reduced to 70 following discussion with the Coombe Women and Infants University Hospital and that all 70 posts were currently filled.

At the time of the investigation, there were three permanent, one temporary and one locum consultant obstetrician.

It is noteworthy that a 2011 position paper produced by the HSE's Obstetrics and Gynaecology Clinical Programme on consultant workforce planning recommended that the use of short-term locum appointments to cover planned leave in smaller units should be phased out<sup>(59)</sup>. This can only really be addressed by the inclusion of the Maternity Department in Portlaoise Hospital in a clinical network within a larger hospital such as the Coombe Women and Infants University Hospital. \*\*

#### **5.4.3 Obstetric anaesthetic care**

An obstetric anaesthetist is an anaesthetist who specialises in the care of pregnant women. There are three general anaesthetists who cover both elective and emergency general and maternity services. The Investigation Team was informed that there is no consultant obstetric anaesthetist at Portlaoise Hospital.

The Investigation Team acknowledges that a maternity department the size of Portlaoise Hospital is unlikely to attract a consultant obstetric anaesthetist. However, as previously discussed in relation to the obstetric workforce, incorporation of Portlaoise Hospital into a clinical network with the Coombe Women and Infants University Hospital would facilitate consultant obstetric anaesthetists to work with local anaesthetists endorsing protocols, standards, clinical guidelines and pathways of care. Such a model of cooperation could facilitate daytime rotation between both hospitals to allow training and sharing of experience.

#### **5.4.4 Non-consultant hospital doctor staffing**

In Ireland, hospital doctors who have not yet reached consultant grade are referred to as non-consultant hospital doctors (NCHDs).

Portlaoise Hospital is recognised by the Institute of Obstetricians and Gynaecologists – the professional and training body for obstetricians and gynaecologists in Ireland – as a training location for non-consultant hospital doctors. It recognises two basic specialist training posts (year one and year two) in obstetrics and gynaecology. However, the Institute identified a number of major issues at the hospital which meant that it did not recognise it as a training location for specialist registrars (senior trainee doctors) or year-three basic specialist training registrars in obstetrics and gynaecology. One of the major issues identified for this decision was the low level of gynaecological surgical throughput, with the Institute concluding that gynaecology-operating arrangements at the hospital are not sufficient.

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\*\* In April 2015, the Authority was informed that as part of the Coombe Governance Model, an additional two permanent consultant obstetrical posts were approved to replace the temporary and locum consultant posts and also to provide clinical leadership.

In addition, Portlaoise Hospital is not recognised by the College of Anaesthetists of Ireland – the training body for doctors in anaesthesia, intensive care and pain medicine – as a training location for non-consultant hospital doctors. As a result, both the obstetrics and gynaecology services and the anaesthetic services at Portlaoise Hospital struggle, and are likely to continue to struggle, to attract and retain non-consultant hospital doctors.

At the time of the investigation, the consultants in obstetrics and gynaecology were supported by 12 NCHD posts comprising six registrars and six more-junior senior house officers. Only one of the six registrars in post had completed the membership examination of the Royal College of Physicians of Ireland's MRCPI in Obstetrics and Gynaecology. Anaesthetic consultants were supported by four anaesthetic registrars, consisting of two permanent post-holders and two employed on temporary contracts referred to as locum contracts.

Experts on the Investigation Team identified the current NCHD staffing arrangements as a serious concern and risk for the sustainability of the maternity services at Portlaoise Hospital. The external experts considered it imperative that a system of rotation be designed between Portlaoise Hospital and a large maternity hospital such as the Coombe Women and Infants University Hospital. This would facilitate a system of rotating NCHDs on training schemes between both sites, thereby ensuring that the maternity services at Portlaoise Hospital progress and develop in tandem with their clinical network partners.\*

#### **5.4.5 Workforce planning**

There is no doubt that historically there was ineffective workforce planning within the HSE. This will be discussed more fully in Chapter 7 of this report. It is now important that going into the future the failures of the past are not repeated and effective workforce planning informed by a national maternity strategy – as recommended by the Authority in 2013 – is put in place and supported by nationally mandated maternity standards.

These should reflect the inclusion of units like the Portlaoise Hospital Maternity Department within an obstetric clinical network. Going into the future, all maternity units throughout Ireland should have a director of midwifery leading the maternity services as part of the clinical and corporate governance structures.

#### **5.4.6 Team working, supervision and communication**

Multidisciplinary team working that is grounded in effective communication is advocated as a means of delivering safer better healthcare outcomes. The importance of close teamwork between midwives, junior doctors and consultants cannot be undervalued. Any breakdown in this teamwork puts women at increased risk by preventing the appropriate escalation and treatment when

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\* In April 2015 The Authority was informed that NCHD staffing arrangements will be considered further under the Coombe Governance Model

required. The efficient use of staff and team support can overcome many areas of staff pressures. It is important that there is a high level of mutual respect and cooperation amongst the team in order to ensure that the team can react appropriately and escalate clinical problems when they arise.

The Chief Medical Officer's report implicated impaired inter-professional relationships and a lack of teamwork at many levels across the maternity services in Portlaoise Hospital. He concluded that this was a contributory factor in the adverse outcomes experienced by parents and patients.

The patients met by the Investigation Team relayed episodes where they had been party to alleged incidents of very poor communication between members of staff in the maternity unit. Although these accounts are unverified, poor standards of multidisciplinary communication were a persistent feature described by many people who used the service and who spoke with the Investigation Team. In addition, the Safety Culture Index© commissioned by the Investigation Team identified that poor working relationships continued to be a significant cause for concern in the maternity service. Significantly, concerns regarding poor professional working relationships were reiterated by many clinical and non-clinical staff members met and interviewed during the course of the investigation.

It is noteworthy and of concern to the Investigation Team that poor multidisciplinary working relationships were raised within the Maternity Department at the hospital as a concern as far back as 2007. Documentation reviewed demonstrated that in 2007, poor multidisciplinary working relationships were raised as a concern in a risk assessment conducted by the Dublin Mid Leinster Regional Quality and Patient Safety Division of the HSE<sup>(60)</sup>. These findings were similar to those of the safety culture assessment commissioned by the Authority as part of this investigation. The 2007 HSE risk assessment identified poor systems of communication across the Portlaoise maternity service including between team members, disciplines, and services. It also identified a series of control measures relevant to effective teamwork relationships that were not introduced. By way of example, in this report, seven years prior to the Chief Medical Officer's report, midwifery staff identified a reluctance to raise concerns in relation to poor clinical practices. Had effective controls been introduced and maintained at that time, they may have potentially averted many of the issues experienced by the parents that the Investigation Team met.

During the course of the investigation, particularly in group meetings, the Investigation Team explored inter-professional working relationships. There was general acceptance that since the arrival of the Interim Management Team, efforts had been focused on improving communication and multidisciplinary team working. New local guidelines have been implemented with regard to effective clinical handover and communication between team members. Specific measures implemented included the introduction of a daily formal multidisciplinary team handover, two ward rounds by the on-call consultant per day and on-call consultant contact with the shift leader every night for an update on patient status.

However, the Investigation Team remained concerned about the following persistent issues reported by staff:

- a reported reluctance on the part of midwives to raise concerns in relation to patient care issues with members of the medical team
- suggestions that some members of the midwifery staff undermined consultants in their dealings with patients
- both midwives and consultants reported a reluctance to rely on agency medical staff and locum NCHDs owing to concerns that some may not have the necessary competence or experience to manage all situations
- the practice of some consultants communicating with midwives rather than with their registrars created dissatisfaction among NCHDs and impacted negatively on their training
- handover for the labour ward is from consultant on-call to the next consultant on-call by telephone
- no formal handover from consultant obstetrician to consultant anaesthetist or anaesthetic registrar on a daily basis.

These are significant problems as they undermine the team structure and the ability to escalate clinical problems when they arise through the team.

These were further explored with the Interim Management Team, which reported in October 2014 that there had been a significant improvement in all these areas and that measures to successfully address these issues included the:

- increase in senior midwifery staff on each shift
- introduction of effective risk management and governance arrangements
- improvement in communication processes.\*

Cognisant that the safety culture assessment identified many of these issues, the HSE should now consider repeating the assessment in order to reassess the safety culture in the Maternity Department in the hospital.

#### **5.4.7 Education and training**

The Chief Medical Officer's report recommended that healthcare professionals should be supported in line with individual learning needs and the needs of the service. The Investigation Team was not in a position to review the efficacy of arrangements that were put in place to meet the education and training needs of the staff in the maternity services at Portlaoise Hospital, given that many of these were at an early stage of development.

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\* The Investigation Team was subsequently informed in February 2015 that arrangements regarding daily handover with the anaesthetic team were under discussion. However, these arrangements had yet to be formalised.

However, the Investigation Team was able to confirm that a clinical skills coordinator had started working in the maternity services and a number of clinical staff had completed the PROMPT (Practical Obstetric Multi-professional Training, skills and drills) train-the-trainers course. The first PROMPT course was held while the Investigation Team was on site in June 2014.

A number of local investigation reports since 2011 have recommended that all midwifery and obstetric staff at Portlaoise Hospital receive cardiotocography (CTG) \*\* training. Given that poor CTG interpretation had been identified as a significant deficit and risk in the hospital, the Investigation Team reviewed the arrangements in place to ensure that midwifery and obstetric staff were competent in the recording and interpretation of CTGs.

The Interim Management Team described a dual approach to CTG training: CTG practical training workshops and an interactive online training programme called the K2 Fetal Monitoring Training System. A local guideline entitled Mandatory K2 fetal monitoring training states that all members of the multidisciplinary team are required to undertake this mandatory K2 training on an annual basis and that staff participation is monitored by the divisional nurse manager and the lead obstetrician via the training database. The guideline outlines that the divisional nurse manager and the lead obstetrician have access to an online programme to monitor progress of all staff in completion of this mandatory training and provide feedback to the Quality and Patient Safety Committee on staff compliance with this training.

At the time of the investigation, data submitted to the Investigation Team showed that only 72.2% of midwives had attended CTG practical training workshops, while figures were not supplied for medical staff attendance. This issue was again explored at the follow-up meeting with members of the Interim Management Team in October 2014. At that time, the hospital was unable to confirm the exact number of midwifery and medical staff that had fully completed the K2 training module as required in its hospital policy.

This is of concern and should be addressed as a matter of urgency. The Investigation Team recommends that all midwives and clinicians involved in caring for women in labour must be competent in the monitoring and interpretation of CTG tracing. Such competence can only be assured with the provision of comprehensive training supported by regular updates. Midwives and clinicians who have not completed the requisite training or the necessary updates should not undertake CTG monitoring or interpretation. Senior midwifery managers and obstetric lead clinicians must maintain up-to-date records of staff training.

This re-emphasises the need for a robust clinical governance structure led by an independent experienced obstetric clinical lead while the Maternity Department in Portlaoise Hospital awaits full integration within the governance structure of the Coombe Women and Infants University Hospital. External obstetric experts on the

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\*\* Cardiotocography is an electronic means of recording the fetal heart beat and the uterine contractions during pregnancy. The machine produces a trace known as a cardiotocograph which illustrates the fetal heart rate and uterine activity.

Investigation Team strongly advise that pending full implementation of the recently signed memorandum of understating there should be rotation of healthcare professionals between Portlaoise Hospital maternity services and the Coombe Hospital to share experience and learning.

## 5.5 Use of information

In 2006, the Lourdes Hospital Inquiry<sup>(61)</sup> identified the importance of audit and analysis and the requirement for an appropriate information technology system for the purpose of data collection in a modern maternity unit. At the time of this investigation, Portlaoise Hospital did not have the necessary information technology infrastructure to support the required collection of, and timely analysis of, data.\* As a result, collection of statistical data was a cumbersome process of manual review of various handwritten registers.

The Investigation Team identified that the data collected by the Maternity Department did not include certain procedures that would be expected to be recorded on such registers. For example, there were no records of trial of forceps in theatre\*\* or full dilatation Caesarean sections\*\*\* recorded in the previous three years. Furthermore, there was no evidence of a formal process of validation of the data collected. This deficiency reiterates the need for effective clinical governance arrangements to be in place in the hospital.

The Lourdes Hospital Inquiry also recommended that annual clinical reports of activity and clinical outcomes should be prepared and published within nine months of the previous year's end. It was reported that Portlaoise Hospital's Maternity Department did not produce an annual report in 2012 or 2013. However, it was reported at interview that a template and database to collect data for an annual report has been developed and that an annual report will be produced for 2014.

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\* In April 2015 the Authority was informed that the Integrated Patient Management System was implemented at Portlaoise Hospital in December 2014

Portlaoise Hospital is the first HSE hospital to implement the National Incident Management System  
Portlaoise Hospital is piloting the National Maternity Computerised Electronic Chart

\*\* Trial of forceps: a trial of instrumental vaginal birth using either obstetric forceps or a vacuum instrument conducted in an operating theatre with preparations made for proceeding to Caesarean section. This technique is used in a small proportion of anticipated difficult births.

\*\*\* Caesarean section performed when the cervix is fully dilated as opposed to earlier on in the labour.

## 5.6 Care environment

This section will report the findings of the Investigation Team in relation to the care environment and will describe any additional risks and or areas of concern that were identified during the on-site component of the investigation.

Maternity and gynaecology services are provided in a number of clinical areas throughout Portlaoise Hospital. The Maternity Department is located on the third floor and includes:

- a three-roomed Maternity Assessment Unit
- four single labour and delivery rooms
- a 29-bed inpatient ward for antenatal, postnatal and gynaecology patients.

In addition, located on the ground floor are:

- an Early Pregnancy Assessment Unit located in the main Emergency Department providing a five day (9am to 5pm) obstetrics and gynaecology emergency service
- an eight-cot Special Care Baby Unit.

Maternity and gynaecology outpatient services are provided in the outpatient department, which is located on the grounds adjacent to the main hospital. The maternity and gynaecology services use the main operating theatres, located on the second floor of the hospital for all routine and emergency surgery, including emergency Caesarean sections. Acutely ill and clinically deteriorating maternity patients are primarily cared for in the Intensive Care Unit or the Coronary Care Unit of the hospital. At the time of the investigation, there was no day obstetric unit at the hospital.

The Chief Medical Officer's report described the general layout of the maternity services on the third floor as having a sense of clutter and lack of space. This was reiterated by patients interviewed as part of this investigation who described their experiences while attending the maternity services at the hospital. Repeatedly, they told the Investigation Team of the negative effect this had had on their care and their experience of the service. A number of parents vividly described the lack of privacy they experienced and how this had impacted on them, particularly following the tragic loss of their baby. Others described the facilities as being cramped and overcrowded.

These findings could not have been surprising to staff and management at the hospital or the HSE since as far back as 2007 a risk assessment conducted by the regional HSE risk management division outlined a lack of space, inappropriateness of patient facilities and the insufficient number of delivery suites as key risks associated with the infrastructure of the hospital. The Investigation Team was informed – and observed during the on-site visits as part of this investigation – that although existing facilities had undergone some refurbishment and essential renovations, basic major inadequacies remained in fundamental aspects of the

environment. The Investigation Team found that staff are continuously challenged by the current infrastructure to deliver a person-centred service, particularly in the context of maintaining patient privacy and dignity. By way of example, Team members observed congestion in waiting areas of the Outpatients Department. Hospital staff reported that due to the volume of patients attending and the inadequacy of the waiting area, obstetric and general patients were required at times to queue outside the main door of the Outpatients Department in the open air.

In addition, the current infrastructure also creates an inherent risk to patient safety. For example, the Maternity Assessment Unit, located across the corridor from the main entrance to the Maternity Department, is designed to facilitate assessment of women who present with concerns about their pregnancy after 22 weeks' gestation. The Maternity Assessment Unit was not designed to accommodate women who are in labour. However, at the time of the investigation it was reported that when all labour rooms are occupied, the Maternity Assessment Unit may be used for delivering a baby.\*

The Investigation Team was concerned to note in submitted documentation that this same risk had been identified by Portlaoise Hospital in 2009. At that time, the practice of delivering a baby in the Maternity Assessment Unit was described as unsafe for both mothers and babies. The documentation reviewed stated that a number of serious incidents, resulting in obstetric emergencies for mothers and babies, had occurred during deliveries in the Maternity Assessment Unit.

The Investigation Team was also informed by members of the Interim Management Team that the risks associated with delivering a baby in the Maternity Assessment Unit were further exacerbated by the:

- significant amount of diverse activity in the unit
- increasing volume of patients attending the unit
- restricted floor space available
- lack of adequate midwifery staffing in that area.

However, despite the fact that senior clinicians and managers were aware of this inherent risk since 2009, the practice of delivering babies in the Maternity Assessment Unit had continued up until 2014.

The Investigation Team concluded that the Maternity Assessment Unit was unsuitable for the volume and type of services currently provided there and was not an environment suitable for delivering a baby. While recognising these deficiencies, the Team also recognised that the current maternity department infrastructure does not have the capacity to expand within the current hospital structure.

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\* In April 2015, the HSE informed the Authority that a fourth labour and delivery suite has been opened at Portlaoise Hospital which will significantly reduce the need to use the Maternity Assessment Unit as an area where babies are delivered.

At a final Investigation Team interview with senior managers for the maternity services, conducted in October 2014, the Investigation Team was advised that the functioning of the Maternity Assessment Unit had been reviewed and that the risks identified are controlled through:

- providing an experienced senior midwife as a shift leader in charge on each shift
- increasing the midwifery staffing numbers
- reviewing the patient activity levels
- implementing a revised risk management system.

Furthermore, the senior Interim Management Team reported that negotiations were underway with the HSE to commission and resource a new maternity outpatient facility as a means of further reducing the activity in the Maternity Assessment Unit.

In relation to the inpatient maternity facilities, clinical and managerial staff at the hospital informed the Investigation Team that in 2006 plans for a new three-floor maternity department had been approved by the HSE but had never been progressed. At the time of the investigation, senior staff reported that this development plan had been re-submitted to the HSE and approval to move to the design phase of the plan had been granted on 15 January 2014. This was further explored by the Investigation Team in October 2014 with senior maternity management staff explaining that they were discussing with the HSE Estates Department the feasibility of using temporary prefabricated accommodation to improve the maternity facilities.

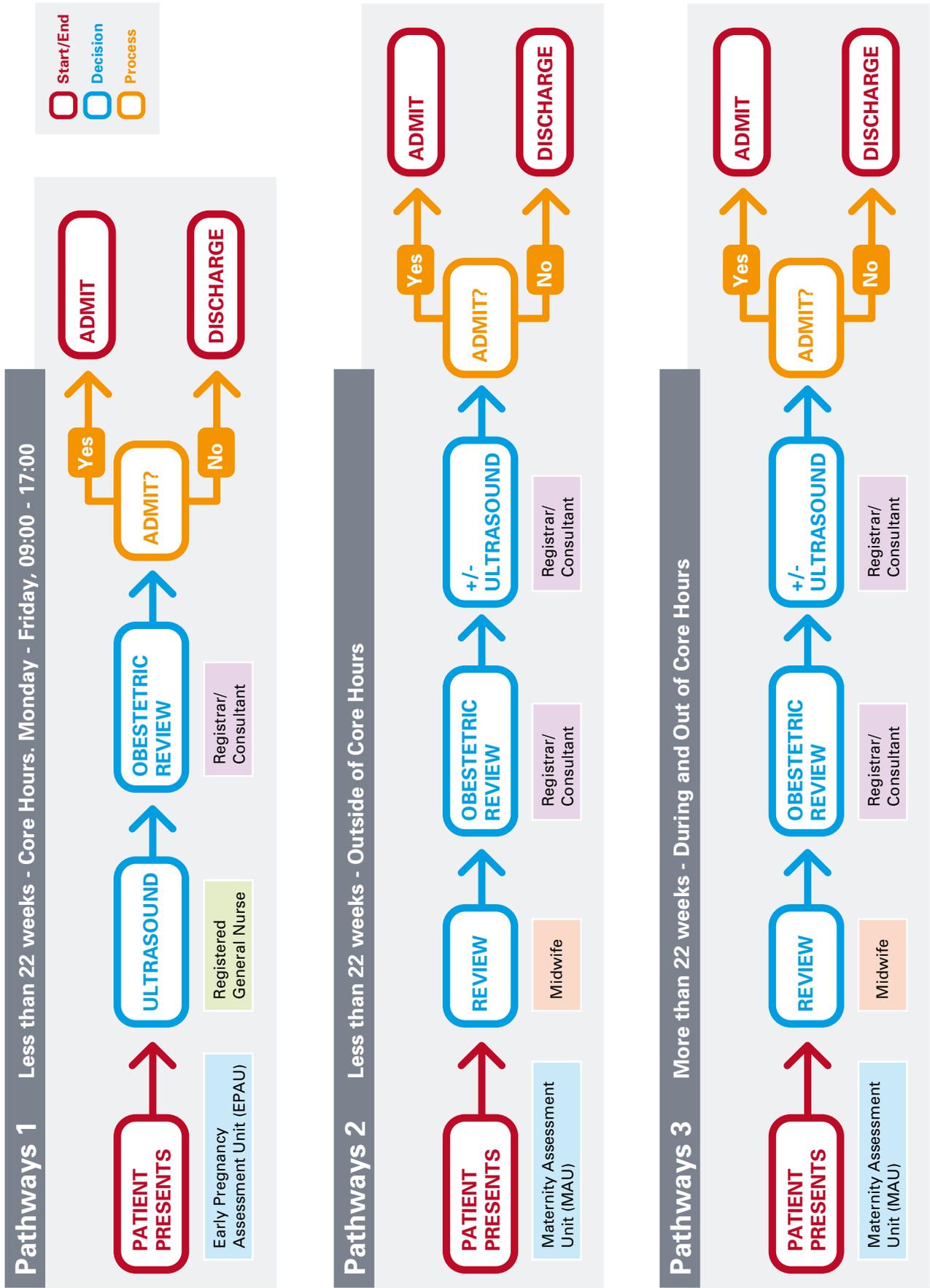
However, at the time of reporting there were no definite plans, defined timelines or formal budget allocation in place to reassure the Investigation Team that this temporary solution will actually happen. While the Authority welcomes this long-term plan, the fact that the current inadequate service and patient facilities remains unchanged continues to be a significant cause for concern.

### **5.6.1 Patient pathways for initial assessment and admission**

The Investigation Team reviewed the patient pathway for pregnant women attending Portlaoise Hospital as an emergency during core hours and outside of core hours to determine the access arrangements in place. 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 9am and 5pm. The purpose of this review was to ensure that women at all stages of their pregnancy can access the care they require when they require it 24-seven.

Figure 2 illustrates the pathway of care for pregnant women who are less than and more than 22 weeks' gestation.

Figure 2. Pathway of care for pregnant women who are less than and more than 22 weeks' gestation



The Investigation Team confirmed that there were defined pathways, understood by the staff, for maternity patients presenting as an emergency both during and outside of core working hours.

During core hours, pregnant women under 22 weeks' gestation requiring emergency assessment attend the Early Pregnancy Assessment Unit, which is located in the Emergency Department. Women who are over 22 weeks' gestation and who present for emergency assessment or review during core hours attend the Maternity Assessment Unit located in the Maternity Department rather than presenting at the Emergency Department. Outside core hours, all pregnant women attend the Maternity Assessment Unit for assessment regardless of their stage of gestation. The Maternity Department is staffed at all times by a midwife who initially reviews the patient and refers to the obstetric team as necessary.

In reviewing the patient pathway, the Investigation Team identified specific areas or arrangements within the pathway which at the time of the investigation were considered a risk in the sustainable delivery of a safe quality service to obstetric patients. This next section of this chapter will explore these risks and the actions taken by the hospital to address these.

### **5.6.2 Obstetric ultrasound**

Pregnant women undergo routine ultrasound scanning as part of their antenatal care to assess the progress of their pregnancy. Additionally and on occasion, pregnant women may require access to non-routine ultrasound to aid their clinician's ability to evaluate, diagnose and treat obstetric emergencies.

The Investigation Team was informed at interview and during the on-site component of the investigation that members of the Interim Management Team had some concerns in relation to ultrasound scanning services at Portlaoise Hospital.\* They reported that these concerns were not based on any evidence of adverse outcomes but in the recognition that the systems and structures in place did not assure the safety of the service. However, the Investigation Team were concerned to note that despite these concerns there had been no efforts to comprehensively evaluate the effectiveness of ultrasound services through clinical audit to rule out or confirm these concerns. The Interim Management Team identified the following concerns:

- capacity of the current ultrasound scanning service to deal with the volume and type of scans that should be undertaken
- inadequate skills and training of some of the healthcare professionals performing scanning
- not enough clinical oversight of the service.

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\* Prior to publication of this report, a serious incident in relation to obstetric ultrasound was reported by the media to have occurred at the Portlaoise Hospital Maternity Department. An investigation into this event is ongoing in the hospital at the time of publication.

In addition, the Investigation Team was informed at interview that the Interim Management Team was also reviewing the current clinical referral criteria and the volume of obstetric ultrasounds being undertaken in the hospital.

The governance of early pregnancy obstetric ultrasound scanning was addressed in 2011 in the National Miscarriage Misdiagnosis Review<sup>(62)</sup> published by the HSE. This report recommended that all trainees in obstetrics and gynaecology must be able to demonstrate completion of training in early pregnancy ultrasound before they undertake any unsupervised ultrasound examinations in early pregnancy. The report also recommended that all clinicians who perform ultrasound in early pregnancy should attend a course in obstetric ultrasound at least once every five years.

The Investigation Team was informed by the Interim Management Team in June 2014 that although only one of the consultant obstetricians had received formal accreditation for the completion of obstetric ultrasound, all hospital consultants, registrars and senior house officers (both grades of doctors in training) were performing both routine and emergency ultrasounds. Furthermore, it was reported that there was a lack of standardisation and training for doctors providing this service.

It is common practice in maternity services for trained midwives accredited to perform ultrasound scanning to provide the routine ultrasound service. However, despite the hospital having funded three midwives to complete the necessary training, the Investigation Team were informed during the course of the on-site inspection and at interview that they had never been reassigned to provide the ultrasound service. Consequently their training, which was funded by the hospital, was out of date at the time of the investigation.

At a meeting with the hospital in October 2014, the Investigation Team explored the changes that were being made at the hospital to assure the Interim Management Team of the quality and safety of the fetal ultrasound service. The Interim Management team reported that a draft model of service was in development whereby a consultant with formal accreditation in fetal scanning would assume a clinical lead position.

In January 2015, the Interim Management Team reported that three registrars and one additional consultant were now in the process of completing formal training in fetal ultrasound scanning. In addition, the clinical lead for fetal ultrasound scanning was in place.

### **5.6.3 Resourcing the Early Pregnancy Assessment Unit**

During core hours (Monday to Friday and between 9am and 5pm) pregnant women under 22 weeks' gestation requiring emergency assessment attend the Early Pregnancy Assessment Unit. Here, ultrasound scanning and assessment services are provided. The Early Pregnancy Assessment Unit is staffed by a registered general nurse who holds a graduate certificate in obstetric ultrasound,

and by a senior house officer (a non-consultant hospital doctor at a relatively junior level). If a scan completed by the registered general nurse detects a miscarriage, the scan is verified by one of the more senior obstetric doctors who as previously discussed at the time of the investigation did not have a formal qualification in obstetric ultrasound.

Responsibility for governing the Early Pregnancy Assessment Unit service lies with the lead obstetrician. A registrar is allocated to the unit for four half-day sessions per week. Outside of these sessions the service is supported remotely by consultants who can be reached by the hospital paging system. The Investigation Team was informed that there is no staff cover for annual leave which means that at times there is no nurse and or midwife with the appropriate ultrasound qualifications working in the unit – despite three midwives already on staff who had received ultrasound training, but who had not been assigned to these duties.

#### **5.6.4 Bereavement services in the Maternity Department**

As outlined in the patient experience chapter, the Authority met with a number of parents whose babies had died while in the care of Portlaoise Hospital. As discussed in that chapter, some parents told the Authority that the care they received in the midst of their grief was poor and added to the trauma they were experiencing.

As part of the investigation, the Authority explored the measures the Maternity Department had now introduced to improve the care and services offered to bereaved parents and families.

National guidelines on The Investigation and Management Of Late Fetal Intrauterine Death and Stillbirth highlight that skilled, sensitive and caring treatment in the time surrounding pregnancy loss can positively impact on the grief experience of bereaved parents<sup>(63)</sup>. These guidelines recommend that supportive care should be made available to all bereaved parents at the hospital and parents should also be advised about local and national support groups.

However, prior to the Chief Medical Officer's report, the Maternity Department at Portlaoise Hospital did not have a midwife or a social worker in post to support bereaved parents and families. A midwife has now been appointed to the role of bereavement specialist and three midwives are also undertaking formal training in the care of bereaved patients.

Local guidelines to inform the care of parents bereaved by pregnancy loss and perinatal death have been developed and implemented by the Maternity Department. The Maternity Department now holds 'Reflective Practice' meetings for staff to review and learn from the care provided to women who experience a stillbirth or miscarriage. It was reported that every effort is made to provide a single room in the surgical ward for women who experience a stillbirth or perinatal death and redeploy a midwife to care for the woman there.

### 5.6.5 Access to the operating theatre

Maternity patients may require elective or emergency Caesarean sections or other surgical procedures as part of their pathway of care. There is no dedicated maternity operating theatre in or immediately adjacent to the Maternity Department at Portlaoise Hospital. Rather, the operating theatres in the main theatre suite are used, which are located one floor below the Maternity Unit.

Members of the Investigation Team were informed by the clinical staff interviewed that they were assured that they have the necessary controls in place to manage this risk. Documentation reviewed identified that these controls included a midwife always accompanying a patient who is transferring to the operating theatre, and ensuring that continuous monitoring of the fetal heart rate and rhythm is standard practice.

Clinical staff at the hospital reported that they were particularly concerned about two emergency Caesarean sections occurring at the same time when the hospital only had one on-call theatre team available outside normal working hours. The Investigation Team acknowledges that the current system of providing undifferentiated surgical services and maternity services increased the potential requirement for emergency theatre access outside of normal working hours.

However, outside of anecdotal evidence, the staff met in June 2014 were unable to quantify the number of times this had occurred. Neither had the hospital conducted a formal risk assessment to inform practice and or the requirement for additional emergency resources. The Authority recommends that the hospital assess the current situation, identify any aligned risks and address the issue in the context of obstetric and surgical emergency services.\*

### 5.6.6 Management of healthcare records

Healthcare professionals need access to all relevant information about the patient at the point of clinical decision-making in order to make informed decisions regarding the patient's clinical condition. Therefore, the effective completion and management of healthcare records\*\* is essential. The Chief Medical Officer's report recommended that healthcare organisations should prioritise ensuring that they review and address any shortfall in the management of healthcare records in line with HSE national policy.

During the course of the on-site visit, the Investigation Team confirmed that the National Maternity Healthcare Record was in use at Portlaoise Hospital for public patients.

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\* In April 2015, the HSE informed the Authority that a risk assessment of this issue had been completed and a policy implemented.

\*\* 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 patients.

The Investigation Team found that the small number of public records examined during the course of the on-site visit were in good order with the chronology of events easy to follow. Clinical entries were dated and timed and the clinician's job title was usually documented.

However, the Investigation Team was concerned when informed that there were two types of maternity healthcare records currently in use. Patients accessing the public maternity services utilised the National Maternity Healthcare Record but some consultant obstetricians used a different healthcare record for health insurance or private patients. In exploring this issue further, members of the Investigation Team were also informed that although the healthcare records of some private patients were stored in a designated area in the Maternity Department, difficulties were experienced in accessing records of some of this group of patients. What this potentially means is that in an emergency situation, the healthcare record, with the patient's clinical details may not be immediately available to inform the on-call obstetric team – this deficit and risk must be addressed and the National Maternity Healthcare Record should be the only record in use.

The Investigation Team was informed by midwives interviewed during the site visit that pregnant women attending Portlaoise Hospital do not retain their own obstetric healthcare record for the duration of their antenatal care at the hospital. As stated in HIQA's 2013 Galway report, the Authority believes that all 19 public maternity units should adopt the practice of maternity patients carrying their own obstetric chart, to ensure seamless informed care throughout their antenatal care<sup>(11)</sup>. 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<sup>(64-66)</sup>.

### **5.6.7 IMEWS and escalation of care**

The Irish Maternity Early Warning System (IMEWS)<sup>\*\*\*</sup> is an early warning scoring system designed to support the early detection of life-threatening illnesses in women who are pregnant or postnatal. National guidelines underpinning the use of IMEWS detail that it is to be used for women who are pregnant and women who have delivered within the last 42 days<sup>(67)</sup>.

IMEWS was introduced for the monitoring of pregnant women at the Maternity Department at Portlaoise Hospital in 2013. However, the Investigation Team reviewed evidence which highlighted that IMEWS was not in use for pregnant and postnatal women that were cared for outside the Maternity Department floor, such as on the surgical floor. Rather the National Early Warning score, which was not designed to detect early clinical deterioration in pregnant women, was being used to monitor these women.

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<sup>\*\*\*</sup> I-MEWS changed to IMEWS in national guideline in July 2014.

Protracted discussions on this risk were evident in the minutes of the National Early Warning Score (NEWS) Midland Regional Hospital Portlaoise Steering Committee from July 2013 until May 2014. The Investigation Team was informed at a final meeting with members of the Interim Management Team in October 2014 that discussions were still ongoing and that IMEWS was still not in use for maternity patients accommodated in general areas of the hospital. This again is an example of where a risk has been identified but measures to address it have not been implemented in a timely fashion. The protracted nature of these discussions also reflects the difficulties inherent in separate management systems for the maternity and the general hospital services. The Investigation Team considers this another example of an issue that would benefit from the provision of strong clinical leadership and integrated governance arrangements to drive change and address identified risks in an efficient manner.

## 5.7 Conclusions in relation to maternity services

Since the publication of the Chief Medical Officer's report in February 2014, there have been significant improvements in the corporate and clinical governance arrangements and in the implementation of the aligned recommendations in the Maternity Department in Portlaoise Hospital. It is regrettable that it has taken a series of tragic events for many of these changes to be resourced, which include the appointment of additional midwifery staff, the increase in senior midwifery shift leaders, clinical midwifery specialists and the introduction of an on-site risk management structure. Undoubtedly, the appointment of a Director of Midwifery is a key contributor to these improvements and as a model should be replicated nationwide. The Maternity Department must continue to build on these improvements to ensure that all staff are empowered to identify and escalate any concerns as they arise and the Department is facilitated to proactively respond to any increasing risks and pressures it faces.

Notwithstanding these improvements many key issues remain unaddressed. There is an urgent requirement (in the interim of Portlaoise Hospital becoming part of a clinical network), for the HSE to support the existing clinical governance arrangements in the Maternity Department with skilled and experienced obstetric clinical leadership. Going into the future, there is an urgent requirement for a national maternity strategy to be agreed and informed workforce planning to be actioned which would, if managed effectively, help reduce the potential of what happened in Portlaoise Hospital to be repeated elsewhere. In addition there should be nationally mandated maternity standards to guide the delivery of safe quality maternity services.

Maternity patients deserve high quality safe care, and a small maternity hospital needs the support of, and should be integrated within, the governance structures of a major obstetric hospital. The proposed hospital group structure with maternity services becoming part of a managed clinical network is a national imperative.

## Chapter 6. General Hospital Services at Portlaoise Hospital

### 6.1 Introduction to the general hospital services at Portlaoise Hospital

This section of the report presents the Investigation Team's findings in relation to the quality and safety of the non-maternity healthcare services currently provided at Portlaoise Hospital.

In reporting these findings, the Investigation Team took into account the implementation status of relevant national recommendations previously made by the Authority<sup>(6-8,11)</sup>, safety and governance of the care provided by the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (AMNCH) professional bodies and other investigations in relation to the delivery of safe and effective healthcare. The Investigation Team also considered two previous Health Service Executive (HSE) reviews<sup>(12,13)</sup> published in 2008 into breast cancer misdiagnosis cases at Portlaoise Hospital. While the experiences of patients informed the Investigation Team, the Team – in line with the Terms of Reference of this investigation – did not investigate individual episodes of care or comment on them in this report.

### 6.2 Overview of general hospital services provided by Portlaoise Hospital

The Midland Regional Hospital, Portlaoise, Co Laois provides services to public patients and privately insured patients, and is legally funded and operated by the HSE. Opened in 1936, it is today an acute general and maternity hospital with a mental healthcare service on site. At the time of the investigation, the hospital had 151 beds, which comprised 108 adult beds, 29 paediatric beds and 14 day beds (10 adult and four paediatric). The hospital employs 552 whole-time equivalent staff, equating to over 600 members of staff. Primarily serving the population of Laois in addition to parts of counties Offaly, Kildare, Carlow and Tipperary, the hospital is located 82.5kms (51.3 miles) from Dublin and is accessible via the M7 Dublin-Limerick motorway.

The general hospital services at Portlaoise Hospital include elective and emergency adult and children's services on an inpatient, day and outpatient basis. Services provided include:

- general medicine including cardiology, endocrinology, cardiac and stroke rehabilitation services
- general surgery (adults and children) including urology
- Intensive Care Unit
- Coronary Care Unit

- paediatrics including Special Care Baby Unit
- 24-hour, seven-days-a-week (24-seven) adult and paediatric emergency care
- anaesthesia (adults and children) and pain management
- Outpatients Department
- diagnostic imaging including CT\* scanning out of hours
- general laboratory including haematology, biochemistry, microbiology and blood transfusion
- speech and language therapy
- tissue viability
- physiotherapy
- occupational therapy
- nutrition and dietetics
- mental healthcare.

Other services – including ophthalmology, haematology, pathology and urology – are provided by visiting consultants with joint sessions and linkages with the Royal Victoria Eye and Ear Hospital, Dublin; Midland Regional Hospital Tullamore; and St James’s Hospital, Dublin.

In the course of the investigation, the Authority looked at a number of critically important clinical services in the hospital with a particular emphasis on the emergency, surgical, paediatric, and medical services and diagnostic imaging. As referenced in Chapter 2, the Investigation Team reviewed these services, in the context of the:

- recommendations of investigations previously conducted in Portlaoise Hospital
- inquiries and reviews previously undertaken by the HSE
- recommendations made by the HSE’s National Clinical Programmes
- findings from local and national investigations published by the Authority.

In this context, the findings in this chapter are a general overview of these clinical services in Portlaoise Hospital and explore whether they have been reorganised and resourced in line with national HSE strategy and in line with the findings and recommendations of previous local and national investigations.

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\* CT stands for computed tomography, an imaging technique used to visualise both soft tissue and bone inside the body.

## 6.3 Findings in relation to the Emergency Department

Portlaoise Hospital provides a 24-hour, seven-days-a-week (24-seven) emergency service for undifferentiated\*\* adult and paediatric patients. In 2013, a total of 32,781\*\*\* adults and 7,061 children attended the Emergency Department at Portlaoise Hospital. Clinical staff at the hospital reported that most patients attending the Emergency Department at Portlaoise Hospital are walk-in patients presenting with minor clinical complaints and injuries.

Data submitted by the hospital indicated that 35 %\*\*\*\* of adult patients who attend the Emergency Department in 2013 were subsequently admitted to the hospital, significantly higher than the national average of 26%<sup>(68)</sup>.

In April 2015, the HSE informed the Authority that this figure was incorrect as it also included maternity admissions, however, the HSE did not provide the Authority with any data to support this statement. This disparity in information is of concern to the Authority as any service providers accountable for providing emergency department services cannot effectively manage, assess and design the service for patients in the absence of readily available and appropriately validated data.

National Ambulance Service bypass protocols\*\*\*\* are in place to ensure that paediatric patients are transported to the most appropriate receiving facility. They are also in place for patients with:

- ST segment elevation myocardial infarction (STEMI) (heart attack)
- a cerebrovascular accident (stroke)
- severe trauma (adult and paediatric patients)
- fractured neck of femur (broken hip).

This means that in theory these patients in the area are taken by ambulance directly to other hospitals better equipped to treat these conditions. However, there was no evidence available at the time of this investigation that Portlaoise Hospital had formally conducted any recent audits to ensure compliance and or to assess the effectiveness of these bypass protocols. This lack of local assurance and oversight was of concern in light of previous recommendations to monitor the efficacy of pre-emergency care by-pass protocols made by the Authority in 2009 and 2010<sup>(7,8)</sup>.

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\*\* Undifferentiated patients include all types of patients with any degree of seriousness or severity of illness.

\*\*\* 32,781 adult presentations to the Emergency Department was comprised of 27,081 new adult presentations, 1,681 adult return presentations and 4,019 obstetrics and gynaecology presentations through the Early Pregnancy Assessment Unit.

\*\*\*\* This calculation is based on data provided by Portlaoise Hospital which demonstrated that, in 2013, a total of 32,781 adult patients attended the Emergency Department (ED). Of those patients, 11,634 were admitted to the hospital resulting in 35% of adult ED attendances being admitted.

\*\*\*\*\* Ambulance bypass protocols divert patients with certain conditions to nominated facilities. For example, patients in the Portlaoise Hospital catchment area with fractured neck of femur are to be taken to the Midland Regional Hospital Tullamore, while patients in the hospital's catchment with signs of stroke are to be taken to Naas General Hospital. Paediatric patients with major trauma are to be transported to Our Lady's Children's Hospital or to Temple Street Children's University Hospital, Dublin.

Following registration in Portlaoise Hospital's Emergency Department, patients are categorised by a nurse in the department using the Manchester triage system.\* However, at the time of the investigation, the hospital did not have an information system that could formally collate and trend the category of patient accessing the service. To gain an overview of the type of patients attending the Emergency Department and the severity of their conditions and their clinical profile, the Investigation Team requested the hospital to manually collate the triage category data. This process confirmed, as already identified by clinical staff, that most patients who presented to the Emergency Department were assigned the less serious categories of 3, 4 and 5.

However, the structure of the Emergency Department at Portlaoise Hospital did not include a minor injuries unit or an advanced-nurse-practitioner service, both of which would have facilitated rapid assessment and treatment of the patient population that was presenting to the department.

At the time of the Investigation, there were two emergency medicine consultants – primarily based at the Midland Regional Hospital in Tullamore – who provided 30 hours' clinical services per week (including travel time) to the Emergency Department in Portlaoise Hospital. Under this arrangement, an emergency medicine consultant attended the Emergency Department weekdays Monday to Thursday, 8am to 2pm. The Investigation Team was informed that these consultants, while working in Portlaoise Hospital, maintained their formal reporting relationship to the Clinical Director based in the Midland Regional Hospital in Tullamore. This arrangement meant that at the time of this investigation there was no formal clinical governance arrangements in place between the executive in Portlaoise Hospital and the post-holders – this is unsafe and should be immediately addressed.\*\*

Furthermore, the Regional Divisional Nurse Manager based at Midland Regional Hospital in Tullamore was reported to provide nursing leadership in relation to emergency services across the region. In practical terms, this meant that the nursing staff had dual reporting relationships: a strategic reporting relationship to the Regional Divisional Nurse Manager, who covered the three midlands regional hospitals; and in her absence an operational reporting relationship to the Divisional Nurse Manager for Medicine at Portlaoise Hospital.

In addition to the two emergency medicine consultants, the Emergency Department was also staffed by a team of medical and surgical non-consultant hospital doctors (NCHDs) assigned to work in the department. Medical NCHDs under the supervision of the medical physicians assessed and treated adult

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\* This is an assessment system to rapidly place patients into categories, according to the type of treatment they need and how quickly they need it.

\*\* The Authority was informed in February 2015 that the newly appointed Chief Executive Officer for the Dublin Midlands Hospital Group had issued an instruction that all medical staff with shared appointments between Portlaoise and other hospitals were to be informed that they reported to the Clinical Director in Portlaoise Hospital for the delivery of medical services in Portlaoise Hospital.

medical patients. Surgical NCHDs assessed and managed adult and paediatric surgical and or trauma patients under the care of the emergency medicine consultants when they were on site, reverting to the supervision of the surgical consultants after these hours. Therefore, the main responsibility of the two emergency medicine consultants was to oversee the clinical management of trauma and surgical patients. Accordingly, the Investigation Team found that there was no single Emergency Department governance structure with responsibility for all patients accessing care in the department.

Specifically in relation to medical patients, it was reported at staff interviews that there was a local agreement in place that meant the medical NCHDs, as a clinical risk management strategy, adopted a lower threshold for admitting patients.

The Investigation Team was concerned about the absence of consistent Emergency Department governance arrangements. Many of the hospital's clinical staff and HSE management staff interviewed conceded that the clinical governance arrangements in the Emergency Department were unsatisfactory and overcomplicated. In essence, there were two distinct governance arrangements in use for medical and surgical patients.

In addition, 16 months prior to this investigation, a review of the Emergency Department in Portlaoise Hospital by the HSE's Emergency Medicine Programme found that the department was not appropriately resourced to provide a 24-seven model of emergency department care. Additionally, both the Emergency Medicine Programme and the HSE's Acute Medicines Programme had previously identified their concerns in relation to the safety of the Emergency Department clinical governance arrangements in Portlaoise Hospital. Furthermore, the HSE's performance review in 2014 concluded that a 24-seven emergency care service at Portlaoise Hospital was not clinically sustainable.

### **6.3.1 Paediatric emergency care**

The Investigation Team also reviewed the care pathways for paediatric patients who present to the Emergency Department in Portlaoise Hospital. Emergency paediatric patients were managed in two separate areas of the hospital by two different clinical teams. Paediatric surgical patients were managed in the Emergency Department by surgical NCHDs based in the Emergency Department under the supervision of an emergency medicine consultant or a surgical consultant (when there was no emergency medicine consultant on duty). Paediatric medical patients were managed in the Paediatric Emergency Medicine Department located in the Paediatric Unit under the care of paediatricians.

Children presenting to the main Emergency Department waiting room are not audio-visually separated from adults,\* contrary to the National Emergency Medicine Programme Report<sup>(69)</sup>.

In reviewing the paediatric care pathway, clinical staff explained that children attending the Emergency Department were redirected, without being formally triaged to assess the severity of their condition, to the paediatric ward which is located on the first floor of the hospital. However:

- access to the Paediatric Emergency Medicine Department was via stairs or a public lift
- access could be subject to delay as there was no facility to ensure priority access to the lift
- activation of the baby alarm system on the maternity ward could result in lockdown of internal corridor doors, therefore limiting access into the Paediatric Emergency Medicine Department from the outside.

Additionally, the Investigation Team observed during their visit to the Paediatric Emergency Medicine Department that there was no formal system of triage in use for paediatric patients presenting there.

These risks were further explored with hospital management. They reported that they were considering relocating the Paediatric Emergency Medicine Department to the main Emergency Department. However, at the time of reporting there was no agreed budget or time frame for the project.

In July 2014 after the on-site component of this investigation, an additional consultant in emergency medicine was appointed. This appointment has increased the number of emergency medicine consultants to 1.78 whole-time equivalents. Hospital management reported that an emergency medicine consultant is now clinically responsible for the care of all patients attending the Emergency Department from 9am to 5pm three days a week and from 9am to 7pm two days a week. Outside of these hours, responsibility for Emergency Department patients reverts to the respective on-call surgical and medical teams.

### **6.3.2 Conclusions in relation to emergency department services**

The Investigation Team found that there was no single Emergency Department governance structure to ensure the quality and safety of care in that department. In addition, the HSE has not routinely collected, reviewed and analysed Emergency Department data to assess the clinical profile of patients attending the department. As a result, it has not developed – in line with national strategies – measures such as advance-nurse-practitioner-led minor injuries services or a revised level of emergency department services.

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\* In emergency departments which cater for both adults and children, audio visual separation means preventing in as much as possible children being able to see and hear distressed adult patients and adult patients being able to see and hear children receiving care.

In line with the findings of the HSE's National Clinical Programmes, the Investigation Team concluded that notwithstanding the Emergency Department cover provided by consultants, the current clinical governance arrangements cannot ensure a safe and sustainable service for patients using the service.\*\*

## 6.4 Critical care services

Critically ill adult patients at Portlaoise Hospital were managed in an intensive care unit which provided intensive care support in the form of advanced respiratory support and or mechanical ventilation or monitoring and support of two or more organ systems excluding renal replacement therapy.

The Intensive Care Unit (ICU) at Portlaoise Hospital was accommodated in an area that had formerly been an inpatient bay for four patients. This converted space was expected to accommodate four non-ventilated patients or two ventilated patients.\*\*\* The Authority was informed during the on-site visit that 185 patients were admitted to the ICU in 2013, of which 53 patients required mechanical ventilation. Thirty nine of the patients who required mechanical ventilation were medical patients.

Although average bed occupancy in the ICU was around 80%, the overall volume of critical care activity was low. It was acknowledged at interview that the ICU occupancy rates did not necessarily reflect the volume of patients requiring critical care as non-acute patients could be admitted to the ICU due to a lack of available inpatient beds.

Patients admitted to the ICU were admitted under the care of their admitting consultant. In the absence of intensive care specialists (intensivists), the anaesthetic consultant staff assumed responsibility or provided advice for patients requiring intensive care.\*\*\*\* At the time of the investigation, there were three anaesthetic consultant posts at Portlaoise Hospital (two permanent and one locum), and one of the permanent consultants was the nominated clinical lead for intensive care.

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\*\* In February 2015 the newly appointed Chief Executive Officer for the Dublin Midlands Hospital Group advised the Authority that all emergency medicine consultants working in the Emergency Department at Portlaoise Hospital had been advised that they reported to the Clinical Director at Portlaoise Hospital for the delivery of medical services in Portlaoise Hospital. However, at that time, there was still no single Emergency Department governance structure with responsibility for all patients accessing care in the Department.

\*\*\* Every ventilated patient accommodated in the Intensive Care Unit required closure of a bed space.

\*\*\*\* If the patient was mechanically ventilated, the anaesthetist assumed responsibility for patient care. If the patient was not mechanically ventilated, the patient remained under the care of the admitting doctor and the anaesthetist provided advice.

The ICU at Portlaoise Hospital in its current format does not meet the minimum requirements for critical care as set out by the Joint Faculty of Intensive Care Medicine of Ireland (JFICMI)<sup>(70)</sup>. By way of example, the unit does not have:

- on-site ICU non-consultant hospital doctors with critical care skills (including airway skills) at all times
- daily ICU consultant sessions committed to ICU alone
- a minimum of two consultants with ICU training and qualifications
- availability of direct access to continuous veno-venous haemofiltration\* (CVVH).

The ICU as reviewed by the Investigation Team was not fit for purpose; floor space was limited compromising patient privacy, comfort and dignity. In addition, the unit was not self-contained with staff having to leave the unit to access facilities shared with the surgical ward including dirty utility, clean utility, \*\* storage and bathroom facilities.

In 2014, an unpublished HSE report which detailed the performance status of the Midland Regional Hospital, Portlaoise (referred to in this HIQA report as the HSE's performance review)<sup>(68)</sup> described the Intensive Care Unit at Portlaoise Hospital as a resource-dependent facility that was potentially exposed to difficulties in maintaining ongoing clinical expertise and competence. This report recommended that critical care services in the hospital should be discontinued, while acknowledging that on-site anaesthesia cover would be required for obstetric patients and that pre-hospital emergency care resources would have to be reconfigured to divert patients requiring admission to an ICU to another facility.

The Investigation Team was informed at interview with senior clinical staff that they had significant concerns in relation to the low numbers of patients with complex clinical needs requiring intensive care. This was considered to be insufficient to maintain the skills and expertise of staff in the care of such patients<sup>(70)</sup>.

Senior clinicians were aware of the limitations of the care that could be safely provided and stated that it was their practice not to begin treating any patient that was likely to require the type of critical care support which could not be safely facilitated, for example, renal replacement therapy. Such patients were transferred to a more appropriate setting for the care they required. Patients who deteriorated in the Emergency Department, or while a patient in the hospital, were stabilised before being reassessed and transferred if necessary.

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\* Continuous veno-venous haemofiltration is a short-term treatment used in ICU patients with acute or chronic kidney failure to facilitate the removal of waste products from the bloodstream.

\*\* A 'dirty' utility room is a temporary holding area for soiled and or contaminated equipment, materials or waste prior to their disposal, cleaning or treatment. A 'clean' utility room holds clean materials and supplies.

In light of the previously mentioned HSE performance review and the concerns of local clinicians, the Investigation Team is not assured that critical care services are sustainable in Portlaoise hospital.

#### **6.4.1 Conclusions in relation to critical care services**

Senior clinicians interviewed were acutely aware of the limitations of the Intensive Care Unit and the critical care services and had adapted their practice to minimise risks to the patients.

The Intensive Care Unit at Portlaoise Hospital as viewed by the Investigation Team was not fit for purpose. The unit was not self-contained, was small and cramped, and staff were seriously challenged in maintaining and complying with the National Standards for the Prevention and Control of Healthcare Associated Infections. Maintaining patient privacy, dignity and confidentiality was not possible within this environment.

### **6.5 Surgical services**

The surgical services at Portlaoise Hospital consisted of two operating theatres,\*\*\* an endoscopy unit, a 10-bed day unit, and 32 inpatient beds.

Surgical services were provided to adults and children over the age of three years. At the time of the investigation, surgical services at Portlaoise Hospital operated on a 24-seven basis. This meant that the surgical services can be called on to deal with acutely ill patients with complex surgical needs at any time. In 2013, there were a total of:

- 1,874 adult surgical patient discharges, comprising:
  - 1,485 (79%) emergency inpatient discharges
  - 389 (21%) elective inpatient discharges.

This illustrates that the majority of hospital inpatients using the surgical services at Portlaoise Hospital were non-elective or unscheduled cases. Elective paediatric surgical activity was also very low. Of a total of 318 paediatric surgical inpatient discharges in 2013, 309 (97%) were emergency admissions and nine (3%) were elective admissions.

The surgical team consisted of three consultant posts, only one of which was filled on a permanent basis,\*\*\*\* six registrars (one of whom was an agency doctor), six senior house officers (one an agency doctor) and two interns (doctors in the final year of basic training). None of the senior house officers were in training posts. The previously described unusual governance structures in the Emergency

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\*\*\* At the time of the investigation, Portlaoise Hospital had two general theatres. The Investigation Team viewed a third room that was being developed for use as a third theatre for day surgery.

\*\*\*\* In April 2015, the HSE advised the Authority that one of the two vacant surgical consultant posts had been filled, but the other had yet to be advertised.

Department also impacted on the surgical services. For example, three of the surgical registrars were effectively rostered to the Emergency Department, reporting to the Emergency Department consultant when there was one on duty and outside of these hours to the consultant surgeon on call.

All gastrointestinal endoscopies were performed by the surgical team, with only one of the two endoscopy suites operational at the time of this investigation. The endoscopy unit was preparing for accreditation by the Joint Advisory Group for Gastrointestinal Endoscopy.\*

A review of data submitted confirmed that low numbers of complex surgical procedures were being carried out at the hospital. For example, data for 2013 showed that out of a total of 5,472 surgical patients, only 29 high-complexity bowel surgeries were performed in the hospital. Previous reports, by the Authority and others, have raised concerns that specialist staff – who do not have the opportunity to treat sufficient numbers of patients and or volume of procedures – can miss audit and competence assurance targets and risk becoming de-skilled<sup>(7,8,71)</sup>.

Two separate HSE reviews\*\* of the surgical services at Portlaoise Hospital both concluded that Portlaoise Hospital on its own was not structured for the provision of safe, acute and elective surgical care. Following an inspection in 2013, senior clinical members of the HSE's National Clinical Programme in Surgery wrote to the HSE's National Director for Acute Hospitals outlining serious concerns that they had regarding significant surgical risks in the hospital which included;

- lack of effective peri-operative governance working group
- limited operative experience within general surgery - with the small numbers of surgeries leading to the de-skilling of surgical staff.

At this time, they advised that the risks associated with surgical care at Portlaoise Hospital could only be dealt with in the context of providing a rationalised surgical service within a hospital-group setting. In March 2014 the College of Surgeons wrote the then Minister of State with responsibility for Primary Care again highlighting their concerns that despite the advice of the National Clinical Leads for Surgery that surgical services at Portlaoise hospital continued in their opinion to pose a serious threat to patient safety and quality of care. Again in 2014, the HSE's performance review also highlighted a number of deficiencies in the scheduled care pathway and concluded that the hospital was not set up to provide safe elective surgical care.

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\* Under the auspices of the Royal College of Physicians in England, a Joint Advisory Group (JAG) on gastrointestinal endoscopy awards accreditation as a formal recognition that an endoscopy service has demonstrated that it has the competence to deliver against the measures in the endoscopy global rating scale standards.

\*\* In 2013, the National Clinical Programme in Surgery (NCPS) Team visited Portlaoise Hospital for the purpose of reviewing the surgical services, while in 2014 a national HSE team reviewed the general services including the surgical services at Portlaoise Hospital.

Despite the findings of both these reports and the expert opinions of national clinical care programme leads, at the time of the investigation, Portlaoise Hospital was in the process of recruiting two general surgeons with a special interest in colorectal surgery without due consideration of the surgical demand or general practitioner (GP) patient referral patterns at the hospital.

### **6.5.1 Conclusions in relation to surgical services**

The surgical services at Portlaoise Hospital are not currently structured to ensure the delivery of safe surgery. The risks associated with insufficient acute and elective surgical presentations to ensure surgeons maintain the necessary competencies and expertise required of such clinicians has not been addressed at Portlaoise Hospital.

## **6.6 Medical services**

Medical services in the hospital were provided by way of a 39-bed inpatient unit and a four-bed Coronary Care Unit. At the time of the investigation, consultant staffing for the medical division consisted of three full-time and one temporary consultant physician. A total of 13 NCHDs completed the medical team: eight senior house officers (SHOs) and five registrars. Only five of the eight NCHD posts are approved for Basic Speciality Training and none of the registrar posts are approved for Higher Speciality Training.

As previously described, the system of care for medical patients attending the Emergency Department at Portlaoise Hospital was reviewed as a result of the reduced availability of emergency medicine consultants and the risks around this. Medical patients attending the Emergency Department at Portlaoise Hospital were triaged and referred directly to a medical registrar for review and treatment. The medical registrar directed the complete plan of care including review, diagnostic testing, treatment, plan of care on discharge or referral for admission as required. Medical consultants were available for consultation by phone or in person as deemed necessary.

The Investigation Team considered that the medical team was under-resourced in light of the fact that consultant physicians were responsible for the management of all adult emergency medical attendances in the Emergency Department in addition to hospital medical inpatients. In addition, one of the consultant physicians was the Clinical Director for the hospital and a member of the senior hospital management team in addition to being the specialty lead for medicine. Local clinicians had identified a requirement for a care of the elderly consultant and a consultant endocrinologist, based on the current patient population and on the National Clinical Programmes being implemented in the hospital.

The Investigation Team was concerned that the medical services at Portlaoise Hospital would continue to struggle to implement the Acute Medicine Programme in the ongoing absence of a medical assessment unit or acute medical assessment

unit, and without a bed management structure, including a discharge planner and a bed manager.

The Investigation Team concluded that the service required significant restructuring and resourcing in order to deliver a service aligned to the HSE's Acute Medicine Programme.

As with other services at Portlaoise Hospital, the Investigation Team found that quality and patient safety structures for the medical services were in the early stages of development. However, there was evidence that effective systems of governance were beginning to take shape in the form of minuted discussions of policy development, staff training requirements, and risk management including review of complaints and adverse events. In addition, senior staff interviewed demonstrated understanding and acceptance of the need to monitor and measure performance on an ongoing basis.

### **6.6.1 Conclusions in relation to medical services**

The Investigation Team concluded that the medical services required significant restructuring and resourcing in order to deliver a service aligned to the HSE's Acute Medicine Programme.

## **6.7 Diagnostic imaging services**

Rapid access to diagnostic imaging is an essential requirement for providing unscheduled care. The Authority found that the radiology service was under pressure to efficiently respond to the demand from unscheduled, scheduled, outpatient and community care services. It was reported to the Authority that some patients were waiting long periods (up to six months) for imaging tests, particularly ultrasound scanning.

The Radiology Service at Portlaoise Hospital is a hospital consultant-led service; there are no junior doctors. When fully staffed, the service had 2.5 whole-time equivalent consultant radiologists, however, at the time of this investigation one of the radiologists was on long-term leave. The availability of locum consultant radiology cover was described as limited and inconsistent. At interview, a senior clinician suggested that the hospital required four full-time consultant radiologists. However, despite a recruitment campaign, no successful appointments had been made. This challenge in attracting consultant radiologists is also seen in other small hospitals, which again reinforces the need for small hospitals like Portlaoise Hospital to be part of a hospital group and viewed as a progressive clinical environment to work in<sup>(15)</sup>. A clinical network linking Portlaoise Hospital with other hospitals in the group would provide support for clinicians, centrally agreed protocols and care pathways and opportunities for peer review and quality assurance across hospitals.

Despite these resourcing constraints, clinical staff at the hospital viewed the service as supportive. The Authority welcomed a number of positive developments in the radiology services following the previous HSE investigations and national initiatives and interactions with the Authority including:

- an expanding programme of clinical audit
- the availability of 24-seven CT scanning in Portlaoise Hospital since October 2013
- the introduction of a Radiology Information System/Picture Archiving and Communication System\* which means that images and data are managed more effectively
- the introduction of the National Integrated Medical Imaging System.\*\*

### **6.7.1 Conclusions in relation to diagnostic imaging services**

The Investigation Team is significantly concerned that the ongoing recruitment difficulties means that the diagnostic imaging service is significantly under-resourced. Additionally, the lack of resources prevents the development of a strong clinical governance structure to ensure the quality of service delivery. The service is currently overly reliant on one lead clinician, and this model of care is clearly not sustainable.

## **6.8 Overall conclusions on the general hospital services**

The Investigation Team concluded that Portlaoise Hospital is not adequately resourced or structured to provide the undifferentiated care that it is currently charged with providing. Although Portlaoise Hospital was regarded as a model-3 hospital, it was not resourced as such and was trying to deliver clinical services without the appropriate funding and staffing. This situation has led to the following circumstances:

- The Emergency Department's clinical governance arrangements are not in line with the HSE's National Clinical Programme.
- The Intensive Care Unit infrastructure is unfit for purpose, while low volumes of critical care activity in the hospital is likely to result in difficulties in maintaining ongoing clinical expertise and competence of staff.
- General medical services in the hospital are not resourced or structured to effectively implement the HSE's Acute Medicine Programme.
- There are insufficient acute and elective surgical presentations to ensure surgeons maintain the necessary competencies and expertise.
- The lack of adequate resources in the diagnostic imaging service constantly challenges the timely access for inpatient and outpatients to diagnostic services.

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\* A radiology information system is a computerised database used to store, view and share patient radiological data and imagery.

\*\* The National Integrated Medical Imaging System is a new, central computer-based system for storing and examining X-rays and scans, managed and controlled by the Health Service Executive.

Risks in relation to general clinical services were previously identified in Portlaoise Hospital through multiple HSE reports. Despite this, remedial actions were not comprehensively implemented by the HSE to safeguard the patient's clinical care journey.

The Investigation Team is of the opinion that any clinical services provided at the hospital must be appropriately resourced and effectively governed to ensure that patients receive safe and effective care. Given the risks described in the general hospital services of the hospital, and the unsustainable nature of some of the existing clinical services, the Authority endorses the urgent need to fully integrate the hospital into a hospital-group structure.

## Chapter 7. Governance

### 7.1 Introduction to governance of Portlaoise Hospital

This investigation is the seventh investigation of its kind into the quality and safety of healthcare services in Ireland undertaken by the Authority since 2007.

In each of the previous investigation reports, the Authority has emphasised that the sustainable delivery of safe, effective and reliable person-centred care depends on service providers having competent capacity and capability in the areas of leadership, governance and management. The Authority has stressed that good governance in healthcare is the integration of effective corporate and clinical governance. This includes the systems, processes and behaviours by which an organisation or service is led, directed, managed and controlled in order to provide a high-quality and safe service.

The Authority's *National Standards for Safer Better Healthcare*, published in 2012, set out the standards necessary to ensure effective systems of governance. They state clearly that a well-governed service is clear about what it does, how it does it, and is accountable to its stakeholders including the people who use the services. These standards are applicable both to the Health Service Executive (HSE) as a provider and the HSE as a commissioner of services. Therefore, they cover local, regional and national HSE structures.

In the context of service delivery, governance systems must ensure patient services are only delivered within the scope of what can be done safely, effectively and sustainably. Therefore, management at a local, regional and national level must ensure that services are planned, controlled, organised and evaluated to ensure that a service can achieve its outcome in the short-, medium- and long-term. Achieving safe high-quality care is critically dependent on the culture of a service at local, regional and national level. Leaders at all levels have an important role to play in strengthening and encouraging their service's culture.

A well-governed and monitored service measures its performance across all organisational levels to ensure reliability so that it provides care, support and treatment that are of a consistently high quality with minimal variation across the wider system. Quality and safety is also assured by compliance with legislation, acting on standards, guidance and recommendations from relevant professional and statutory bodies.

This section of the report will detail the findings of the Investigation Team in respect of the national, regional and local governance and management tiers responsible for the planning, delivery and monitoring of the quality and safety of clinical services in Portlaoise Hospital.

## 7.2 Health Service Executive – National

The Health Service Executive (HSE) is the organisation charged with responsibility for providing all of Ireland's public healthcare services, in hospitals (such as Portlaoise Hospital) and communities across the country<sup>(72)</sup>.

It was evident throughout interviews held with national HSE managers that up until the latter part of 2014, the HSE was focused on budgetary austerity measures and the Government imperative to control healthcare expenditure. In line with national fiscal policy, this included an emphasis on reducing the number of people employed in the health services. The HSE stressed the challenges and difficulties that it was encountering in working within these resource constraints, and identified the urgent need for the 2015 health budget to be increased or at the very least maintained at 2014 levels.\*

At the time of this investigation – similar to previous investigations conducted by the Authority – the national HSE organisational structure was being changed, with a newly chosen Director of Acute Services being appointed in May 2014.\*\* In October 2014, the Authority was notified of a further reconfiguration to reflect the appointment of a national director of quality assurance and verification, and a national director of quality improvement.

In addition, in late 2014, through a process of staff redeployment, the HSE appointed a chief executive officer to each of the newly formed hospital groups. A national initiative to establish hospital groups was outlined in the Programme for Government (2011)<sup>(73)</sup>, *Securing the Future of Smaller Hospitals: A Framework for Development* (2013) and *Establishment of Hospital Groups as a transition to Independent Hospital Trusts* (2013)<sup>(57)</sup>. Each chief executive officer of the six hospital groups reports directly to the post of the National Director of Acute Services. Group management teams to support each of the chief executive officers were being recruited at the time of preparing this report.

Many senior HSE managers interviewed by the Investigation Team placed significant weight on the organisation's future plans, particularly in the context of the patient quality and safety agenda. Such future plans included the 2015 HSE Service Plan and aligned initiatives which included plans for the development of the hospital-group structures within the acute sector. Although it was articulated at interview that the Director of Acute Services was responsible for ensuring the quality and safety of services delivered within the acute hospital sector, the HSE later clarified that no one person was responsible. It explained that the HSE

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\* Budget 2015 provides for the delivery of health and social care services within the funding allocation of €12.131 billion net revenue budget, plus an additional €35 million for mental healthcare services. This funding allocation includes an additional €625 million (5.4%) as part of the two-year programme to increase health funding and as the first step in establishing a multi-annual funding approach. As the additional €625 million includes funding for the €510 million deficit (the excess of spending over income) in 2014, the net increase in funding for 2015 is €115 million.

\*\* The post-holder appointed in May 2014 moved on from this post in early 2015. At the time of publication of this report, the HSE had filled the post on a temporary basis.

Executive was collectively responsible for ensuring the quality and safety of services delivered within the acute hospital sector with individuals being held to account as part of the organisational performance management arrangements.

The Authority acknowledges the 2015 HSE Service Plan, the identification of a broad suite of critical patient quality and safety performance indicators, and the development of a Quality and Patient Safety Enablement framework<sup>(74)</sup>. However, at the time of reporting, the efficacy of these initiatives and plans remained untested. The following section of this report outlines the findings of the Authority's investigation up until October 2014 – and, where appropriate, the Authority will make related recommendations.

### **7.2.1 A culture of patient safety at national HSE level**

As previously outlined in Chapter 2 of this report, there had been many significant indicators – which included HSE local and national inquiries, statutory investigations conducted by the Authority, national recommendations and the findings of local clinical reviews conducted in Portlaoise Hospital – as to why the HSE should have maintained very close oversight of the quality and safety of services at Portlaoise Hospital.

However, prior to the publication of the Chief Medical Officer's report in February 2014, there was little evidence available to the Investigation Team to show that at a national level, meaningful oversight of the hospital was maintained. Sadly, such a lack of oversight at a national level had implications for the experiences of the people using the maternity services at the hospital who met and spoke with the Investigation Team.

The Health Service Executive (Governance) Act 2013<sup>(75)</sup> created a directorate structure known as the Health Service Directorate, which replaced the former board structure of the HSE. The Health Service Directorate oversees the entire HSE organisation and all public healthcare services in the Republic of Ireland. The Investigation Team expected to find that patient safety was at the top of the HSE's agenda, that it would be a standing item at all meetings, and that senior HSE staff were aware of what was happening in Portlaoise Hospital. However, the evidence reviewed by the Investigation Team indicates that this was not the case. Indeed correspondence from the HSE to the Department of Health in 2013 admitted that issues of quality and safety had been overshadowed by the focus on the financial performance of the organisation.

It was apparent at interview and in the documentation reviewed that patient safety issues were not a standing agenda item for discussion at the Health Service Directorate up until late 2014. This deficit was compounded by the HSE's National Director of Quality and Patient Safety not being a member of the Health Service Directorate.

As a result, issues of quality and patient safety were not formally represented at this most senior level of HSE management.\*

Leaders at all levels in the health service play a pivotal role in strengthening and encouraging the culture of a service, particularly in the context of patient safety and quality. Therefore, it was of significant concern to the Investigation Team that, in light of the seriousness of the patient safety concerns at Portlaoise Hospital at the time of the RTÉ Investigations Unit *Prime Time* programme, there was no evidence that key senior national HSE managers who had ultimate responsibility for health service delivery had visited the hospital to assess the situation in the maternity services.

In addition, it was noticeable to the Investigation Team that, outside of the HSE's Your Service Your Say policies and procedures, there was no formal assessment in place to ensure that the HSE receives – or indeed that it actively looks for – feedback from patient experiences. An extreme example of this was the scarcity of any evidence to confirm that worthwhile discussions had taken place at HSE directorate or leadership levels in relation to the experiences of people who used the services at the Maternity Department at Portlaoise Hospital.

The Clinical Indemnity Scheme, established in 2002, is the main scheme under which the State Claims Agency manages, on behalf of the Department of Health, all clinical negligence claims taken against healthcare enterprises, hospitals and clinical, nursing and allied healthcare practitioners covered by the scheme.\*\* Claims made under the scheme are managed by a team of clinical claims managers within the State Claims Agency. This team of clinical risk advisers collaborate with risk management and other relevant clinical and administrative personnel to support patient safety and to help minimise the occurrence of clinical claims.

At the time of this investigation, hospitals used a system called STARSWeb\*\*\* to record and inform the State Claims Agency of actual and potential adverse events. As a result, the State Claims Agency is the main repository for this information. At interview, senior staff from the State Claims Agency informed the Investigation Team that as far back as 2007 it had significant concerns in relation to the quality and safety of the maternity services in Portlaoise Hospital. However, at that time there were no effective communication processes in place between the HSE and the State Claims Agency to ensure that staff from the State Claims Agency could formally advise or alert national HSE managers in relation to specific concerns. Senior managers within the HSE reported that the State Claims Agency had access to information that was not available to the HSE.

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\* The Authority notes the inclusion of the National Director for Quality Improvement on the Directorate of the HSE in April 2015.

\*\* The State Claims Agency does not have statutory powers by which it can compel healthcare institutions, including the HSE, to engage with it or to implement any recommendations which it may make.

\*\*\* STARSWeb is a national web-based 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. The Clinical Indemnity Scheme is currently in the process of updating STARSWeb and it will be replaced by the National Adverse Event Management System (NAEMS).

More worryingly, the senior managers from the State Claims Agency reported that they had met with the HSE in 2007 and discussed with them their concerns in relation to the maternity services at Portlaoise Hospital, including a plan to commission an independent obstetric expert to conduct an external review of these services. However, they reported that the HSE declined the offer, reassuring the State Claims Agency that they were addressing the issues. Although the HSE conducted a risk assessment of the maternity services at Portlaoise Hospital, the State Claims Agency was of the opinion that any changes that resulted were inadequate.

It is of significant concern that seven years prior to the Chief Medical Officer's report, the State Claims Agency had been aware of actual or potential risks in the maternity services at Portlaoise Hospital. However, the interaction between the HSE and the State Claims Agency in relation to the sharing and use of the available information did not result in effective mitigation of the identified risks. As a result, the Investigation Team was not surprised when some senior HSE managers informed them at interview that before the RTÉ Investigations Unit *Prime Time* programme they were unaware of any safety concerns in relation to Portlaoise Hospital. This was particularly evident in relation to reported poor staffing levels in, for example, the Maternity Department of the hospital. One senior HSE manager explained to the Investigation Team that they would have used their influence to address the issue had they been aware that there was a problem.

Furthermore, some senior HSE managers explained that they were not informed of the sentinel cases identified on the *Prime Time* programme in a timely fashion, explaining at interview that no alerts or serious incidents were escalated to them nationally through expected risk management processes. Even more worryingly, one senior HSE manager told the HIQA Investigation Team that these circumstances were not surprising and will very likely reoccur elsewhere in the system.

While the Investigation Team did not investigate any individual cases of patient care, it did explore (as the Authority had previously done in other investigations) the national arrangements in place to effectively investigate and communicate with families in cases that have been escalated for investigation at a national level. As outlined in Chapter 2, following the Fitzgerald report<sup>(12)</sup> in 2008, the HSE had committed to promoting and supporting improvements in the management and investigation of incidents. This was to include a standardised approach to incident management, with supporting policies, procedures and guidelines to streamline the process of investigation and timely responses.

However, it was evident that the HSE mechanisms in place for reporting and escalating adverse events did not work for the sentinel cases in the RTÉ Investigations Unit *Prime Time* programme. Described by a senior HSE manager as unnecessarily bureaucratic, the process is often protracted and leaves families with unanswered questions pending the publication of a final report, thereby increasing their upset and trauma. It also potentially means that underlying quality

and safety issues may remain unidentified and unresolved for lengthy periods of time. The Authority is aware that delays in the investigation of adverse events have occurred elsewhere in the health services. Unnecessarily prolonged and protracted investigations are not consistent with a high-quality approach to incident management or a dominant culture of patient safety.

In October 2014, the Authority wrote to the Director General of the HSE to highlight concerns in relation to the protracted nature of investigations into adverse events as highlighted by bereaved families. The Authority sought assurances from the HSE regarding the Authority's concerns about the unacceptable delays incurred in the investigation of serious clinical incidents and an update regarding the structures in place to manage adverse events. In response, the HSE – as outlined in its 2015 Service Plan – identified key performance indicators (specific and measurable elements of practice that can be used to assess quality and safety of care) to include a 16-week turnaround time for investigations, and the revised organisational structure and supporting Quality Patient Safety and Enablement Programme. The key responsibilities of this programme are to be assigned to two national directors in the HSE, namely the National Director of Quality Assurance and Verification, and the National Director of Quality Improvement. In addition, a National Adverse Event Management System (NAEMS)\* (to replace STARSWeb) is to be introduced in collaboration with the State Claims Agency to enable more accurate reporting on timelines.

Notwithstanding these revised structures, it is the opinion of the Investigation Team following interviews with the HSE that prior to the Chief Medical Officer's report, the HSE simply did not proactively address the inherent risks identified in Portlaoise Hospital. While they were monitoring nationally reported performance data from the hospital, these metrics are not sufficient to highlight actual and potential risks, monitor patient experience and assess the prevailing safety culture. In addition, it is evident from the findings of this investigation – and that of the Authority's previous 2013 Galway report on maternity services – that the HSE did not effectively seek and use the information collected by the State Claims Agency to inform its patient safety activities.

It is now imperative that the HSE recognises that devolving the responsibility for quality and patient safety to those charged with the delivery of care is not a substitute for senior HSE managers maintaining adequate oversight of this key aspect of the service that they preside over. Acute-care hospitals are complex environments and many factors contribute to patient safety within them. Improving patient safety is a multi-faceted task that requires involvement of all the players in a healthcare organisation. Managers of healthcare organisations need to become visible on the ground in clinical care areas as patient safety champions.

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\* In April 2015 the Authority was advised that NAEMS would be rebranded as the National Incident Management System (NIMS).

## 7.2.2 Clinical services at Portlaoise Hospital – national planning and oversight

The *National Standards for Safer Better Healthcare* identify that the national and local governance systems should ensure that clinical services only deliver within the scope of what they can do safely, effectively and sustainably. While accepting that the workforce exercises personal and professional responsibility for the quality and safety of services it is delivering, national governance arrangements must ensure that adequate resources are deployed. National governance systems must also monitor services' performance to ensure reliability so that they provide consistently high-quality care, treatment and support across all the services, hospitals and hospital groups that they govern.

The Investigation Team reported its findings in relation to the systems of care found in the hospital in Chapters 5 and 6 of this report. In the context of governance, national planning and oversight of the quality and safety of clinical services, the Investigation Team identified significant concerns in relation to the HSE's oversight of the safety and or appropriateness of services being provided at Portlaoise Hospital. As outlined in Chapter 2 of this report, there have been a number of national recommendations following statutory investigations conducted by the Authority into safety and quality of services, particularly in smaller hospitals. Standard 5.8 of the *National Standards for Safer Better Healthcare* identifies prompt action on recommendations made by a regulatory body as a key feature of effective governance, leadership and management. The Investigation Team is concerned that the findings of this investigation indicate that nationally the HSE has not completely adopted this approach. For example, the Investigation Team found – contrary to the recommendations of both the Authority's earlier Ennis and Mallow hospitals investigations – that Portlaoise Hospital continues to provide:

- undifferentiated care in an Emergency Department with inappropriate governance structures (as outlined in Chapter 6)
- an under-resourced radiology service.
- an acute general surgical service where there are insufficient acute and elective surgical presentations to ensure surgeons maintain the necessary competencies and expertise.

In addition, the Investigation Team found that Portlaoise Hospital had other major deficiencies in governance including the absence of:

- a well-resourced and supported clinical directorate structure
- effective risk management structures to include dealing with patient incidents and or complaints
- effective clinical audit arrangements
- comprehensive systems of workforce planning.

These national recommendations are basic requirements necessary to ensure safe care. Therefore it is of significant concern that these deficiencies were not addressed by the HSE to the detriment of the systems of care in Portlaoise Hospital.

Senior HSE and local hospital staff described Portlaoise Hospital as a model-3 hospital. However, the Investigation Team found that the hospital was neither resourced nor equipped to safely deliver that level of clinical services. Furthermore, the HSE's National Clinical Programmes in surgery and emergency medicine, constituents of a national HSE directorate, had specifically in 2012 and 2013 identified clinical risks associated with the delivery of these particular services at that time in the hospital, going as far as to say that surgical services should cease. At the time of this investigation, its own findings had not been addressed by the HSE and the hospital continued to deliver these services.

The HSE stated that unlike other hospitals, Portlaoise Hospital's 2014 annual budget had not been reduced. This was explored further with the HSE, which explained that this was viewed as a positive and supportive signal to the hospital. The Investigation Team would not agree with this premise. Instead, members of the Investigation Team considered this position to be a misguided justification for the failure to address the substantive issue, that is to say that the hospital was not adequately resourced (clinically or from the perspective of workforce or infrastructure) and not governed appropriately to be classified as a model-3 hospital.

This investigation started in March 2014, and three months later in June 2014, the Authority received a copy of an unpublished 2014 HSE report which detailed the performance status of the Midland Regional Hospital, Portlaoise<sup>(68)</sup> (referred to in this HIQA report as the HSE's performance review). In essence, this report mirrors what the Investigation Team has found. For example, the HSE review team reported findings which included:

- a weak management team
- an absence of any service and strategic plan
- inadequate risk management structures and arrangements
- poor workforce planning
- an emergency service that was not sustainable
- surgical services which should not provide acute and elective surgery
- critical care activity of very low volume
- an inadequate rota of consultant radiologists and diagnostic imaging support
- inadequate numbers of medical, surgical and emergency medicine consultants.

The findings of this HSE performance review<sup>(68)</sup> were subsequently explored with the HSE, which appeared reluctant to comment on the findings to members of the Investigation Team. However, the HSE indicated that as a result of the findings contained in its performance review<sup>(68)</sup> it had:

- assigned a senior HSE manager to work on site with the hospital management team to ensure that patient pathways of care were safe
- reinforced the paediatric trauma bypass protocol
- began the process of creating the hospital-group structure, citing examples of clinicians meeting to work towards agreeing the best possible patient pathways and service model for people attending Portlaoise Hospital.

At the time of reporting, it was too early for the Investigation Team to assess the efficacy of these arrangements. These plans, which are long term, are intrinsically dependent on the formation of a hospital-group structure supported through effective clinical and corporate governance structures and arrangements. The Authority is of the opinion that the success of any hospital-group structure depends on the development of formal clinical arrangements which facilitate clinical cooperation. As previously outlined with respect to the maternity clinical network, clinical cooperation must include:

- common systems of governance
- capacity for staff to be appointed to a group and rotate between the different sites to facilitate training and service delivery
- risk categorisation of patients to ensure that higher-risk patients are managed at the most appropriate site within the group
- a group cooperative approach to service delivery which ensures that each hospital site within the group delivers care appropriate to the resources, facilities and services available on that site.

Therefore, given the findings of this investigation, the risks identified in the HSE's performance review<sup>(68)</sup> and the expert opinions of the HSE's National Clinical Programme leads, the Authority is not assured that the service model and inherent risks associated with undifferentiated care, acute and elective surgical services, under-resourced radiology services and governance deficiencies have been adequately addressed.

As a consequence, the Investigation Team explored the governance arrangements and the controls put in place at a regional and local level to assure the national HSE of the safety and quality of services currently being delivered in the general adult and paediatric services of Portlaoise Hospital. The findings of this element of the investigation are now outlined here.

### 7.2.3 Strategic direction – Portlaoise Hospital

Throughout this investigation, the management team and senior clinicians at Portlaoise Hospital expressed considerable frustration at the lack of a nationally agreed and funded strategic direction for the hospital. While staff across all levels of the organisation reported that the hospital is a model-3 hospital, they believed that it is funded and resourced as a model-2 hospital.

In the HSE's performance review<sup>(68)</sup> in 2014, the HSE's review team criticised Portlaoise Hospital for not having a strategic and service plan. However, it should be noted that when the Investigation Team requested copies of the current HSE Dublin Mid Leinster Corporate Strategy and the Dublin Mid Leinster Annual Report for 2012 and 2013, it was informed by the HSE that these documents did not exist. A review of the Dublin Mid Leinster Business Plan for 2013 yielded minimal information specific to Portlaoise Hospital and no such plan existed for 2014. The situation was further complicated by the inclusion and subsequent exclusion of Portlaoise Hospital from the Department of Health and HSE's Small Hospitals Framework.

In the absence of clear national and regional guidance and direction, it was unclear to the Investigation Team how the management team at Portlaoise Hospital could have devised any practical strategic plan. Not surprisingly, the hospital's management team reported that in the absence of specific national or regional guidance – aside from the implementation of selected National Clinical Programmes – it strove to maintain the current level and range of clinical services within its allocated budget.

Meanwhile, the HSE's 2015 Service Plan identifies the formation of the hospital groups as a priority action. However, at the time of reporting, the relevant hospital group that would incorporate Portlaoise Hospital is in the very early stages of development. There is still no clearly defined strategic and or service plan for the group detailing the range of clinical services that will be delivered in Portlaoise Hospital.

The Authority was also significantly concerned to note the planned appointment of further consultant surgical staff. Such appointments were being made in the absence of any clear direction for the hospital and despite the findings of two senior national HSE groups<sup>(68,76)</sup> that Portlaoise Hospital was not set up to provide safe acute and elective surgical care. The hospital management team reported in July 2014 that it was actively seeking to recruit two full-time colorectal surgeons in order to regenerate the surgical services. The appropriateness of appointing two such speciality posts to a hospital that is not currently set up to provide such a speciality service was explored further with senior HSE managers in July 2014. They told the Investigation Team that these appointments would not be made. However, at a final meeting in October 2014, the Investigation Team was surprised to be informed by the hospital management team that national approval had been received to progress these appointments through the recruitment process.

At that meeting in October 2014, it was clear to the Investigation Team that there was still no clear plan or agreement as to the future direction of the surgical services at Portlaoise Hospital.

Nonetheless, at that same meeting in October 2014, the Investigation Team was reassured to note that the hospital was in the process of recruiting two medical consultants. The hospital management team said these pending appointments would at last facilitate the release of the hospital's Clinical Director from general medical duties for 25 hours each week in order to increase time spent on carrying out the functions of the clinical director role. The chosen specialties (care of the elderly and endocrinology) would also address some of the deficiencies previously identified by the HSE's Acute Medicine Programme and the National Clinical Programmes in Emergency Medicine. They would at the same time help implement the Clinical Programmes in Diabetes and Stroke Care. The Investigation Team was reassured to note that these pending medical appointments demonstrated strategic thinking and planning in relation to medical services at Portlaoise Hospital. However, before these appointments are made, the model of care at the time of this investigation – and its associated risks – remains unchanged.

As a priority, the HSE must determine, publish, and implement the range of clinical services that Portlaoise Hospital can safely deliver. This is crucial in light of the findings of this HIQA investigation, previous HSE reports and reviews, and while the relevant hospital group is being finalised.

### **7.3 HSE regional and local corporate and clinical governance arrangements in Portlaoise Hospital**

This section of the report refers to the regional and local governance arrangements that were in place for the entire hospital prior to the publication of the Chief Medical Officer's report in February 2014 and which remained in place for the general hospital services at the time of this investigation.

#### **7.3.1 Regional management structures**

As reported in Chapter 2 of this report, when the HSE assumed responsibility for providing health and social care services in 2005, Portlaoise Hospital was part of the Dublin Mid Leinster Region, the largest of the four regions catering for a population 1.31 million<sup>(77)</sup> with a budget allocation of €2.6 billion in 2012.

In 2009, a regional director of operations (RDO)\* was appointed to the HSE Dublin Mid Leinster Region with delegated accountability and responsibility for all issues relating to health and social care within that region. The post-holder formally

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\* From 2009, regional directors of operations (RDOs) were the senior managers on regional HSE management teams. Initially, the RDO position reported directly to the National Director for Integrated Services and later to the Director of the National Hospitals Office. Regional directors of performance and integration (RDPIs) replaced the RDOs in 2013 as managers of performance and integration across hospital and community services.

reported to the HSE National Director of Integrated Services – Performance and Financial Management. This post, following a HSE organisational restructuring, was replaced in July 2013 by a regional director of performance and integration (RDPI), who reported to the then National Director of Acute Services.

The roles of the former regional director of operations, and the replacement regional director of performance and integration, involved an extensive remit incorporating acute, community and primary care sectors, the development of integrated services, and the delivery of service plan commitments. Portlaoise Hospital with an annual budget of €44 million in 2012 was one of the smaller service providers within the Dublin Mid Leinster Region.

From 2005 to 2010, a regionally-based general manager managed the three Midlands Regional Hospitals in Tullamore, Mullingar and Portlaoise,\* initially reporting to a network manager with responsibility for acute hospital services and subsequently reporting to the Regional Director of Operations. Following the retirement of the last regional general manager in 2010, an Assistant National Director within the HSE was redeployed to fill the vacancy in December 2010.

The Assistant National Director initially reported to the relevant regional director of operations and later in 2013 to the relevant regional director of performance and integration. In October 2014 – following further restructuring within the HSE which resulted in the formation of the Dublin Mid Leinster Hospital Group – the Assistant National Director stopped reporting to the Regional Director of Performance and Integration and began reporting to the newly appointed Chief Executive Officer of the Dublin Mid Leinster Hospital Group.

The Investigation Team was informed that the Assistant National Director had been redeployed from a previous strategic position to a role which had a specific remit to integrate the three Midland Regional Hospitals into a single integrated service. However, this plan was not progressed. Instead, the three hospitals continued to function as independent hospitals with authority for their management, including ensuring the quality and safety of their services, delegated by the Regional Director of Operations to the Assistant National Director.

The Authority found that although senior HSE managers understood that the role of the Assistant National Director had delegated responsibility for the management of Portlaoise Hospital, including ensuring the quality and safety of its services, the post-holder did not consider that he had the necessary experience, resources, training or direction for this role. The Investigation Team was informed by the Assistant National Director that he did not have a written job description for this new role and its associated delegated authority.

Notwithstanding this delegation of authority, the HSE as the service provider retains overall responsibility and accountability for the quality and safety of services delivered at Portlaoise Hospital. Regional HSE oversight of Portlaoise Hospital was

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\* Midlands Regional Hospital Mullingar, Midlands Regional Hospital, Portlaoise and Midlands Regional Hospital Tullamore.

facilitated through its functions of human resources, finance, quality and patient safety management and the post of the Assistant National Director. This regional management structure was accountable for major financial and strategic decisions in relation to Portlaoise Hospital.

Reporting into the regional management structure was a system of local management within Portlaoise Hospital. The Investigation Team noted that prior to the Chief Medical Officer's report, Portlaoise Hospital did not have a general manager. Within HSE managerial structures, a general manager has greater seniority and associated responsibilities than a hospital manager. At the time of this investigation, the Portlaoise Hospital management team consisted of a hospital manager, a director of nursing and a clinical director reporting collectively to the Assistant National Director as a management team and individually in respect of their individual roles.\*\* The Hospital Manager had overall responsibility for the operational and business management of the hospital, with the Director of Nursing and the Clinical Director reporting to the Hospital Manager on the day-to-day running of the hospital.

In 2013, HIQA identified concerns in relation to the governance arrangements in place at Portlaoise Hospital. As a result, the then Regional Director of Operations requested the Assistant National Director to work on site at the hospital two days per week, thereby increasing the interaction between regional and local management structures and bringing decision-making powers onto the hospital site.

The Investigation Team reviewed the arrangements in place for regional structures to maintain oversight of Portlaoise Hospital. This was achieved through the HSE Dublin Midlands Hospital Group Performance meeting and the Midland Regional Hospital Portlaoise Management Team meeting. These groups were attended by the Portlaoise Hospital management team and senior regional managers with responsibility for acute hospital services, finance, medical manpower, and human resources.

The minutes provided to the Investigation Team indicate that the purpose of these meetings was to review the performance of Portlaoise Hospital under the headings of finance, key performance indicators, departmental performance, human resources and quality and risk. However, the reviewed minutes show that HSE Dublin Midlands Hospital Group Performance meetings were poorly attended.

These meetings, as presented in the minutes, were a system for ongoing oversight of financial and activity levels. There was minimal evidence of a strategic approach to identified concerns including staffing deficiencies, increasing usage of agency staff and financial overspending. Despite evidence that the management team at Portlaoise Hospital was struggling to deliver the service, the HSE did not step in and take control of the situation.

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\*\* In early 2015, a general manager was appointed to Portlaoise Hospital. The post-holder would report directly to the Chief Executive Officer for the Dublin Midlands Hospital Group.

The evidence indicates that the HSE continued to advise and support even though it was clear that this advice and support was not resulting in improvements.

The Investigation Team also reviewed the regional structures in place for the governance of quality and patient safety and risk management. Although there were three regional management committees\* responsible for the management of performance in relation to the quality and safety of services, only one of these, the Midlands Area Acute Hospital Services Risk Register Committee, was specific to the acute hospitals in the region. The broad attendance (acute hospitals, community health and mental healthcare facilities) at the meetings of regional committees was not conducive to addressing issues of quality and patient safety in a small acute hospital, as discussions were not targeted to address issues at hospital level. The only committee that was specific to the acute hospitals was dedicated to the management of risk registers.

The lack of an effective connection between local and regional risk management structures was explored further at interview. The Investigation Team found that local and regional HSE managers had very different opinions on what constituted the most immediate and serious risks for Portlaoise Hospital. For example, at a regional level the Investigation Team was informed that the most serious risks at the hospital were its Emergency Department, access to 24-hour CT scanning and the difficulties in recruiting medical staff. On the other hand, most local managers told the Investigation Team that the rising birth-rate, within the context of deficiencies in midwifery staffing and financial deficits were the most serious risks for the hospital.

The Investigation Team was concerned that the minutes of meetings of the above mentioned local and regional management structures do not show that the hospital management team was able to use these structures to address issues of concern with the HSE in order to achieve positive outcomes for the hospital. Additionally, in February 2014, following the RTÉ Investigations Unit's *Prime Time* programme, the minutes of meetings reviewed do not detail any remedial action at regional level to either deal with the issues that gave rise to the programme or to support the hospital management team in dealing with its aftermath, in an informed, systemic and focused manner. The Investigation Team could not find any evidence that decisive action occurred or was even considered. As a consequence, although the HSE was aware of risk management deficiencies at the hospital, known risk management gaps were not actively addressed. By way of example, in December 2012 the Authority raised with the HSE the immediate requirement to appoint an experienced and qualified risk manager to the hospital. However, this had not happened up to the time of reporting.

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\* The HSE Dublin Mid Leinster Governance Committee, the Midlands Area Acute Hospital Services Risk Register Committee and the Midlands Integrated Quality, Safety and Risk Governance Group.

### **7.3.2 Local management at Portlaoise Hospital**

As previously stated, Portlaoise Hospital had a hospital management team consisting of a hospital manager, a director of nursing and a clinical director reporting collectively to a regionally-based assistant national director.

The hospital management team was responsible – up until the publication of the Chief Medical Officer’s report in February 2014 – for all clinical services including maternity services. As described in Chapter 5, this structure was revised by the HSE in March 2014 with the result that the maternity services were governed separately while management arrangements for the general hospital services remained the same.

Within the hospital management team, the Hospital Manager was directly responsible for administration of the hospital, finance, maintenance and capital developments. In addition, the post-holder also held operational responsibility for complaints management, health and safety, risk coordination and administrative supports.

The Director of Nursing was professionally responsible for the standard of the nursing services and for the management of nursing, midwifery and housekeeping staff.\*\* The role of the Clinical Director was primarily to manage and plan how clinical services were delivered and to contribute to the process of strategic planning, influencing and responding to organisational priorities. With the exception of the Emergency Medicine Consultants, each hospital consultant reported to the Clinical Director. At the time of the investigation, the Clinical Director did not have an assigned nurse manager or business manager to support him in delivering the functions of the role as described in his job description. This situation was further compounded by the post-holder providing a full-time clinical commitment with no locum consultant back up.

### **7.3.3 Senior Hospital Management Committee**

The Investigation Team reviewed the local management arrangements in place. A Senior Hospital Management Committee was responsible for providing safe effective services through leading and directing the performance of the hospital. This committee is chaired by an Assistant National Director, who is the named accountable person for the quality and safety of services provided at Portlaoise Hospital. The committee included the Hospital Manager, the Director of Nursing, the Clinical Director and a quality and patient safety risk coordinator.

The Investigation Team reviewed the terms of reference for this committee which indicated that the committee was to meet each week. In addition, one meeting in four was attended by a consultant representative, an allied health representative and a regional finance manager.

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\*\* Following publication of the Chief Medical Officer’s report, midwifery staff commenced reporting to the Director of Midwifery.

However, documentation provided by the hospital showed that meetings were irregular with minutes available for nine meetings between April 2013 and March 2014.

Although complaints and incidents were recorded as being discussed at some of these meetings, quality and patient safety was not a standing agenda item. Rather, the meetings focused on budgets, hospital activity and staffing numbers. In the minutes reviewed by the Investigation Team, there was little evidence that actions were taken to resolve issues raised at the meetings. As a consequence, unaddressed issues appear repeatedly in the minutes.

For example, consecutive minutes detail staff shortages in several departments of the hospital, including maternity, medicine and the Emergency Department. However, the hospital management team did not have the means to speed up the recruitment processes for these posts.

### **7.3.4 Quality and Safety Executive Committee**

The Investigation Team also viewed the arrangements in place for the management of quality and patient safety. In 2012, Portlaoise Hospital became a pilot site for a national quality and safety clinical governance development initiative. Working with a senior HSE manager, who was a national lead for the development of clinical governance, the hospital participated in a project to review and strengthen its clinical governance arrangements.

As a result of this project, a hospital committee structure (approximately 20 different local committees) was organised under a Quality and Safety Executive Committee. For example, each of the seven\* speciality groupings had its own Quality and Safety Speciality Committee chaired by the nominated clinical lead. These quality and safety speciality committees discussed issues of concern to that speciality and provided feedback to the overarching Quality and Safety Executive Committee. Agendas for discussion were appropriately structured around the *National Standards for Safer Better Healthcare*. The system was designed to facilitate areas in the hospital to have local discussions about issues of quality and patient safety, and then provide a pathway to escalate issues of concern to more senior managers.

However, the reality was that in a hospital the size of Portlaoise Hospital, the hospital management team were members of the overarching Quality and Safety Executive Committee Team and were also listed as members of many of the local committees. As well as attending local committee meetings, they attended the monthly Quality and Safety Executive Committee meeting and received feedback from the committee structures. The same small group of people were responsible for directing the implementation of quality and patient safety at local committee level and overseeing the entire process at executive management level.

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\* Medicine, emergency medicine, perioperative, obstetrics and gynaecology, paediatrics, radiology and pathology.

Senior managers expressed concern at the amount of time that was spent attending meetings; in particular they pointed to the monthly Quality and Safety Executive Committee meetings which often ran for several hours and resulted in 16 pages of minutes.

Despite the time committed to the monthly Quality and Safety Executive Committee, the minutes reviewed do not show that this forum facilitated effective management of issues that should have been of concern. For instance, although the minutes reviewed state that complaint management statistics were issued to the committee, the same minutes do not demonstrate the fact that only 16% of complaints were managed within required timelines, or that this was discussed or if any remedial action was put in place to improve the response rate.

The Investigation Team explored these arrangements further with some senior staff who reported that they felt that the committee structure was overly complicated. However, the usefulness of these arrangements was not evaluated in terms of time, benefit and worth, nor were steps taken to manage the processes that had been put in place.

Some front-line staff found the committee structure beneficial with some areas demonstrating tangible changes that had been effected through these structures. These included the 'Productive Ward' \*\* initiative in the surgical ward.

This disconnect between senior management and front-line staff may be a reflection of the findings of the safety culture assessment as described in Chapter 3, where staff felt that senior management were not visible on the ground and the monitoring of safety standards were not a priority. The Investigation Team was consistently informed that – with the exception of the Clinical Director – there was poor visibility of the hospital management team at ward level. The hospital management team did not routinely visit patient care areas and did not conduct safety walk-rounds. The Investigation Team considered this a missed opportunity for local managers to meet and talk with staff and patients and evidence of the failure to prioritise issues of quality and patient safety. Members of the Hospital Management team should have a visible presence in all areas in order to assure themselves of the standards of care being provided.

### **7.3.5 Workforce planning**

The Investigation Team believed there were significant ongoing problems with workforce planning relating to Portlaoise Hospital. The absence of a clear vision for the hospital coupled with the national imperative to reduce the headcount reduced workforce planning to the level of counting staff rather than focusing attention on the type of service the hospital should be delivering and the workforce needed to deliver that service.

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\*\* The Productive Ward initiative is a national programme which aims to empower front-line staff to promote changes and improvements in how healthcare is delivered.

In 2014, the Chief Medical Officer's report<sup>(3)</sup> and the HSE's unpublished performance review<sup>(68)</sup> identified an excessive reliance on agency NCHDs, nurses and midwives. At the time of the investigation, it was clear from interviews and in the documentation reviewed, that local hospital management had highlighted the staffing challenges in the hospital and had constantly escalated their concerns through the HSE system. Notwithstanding this, the Investigation Team was of the opinion that local management had not exhausted the option of reviewing duty rosters to make the best use of available resources including, for example, changing the practice of staff self-rostering.

At a final meeting with senior hospital management in October 2014, the Investigation Team was assured that many of the staffing difficulties at Portlaoise Hospital were being resolved. However, it is the opinion of the Investigation Team that incorporating Portlaoise Hospital into a clinical network within a hospital-group structure – with certain grades of staff including hospital consultant, non-consultant doctors and speciality nurses being obliged to rotate between sites as required – is necessary to assure the ongoing provision of a clinically competent and stable workforce at the hospital.

As detailed in the previous section (Chapter 6), the Investigation Team identified other concerns in relation to workforce planning at Portlaoise Hospital including:

- not enough consultants in emergency and general medicine and unfilled consultant posts in radiology and surgery
- failure to progress the appointment of an advanced nurse practitioner post in the Emergency Department.

The absence of a dedicated risk manager at Portlaoise Hospital was first identified as cause for concern by the Authority during the course of an announced inspection against the *National Standards for the Prevention and Control of Healthcare Associated Infections* in December 2012. The Authority recommended at that time that the hospital should identify and put in place a dedicated risk manager. In June 2014, the Investigation Team was informed that the hospital had created a 'quality and patient safety risk coordinator' post. However, the Investigation Team was informed that the post-holder did not have previous experience in working in a risk management role or formal qualifications in risk management. This post, as described to members of the Investigation Team, was focused on following up on incidents which occurred and ensuring that the appropriate paperwork had been completed and submitted. While this post facilitated timely feedback to the senior hospital management team about incidents that occurred throughout the hospital, it did not bring about a hospital-wide system of risk management.

Such a system would include ensuring that systems and processes were in place to:

- minimise risk
- develop and monitor the implementation of a risk management strategy
- review high-level reports on complaints, critical incidents and near misses
- manage the hospital's risk registers including the escalation of high-level risks.

On 30 June 2014, the Authority wrote to the HSE to request the interim assignment of a qualified risk manager with the required experience and competencies to address the deficiencies identified above. At a final meeting with senior hospital managers in October 2014, the Investigation Team was informed that although roles had been restructured and approval had been received to recruit additional resources, at that time the situation in relation to the availability of risk management expertise remained unchanged.

### **7.3.6 Risk management**

Effective clinical and non-clinical risk management embodies the systematic identification, evaluation and management of risk. It is an important means of ensuring the safety and quality of patient care, the care environment and the supporting structures.

Providers must ensure that every effort is made to avoid harm to patients by providing safe systems of care that minimise risks. Strong and reliable clinical and non-clinical risk management processes have been identified previously by the Authority as vital to the delivery of a safe health service<sup>(8)</sup>.

In the context of this investigation, the Investigation Team reviewed clinical risk management structures in place in the general services at Portlaoise Hospital and found an absence of ownership of risk in the hospital. The Investigation Team found that risks were not comprehensively reviewed or addressed at a senior level in an effective and proactive manner, while risk management structures in the hospital as described to the Investigation Team were poorly developed.

For instance, deficiencies in risk management structures were seen in the system of managing risk registers in the hospital. Significant time and energy was focused on compiling and maintaining the risk register. Despite this, the hospital register reviewed by the Investigation Team did not show evidence of ongoing systematic review or progressive management of risks. In addition, the system did not capture all known risks in the hospital, for example, the dependence on agency staff, safety of the surgical services and a lack of senior clinical decision makers in the Emergency Department. Risks identified following investigation of complaints and clinical incidents were also not included.

The system of risk registers at Portlaoise Hospital was explored with regional and local HSE managers, who provided conflicting accounts of how the process worked. Regional HSE managers said they expected managers in Portlaoise Hospital to manage their own risks while they would provide regional advice and support. However, local managers in Portlaoise Hospital reported that they didn't have the necessary authority and or financial resources required to reduce or eliminate many risks. Irrespective, the end result was that serious risks remained unresolved at Portlaoise Hospital, such as staff shortages, unfit infrastructure in the Intensive Care Unit and the absence of an acute medical assessment unit on site.

It was also evident at interview that hospital staff did not have confidence in the local and regional systems in place to deal with and resolve risk issues. Staff members described an endless process of escalation which did not result in informative feedback or tangible results.

### **7.3.7 Management of adverse incidents**

Service providers are required to have processes in place to ensure that all adverse incidents are assessed and managed in order to determine the most appropriate level of response to, and management of, each incident.

The process of incident management at Portlaoise Hospital as described to the Investigation Team was largely a reactive process focused on recording incidents that had occurred. These reported incidents were then forwarded to the Regional Risk Management Office in Tullamore where a clerical officer entered them on the National Incident Reporting Database called STARSWeb. For the period from 1 June 2013 to 31 March 2014, an overall total of 1,338 incidents were reported at the hospital. The most frequent incidents reported related to treatment, perinatal care and patients' slips, trips and falls. This process meant that there was no validation or indeed ownership to ensure that what was entered on the STARSWeb system was accurate and timely. This practice of forwarding incident forms to a regional office for input onto STARSWeb was unique to the three Midlands Regional Hospitals and contrary to the HSE National Safety Incident Management policy.

A crucial step in the management of adverse incidents is the review of incidents which have occurred. This is an important means of ensuring that the system learns from adverse incidents in order to prevent a reoccurrence. As a result of this off-site process, there was no local system of collating data which in turn meant that hospital staff who were ultimately responsible for the quality and safety of services did not corporately collate, analyse, trend or use this information proactively to address risks, investigate incidents and share any resulting lessons.

During the investigation, Portlaoise Hospital was asked to submit examples of quality improvement initiatives that had been implemented following the investigation of any identified adverse incidents from June 2013 to March 2014.

Despite the fact that 1,338 incidents were reported during that time frame, only four quality improvement initiatives were submitted. Furthermore, the quality improvement initiatives that were submitted were speciality-specific with no evidence to demonstrate that recommendations were shared across the wider system.

In essence, the hospital had poor risk management processes which lacked the required staff competencies to develop a strong and reliable risk management structure. This contributed to the poor experiences as described by patients who met with the Investigation Team, in particular in the sentinel cases reported on the *Prime Time* programme. Some senior hospital managers at interview reported that they did not know about the sentinel tragic events in a timely manner. Furthermore, when they were informed, senior managers stated that they did not have staff with the experience and expertise required to oversee the process of an investigation and said there was insufficient education and mentoring available regionally and nationally to address their learning needs.

The Chief Medical Officer's report also identified concerns relevant to how incidents were reviewed and investigated at Portlaoise Hospital, including protracted time frames for completing reviews and the variable quality in the standard of reviews. As a result, the maternity services at Portlaoise Hospital, within their new governance structure, had been resourced to appoint an experienced quality and patient safety manager and had begun inputting data to STARSWeb locally. However, at the time of reporting, similar resources and processes had not been allocated to the general hospital services at Portlaoise Hospital and as such the system there for the most part remained unchanged, a situation which is unacceptable. The Authority has made recommendations accordingly.

### **7.3.8 Complaints management**

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

At the time of the investigation, Portlaoise Hospital did not have a dedicated on-site complaints manager. The management of complaints was assigned – along with what the Investigation Team believed was an excessive number of other duties – to a deputy hospital manager. Also, Portlaoise Hospital had not developed a standardised methodology for the management of patient complaints aligned to the national HSE complaints management process and its Complaints Policies and Procedures Manual, 'Your Service Your Say.' This is demonstrated by the level of non-compliance with the timelines set out in Your Service Your Say. In 2013, only 16% of complaints were investigated and concluded within the prescribed 30-day time frame. Only 51% of those who had submitted a complaint were communicated with in relation to the delay and none were updated every 20 days as required by the HSE policy.

Further shortcomings in the management of complaints were identified by the Investigation Team during the course of interviews and following a review of documentation submitted. Minutes that were submitted for review did not demonstrate robust review of complaints at senior hospital management committee level. In addition, documentation reviewed by the Investigation Team pointed to a failure to take decisive action in relation to individuals who did not cooperate with the complaints management process in a timely fashion.

There was little evidence of learning following investigations into specific complaints being put into practice for the benefit of other patients. Furthermore, the structures were not in place to ensure that learning from complaints was shared across specialities and services, thereby reducing the potential of collectively improving patient services. Up to the time of this investigation, it is clear there had been a failure to recognise the importance of addressing and learning from complaints. This failure in turn meant that patients and their families were often left with unresolved concerns and genuine upset.

It was accepted by local staff at interview that the management of complaints at Portlaoise Hospital was inadequate. Reasons proffered included lack of a dedicated complaints manager, failure of the organisation to prioritise the management of complaints, insufficient time and resources allocated to managing complaints, inadequate staff training and failure of some senior clinical staff to engage with the process of responding to complaints in a timely manner.

At a final meeting between the HSE, hospital and Investigation Team in October 2014, members of the Investigation Team were informed that the system of complaints management within the hospital had been reviewed and the following steps had been taken.

- The manager with responsibility for complaints has had some of their previous duties redistributed.
- A clerical officer had been assigned to support the management of complaints.
- The Complaints Manager attended a monthly meeting of the management team to provide feedback on complaints received and their management.
- The Complaints Manager provided feedback to the systems of care via quality and patient safety meetings to improve learning from complaints received.

As a result of these changes, senior hospital managers reported that the system of complaints management had improved dramatically. At that time there were 26 active complaints, 17 of which had exceeded the 30-day HSE policy time frame for resolution. However, in all cases the families had been informed of the delay and were being updated in relation to progress. Also, the system of the Complaints Manager providing regular timely feedback was perceived to be having a positive effect on staff's attitude to the receipt and management of complaints.

### 7.3.9 Clinical audit

Clinical audit is the review of current clinical practice for the purpose of quality improvement. Clinical audit identifies good practice as well as areas of practice that require improvement. It is recommended that all clinicians actively participate in clinical audit in compliance with national standards and priorities.

As a result of the previously described failure to support the position of the hospital's Clinical Director, the post-holder was not in a position to develop the clinical audit function across the clinical services. There was a regional clinical audit function which was described as 'supportive and advisory', but there was no dedicated staff member on site with oversight of clinical audit. In addition, the hospital did not have the information technology structures necessary to support an effective system of multidisciplinary audit.

Despite these shortcomings, there were examples of some audits being carried out throughout the hospital. Areas of clinical audit included the prevalence of pressure ulcers, assessment of falls, the use of the National Early Warning Score, medication management, nursing documentation and discharge planning.

There was evidence from the quality and safety speciality committee meetings for acute medicine that outcomes of existing audits were reviewed and that new areas for audit were identified and discussed. Systems of peer review were also in evidence in the Medicine Department, which held weekly multidisciplinary team meetings on the medical ward to discuss mortality and end-of-life cases. In addition, monthly perinatal morbidity and mortality meetings were attended by staff from the Maternity Department and the Paediatric Department.

As previously discussed in Chapter 6, the Radiology Department had a comprehensive audit plan for 2014 with audits assigned to each of the consultant radiologists and other members of the radiology department. The Laboratory Department also had a comprehensive system of audit in place, which included audits for turnaround times for emergency blood tests and blood grouping and cross-matching. There was evidence in its quality management meetings that audit results were discussed, actions implemented and re-audits undertaken.

## 7.4 Conclusions in relation to governance

The HSE, as the service provider, is responsible and accountable for ensuring that patients receive safe and high-quality care. The Authority's *National Standards for Safer Better Healthcare* set out the standards necessary to ensure good governance in healthcare services. These standards also clearly state that the HSE is the body charged with ensuring that recommendations made by the Authority and other regulatory bodies are promptly implemented.

Between 2007 and 2013, the Authority worked on and completed six investigations into care provided in acute hospitals in Ireland. In addition there have been a number of local and national reviews conducted by the HSE in respect of Portlaoise Hospital. Furthermore, the HSE National Clinical Programmes have reviewed the current model of clinical services provided at the hospital and have made specific recommendations which included the cessation of surgical services at the hospital.

However, at the time of this investigation there was no clearly articulated strategy to define the type and level of clinical services that can be safely provided at Portlaoise hospital.

While the HSE is monitoring nationally reported metrics from the hospital, these metrics are not sufficient to highlight actual or potential risks, monitor patient experience and assess prevailing safety culture. In addition, the HSE did not effectively seek and use the information collected by the State Claims Agency to inform its patient safety activities. Prior to February 2014, senior HSE managers simply did not proactively address the inherent risks identified in Portlaoise Hospital, with their efforts predominantly focused on budgetary austerity measures and the Government's imperative to control healthcare expenditure.

The governance, leadership and management arrangements at a regional and local level were not sufficiently focused to ensure effective risk management arrangements in the hospital and as a consequence there was ineffective monitoring, reporting and investigating of adverse events, protracted dealing with patient complaints and weak monitoring of patients safety and quality standards.

Regional HSE management did not respond appropriately to the deteriorating situation at the hospital. The HSE's regional and local management structures were unnecessarily bureaucratic and ineffective, with multiple committees failing to take decisive action to improve patient care and reduce risks at the hospital.

While in early 2014 the maternity services at Portlaoise Hospital had been resourced to appoint an experienced quality and patient safety manager and while Maternity Department staff had begun inputting data directly to STARSWeb locally, at the time of reporting similar resources and processes had not been allocated to the general hospital services.

The initial progress made in respect of the development of hospital groups is to be welcomed. However, despite some progress to improve systems of care in Portlaoise Hospital, the inherent clinical and governance risks within Portlaoise Hospital need to be clearly identified and addressed now and throughout the transition period.

## Chapter 8. Conclusions and recommendations

### 8.1 Introduction to conclusions

This investigation was carried out by the Health Information and Quality Authority (the Authority, or HIQA) at the request in 2014 of the then Minister for Health following the publication of the Chief Medical Officer's report into perinatal deaths at Portlaoise Hospital.

Central to setting up this investigation were those patients and families who had raised significant concerns about the care they received in Portlaoise Hospital. As a result, the Authority met with a number of people who had experienced care at the hospital. Their experiences, as outlined to the Investigation Team and as detailed in this report, conveyed a picture of care that lacked the compassion and candour that would be expected in 21st Century healthcare in any developed society.

Following the deficiencies outlined in the Chief Medical Officer's report, and as an essential part of this investigation, the Authority looked in detail at the safety, quality and governance of the system of care in place for maternity patients in Portlaoise Hospital. As part of that assessment – and as outlined in the Chief Medical Officer's report and the Terms of Reference for this HIQA investigation – the Authority commissioned an external independent evaluation of the culture of safety that prevailed in the hospital at that time.

In recognition of the interdependent relationship that the hospital had with the Health Service Executive (HSE), the Authority reviewed the effectiveness of regional and national governance, management and leadership arrangements. This was carried out through interviews with management and staff, review of documentation and data, and on-site assessment of relevant services in the hospital. In addition, the Authority reviewed how relevant findings and recommendations from a series of reviews conducted by the HSE, professional bodies and HIQA had been applied in Portlaoise Hospital.

Similar to HIQA's 2013 Galway report, this investigation report identifies opportunities to improve the delivery of maternity services nationally. In particular, it calls again for a national maternity services strategy to be developed and implemented as a matter of significant priority to support the provision of a consistently applied and integrated model of maternity care in Ireland.

The outcomes of this investigation highlight the Authority's concerns in relation to the country's smaller hospitals continuing to work in isolation without:

- the support of a clinical network involving larger hospitals
- shared senior clinical expertise, appropriately resourced
- integrated patient care pathways across multiple hospital sites.

The development of hospital groups in Ireland is welcomed. However, the continued absence of a defined legal framework to formalise the role and function of the Group Management Board means that the governance and aligned accountability structures are not formalised and cannot be effective. In the interim, as supporting legislation is being developed, the HSE through the chief executive officers, who have been appointed to the hospital groups, must prioritise the development of management and accountability frameworks across the hospital groups' structure and the development of clinical networks within each clinical speciality.

A clinical-network approach to service delivery would ensure that each hospital site within a hospital group delivers care appropriate to the available resources, facilities and services. More specifically, as a result of the findings of this investigation, the Authority believes that there is a need for formalised clinical networks linking Portlaoise Hospital within the Dublin Midland Hospitals Group structure. This would provide vital support for local clinicians, minimise risk and improve the quality and safety of patients by facilitating centrally agreed protocols, care pathways, opportunities for peer review and formalised quality assurance mechanisms.

It is regrettable and unacceptable that a number of the issues identified by this investigation have previously been examined in detail as part of the previous six investigations carried out by HIQA over the last seven years. These recurring findings indicate a basic and worrying deficit in the Irish health services: namely the capacity and capability to reflect on the findings of all reports, reviews and investigations and apply system-wide learning from these findings for the benefit of all service users.

It is therefore vitally important that the HSE respond in a clear and measurable way to the publication of the findings of this investigation. This is necessary to ensure that these findings do not constitute yet another lost opportunity for service improvement across the wider healthcare system.

The following sections outline the key conclusions of this investigation.

## 8.2 Overview of conclusions

During this investigation, the Authority found that Portlaoise Hospital and the Health Service Executive (HSE) at local, regional and national level were aware for many years of numerous patient safety risks in the hospital but failed to act decisively to reduce these risks.

These risks were present in both the general acute services and in the Maternity Department. There was little evidence to show that appropriate measures had been put in place to decrease these risks. The Investigation Team concluded that there was a widespread lack of urgency to respond to these risks within the system.

This report outlines that in spite of numerous proposals and recommendations nationally and locally from various internal and external organisations to change the services provided, Portlaoise Hospital and the HSE regionally and nationally were beset by indecision over the hospital, including:

- its position in the emerging acute-hospital-service models
- the range of services that it could provide safely
- the management of a series of patient safety incidents and other significant risks.

In the absence of clear decisions being made, systemic problems remained unresolved and in some instances were compounded by this uncertainty, leading to unacceptable risks for patients.

In recent years, a number of local and national reviews and investigations into serious adverse events in Portlaoise Hospital and systems of care in other acute hospitals, conducted by the HSE as well as HIQA, have made numerous recommendations, which if acted on may have addressed many of these risks. However, many recommendations were not implemented in a full or timely manner, despite clear risks for patients.

Despite the critical nature of the findings and recommendations of these investigations and reviews, national and local HSE responsibility and accountability for their timely implementation has been, and remains, unclear. This lack of clarity has been further complicated by the frequent organisational restructuring within the HSE – leading to a loss of continuity, ownership and accountability for the implementation of findings, findings aimed at preventing or reducing harm to patients and families in receipt of services.

Regrettably, significant patient safety issues were only exposed when a number of brave and tenacious people who had experienced the maternity services at Portlaoise Hospital came forward publicly and highlighted their concerns in relation to the care they had received. Their pursuit of these issues further highlighted inadequacies in how their concerns were subsequently addressed by the mechanisms used within the various layers of the HSE. This ultimately led to the

Chief Medical Officer's review of the maternity services at the hospital, published in February 2014.

The Investigation Team believes that the Chief Medical Officer's report resulted in a swift reaction by the HSE to immediately address the identified governance deficits by redeploying senior managers from other similar areas within the wider health system to bolster the arrangements in the Maternity Department of the hospital. However, at the time of this investigation and prior to the appointment of a general manager in early 2015, the pre-existing governance arrangements for the other hospital services remained unchanged and the governance deficiencies in the general hospital had not been addressed by the HSE.

The Dublin Midland Hospitals Group Chief Executive Officer was appointed in October 2014 and the vital work of putting in place management and accountability structures has begun at the time of writing this report. In March 2015, the Minister for Health announced that a memorandum of understanding was signed between The Coombe Women and Infants University Hospital and the Dublin Midlands Hospital Group / Health Service Executive which will see the Coombe Women and Infants University Hospital assume responsibility for the governance, management and provision of maternity services at Portlaoise Hospital. This is the first step in formalising the clinical governance of maternity services with the Coombe Women and Infants University Hospital, which must now be implemented as a matter of urgency.

### **8.3 Patient safety culture in Portlaoise Hospital**

A strong patient safety culture is always characterised by effective governance arrangements which place patient safety at the top of an organisation's agenda. An assessment of the patient safety culture at Portlaoise Hospital, specifically requested of HIQA by the Chief Medical Officer in his report in February 2014 and carried out during this investigation, suggested that a strong safety culture did not exist in the hospital at that time. In addition, the manner in which the HSE failed to communicate the findings of the assessment to some senior managers in a timely fashion is a missed opportunity to assist in the development of an effective patient safety culture at the hospital.

### **8.4 The patient experience**

One of the most notable characteristics of this investigation was the number and nature of patients and families who came forward to recount their negative experiences of services in Portlaoise Hospital and in some instances other hospitals and maternity services. The narratives provided by patients and families demonstrated that the failure by some staff to show compassion in the care they provided, and what those patients and families felt to be the absence of openness from those managers and clinical staff that they subsequently engaged with, resulted in devastating consequences for them.

The interactions involving the hospital and patients and families, as described to the Authority by patients and families during this investigation, has shown a complete disconnection between the response the patient expected to receive and what they experienced at individual, local and national health service levels. This separation appears to have occurred at both an individual and systemic level. It is for these reasons that it is important to look at, evaluate and address the deficiencies within such a care environment. Changes must orientate the culture towards the inherent qualities of compassion and openness in the care of patients and families, particularly when a devastating life experience has happened.

## 8.5 Maternity services

In October 2013, the Authority published its *Report of the 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* (referred to in this report as HIQA's 2013 Galway report). At that time, the Authority recognised the need for a national maternity services strategy to be agreed and implemented. This current investigation provides further evidence of the need for such a strategy. However, the development of this strategy does not appear to have progressed substantially in the intervening period.\* As a result of this investigation, the Investigation Team believes such a strategy must be supported by nationally mandated maternity care standards to guide the delivery of safe high-quality maternity services.

Hospital-group structures, with maternity services becoming part of a managed clinical network, are crucial for patient safety nationally. Such initiatives would help to integrate smaller maternity services such as those provided in Portlaoise Hospital within the governance structures of a major obstetric centre. But until the recently signed memorandum of understanding between the Coombe Women and Infants University Hospital and Portlaoise Hospital is implemented and operational there is an urgent requirement for skilled and experienced obstetric clinical leadership in the Maternity Department at Portlaoise Hospital to support the existing clinical governance arrangements there.

The Chief Medical Officer's report and the patients and families that the Investigation Team spoke with highlighted many deficiencies in the Maternity Department at Portlaoise Hospital. This investigation found that since that report's publication in February 2014, significant improvements in the corporate and clinical governance arrangements in the Maternity Department have taken place.

Undoubtedly, the appointment of a director of midwifery was significant in effecting key changes in midwifery leadership and a resulting impact on quality, safety and the patient experience. The Investigation Team believes that this model of governance

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\* On 30 April 2015, the Minister for Health announced the establishment of a Steering Group to advise on the development of a National Maternity Strategy and published a list of its membership.

should be replicated nationally. Other improvements noted in the Maternity Department since the Chief Medical Officer's report included the appointment of additional midwifery and obstetric staff, senior midwifery shift leaders, clinical midwifery specialists and an experienced quality and safety manager. The Maternity Department must now continue to build on these improvements to ensure that all staff are empowered to address any concerns as they arise and facilitated to proactively respond to emerging risks and pressures.

## 8.6 General hospital services

The Authority concluded that at the time of this investigation the governance and assurance arrangements at Portlaoise Hospital were not adequate to ensure the sustainable delivery of a safe quality service to patients.

The HSE lacked a clear strategy or vision for Portlaoise Hospital. Portlaoise Hospital was regarded by the HSE as a model-3 hospital; a hospital which can provide acute services to patients presenting with all manner of injury and illness, including life support. However, this HIQA investigation found that the hospital was not funded, equipped nor resourced to provide this range of services. The Authority's investigation found a number of examples of how the hospital was not resourced to safely provide services at a level that would be expected of a model-3 hospital. This situation has led to the following unacceptable ongoing risks for patients attending the hospital:

- There is no single Emergency Department governance structure with responsibility for all patients accessing emergency services in the hospital.
- Portlaoise Hospital does not have arrangements in place for the routine audit of the effectiveness of national ambulance bypass protocols to ensure patients are taken to the most appropriate care setting.
- The hospital is not currently structured to provide safe surgery as there are insufficient acute and elective surgical presentations to ensure surgeons maintain the necessary competence and expertise.
- The diagnostic imaging service is significantly under-resourced and does not have a strong clinical governance structure.
- The Intensive Care Unit infrastructure is unfit for purpose.
- The low volumes of critical care activity in the Intensive Care Unit presents difficulties in maintaining ongoing clinical expertise and competence of staff.
- General medical services in the hospital are not resourced or structured to effectively implement the recommendations of the HSE's Acute Medicine Programme.

Whatever the rationale for the decision of the HSE to assign Portlaoise Hospital as a model-3 hospital, it would be expected that once the decision had been made that changes would be put in place at the hospital to ensure that it was safely structured and resourced to perform as a model-3 hospital (that is to say, to admit

undifferentiated patients, and provide 24-hour, seven-days-a-week (24-seven) acute surgery, acute medicine, and critical care).

Clinical services must be appropriately resourced and effectively governed to ensure patients receive safe and effective care. Given the risks found in the general services of the hospital, and the unsustainable nature of some of the existing clinical services, the Authority is unable to definitively conclude that services at the hospital are safe. It is notable that in a 2014 unpublished report on the quality and safety of services at the hospital, similar conclusions were reached by the HSE itself. The Investigation Team believes that as a matter of urgency, Portlaoise Hospital must be fully integrated into a hospital-group structure with associated clinical networks.

The Authority acknowledges the progress in the development of the Dublin Midlands Hospital Group. In driving the development of this hospital-group structure, the newly appointed management team in the Dublin Midland Hospital Group must define the services that will be delivered at Portlaoise Hospital and ensure that they are safe and resourced appropriately. This must include prioritising the development of speciality-based clinical networks between Portlaoise Hospital and larger hospitals within the Dublin Midlands Hospital Group

## 8.7 Governance

There is still no clearly articulated strategy to define the type and level of clinical services that can be safely provided at Portlaoise Hospital. This is despite previous HIQA investigations into acute healthcare in Ireland, local and national reviews conducted by the HSE in respect of Portlaoise Hospital, and a review by the National Clinical Programme in Surgery which specifically recommended the cessation of surgical services at the hospital.

The evidence gathered by the Investigation Team shows that before February 2014, senior HSE managers at a national level simply did not proactively address the inherent risks identified in Portlaoise Hospital. The efforts of senior HSE managers were predominantly focused on budgetary austerity measures and the imperative to control healthcare expenditure. While the HSE was monitoring nationally reported data from the hospital, the information collected did not highlight actual or potential risks to patients. In addition, the HSE did not effectively seek and use the information collected by the State Claims Agency, the organisation set up to manage clinical negligence claims and associated risks in public healthcare services, to inform its patient safety activities. This meant that there was a failure to recognise the impact that these risks were having on the quality and safety of services and the experiences of those accessing these services.

This investigation has found that the governance, leadership and management arrangements in the HSE at national, regional and local levels were not sufficiently focused to ensure effective risk management arrangements in the hospital.

As a result, there was:

- ineffective monitoring, reporting, review and analysis of adverse events
- delayed patient complaint management
- protracted incident investigation
- poor general oversight of patient safety and quality standards.

These deficiencies were reflected in the circumstances that led to the poor experiences related to the Authority by parents and families who attended the hospital.

## 8.9 Concluding remarks

The Higgins' report in 2013 recommended that Portlaoise Hospital would become part of the new Health Dublin Midlands Group, now referred to as the Dublin Midlands Hospital Group. However, at the time of this report, the formation of this hospital group, like a number of other hospital groups and associated clinical networks, remains in the early stages of development. As a result, there is still no clearly defined plan detailing the range of clinical services that will be delivered in Portlaoise Hospital.

Portlaoise Hospital lacked formal systems to ensure close clinical cooperation, communication and integrated systems of clinical governance between it and a larger training hospital. At the time of this report, the hospital continues to operate as a stand-alone hospital, providing a model of care for which the Investigation Team believes it is neither resourced nor equipped to safely deliver. Although significant progress has been made in restructuring the maternity services at Portlaoise Hospital, until the memorandum of understanding with the Coombe Women and Infants Hospital is fully implemented and operational, this service continues to function without senior clinical leadership and without the support of being in a larger network of maternity care.

The proposed hospital-group structure with associated clinical maternity networks urgently needs to be introduced nationally. This structure will facilitate safer models of care for pregnant women and help ensure that the negative experiences of the patients and families who participated in this investigation are prevented in the future.

Portlaoise Hospital still does not have formalised arrangements in place to ensure close clinical cooperation, communication and integrated systems of clinical governance between it and a larger training hospital. The initial progress made in respect of the development of hospital groups is to be welcomed. However, the ongoing inherent clinical and governance risks within Portlaoise Hospital need to be clearly managed throughout the transition period.

## 8.10 Moving forward

In moving services on constructively, the Authority acknowledges the appointment of a chief executive officer, a chief operating officer and a group director of nursing to the Dublin Midlands Hospital Group. The Authority welcomes the inclusion of quality and safety within the remit of the newly appointed Group Director of Nursing, ensuring that issues of quality and safety will be managed at group executive level.

Whilst the Authority acknowledges the work to date to incorporate the maternity services at Portlaoise Hospital into a clinical network with the Coombe Women and Infants University Hospital, this work needs to be completed without delay. A national maternity strategy must be developed, published and implemented as a matter of urgency. The purpose of such a strategy will be to agree and implement standard, consistent, modern-day models of maternity care for the delivery of maternity services nationally in order to ensure that all pregnant women have choice and access to the right level of safe care and support on a 24-hour basis.

The HSE through the hospital group structures should now proactively assess other hospitals to ensure that similar risks and deficiencies are identified and addressed as a matter of priority, and publicly report its findings. The HSE at a national level must be accountable for the oversight of the necessary improvements as part of its internal performance management arrangements and through those arrangements demonstrate publically that it is an organisation capable of recognising and addressing such circumstances into the future.

The Department of Health should maintain oversight at a national level to ensure the HSE implements the recommendations contained in this investigation report.

The Health Information and Quality Authority – in conjunction with the relevant clinical and professional organisations and patient advocacy groups – will, in 2015 develop for public consultation, service-specific draft standards for maternity services in Ireland, which will be a sub-set of the Authority's *National Standards for Safer Better Healthcare*.

In recognition of the findings of this investigation, the Authority believes that those in management and leadership positions in acute hospital care must now reflect on these findings and on the eight recommendations set out by the Investigation Team, and allocate responsibility and timescales for their implementation.

## Recommendations

### Recommendation 1

The Department of Health should commence discussions with the Health Service Executive (HSE) to establish an independent patient advocacy service, with a view to having a service in place by May 2016. This service's role would be to ensure that patients' reported experiences are recorded, listened to and learned from. Such learning needs to be shared between hospitals within hospital groups; between hospital groups; nationally throughout the wider health system; and published. In the interim, the Department of Health and the HSE should provide regular updates on their websites to inform the public on the progress of establishing this service.

### Recommendation 2

The Department of Health should, in line with its published Profile Table of Priority Areas, Actions and Deliverables for the Period 2015-2017, ensure implementation of the recommendations contained in this investigation report and previous investigations undertaken by the Authority.<sup>(1)</sup>

### Recommendation 3

- A. The Department of Health must now develop a national maternity services strategy for Ireland, as specified in recommendation N7 of the Authority's October 2013 *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*.\*
- B. The Department of Health should provide regular updates on its website to inform the public of progress with developing and implementing this national maternity strategy.

\* On 30 April 2015, the Minister for Health announced the establishment of a Steering Group to advise on the development of a National Maternity Strategy and published a list of its membership.

## Recommendation 4

In line with the Department of Health's policy to develop independent hospital groups, the Department should expedite the necessary legal framework to enable the group boards of management and chief executive officers of each hospital group to comprehensively perform their governance and assurance functions.

## Recommendation 5

The Health Service Executive (HSE) should ensure the appointment of a director of midwifery, before September 2015, in all statutory and voluntary maternity units and hospitals in Ireland that currently do not have such a post.

## Recommendation 6

The Health Service Executive (HSE), along with the chief executive officers of each hospital group, must ensure that the new hospital groups prioritise the development of strong clinical networks underpinned by:

- a. a group-based system of clinical and corporate governance informed by the *National Standards for Safer Better Healthcare*.
- b. a clearly defined, agreed, resourced and published model of clinical service delivery for each hospital within the group. This must be supported by clearly defined, agreed and documented patient care pathways to ensure that patients are managed in or transferred to the most appropriate hospital.
- c. regular evaluation and audit of the quality and safety of services provided.
- d. systems to support a competent and appropriately resourced workforce
- e. a system to proactively evaluate the culture of patient safety in each hospital as a tool to drive improvement.
- f. systems in place to ensure patient feedback is welcomed and used to improve services and that patient partnership and person-centred care is promoted, as per the *National Standards for Safer Better Healthcare*.
- g. effective arrangements to ensure the timely completion of investigations and reviews of patient safety incidents and associated dissemination of learning. These arrangements must ensure that patients and service users are regularly updated and informed of findings and resultant actions.

## Recommendation 7

The Health Service Executive (HSE), in conjunction with the Chief Executive Officer of the Dublin Midlands Hospital Group should:

- A. review all of the findings of this investigation and address the patient safety concerns at the Midland Regional Hospital, Portlaoise
- B. immediately address the local clinical and corporate governance deficiencies in the maternity and general acute services in Portlaoise Hospital
- C. publish an action plan outlining the measures and timelines to address the safety concerns and risks at Portlaoise Hospital, to include both general and maternity services. This action plan should include a named person or persons with responsibility and accountability for implementation of recommendations and actions in internal and external reviews and investigation reports, and be continuously reviewed and updated in order to drive improvement and mitigate risk.

The HSE and hospital group CEOs must now ensure that every hospital undertakes a self-assessment against the findings and recommendations of this investigation report, and develop, implement and publish an action plan to ensure the quality and safety of patient services.

## Recommendation 8

The Health Service Executive (HSE), the chief executive officer of each hospital group and the State Claims Agency must immediately develop, agree and implement a memorandum of understanding between each party to ensure the timely sharing of actual and potential clinical risk information, analysis and trending data. This information must be used to inform national and hospital-group patient safety strategies.

## Chapter 9. Reference List

- (1) Department of Health. *Profile Table of Priority Areas, Actions and Deliverables for the Period 2015-2017*. Dublin: Department of Health; 2015. Available online from: <http://health.gov.ie/blog/press-release/varadkar-lynch-publish-health-priorities-for-2015/>.
- (2) *Prime Time*. Fatal Failures. Electronic Recording. Dublin: RTÉ Investigations Unit; 30 January 2014. Available online from: <http://www.rte.ie/news/player/prime-time/2014/0130/>.
- (3) Holohan T. *HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date)*. Department of Health; 2014. Available online from: [http://health.gov.ie/wp-content/uploads/2014/03/portlaoise\\_perinatal\\_deaths.pdf](http://health.gov.ie/wp-content/uploads/2014/03/portlaoise_perinatal_deaths.pdf).
- (4) Health Act. Dublin: The Stationery Office; 2007.
- (5) Health Information and Quality Authority. *National Standards for Safer Better Healthcare*. Dublin: 2012. Available online from: <http://www.hiqa.ie/standards/health/safer-better-healthcare>.
- (6) Health Information and Quality Authority. *Report of the investigation into the quality, safety and governance of the care provided by the Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (AMNCH) for patients who require acute admission*. Dublin: 2012. Available online from: <http://www.hiqa.ie/publications/report-investigation-quality-safety-and-governance-care-provided-adelaide-and-meath-hos>.
- (7) Health Information and Quality Authority. *Report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at Mallow General Hospital*. Dublin: 2011. Available online from: <http://www.hiqa.ie/publications/report-investigation-quality-and-safety-services-and-supporting-arrangements-provided-h>.
- (8) Health Information and Quality Authority. *Report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at the Mid-Western Regional Hospital Ennis*. Dublin: 2009. Available online from: <http://www.hiqa.ie/publication/report-investigation-quality-and-safety-services-and-supporting-arrangements-provided-hs>.
- (9) Health Information and Quality Authority. *Report of the investigation into the circumstances surrounding the provision of care to Rebecca O'Malley, in relation to her symptomatic breast disease, the Pathology Services at Cork University Hospital and Symptomatic Breast Disease Services at the Mid Western Regional Hospital, Limerick*. Dublin: 2008. Available online from: <http://www.hiqa.ie/publication/investigation-circumstances-surrounding-provision-care-rebecca-omalley-relation-her-symp>.

- (10) Health Information and Quality Authority. *Report of the investigation into the provision of services to Ms A by the Health Service Executive at University Hospital Galway in relation to her symptomatic breast disease, and the provision of Pathology and Symptomatic Breast Disease Services by the Executive at the Hospital*. 2008. Available online from: <http://www.hiqa.ie/publication/investigation-report-pathology-service-and-symptomatic-breast-disease-service-university>.
- (11) Health Information and Quality Authority. *Report of the 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*. Dublin: Health Information and Quality Authority; 2013. Available online from: <http://www.hiqa.ie/publications/patient-safety-investigation-report-services-university-hospital-galway-uhg-and-reflect>.
- (12) Fitzgerald J. *Management, Governance and Communications issues arising from the Review of Breast Radiology Services at Midland Regional Hospital Portlaoise*. Department of Health and Children; 2008. Available online from: <http://lenus.ie/hse/bitstream/10147/45779/1/9133.pdf>.
- (13) Doherty A. *Report on the Circumstances that led to the decision by HSE in August 2007 to suspend breast radiology services, initiate a clinical review of symptomatic breast radiology service, place a consultant radiologist on administrative leave*. Department of Health and Children; 2008. Available online from: <http://lenus.ie/hse/bitstream/10147/45867/1/9469.pdf>.
- (14) Cobain E. *The Draft Report of the Patient Dependency and Nursing Staff Levels in the Maternity and Gynaecology Unit in the Midland Regional Hospital at Portlaoise*. The Midland Area: Health Service Executive; 2006.
- (15) Health Service Executive, Department of Health. *The Framework for Development - Securing the Future of Smaller Hospitals*. Dublin: Department of Health; 2013. Available online from: <http://health.gov.ie/wp-content/uploads/2014/03/SecuringSmallerHospitals.pdf>.
- (16) Department of Health and Children. *Quality and Fairness: A Health System For You*. Dublin: The Stationery Office; 2001.
- (17) National Clinical Effectiveness Committee. *The Irish Maternity Early Warning System (IMEWS)*. National Clinical Guideline No. 4. Dublin: Department of Health; 2014. Available online from: <http://health.gov.ie/wp-content/uploads/2015/01/National-Clinical-Guideline-No.-4-IMEWS-Nov2014.pdf>.
- (18) National Clinical Effectiveness Committee. *Communication (Clinical Handover) in Maternity Services*. National Clinical Guideline No. 5. Dublin: Department of Health; 2014. Available online from: <http://health.gov.ie/wp-content/uploads/2015/01/National-Clinical-Guideline-No.-5-Clinical-Handover-Nov2014.pdf>.

- (19) National Clinical Effectiveness Committee. *Sepsis Management. National Clinical Guideline No. 6*. Dublin: Department of Health; 2014. Available online from: <http://health.gov.ie/wp-content/uploads/2015/02/Feb-2015-Update-National-Clinical-Guideline-No.-6-Sepsis-Management-Nov2014.pdf>.
- (20) Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland, Directorate of Strategy and Clinical Programmes, Health Service Executive. *Clinical Practice Guideline. The Management of Second Trimester Miscarriage*. Health Service Executive; 2014. Available online from: <http://www.hse.ie/eng/about/Who/clinical/natclinprog/obsandgynaeprogramme/second%20trimester.pdf>.
- (21) Health Service Executive National Clinical Programmes in Obstetrics and Gynaecology, Anaesthesia and Critical Care, Guidelines for the Critically Ill Woman in Obstetrics Working Group. *Guidelines for the Critically Ill Woman in Obstetrics*. Health Service Executive; 2014. Available online from: <http://www.hse.ie/eng/about/Who/clinical/natclinprog/criticalcareprogramme/publications/guidelines.pdf>.
- (22) Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland, Health Service Executive. *Clinical Practice Guideline. Resuscitation for the Pregnant Woman*. Health Service Executive; 2014. Available online from: <http://www.hse.ie/eng/about/Who/clinical/natclinprog/obsandgynaeprogramme/resuscitationpregnantwoman.pdf>.
- (23) Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland, Directorate of Clinical Strategy and Programmes, Health Service Executive. *Clinical Practice Guideline. The Diagnosis and Management of Ectopic Pregnancy*. Health Service Executive; 2014. Available online from: <http://www.hse.ie/eng/about/Who/clinical/natclinprog/obsandgynaeprogramme/guidelines/guidelines/ectopicpregnancy.pdf>.
- (24) Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland, National Clinical Programme in Obstetrics and Gynaecology. *Clinical Practice Guideline. Bacterial Infections Specific to Pregnancy*. Health Service Executive; 2015. Available online from: <http://www.hse.ie/eng/about/Who/clinical/natclinprog/obsandgynaeprogramme/guidelines/guidelines/bacterialinfectionpregnancy.pdf>.
- (25) Health Service Executive. *Safety Incident Management Policy*. Health; 2014. Available online from: <http://www.hse.ie/eng/about/Who/qualityandpatientsafety/incidentrisk/Riskmanagement/SafetyIncidentMgtPolicy2014.pdf>.
- (26) Health Information and Quality Authority. *Report of the announced monitoring assessment at Midland Regional Hospital Portlaoise*. Dublin: Health Information and Quality Authority; 2013. Available online from: <http://www.hiqa.ie/inspection-reports/report-announced-monitoring-assessment-midland-regional-hospital-portlaoise>.

- (27) Health Information and Quality Authority. *Business Plan 2014*. Dublin: Health Information and Quality Authority; 2014. Available online from: <http://www.higa.ie/publications/business-plan-2014>.
- (28) O'Doherty A. *Report on a clinical review of mammography service at Midland Regional Hospital Portlaoise for the Health Service Executive Dublin Mid-Leinster*. Health Service Executive; 2008. Available online from: <http://lenus.ie/hse/bitstream/10147/45773/1/9099.pdf>.
- (29) Health Service Executive. *Report on Clinical Review of Breast Ultrasound Services at Midland Regional Hospital, Portlaoise*. Health Service Executive; 2008. Available online from: <http://www.lenus.ie/hse/bitstream/10147/45891/1/9510.pdf>.
- (30) Royal College of Physicians of Ireland, Irish Association of Directors of Nursing and Midwifery, Therapy Professions Committee, Health Service Executive, Quality and Clinical Care Directorate. *Report of the National Acute Medicine Programme*. Health Service Executive; 2010. Available online from: <http://www.hse.ie/eng/about/Who/clinical/natclinprog/acutemedicineprogramme/report.pdf>.
- (31) *Joint Committee on Health and Children Debate*. 2011. Available online from: <http://debates.oireachtas.ie/HEJ/2011/07/21/00004.asp>.
- (32) Office for Health Management. *Clinicians in management: a review of clinical leadership, Discussion Paper No. 4*. Dublin: OHM; 2003. Available online from: <http://lenus.ie/hse/bitstream/10147/45812/1/9310.pdf>.
- (33) Health Service Executive. *Clinical Director - Job Description*. Dublin: Health Service Executive; 2007. Available online from: [http://www.ihca.ie/fileupload/Publications/CN20070220-Clinical-Directors\\_03291754.pdf](http://www.ihca.ie/fileupload/Publications/CN20070220-Clinical-Directors_03291754.pdf).
- (34) Health Service Executive. *Consultants' Contract 2008 as of 29th November 2012*. Dublin: Health Service Executive; 2012. Available online from: [http://www.hse.ie/eng/staff/Resources/Terms\\_Conditions\\_of\\_Employment/ccontract/ContractNov2012.pdf](http://www.hse.ie/eng/staff/Resources/Terms_Conditions_of_Employment/ccontract/ContractNov2012.pdf).
- (35) Sammer CE, Lykens K, Singh KP, Mains DA, Lackan NA. What is patient safety culture? A review of the literature. *Journal of Nursing Scholarship*. 2010; 42(2): pp.156-65. Available online from: <http://www.ncbi.nlm.nih.gov/pubmed/20618600>.
- (36) Useem J, Useem R, Donoghue J. Men in the Middle of the Third Culture: The Roles of American and Non-Western People in Cross-Cultural Administration. *Human Organisation*. 1963; 22(3): pp.169-79. Available online from: <http://sfaa.metapress.com/content/5470n44338kk6733/>.

- (37) Department of Health and Children. *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance*. Dublin: The Stationery Office; 2008. Available online from: <http://health.gov.ie/blog/publications/building-a-culture-of-patient-safety-report-of-the-commission-on-patient-safety-and-quality-assurance/>.
- (38) Applied Research Ltd. *Assessment of Safety Culture in Midland Regional Hospital, Portlaoise (MRHP) Using the Safety Culture Index (SCI)* Unpublished. 2014.
- (39) World Health Organisation. *Patient Safety* [Online]. Available from: <http://www.who.int/patientsafety/about/en/>.
- (40) Healthcare Commission. *Investigation into outbreaks of Clostridium difficile at Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust*. London: Healthcare Commission; 2006. Available online from: <http://www.buckinghamshirehospitals.nhs.uk/healthcarecommision/HCC-Investigation-into-the-Outbreak-of-Clostridium-Difficile.pdf>.
- (41) Department of Health (United Kingdom). *High Quality Care for All*. The Stationery Office; 2008. Available online from: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/228836/7432.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228836/7432.pdf).
- (42) Flin R. Measuring safety culture in healthcare: A case for accurate diagnosis. *Safety Science*. 2007; 45(6): pp.653-67. Available online from: <http://www.sciencedirect.com/science/article/pii/S0925753507000203>.
- (43) Nieva VF, Sorra J. Safety culture assessment: a tool for improving patient safety in healthcare organisations. *Quality and Safety in Health Care*. 2003; 12((Suppl 2)): p.ii17-ii23. Available online from: [http://qualitysafety.bmj.com/content/12/suppl\\_2/ii17.full.pdf](http://qualitysafety.bmj.com/content/12/suppl_2/ii17.full.pdf).
- (44) Clarke S. Safety culture: under-specified and overrated? *International Journal of Management Reviews*. 2000; 2(1): pp.65-90. Available online from: <http://onlinelibrary.wiley.com/doi/10.1111/1468-2370.00031/abstract>.
- (45) Reiman T, and Oedewald P. *The assessment of organisational culture. A methodological study*. VTT Industrial Systems; 2002. Available online from: <http://www2.vtt.fi/inf/pdf/tiedotteet/2002/T2140.pdf>.
- (46) Pumar-Méndez MJ, Attree M, Wakefield A. Methodological aspects in the assessment of safety culture in the hospital setting: A review of the literature. *Nurse Education Today*. 2014; 34(2): pp.162-70.
- (47) Health Service Executive. *Patient Safety Culture Survey of Staff in Acute Hospitals, Report for the Midland Regional Hospital Portlaoise (unpublished)*. 2014.
- (48) Cacciatore J. Psychological effects of stillbirth. *Seminars in Fetal and Neonatal Medicine*. 2013; 18(2): pp.76-82. Available online from: <http://www.sciencedirect.com/science/article/pii/S1744165X12001023>.

- (49) Parliamentary and Health Service Ombudsman. *Four investigation reports concerning the University Hospitals of Morecambe Bay NHS Foundation Trust*. Parliamentary and Health Service Ombudsman; 2014. Available online from: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/285604/1096.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/285604/1096.pdf).
- (50) *Prime Time*. Further evidence of the treatment of parents at Midlands Regional Hospital Portlaoise. Electronic Recording. Dublin: RTÉ Investigations Unit; 3 April 2014. Available online from: <http://www.rte.ie/news/player/prime-time/2014/0403/>.
- (51) Health Research and Information Division, The Economic and Social Research Institute. *Perinatal Statistics Report 2012*. The Economic and Social Research Institute; 2013. Available online from: [http://www.esri.ie/\\_uuid/9495a3d4-7e97-4588-a1d3-c091fa1e7838/NPRS2012.pdf](http://www.esri.ie/_uuid/9495a3d4-7e97-4588-a1d3-c091fa1e7838/NPRS2012.pdf).
- (52) Department of Health. *National Healthcare Quality Reporting System - First Annual Report*. Dublin: Department of Health; 2015. Available online from: <http://health.gov.ie/wp-content/uploads/2015/03/NHQRS-Annual-Report-2014.pdf>.
- (53) Manning E, Corcoran P, Meaney S, Greene R A, on behalf of the Perinatal Mortality Group. *Perinatal Mortality in Ireland Annual Report 2011*. Cork: National Perinatal Epidemiology Centre; 2013. Available online from: <http://static.rasset.ie/documents/news/perinatal-mortality-in-ireland-annual-report-2011.pdf>.
- (54) Health Service Executive. *Code of Governance. Framework for the Corporate and Financial Governance of the Health Service Executive*. Dublin: Health Service Executive; 2011. Available online from: <http://www.hse.ie/eng/services/publications/corporate/codeofgovernance.pdf>.
- (55) Midland Health Board. *Annual Report 2004*. Midland Health Board; 2004. Available online from: <http://www.lenus.ie/hse/bitstream/10147/85779/1/MHBAR2004.pdf>.
- (56) Institute of Obstetricians and Gynaecologists. *Report from Institute Subgroup. The Future of Maternity and Gynaecology services in Ireland 2006 - 2016*. Dublin: 2006. Available online from: [http://www.rcpi.ie/content/docs/000001/372\\_5\\_media.pdf](http://www.rcpi.ie/content/docs/000001/372_5_media.pdf).
- (57) Higgins J R and Department of Health. *The Establishment of Hospital Groups as a transition to Independent Hospital Trusts. A report for the Minister for Health, Dr James Reilly TD*. Dublin: Department of Health; 2013. Available online from: <http://health.gov.ie/blog/publications/the-establishment-of-hospital-groups-as-a-transition-to-independent-hospital-trusts/>.

- (58) Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland, Directorate of Strategy and Clinical Programmes, Health Service Executive. *Clinical Practice Guideline. Prevention and Management of Primary Postpartum Haemorrhage*. Health Service Executive; 2012. Available online from: <http://hdl.handle.net/10147/275632>.
- (59) Health Service Executive. *Programme in Obstetrics and Gynaecology. Consultant workforce planning for obstetrics and gynaecology in the Republic of Ireland 2012-2022*. Dublin: Health Service Executive. Programme in Obstetrics and Gynaecology; 2011.
- (60) Midland Area Healthcare Risk Management Service. *Risk Assessment of the Maternity Department, Midland Regional Hospital, Portlaoise*. Health Service Executive; 2007.
- (61) Harding Clark M. *The Lourdes Hospital Inquiry. An inquiry into peripartum hysterectomy at Our Lady of Lourdes Hospital Drogheda. Report of Judge Maureen Harding Clark SC*. Dublin: The Stationery Office; 2006. Available online from: <http://health.gov.ie/wp-content/uploads/2014/05/lourdes.pdf>.
- (62) Health Service Executive. *National Miscarriage Misdiagnosis Review*. Health Service Executive; 2011. Available online from: <http://www.lenus.ie/hse/bitstream/10147/128265/1/miscarriagemisdiagnosis.pdf>.
- (63) Health Service Executive and Royal College of Physicians of Ireland. *Investigation and Management of Late Fetal Intrauterine Death and Stillbirth. Clinical Practice Guideline*. Health Service Executive; 2011. Available online from: [http://www.rcpi.ie/content/docs/000001/668\\_5\\_media.pdf](http://www.rcpi.ie/content/docs/000001/668_5_media.pdf).
- (64) National Institute for Health and Care Excellence. *Antenatal Care, NICE Clinical Guideline 62*. London: National Institute for Health and Clinical Excellence; 2008. Available online from: <http://www.nice.org.uk/guidance/cg62/resources/guidance-antenatal-care-pdf>.
- (65) Department of Health, Social Services and Public Safety (N.I.). *A Strategy for Maternity Care in Northern Ireland 2012 - 2018*. Belfast: Department of Health, Social Services and Public Safety; 2012. Available online from: <http://www.dhsspsni.gov.uk/maternitystrategy.pdf>.
- (66) Royal College of Obstetricians and Gynaecologists, Royal College of Midwives, Royal College of Anaesthetists, Royal College of Paediatrics and Child Health. *Standards for Maternity Care. Report of a Working Party*. London: RCOG Press; 2008. Available online from: <https://www.rcm.org.uk/sites/default/files/WPRMaternityStandards2008.pdf>.
- (67) Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland, and Directorate of Clinical Strategy and Programmes, Health Service Executive. *Clinical Practice Guideline. The Irish Maternity Early Warning System (I-MEWS)*. Royal College of Physicians of Ireland; 2013. Available online from: [http://www.rcpi.ie/content/docs/000001/1067\\_5\\_media.pdf](http://www.rcpi.ie/content/docs/000001/1067_5_media.pdf).

- (68) Health Service Executive. *Performance Diagnostic, Midland Regional Hospital Portlaoise, HSE Dublin Mid Leinster (unpublished)*. Dublin: Health Service Executive; 2014.
- (69) National Emergency Medicine Programme Working Group. *The National Emergency Medicine Programme*. Dublin: Health Service Executive; 2012. Available online from: <http://www.hse.ie/eng/about/clinicalprogrammes/emp/empreport2012.pdf>.
- (70) Health Service Executive. *Right Care, Right Now: Model of Care for Adult Critical Care. National Clinical Programme for Clinical Care*. Health Service Executive; 2014. Available online from: <http://www.hse.ie/eng/about/Who/clinical/natclinprog/criticalcareprogramme/modelofcare/criticalcare.pdf>.
- (71) Department of Health and Children, Hanly D. *Report of the National Task Force on Medical Staffing [Hanly report]*. Dublin: Department of Health and Children; 2003. Available online from: <http://www.lenus.ie/hse/bitstream/10147/46569/1/1680.pdf>.
- (72) Health Service Executive. *The Health Service Executive* [Online]. Available from: <http://www.hse.ie/eng/>.
- (73) Department of the Taoiseach. *Programme for Government 2011 - 2016*. Department of the Taoiseach; 2011. Available online from: [http://www.taoiseach.gov.ie/eng/Work\\_of\\_the\\_Department/Programme\\_for\\_Government/](http://www.taoiseach.gov.ie/eng/Work_of_the_Department/Programme_for_Government/).
- (74) Health Service Executive. *National Service Plan 2015*. Health Service Executive; 2015. Available online from: <http://www.hse.ie/eng/services/publications/corporate/sp2015.pdf>.
- (75) Health Service Executive (Governance) Act 2013. The Stationery Office; 2013. Available online from: <http://www.irishstatutebook.ie/pdf/2013/en.act.2013.0023.pdf>.
- (76) Joint Leads National Clinical Programme in Surgery. Personal communication. [Letter regarding National Clinical Programme in Surgery recent visit to the Midland Regional Hospital, Portlaoise]. 19 August 2013. Recipient: National Director of Acute Hospitals.
- (77) Central Statistics Office. *Census 2011 Results: Area Profile for County Laois*. 2011. Available online from: <http://census.cso.ie/areaprofiles/PDF/CTY/laois.pdf>.

## Appendices

### Appendix 1 Request to the Health Information and Quality Authority to carry out an investigation in accordance with Section 9(2) of the Health Act 2007



An Roinn Sláinte  
DEPARTMENT OF HEALTH

Oifig an Aire  
Office of the Minister



27<sup>th</sup> February 2014

Mr Brian McEnery  
Chairman  
Health Information and Quality Authority  
Unit 1301, City Gate  
Mahon  
Cork



Dear Mr McEnery

I refer to the Report, *HSE Midland Regional Hospital Portlaoise Perinatal Deaths (2006-date)* presented to me by Chief Medical Officer, Dr Tony Holohan on 24<sup>th</sup> February 2014. I requested this Report following a *Primetime Investigates* programme relating to Portlaoise Hospital Maternity Services on 30<sup>th</sup> January 2014.

The Chief Medical Officer's Report raises sufficient concerns to conclude that the Portlaoise Hospital Maternity Service "cannot be regarded as safe and sustainable within its current governance arrangements as it lacks many of the important criteria required to deliver, on a stand-alone basis, a safe and sustainable maternity service".

I am therefore satisfied that, under the provisions of Section 9 (2) of the Health Act 2007, there are reasonable grounds to believe that there is a serious risk to the health or welfare of a person receiving services at Portlaoise Hospital Maternity Services. I am therefore requesting HIQA under the provisions of Section 9 (2) of the Health Act 2007 to commence an immediate investigation of the HSE Midland Regional Hospital Portlaoise. This will allow a number of the issues found in the Chief Medical Officer's Report to be examined in more detail. The HIQA investigation should include:

- The extent of serious adverse incidents at PHMS with regard to patients known and unknown
- Other relevant aspects of maternity services in Portlaoise Hospital
- Maternity services in other similarly-sized units in Ireland
- Governance and patient safety in Portlaoise Hospital generally
- Oversight and support from HSE at regional and national level
- Implementation in maternity units of recommendations of *Patient Safety Investigation Report into Services at University Hospital Galway* (HIQA, 2013).



Oifig an Aire  
Office of the Minister



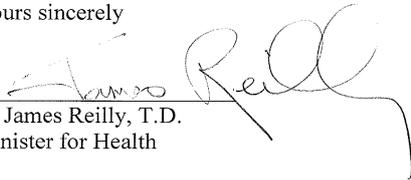
-2-

The Chief Medical Officer's Report also identified a number of other critically important issues and made recommendations to address them, and I am requesting HIQA, in 2014, to lead the implementation of the following actions:

- To undertake an immediate assessment of the patient safety culture at Portlaoise Hospital.
- To develop national standards for the conduct of reviews of adverse incidents.
- To adopt/adapt a standard tool for the assessment of patient safety culture and team working and to use its monitoring role to ensure that it is implemented throughout the healthcare system.
- To develop national standards for the conduct of reviews of adverse incidents.

My officials would be happy to discuss formal terms of reference and a timescale for the review with the Chief Executive Officer. I would envisage the investigation being completed by end 2014.

Yours sincerely

  
Dr James Reilly, T.D.  
Minister for Health

## Appendix 2 **Terms of Reference for the investigation as approved by the Board of the Health Information and Quality Authority on 18 March 2014 and published on 21 March 2014**



### **Investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the Midland Regional Hospital, Portlaoise**

#### **Terms of Reference**

Following a request from the Minister for Health in accordance with section 9(2) of the Health Act 2007, 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 in the Midland Regional Hospital, Portlaoise. The Authority will investigate and assess how local, regional and national clinical and corporate governance arrangements are supporting safe care in Midland Regional Hospital, Portlaoise (the Hospital). This Investigation will be further to and cognisant of the report of the assessment<sup>1</sup> made by the Chief Medical Officer. The Investigation will be carried out on the basis of the following Terms of Reference:

1. To assess the patient safety culture in the Hospital.
2. To investigate and assess how local, regional and national clinical and corporate governance arrangements provided by the HSE are supporting the safety and quality of services at the Hospital for general and maternity patients, identifying whether risks to patients in the Hospital's models of service provision have been identified, assessed and mitigated. The Investigation will specifically include the:
  - a. Extent of serious adverse incidents at the Hospital
  - b. HSE's actions, inactions and governance response to serious adverse incidents and dissemination of learning
  - c. Associated relationship and communication between the HSE and patients and families and their experience.
3. To investigate what measures have been taken by the Hospital and the HSE in the implementation of national recommendations from previous investigations and reports including but not limited to:
  - a. *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*

<sup>1</sup> [HSE Midland Regional Hospital, Portlaoise Perinatal Deaths \(2006-date\).](#)

*Galway, and as reflected in the care and treatment provided to Savita Halappanavar*

*b. HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date).*

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 or persons receiving 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(2) 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 Minister for Health and 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.

In addition to the Terms of Reference for the Investigation above and in recognition of the wider, national issues highlighted in recommendation O.R.8 in the Chief Medical Officer's report, the Authority will conduct a focused programme of monitoring of compliance with the *National Standards for Safer Better Healthcare* across maternity services nationally, pursuant to section 8(1)(c) of the Health Act 2007.

These Terms of Reference were approved by the Board of the Authority on 18 March 2014.

## Appendix 3 **Members of the Investigation Team appointed as authorised persons to conduct the investigation, in line with Section 70(1) (b) of the Health Act 2007\***

Name of Investigation Team member	Role and experience
<p><b>Margaret Murphy</b></p>	<p><b>Patient advocate</b></p> <p>Margaret Murphy began her work as a patient advocate in 2004. Her role as patient advocate is contributing to healthcare policy, research, education, accreditation and regulation. Since 2004, she has presented at national and international conferences on issues relevant to patient safety and advocacy, and has been a member of national and international investigations and patient safety reviews.</p> <p>Margaret has worked with the Irish Patients Association and the advocacy group Patient Focus and is:</p> <ul style="list-style-type: none"> <li>■ External Lead Advisor of the Patients for Patient Safety programme of the World Health Organization’s World Alliance for Patient Safety</li> <li>■ designated as one of the International Society for Quality in Health Care’s (ISQua’s) 70 global experts on patient safety and Advocacy</li> <li>■ a member of the inaugural steering committee of the World Alliance for Patient Safety Collaborative Centre for Patient Safety Solutions</li> <li>■ a Council Member of the Irish Society for Quality and Safety in Healthcare</li> <li>■ a member of the Patient Forum, Cork University Hospital, Ireland</li> <li>■ a member of the Irish Medical Council.</li> </ul>

\* Internal HIQA staff were also authorised members of the Investigation Team.

<b>Name of Investigation Team member</b>	<b>Role and experience</b>
<b>Mai Buckley</b>	<p><b>Director of Midwifery and Gynaecology and Supervisor of Midwives</b></p> <p>Mai Buckley is the Director of Midwifery and Gynaecology and Supervisor of Midwives at the Royal Free London NHS Foundation Trust.</p> <p>Mai qualified as a registered general nurse at Whipps Cross Hospital, London, in 1986 and as a registered midwife in 1988 at St Mary's Hospital, Paddington, London.</p> <p>She was appointed as a Supervisor of Midwives in 1994 and in 1995 completed her Masters Degree in Advanced Midwifery Practice.</p> <p>She has practised as a midwife mainly in London hospitals in a variety of settings since she qualified. Mai has also worked in Saudi Arabia and in Australia.</p> <p>She has implemented strong clinical governance structures and addressed the key failures of maternity services following the implementation of special measures at North West London NHS Trust (2005) and the Care Quality Commission (CQC) notice issued to Barking, Havering and Redbridge Hospitals (2011/2012).</p> <p>She has a track record of leading maternity service reconfiguration and the effective development of multidisciplinary teams at The Whittington Hospital (1995-2000), The Royal London Hospital (2000-2008), and Royal Free London NHS Foundation Trust (2008-present).</p> <p>Mai has also been a key advisor for the development of the North Central London (NCL) Maternity Network Board (2008-2010). She has maintained a passion for midwifery and the delivery of safe effective services for women and their families.</p>

<b>Name of Investigation Team member</b>	<b>Role and experience</b>
<b>Dr Patrick Loughran</b>	<p><b>Clinical director (retired)</b></p> <p>Patrick Loughran was a clinical director in a hospital until he retired. He was a consultant anaesthetist from 1983 until 2007 at Daisy Hill Hospital, Newry, Northern Ireland. He was also employed part-time as a medical director from 1993 until 2007, and then full-time until 2011 with the Southern Health and Social Services Trust, Northern Ireland.</p> <p>The majority of his work as a medical director was in developing and monitoring patient safety initiatives. He was also responsible for agreeing with clinical staff the systematic gathering and analysis of quality and safety measurements, including adverse incidents. These clinical outcome measures were reported within the senior management team and to the trust board. He retired from the NHS in 2011, and currently serves as a volunteer Vice-Chairperson of St John's House which provides inpatient and day-care hospice services to the population of the southern region of Northern Ireland.</p>

Name of Investigation Team member	Role and experience
<p><b>Dr Meabh Ni Bhuinneain</b></p>	<p><b>Consultant obstetrician</b></p> <p>Dr Meabh Ni Bhuinneain MB, BCh, BAO, MSc, FRCOG, MRCPI, graduated in medicine (UCD 1990) and completed postgraduate training in general practice and obstetrics and gynaecology. Following higher training in Monash Medical Centre, Melbourne, Australia, she was appointed as consultant in general obstetrics and gynaecology to Mayo General Hospital in 2000.</p> <p>During her tenure at Mayo General Hospital, she has held various roles in the development of obstetric ultrasound and ambulatory gynaecology services. She is a trainer for higher specialty training in obstetrics and gynaecology and is adjunct lecturer at NUI Galway for Global Health and Development and Obstetrics and Gynaecology.</p> <p>She has held various roles nationally in the Institute of Obstetricians and Gynaecologists including membership of the Executive Committee, the Specialty Training Committee, the Clinical Advisory Group and the Review of Maternity and Gynaecology Services. She has chaired an institutional link between Mayo General Hospital and Londiani District Hospital, Kenya, and serves on the board of the charity, Friends of Londiani.</p>
<p><b>Martin Turner</b></p>	<p><b>Governance expert</b></p> <p>Martin Turner has worked as a management consultant to the ministries of health in Iraq, Kazakhstan and Serbia since 2011. Until 2011, he was Chief Executive Officer for the Adelaide Health Service in South Australia. For almost 20 years prior to this, he was a Chief Executive in the National Health Service in Wales.</p> <p>Martin has led large organisations, including teaching hospitals, and has been responsible for managing a number of mergers and reorganisations. He was also Chairman of the Institute of Healthcare Management in Wales. He is the current global President and Fellow of the Association of Chartered Certified Accountants. He is a graduate of the Advanced Management Program in Harvard Business School.</p>

<b>Name of Investigation Team member</b>	<b>Role and experience</b>
<b>Professor James Walker</b>	<p><b>Professor in obstetrics</b></p> <p>Professor James Walker is a consultant obstetrician working in Leeds. He has extensive experience in high risk obstetrics and clinical governance. He was Chairman of the Confidential Enquiries into Maternal and Neonatal Death, obstetric advisor to the National Patient Safety Agency in the UK, and lectures and teaches on the importance of clinical audit, case review and guideline development.</p> <p>His main clinical interests are in pre-eclampsia and early pregnancy loss. He is clinically active working in the labour ward and high-risk clinical areas as well as leading a perinatal research group into the causes of pre-eclampsia, growth restriction and premature labour.</p> <p>He is a non-executive Director of the Bradford Teaching Hospitals, NHS Foundation Trust, England, and chairs its Quality and Safety Committee. He has extensive experience in assessment of clinical practice, hospitals in difficulty and doctors under investigation. He has worked and given advice in this area in the UK, Ireland, the Middle East, Turkey, Hong Kong and the US.</p>

## Appendix 4 Formal HIQA data requests

### From Midland Regional Hospital, Portlaoise

#### Complaints (2012/2013):

- number of complaints, including type of complaint and number dealt with within 30 working days, for both the maternity service and general service
  - Number of complaints for which a complaints investigation was conducted and or an incident investigation was carried out
- number of complainants informed an investigation was conducted
- complaint investigations
  - status of complaints investigations for 2012/2013
  - number of complaint investigations not completed within 30 working days and number of complainants informed of delay and who received a progress update every 20 days
  - number of complaint investigations for 2012/2013 completed at time of data request and number of final reports produced and provided to HSE senior management.

#### Risks (2012/2013):

- total number of risks identified for maternity and general services and number risks rated red as per the HSE Risk Assessment Tool
- number of risks escalated:
  - regionally, to:
    - Assistant National Director of Midlands Hospitals
    - Regional Director of Performance and Improvement
  - nationally: National Incident Management Team (NIMT).

#### Incidents (2012/2013):

- number of incidents identified for maternity and general services:
  - number categorised as an adverse event / near miss / serious reportable event) and number that resulted in death or serious harm
  - number rated major or extreme as per HSE Incident Management Policy and Procedure
  - and number reported to the Clinical Indemnity Scheme (CIS) through STARSWeb/National Adverse Event Management System (NAEMS) or other

- number escalated regionally and/or nationally to the National Incident Management Team (NIMT); notified to the Office of the HSE CEO/DG, the HSE Board and/or the Department of Health
- number of incidents that resulted in a local incident investigation being conducted and/or nationally by the National Incident Management Team (NIMT)
  - number of families involved informed an investigation was being conducted and number of investigation reports completed and copy of final report provided to the family.

## Midland Regional Hospital, Portlaoise activity monthly data sheet May 2014

### General services and maternity/obstetric services activity (2011/2012/2013):

- number / occupancy rate of beds in the following categories:
  - inpatient and day case (average length of stay [ALOS])
  - intensive care beds for Level 1, 2 and 3 intensive care / critical care beds / High Dependency Unit beds.
- number of inpatient discharges (adult, paediatric, elective, non-elective/emergency, specialty [2013])
- number of delayed discharges 2013, 2014 (up to March)
- emergency re-admission for acute medical conditions within 28 days of discharge (2013, 2014 [up to March])
- number of admissions to the Intensive Care Unit (ICU) and those who were readmitted to the ICU within the same hospital-admission episode and who required transfer to another hospital (including reason for transfer and location).

### Emergency Department (ED) attendances and admissions (2011/2012/2013):

- number of adult/paediatric ED attendances by new/return attendance, by Manchester Triage Category and number admitted as an inpatient
- timeliness of ED attendances/admissions (percentage who were discharged or admitted within six hours and nine hours of registration (2013, 2014 [up to March])
- average ED trolley waits reported per month (2013, 2014 [up to March])
- other emergency attendances and admission (excluding the ED)
- audit of ED attendances/admission from 30 June to 14 July 2014 from time of registration in ED to discharge from ED or admission to hospital including source of referral, triage category and admitting specialty.

### **Maternity/obstetric activity (2011/2012/2013):**

- number of obstetric outcomes by mode of delivery including number of emergency or elective Caesarean sections and number of live births and number of maternal deaths
- number of women who were offered bereavement counselling.

### **Maternity/obstetric access to High Dependency Unit / Intensive Care / Special Care Baby Unit activity (2011/2012/2013):**

- details of the arrangements in place to ensure 24/7 access to High Dependency Unit / Intensive Care / Special Care Baby Unit
- reason for admission to High Dependency Unit / Intensive Care / Special Care Baby Unit
- number of women/babies who required transfer to another hospital for intensive care, reason for and location of transfer
- infants transferred out of SCBU MRHP by referral hospital and reason for referral.

### **Maternity/obstetric services information reported by Midland Regional Hospital, Portlaoise to the National Perinatal Epidemiology Centre (NPEC) ((2011/2012/2013):**

- copy of National Perinatal Epidemiology Centre reports specific to MRHP reported notifications for 2011, 2012, 2013
- number of forms completed and submitted to NPEC regarding:
  - severe maternal morbidity notifications
  - major obstetric haemorrhage case assessments
  - perinatal mortality
- number/type of severe maternal morbidity events reported to NPEC, by:
  - number who required ICU/CCU admission by event type number who required (and reason for) interventional radiology
  - number by distribution of parity and by gestational age at onset of morbidity and by primary mode of delivery
- number/cause of major obstetric haemorrhage events reported to NPEC
  - number by timing of onset of haemorrhage, by gestational age at onset of morbidity and by primary mode of delivery
  - percentage of events by presence of healthcare professional present

## Midland Regional Hospital, Portlaoise – hospital report from the National Perinatal Reporting System (NPRS), 2008 to 2012

### Surgical/operating theatres

- number / core working hours of operating theatres and number of theatres closed (at time of reporting)
- details of operating theatre schedule for elective / emergency surgery and details of location of theatres in relation to transfer from patient wards
- percentage of elective surgical inpatients who had principal procedure conducted on day of admission (2013/2014 up to March)

### Infection control

- Infection rates, per quarter 2013, for MRSA bloodstream infections / Clostridium Difficile associated diarrhoea
- Antibiotic consumption rate – bi-annual 2013.

### Workforce

- Staff allocation for maternity services and general services.

### Total number of general services – nursing posts, by number of posts filled by

- nurses employed by Midland Regional Hospital, Portlaoise
- nurses employed on a constant basis from an agency
- different nurses employed on an ad hoc basis from an agency
- number of vacant posts.

### General services, number of nurses working in specialty units with relevant specialty nursing qualification:

- critical care: ICU/CCU/Cardiac ICU
- theatre or anaesthetics
- paediatrics
- Emergency Department.

Number of qualified nurse prescribers working in the Emergency Department with an ED qualification and/or are qualified to prescribe ionising radiation

Listing of non-consultant hospital doctors (NCHDs) according to contract status

Maternity services information systems in place

## From HSE

Number of complaints for HSE nationally and for Midland Regional Hospital Portlaoise, including type of complaint and number dealt with within 30 working days.

Emergency Department (ED) attendances and admissions at Midland Regional Hospital Portlaoise: timeliness of ED attendances/admissions (percentage who were discharged or admitted within six hours and nine hours of registration (2013, 2014 [up to March])

## From Healthcare Pricing Office

### **Data source: Hospital In-Patient Enquiry Scheme (HIPE) for Midland Regional Hospital, Portlaoise – General Hospital Services, 2011, 2012, 2013**

- top 20 principal diagnosis report:
  - by inpatient discharges, day-case attendances by age group
  - for emergency inpatient discharges admitted through ED
  - for inpatient discharges with number of days in intensive care environment recorded
  - for inpatient discharges transferred to other hospital.
- major diagnostic category
- principal procedure (inpatient discharges/day-case attendances/age group)
- top 10 AR-DRG (Australian Refined – Diagnosis Related Group) reports.

### **Data source: Hospital In-Patient Enquiry Scheme (HIPE) for Midland Regional Hospital, Portlaoise – Maternity Services, 2011, 2012, 2013**

- top 10 principal diagnoses delivery discharges (including discharges with a Caesarean section procedure)
- top 10 principal procedure blocks delivery discharges
- number of discharges with a diagnosis of:
  - perineal trauma after spontaneous vaginal delivery
  - third-degree perineal laceration during delivery
  - newborns (age one to six weeks) with a diagnosis of sepsis
- number of elective/emergency C-sections for discharges where outcome of delivery is stillbirth
- length of stay for delivery discharges

- method of delivery by:
  - outcome of delivery
  - mother's age
  - day of admission
- maternity delivery discharges
  - list of principal procedures
  - number of procedures with epidural analgesia used in labour
  - number with a procedure of fetal blood sampling reported
- inborn infants (newborns and other neonates):
  - AR-DRG by patient type, admission type and length of stay
  - top 10 principal diagnosis with discharge destination: transfer to other hospital and location of transfer
  - number of inborn infants with a diagnosis of intraventricular haemorrhage.

**Data source: National Perinatal Reporting System (NPRS) for Midland Regional Hospital, Portlaoise – Maternity Services, 2011, 2012, 2013**

- number of total births, live births, stillbirths, early neonatal deaths, mortality rates and maternities by:
  - birth weight
  - gestational age (weeks) at delivery
- number of obstetric outcome (live birth / stillbirth / total) by age of mother
- parity of mothers by nulliparous and multiparous
- births <[less than]500g birth weight
- life status of baby (antepartum / intrapartum) at the onset of care in labour for stillbirths
- number of perinatal deaths, antepartum/intrapartum stillbirths, stillbirth rate, early neonatal deaths, early neonatal mortality rate, perinatal mortality rate (PMR), adjusted PMR by birth weight, by gestational age
- perinatal deaths by:
  - cause of death (ICD-10)
  - birth weight
  - post-mortem examinations.

## Appendix 5 Formal HIQA documentation requests

### From HSE nationally

#### Governance

Membership of the senior management team of the HSE, to include the following: role, job description, name of current post-holder and date of commencement.

Organograms of:

- National HSE corporate governance structures demonstrating clear lines of accountability and reporting relationships to include the Acute Hospitals Office as of May 2014.
- National governance structures for acute general and maternity hospital services in Ireland.
- the interface between the HSE national and the Dublin Mid Leinster regional corporate structures, to include the Acute Hospitals Office.
- National governance structures for the management of risks pertaining to the provision of acute general and maternity hospitals in Ireland.

Implementation Strategy to include timelines for the formation of the Health Dublin Midlands Hospital Group, which includes the Midland Regional Hospital, Portlaoise.

Report (draft or otherwise) of the diagnostic review conducted at the Midland Regional Hospital, Portlaoise 'Performance Diagnostic of the Midland Regional Hospital Portlaoise by the Health Service Executive, Dublin Mid Leinster', by the Acute Hospitals Office, HSE, (approximately February 2014) and a self-assessment of the status of implementation of recommendations of this diagnostic review.

Report (draft or otherwise) and/or results of the staff survey of patient safety culture in Midland Regional Hospital, Portlaoise, conducted by the Quality and Patient Safety Division.

Report completed by the National Lead for Quality and Safety Governance Development, Quality and Patient Safety Division, reflecting the post-holders engagement with Midland Regional Hospital, Portlaoise.

Copy of any assessments/reviews:

- conducted by, or on behalf of, the National Clinical Care Programmes, in relation to the clinical services provided by Midland Regional Hospital, Portlaoise since 2010 to May 2014.
- conducted by the professional bodies on clinical/speciality services at Midland Regional Hospital, Portlaoise and/or the suitability of MRHP to deliver certain clinical/speciality services (2011 to May 2014).

National Clinical Programme implementation plan relevant to Midland Regional Hospital, Portlaoise, including timelines and accountable person.

### **Patient experience**

Copy of the list of named individuals that contacted the Department of Health and the Health Service Executive (HSE) with regard to their concerns about care provided by the Midland Regional Hospital, Portlaoise (for the time period 2006 to date [April 2014] following the RTÉ Investigations Unit *Prime Time* programme and the publication of the report of the Chief Medical Officer (CMO) of the Department of Health, where incidents occurred from 2006 to date [April 2014].

### **Complaints**

Copies of reports compiled by the Area Manager for Consumer Affairs in the Dublin Mid Leinster (DML) region, Midlands Area and submitted to the Head of Consumer Affairs, with regard to complaints data for the Midland Regional Hospital, Portlaoise, for the years 2012 and 2013 including:

- reports on performance indicators reported to the CEO/Director General of the HSE
- general reports on the performance of the HSE's complaints management processes including Midland Regional Hospital, Portlaoise, submitted by the HSE to the Minister for Health for the years 2012 and 2013.

Copies of the reports of the Midland Regional Hospital, Portlaoise provided to the HSE with regard to complaints received by the service provider (MRHP) on the complaints received during the years, 2012 and 2013 to include the total number of complaints received, the nature of the complaints, the number of complaints resolved by informal means, the outcome of any investigations into the complaints.

List of training provided by the Patient Advocacy Unit at Midland Regional Hospital, Portlaoise to include dates provided and attendance rates per discipline.

List of standardised definitions for specific terms used within the HSE.

### **Risk Management / Incident Management**

- HSE Risk Management strategy
- Terms of Reference, membership, schedule, agenda and minutes of the HSE Risk Committee (January – May 2014)
- HSE Risk Register as pertains to the Midland Regional Hospital, Portlaoise for 2013/2014
- List the national policies which underpin the management of serious incidents/adverse events within the HSE

- Copies of the reports (draft or final) of reviews, investigations, assessments, diagnostic reviews, culture assessments, conducted by or on behalf of the HSE in relation to Midland Regional Hospital, Portlaoise for the time period 2006 to date [May 2014].
- List the criteria utilised to commence a clinical investigation and/or clinical review and/or serious incident review
- List and provide copies of any correspondence from the Clinical Indemnity Scheme of the State Claims Agency in relation to risk management arrangements at Midland Regional Hospital, Portlaoise, to include the reporting of serious incidents and adverse events from 2006 to date [May 2014], and any resulting actions.
- Final Report Incident Review [specified incident] – minutes/details/action plans of any internal meetings and any external stakeholder meetings held in relation to this investigation and report by the HSE at a national, regional and local level up to September 2014.
- Agenda and minutes of any meetings that were held to discuss the review of the care of a specified case.
- Copy of the directive for ‘instantaneous reporting’ of never events that was issued from the HSE (as per R.21 of the Chief Medical Officer’s report, *HSE Midland Regional Hospital, Portlaoise Perinatal Deaths 2006-date*).

### Implementation of Recommendations

Terms of reference and membership (specify chair and vice-chair) of the committee responsible for the implementation of the recommendations including self-assessment and declaration of the status of the implementation of the specified recommendations related to the Health Service Executive, pertaining to:

- the *HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date)*, Report to the Minister for Health from the Chief Medical Officer, dated 24 February 2014
- report of the *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* (HIQA, 2013)
- Specified HSE Incident Report of the investigation into the circumstances surrounding the care management and treatment delivered at the Midland Regional Hospital, Portlaoise (2012)
- *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* (Published June 2013).

## Workforce

Copy (draft or otherwise) of any review/evaluation/workforce planning in relation to the staffing allocation per discipline and speciality conducted since 2010 to date [May 2014] at Midland Regional Hospital Portlaoise.

## From the Chief Medical Officer (CMO), Department of Health

### Implementation of recommendations

Terms of reference and membership (specify chair and vice-chair) of the committee responsible for the implementation of the recommendations including self-assessment and status of the implementation of the specified recommendations related to the Department of Health, pertaining to:

- the *HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date)*, report to the Minister for Health from the Chief Medical Officer, dated 24 February 2014
- report of the *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* (HIQA 2013).

## From Midland Regional Hospital Portlaoise

### Governance

Confirmation of hospital-model type for the Midlands Regional Hospital, Portlaoise in line with the National Acute Medicine Programme.

Organograms of the:

- regional corporate and clinical governance structures for Dublin Mid Leinster, demonstrating clear lines of accountability and reporting relationships, including the interface between the regional and local corporate and clinical structures (Dublin Mid Leinster and Midlands Regional Hospital, Portlaoise)
- Midlands Regional Hospital, Portlaoise (general services) organisational chart
- clinical governance structure for Midlands Regional Hospital, Portlaoise (general services), demonstrating clear lines of accountability and reporting relationships within the hospital and the interface between the corporate and clinical governance structure of Midlands Regional Hospital, Portlaoise (general services)
- Midlands Regional Hospital, Portlaoise (maternity services) organisational chart

- clinical governance structure for Midlands Regional Hospital, Portlaoise (maternity services), demonstrating clear lines of accountability and reporting relationships in the hospital and the interface between the corporate and clinical governance structure of Midlands Regional Hospital, Portlaoise (maternity), and with the Coombe Women and Infants University Hospital.
- risk management structure in place for general services and maternity services
- clinical governance structure for the provision of adult emergency department (ED) services at Midlands Regional Hospital, Portlaoise, demonstrating clear lines of accountability and reporting relationships to include 24 hour ED management and clinical cover arrangements.
- local clinical governance structure for the provision of surgical services at Midlands Regional Hospital, Portlaoise (local) demonstrating clearly defined roles, accountability and responsibility throughout the service to include 24-hour surgical cover arrangements
- any other organograms to describe the hospital governance structures.

Dublin Mid Leinster Region:

- Corporate Strategy to include Midlands Regional Hospital, Portlaoise
- Corporate Business Plan for 2013 and 2014
- Annual Report for 2012 and 2013.

List of regional management committees responsible for the management of performance in relation to the quality and safety of clinical services and provide terms of reference, membership, schedule and minutes of meetings between Midlands Regional Hospital, Portlaoise and the regional management team between June 2013 to March 2014.

Regional implementation plan and timelines for the implementation of the National Clinical Programmes (to include Midlands Regional Hospital, Portlaoise).

Terms of reference / membership / agenda and minutes (from June 2013 to March 2014) of:

- regional acute hospital services management team with responsibility for Portlaoise, Tullamore and Mullingar acute hospitals
- general hospital senior/executive management team (or equivalent) the level 2 governance committee
- maternity hospital senior management team (or equivalent)
- any maternity related meetings/forums at the hospital to include those with the Coombe Women and Infants University Hospital.

Midland Regional Hospital, Portlaoise general services and maternity services:

- Hospital Code of Governance
- Corporate Strategy
- Corporate Business Plan for 2013 and 2014
- Annual Report for 2012 and 2013
- Governance and Quality Improvement Plan
- Risk Management Strategy
- Quality Improvement Strategy
- Clinical Audit Strategy
- Patient Involvement Strategy
- Human Resources Strategy.

List of all existing clinical governance committees of the Midlands Regional Hospital, Portlaoise general services and maternity services responsible for the management of performance in relation to the quality and safety of clinical services at Midlands Regional Hospital, Portlaoise and terms of reference, membership, schedule and minutes of meetings for each committee listed from June 2013 to March 2014.

Contracts of agreement between Midlands Regional Hospital, Portlaoise (general) and the third-party providers (public and private) of radiology services on behalf of Midlands Regional Hospital, Portlaoise.

### **Risk management / complaints / quality improvement**

Risk Register for 2013/2014, for:

- Dublin Mid Leinster / Dublin Midlands Hospital Group
- Midlands Regional Hospital, Portlaoise general services
- Midlands Regional Hospital, Portlaoise maternity services
- Midlands Regional Hospital, Portlaoise emergency department.

Confirmation if a dedicated risk manager and a dedicated complaints manager for the general services and maternity services were in place and date of commencement.

Job specification and terms and conditions for the:

- Quality, Patient Safety and Complaints Manager
- Patient Safety Coordinator.

List of the incidents identified within Midlands Regional Hospital, Portlaoise, for the maternity service and the general hospital, from 2006 to date [April 2014], for which an incident investigation was conducted.

Reports of clinical incident trend analyses including list of all incident root cause analyses conducted and details of resultant actions, for both Midlands Regional Hospital, Portlaoise General and Maternity Services from June 2013 to March 2014; and details of serious incidents reported to National Incident Management Team for the previous 12 months (from May 2014).

List of any quality improvement initiatives implemented by the Midland Regional Hospital, Portlaoise General and Maternity Services as an action following investigation of any identified clinical incidents/adverse events from June 2013 to March 2014.

Incident / near miss pro forma report form.

Details of the process to ensure learning is disseminated from locally reported incidents and adverse events as well as from national and international reports including those pertaining to the management of maternity cases.

List of the standardised definitions in use within Midlands Regional Hospital, Portlaoise for terms with regard to complaints and incident management.

Confirmation of date HSE's 'Risk Assessment Tool and Guidance' was implemented at Midlands Regional Hospital, Portlaoise.

List of the HSE policies and procedures [including status dates] in use at Midlands Regional Hospital, Portlaoise for the management of complaints, incidents and for the management of significant adverse events.

Policy and/or procedure in place at both Midlands Regional Hospital, Portlaoise general and maternity services for reviewing and responding to complaints and compliments and implementing any subsequent quality improvement actions.

A summary of complaints received for the previous 12 months [from May 2014] in both Midlands Regional Hospital, Portlaoise general and maternity services, including a list of any quality improvement initiatives implemented as an action following investigation of any complaints June 2013 to March 2014.

List of quality improvement initiatives implemented as part of the Midlands Regional Hospital, Portlaoise general and maternity services quality improvement strategy.

List of clinical audit activities undertaken at both Midlands Regional Hospital, Portlaoise general and maternity services between June 2013 and March 2014.

Report of audit of 'knife to skin' completed in the last 18 months/24 months (from June 2014) by consultant obstetricians at Midland Regional Hospital, Portlaoise.

Surgical site surveillance, LSCS, Midlands Regional Hospital, Portlaoise Quality Improvement Plan, 20 August 2014.

## **Service-user involvement**

List and reports of patient satisfaction surveys carried out by both Midlands Regional Hospital, Portlaoise general and maternity services since January 2013.

## **Effective and safe care**

Copies of guidelines/protocol/policy/standard operating procedures in place pertaining to:

- admission, discharge and transfer protocols for critical care services
- bypass protocols, including ambulance bypass protocols
- full-capacity protocol, as of June 2014
- reporting of significant/urgent laboratory results
- 'out of hours' operating theatre protocol
- list of any guidelines/policy/standard operating procedures in place in the maternity and neonatal services including any which guide access to senior clinical decision-making and transfer to other facilities.

Arrangements in place for out-of-hours (to include weekends) emergency access to radiology services (to include ultrasound and CT).

All clinical policies, procedures, guidelines and standard operating procedures in use by members of the multidisciplinary team in the general services and maternity services including Special Care Baby Unit, including:

- Management of primary postpartum haemorrhage, maternity services
- agenda and minutes of the meetings, from December 2013 to June 2014, of the:
  - medical board
  - obstetric team
  - clinical audit teams (general and maternity services)
  - mortality and morbidity (maternity services) team
  - any quality and safety committees specific to the maternity services
  - midwife/ nurse management teams (general and maternity services)
  - ward managers meeting for the Labour Unit, the Maternity Ward, and the Early Pregnancy Assessment Unit.

Reports / presentations of clinical audit activity (maternity services) from June 2013 to March 2014.

## Access to clinical services

Questions in relation to whether there was 24-seven on-site access to clinical services related to:

- anaesthetic/intensivist expertise at consultant/senior registrar level
- senior clinical decision-making at specialist registrar or consultant level in the maternity hospital/division
- radiology services (to include ultrasound and CT)
- laboratory services (to include microbiology)
- alternative arrangements for access to clinical services in the case when clinical expertise is not available on-site 24/7.

## Open disclosure

- project plan, and/or details of the pilot programme for the development of guidance on open disclosure, to include terms of reference (TOR) and membership of the group responsible for its implementation
- confirmation that the HSE policy on open disclosure is in use in Midlands Regional Hospital, Portlaoise general and maternity services.

## Implementation of recommendations

Self-assessment and declaration of the status of the implementation of the specified recommendations as they apply to the Midlands Regional Hospital, Portlaoise, pertaining to:

- recommendations issued to the Midlands Regional Hospital, Portlaoise by the Authority in formal correspondence since December 2012
- report of the *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* (HIQA 2013)
- report of the investigation into the quality and safety and governance of care provided by Adelaide and Meath Hospital, Dublin incorporating the National Children's Hospital (AMNCH) for patients who require acute admission (HIQA 2012)
- report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at Mallow General Hospital (HIQA 2011)
- report of the investigation into the quality and safety of services and supporting arrangements provided by the Health Service Executive at the Mid-Western Hospital Ennis (HIQA 2009)

- specified HSE incident report of the investigation into the circumstances surrounding the care, management and treatment delivered at the Midland Regional Hospital, Portlaoise (HSE 2012).

### **Workforce (general and maternity services)**

Policy and/or procedure for:

- verifying registration status with regulatory bodies for permanent and temporary clinical staff
- maintaining records of mandatory training and continuous professional development.

Induction programme for new staff, both clinical and non-clinical.

List of the categories of staff that are on the emergency response team (core hours) / (outside of core hours).

List of training provided by the Patient Advocacy Unit, to include dates provided and description of the group in attendance.

Training records detailing education and training of all members of the multidisciplinary team (obstetric services) over the past two years (from June 2014), including anaesthetic update training for midwives.

Timetable for and compliance with mandatory training requirements for all members of the multidisciplinary team (general services).

Percentage split of agency midwives that cover the day duty and night duty when compared to the non-agency midwives.

Monthly employment monitoring summary sheet May 2014 and March 2014.

Contact details for key hospital management and clinical staff members.

### **Information systems**

Details of information system is in use in both Midlands Regional Hospital, Portlaoise general and maternity services for the national reporting of serious and critical incidents at a local level and a copy of the standard operating procedure that guides the use of this system.

## Appendix 6 Correspondence from the Health Information and Quality Authority to the Minister for Health



### STRICTLY PRIVATE AND CONFIDENTIAL

Dr James Reilly TD  
Minister for Health  
Department of Health  
Hawkins House  
Hawkins Street  
Dublin 2

6 June 2014

Ref: BMcE/MW/JR/060614

Dear Minister,

**Re: Investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the Midland Regional Hospital, Portlaoise**

Further to the commencement of the above investigation, the Health Information and Quality Authority (HIQA) has been contacted by, and has subsequently engaged with, a significant range of people who had availed of services within Portlaoise Hospital and from other hospital services across the country. The vast majority of these service users have been in receipt of maternity services.

The experiences as recounted to the HIQA Investigation Team engaged in the patient and family interviews have been identified as a significant concern. The Team involved in these interviews have recorded the traumatic and at times deeply disturbing stories across the families and patients interviewed. While the incidents described were traumatic in a significant number of cases, the experiences of how individuals and families were dealt with were shocking, in some instances becoming victims of what should be regarded as a caring and compassionate service. The extent of these stories, their common themes and collective impact could potentially be regarded as a significant national issue.

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The current breakdown of those who have contacted HIQA is as follows:

- six from the Chief Medical Officer's office
- 53 names referred from Health Service Executive (HSE) with the perceived source being the helpline set up after the RTE Prime Time programme or the Patient Focus group. (It should be noted that some of these referrals were redacted to names and addresses only with no detail of the circumstances of their concerns.)
- nine direct contacts to HIQA from people who have used services.

In line with the Terms of Reference for the investigation, namely:

*To investigate and assess how local, regional and national clinical and corporate governance arrangements provided by the HSE are supporting the safety and quality of services at the Hospital to general and maternity patients, identifying whether risks to patients in the Hospital's models of service provision have been identified, assessed and mitigated.*

- a. *To specifically include the HSE's actions, inactions and governance response to serious adverse incidents and dissemination of learning*
- b. *the associated relationship and communication between the HSE and patients and families and their experience*

HIQA commenced a formal process of engagement with a range of families to ascertain their experiences and associated communication with staff at Portlaoise Hospital and by the HSE regionally and nationally. To date we have interviewed 15 patients and or family members. The interviews were carried out by members of the Investigation Team with specific involvement of Margaret Murphy, World Health Organization patient experience representative.

It would appear from those individuals that we have met to date that the issues highlighted by the original Prime Time programme appeared to have triggered contact from a range of patients and families who had attended Portlaoise Hospital and other maternity services to come forward seeking an opportunity to recount their negative experiences. This number exceeds those originally anticipated and to some extent highlights the widespread nature of the issues of poor individual and family care in the aftermath of serious adverse incidents, a number of which involved a perinatal death. In some incidences these families had not made previous contact with the HSE about their experiences.

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Furthermore, as a result of the information we have received it is our view that this should be seen as a national issue, not specifically confined to Portlaoise Hospital. Patient Focus has informed HIQA that it has had contact from at least 90 patients on such issues.

There is evidence that a number of the experiences have resulted in negative psychological impact on individuals. As outlined above, a number of people interviewed described themselves as damaged and traumatised from their experiences in the aftermath of incidents. We feel that while patients have acknowledged to the Team that they were grateful to be able to recount their stories, we have initiated an investigation and reporting process that may not be able to adequately address their ongoing psychological needs or their expectations.

We are of the opinion that a number of these individuals require ongoing psychological support. In some instances some of the cases require fresh or revised clinical investigation. Both of these issues fall outside the scope of the investigation and outside the remit of HIQA as a regulator. We note that a number of families have been offered and availed of psychological support from the HSE. However, some are deeply distrustful of the HSE, in some instances the Department of Health and by association HIQA.

It is apparent that there is no structured pathway or centralised structure or process that facilitates access to such support and or clinical investigation. In the main this group of patients are relatively young, and the pain and residual impact of their experiences could have longer-term consequences.

It is our belief that a national alternative approach, separate to the current investigation process needs as a priority to be created. This approach should facilitate:

- a trusted and single point of access
- rigorous consideration of individual and family experiences
- a review of clinical outcomes (as necessary), and
- the provision of relevant psychological support for these individuals and their families.

We believe that to deal with these experiences in the normal course of an investigation would not do justice to the stories of some of these individuals. A single chapter summarising the experience of these individuals and families will only add to further distrust and fear and ultimately fail these individuals.

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Having identified these issues so early in the investigation process provides for an opportunity to find a solution and associated supports for those who have come forward to share their experiences. Failure to deal with these issues in a meaningful way and in advance of publication may be perceived as a further let down for many of those involved.

As a regulator, HIQA does not have the capacity, capability or remit to deal with the issues identified. While these issues identified will be reflected in our report, there is a moral and ethical duty on us to highlight these issues to the Minister who is the commissioner of the investigation and to seek early views from his officials on potential solutions to the issues raised.

Please feel free to make contact with me directly in relation to this correspondence.

Yours sincerely,



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**Brian McEnery**  
Chairperson

**CC**

Dr Ambrose McLoughlin, Secretary General, Department of Health  
Dr Tony Holohan, Chief Medical Officer, Department of Health  
Professor Jane Grimson, Acting Chief Executive, HIQA  
Phelim Quinn, Director of Regulation, HIQA

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## Appendix 7 Non-compliances with the National Standards for Safer Better Healthcare at Midland Regional Hospital, Portlaoise

Standard number	National Standard	Portlaoise Hospital finding
1.1	<b>The planning, design and delivery of services are informed by services users' identified needs and preferences.</b>	<ul style="list-style-type: none"> <li>No active engagement with patients and or their families to identify their needs and preferences.</li> </ul>
1.4	<b>Service users are enabled to participate in making informed decisions about their care.</b>	<ul style="list-style-type: none"> <li>Patients were not consistently facilitated to access patient support services including, where appropriate, independent support groups.</li> </ul>
1.6	<b>Service users' dignity, privacy and autonomy are respected and promoted.</b>	<ul style="list-style-type: none"> <li>Service users were not consistently communicated with in a manner that respected their dignity and privacy.</li> <li>The attitudes and behaviours of some of the workforce towards service users and each other did not consistently promote service users' autonomy.</li> <li>The design and management of the physical environment did not respect service users' dignity, particularly following bereavement.</li> </ul>

Standard number	National Standard	Portlaoise Hospital finding
1.7	<p><b>Service providers promote a culture of kindness, consideration and respect.</b></p>	<ul style="list-style-type: none"> <li>■ The hospital did not promote a culture of kindness, consideration and respect through the service’s mission statement, service design, code of conduct, training, development and evaluation processes.</li> <li>■ The hospital did not consistently recognise that at certain stages of a patient’s care and treatment some individuals may be more vulnerable than others.</li> <li>■ The hospital did not consistently seek and respect service users’ views, values and preferences and take these into account in the provision of care.</li> </ul>

Standard number	National Standard	Portlaoise Hospital finding
1.8	<p><b>Service users' complaints and concerns are responded to promptly, openly and effectively with clear communication and support provided throughout this process.</b></p>	<ul style="list-style-type: none"> <li>■ Complaints procedures did not ensure timely responses or consistently fully address the issues raised by the complainant.</li> <li>■ Complaints procedures did not consistently identify the expectations of complainants and ensure that these expectations were taken into account and addressed throughout the process.</li> <li>■ The hospital did not consistently provide a supportive environment for service users that encouraged them to provide feedback, raise concerns or make complaints verbally or in writing in a culture of openness and partnership.</li> <li>■ The hospital did not consistently provide structured arrangements to ensure that service users who make a complaint are facilitated to access support services, such as independent advocacy services.</li> <li>■ The hospital did not consistently demonstrate how learning from complaints and concerns had been shared and implemented.</li> </ul>

Standard number	National Standard	Portlaoise Hospital finding
2.1	<p><b>Healthcare reflects national and international evidence of what is known to achieve best outcomes for service users.</b></p>	<ul style="list-style-type: none"> <li>■ There were no formal multidisciplinary arrangements or associated governance structure for the prioritisation, development, sharing and monitoring of usage of policies, guidelines, protocols and care pathways based on best available evidence.</li> <li>■ Management and support of bereaved parents was not consistently in line with best available evidence.</li> <li>■ The Irish Maternity Early Warning System was not used for all pregnant women cared for in the general hospital.</li> </ul>
2.2	<p><b>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.</b></p>	<ul style="list-style-type: none"> <li>■ Children attending the hospital for emergency paediatric care were not consistently formally assessed and triaged within 15 minutes of presentation.</li> </ul>
2.6		<ul style="list-style-type: none"> <li>■ There was no formal review of the level and type of services that could be safely and effectively delivered.</li> <li>■ There was no regular review of the services provided to ensure that the defined model of service could be safely delivered.</li> </ul>

Standard number	National Standard	Portlaoise Hospital finding
2.7	<b>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.</b>	<ul style="list-style-type: none"> <li>■ The physical infrastructure of the Maternity Department, Paediatric Emergency Department, Intensive Care Unit, Outpatients Department and the Day Ward did not support the delivery of high-quality, safe and reliable healthcare nor protect the health and welfare of service users.</li> </ul>
2.8	<b>The effectiveness of healthcare is systematically monitored, evaluated and continuously improved.</b>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not consistently use national performance indicators and benchmarks to monitor and evaluate the quality and safety of the care and its outcomes.</li> <li>■ Portlaoise Hospital did not use available outcome measures to evaluate the effectiveness of healthcare, for example, service users' experience of care.</li> </ul>
3.1	<b>Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.</b>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not proactively monitor, analyse and respond to information relevant to the provision of safe services.</li> <li>■ Portlaoise Hospital did not consistently identify, evaluate and manage immediate and potential risks to service users and take necessary action to eliminate or minimise these risks.</li> </ul>

Standard number	National Standard	Portlaoise Hospital finding
3.2	<b>Service providers monitor and learn from information relevant to the provision of safe services and actively promote learning both internally and externally.</b>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not have formal structured processes in place to assist in the sharing of findings and learning from adverse incidents and patient complaints.</li> </ul>
3.3	<b>Service providers effectively identify, manage, respond to and report on patient-safety incidents.</b>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not ensure that all patient-safety incidents were reported in a timely manner through national reporting systems in line with national legislation, policy, guidelines and guidance.</li> <li>■ Portlaoise Hospital did not facilitate fair and effective investigations to identify the causes of patient-safety incidents and to identify necessary actions.</li> </ul>
3.5	<b>Service providers fully and openly inform and support service users as soon as possible after an adverse event affecting them has occurred, or becomes known, and continue to provide information and support as needed.</b>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not consistently practise open disclosure with patients following an adverse event.</li> <li>■ Portlaoise Hospital did not consistently involve service users in adverse-event investigations. Nor did it keep service users informed of the progress of any investigation.</li> </ul>
3.6	<b>Service providers actively support and promote the safety of service users as part of a wider culture of quality and safety.</b>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not have specific arrangements in place that actively promoted a patient-safety culture including service design, allocation of resources and training, development and evaluation processes.</li> </ul>

Standard number	National Standard	Portlaoise Hospital finding
5.2	<b>Service providers have formalised governance arrangements for assuring the delivery of high-quality, safe and reliable healthcare.</b>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not have effective integrated corporate and clinical governance arrangements, which clearly defined roles, accountability and responsibilities throughout the service for assuring quality and safety.</li> <li>■ Portlaoise Hospital did not have a single governance structure in the Emergency Department to ensure the quality and safety of care in that department.</li> </ul>
5.4.	<b>Service providers set clear objectives and develop a clear plan for delivering high quality, safe and reliable healthcare services.</b>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not have plans that set clear direction for delivering quality and safety in the short, medium and long-term.</li> </ul>
5.5	<b>Service providers have effective management arrangements to support and promote the delivery of high-quality, safe and reliable healthcare services.</b>	<ul style="list-style-type: none"> <li>■ There were deficiencies in the management arrangements for workforce management, communication, information management, risk management, patient-safety improvement, service design, environment and physical infrastructure management.</li> </ul>
5.6	<b>Leaders at all levels promote and strengthen a culture of quality and safety throughout the service.</b>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not have a strong culture of patient safety.</li> </ul>

Standard number	National Standard	Portlaoise Hospital finding
5.8	<p><b>Service providers have systematic monitoring arrangements for identifying and acting on opportunities to continually improve the quality, safety and reliability of healthcare services.</b></p>	<ul style="list-style-type: none"> <li>■ Recommendations from HSE national clinical programmes were not comprehensively acted upon in order to proactively improve the quality and safety of service.</li> <li>■ Portlaoise Hospital did not have adequate risk management structures and processes to proactively identify, manage and minimise clinical risks.</li> <li>■ Portlaoise Hospital did not act on service-user feedback</li> </ul>
5.11	<p><b>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.</b></p>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not fully act on recommendations made by the Health Information and Quality Authority, specifically the recommendation by the Authority to appoint a risk manager in 2012.</li> </ul>
6.1	<p><b>Service providers plan, organise and manage their workforce to achieve the service objectives for high-quality, safe and reliable healthcare.</b></p>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not sufficiently plan and organise its services to ensure there were enough staff with the necessary qualifications, skills and experience to deliver safe high-quality care for service users at all times.</li> </ul>
6.2	<p><b>Service providers recruit people with the required competencies to provide high-quality, safe and reliable healthcare.</b></p>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not have enough staff with the requisite qualifications, skills and experience to ensure the safe and effective delivery of a model-3 hospital service at all times.</li> </ul>

Standard number	National Standard	Portlaoise Hospital finding
6.3	<b>Service providers ensure their workforce have the competencies required to deliver high-quality, safe and reliable healthcare</b>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not ensure that all staff involved in caring for patients during labour and delivery adhered to hospital policy and completed the training identified as necessary to ensure ongoing competence in cardiotocography (CTG) recording and interpretation.</li> <li>■ Portlaoise Hospital did not have staff with the competencies and skills necessary to investigate complex serious incidents.</li> </ul>
6.4	<b>Service providers support their workforce in delivering high-quality, safe and reliable healthcare.</b>	<ul style="list-style-type: none"> <li>■ The Clinical Director was neither afforded protected time nor appropriate supports to carry out the role of a clinical director.</li> </ul>
7.1	<b>Service providers plan and manage the use of resources to deliver high-quality, safe and reliable healthcare efficiently and sustainably.</b>	<ul style="list-style-type: none"> <li>■ Portlaoise Hospital did not regularly monitor its current services to ensure it had adequate resources to continue delivering its model of service safely and effectively.</li> </ul>
8.1	<b>Service providers use information as a resource in planning, delivering, managing and improving the quality, safety and reliability of healthcare.</b>	<ul style="list-style-type: none"> <li>■ High-quality information was not available to inform the planning, management and delivery of services.</li> <li>■ Information to inform national key performance indicators such as patient experience time could not be recorded electronically.</li> </ul>

## Appendix 8 HSE non-compliances with the National Standards for Safer Better Healthcare at the Midlands Regional Hospital, Portlaoise

Standard number	National Standard	HSE finding
1.1	<b>The planning, design and delivery of services are informed by services users' identified needs and preferences.</b>	<ul style="list-style-type: none"> <li>The HSE did not actively engage with service users at Portlaoise Hospital to identify their needs and preferences.</li> </ul>
1.7	<b>Service providers promote a culture of kindness, consideration and respect.</b>	<ul style="list-style-type: none"> <li>The HSE did not consistently seek and respect service users' views, values and preferences and take these into account in the provision of their care.</li> </ul>
2.1	<b>Healthcare reflects national and international evidence of what is known to achieve best outcomes for service users.</b>	<ul style="list-style-type: none"> <li>The governance structure for monitoring the use of policies, guidelines, protocols and care pathways based on best available evidence was not effective.</li> </ul>
2.6	<b>Care is provided through a model of service designed to deliver high-quality, safe and reliable healthcare.</b>	<ul style="list-style-type: none"> <li>The Maternity Department at Portlaoise Hospital was not part of an integrated clinical network with the Coombe Women's and Infants University hospital.</li> <li>The HSE did not review the model of service delivery at Portlaoise Hospital to ensure that it was safe.</li> </ul>

Standard number	National Standard	HSE finding
2.7	<b>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.</b>	<ul style="list-style-type: none"> <li>■ The infrastructure of Portlaoise Hospital did not support the delivery of high-quality, safe and reliable healthcare and did not protect the health and welfare of service users.</li> </ul>
2.8	<b>The effectiveness of healthcare is systematically monitored, evaluated and continuously improved.</b>	<ul style="list-style-type: none"> <li>■ The HSE did not evaluate the effectiveness of the service provided at Portlaoise Hospital.</li> <li>■ The arrangements in place to ensure that all adverse incidents were reported – to the Clinical Indemnity Scheme of the State Claims Agency – were ineffective.</li> </ul>
3.1	<b>Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.</b>	<ul style="list-style-type: none"> <li>■ The HSE did not proactively monitor, analyse and respond to information relevant to the provision of safe services at Portlaoise Hospital.</li> <li>■ The HSE did not consistently identify, evaluate and manage immediate and potential risks to service users and take necessary action to eliminate or minimise these risks.</li> </ul>

Standard number	National Standard	HSE finding
3.3	<b>Service providers effectively identify, manage, respond to and report on patient-safety incidents.</b>	<ul style="list-style-type: none"> <li>■ The HSE did not have effective arrangements in place to identify patient safety incidents through structured incident-reporting mechanisms.</li> <li>■ The HSE did not utilise the information that was available in relation to the provision of safe services.</li> <li>■ The HSE did not have effective arrangements in place to facilitate robust, fair and effective investigations for the purpose of identifying the causes of patient-safety</li> </ul>
3.6	<b>Service providers actively support and promote the safety of service users as part of a wider culture of quality and safety.</b>	<ul style="list-style-type: none"> <li>■ The HSE did not have clear accountability arrangements throughout the service to ensure that all members of the workforce are aware of their responsibilities and contribute to improving the quality and safety of healthcare for service users.</li> </ul>

Standard number	National Standard	HSE finding
5.1	<p><b>Service providers have clear accountability arrangements to achieve the delivery of high-quality, safe and reliable healthcare.</b></p>	<ul style="list-style-type: none"> <li>■ Named accountability and delegated responsibility was unclear for:                             <ul style="list-style-type: none"> <li>– the dissemination of learning</li> <li>– the implementation and monitoring of recommendations within defined timelines and the incorporation of national learning into future clinical guidelines</li> <li>– clinical audit activity and health policy.</li> </ul> </li> </ul>
5.2	<p><b>Service providers have formalised governance arrangements for assuring the delivery of high-quality, safe and reliable healthcare.</b></p>	<ul style="list-style-type: none"> <li>■ The HSE did not have integrated corporate and clinical governance arrangements, which clearly define roles, accountability and responsibilities throughout the service for assuring quality and safety.</li> <li>■ The HSE did not have governance arrangements in place to ensure that the primary focus of the service is on quality and safety outcomes for service users. These arrangements include regular review of available information relating to quality and safety outcomes for service users.</li> <li>■ The HSE did not ensure that there was a single robust governance structure in the Emergency Department at Portlaoise Hospital to ensure the quality and safety of care in that department.</li> </ul>

Standard number	National Standard	HSE finding
5.5	<b>Service providers have effective management arrangements to support and promote the delivery of high-quality, safe and reliable healthcare services.</b>	<ul style="list-style-type: none"> <li>■ The HSE did not ensure that the management arrangements in place for Portlaoise Hospital were sufficient to effectively and efficiently achieve planned objectives.</li> </ul>
5.6	<b>Leaders at all levels promote and strengthen a culture of quality and safety throughout the service.</b>	<ul style="list-style-type: none"> <li>■ The HSE did not prioritise a culture of quality and safety.</li> </ul>
5.8	<b>Service providers have systematic monitoring arrangements for identifying and acting on opportunities to continually improve the quality, safety and reliability of healthcare services.</b>	<ul style="list-style-type: none"> <li>■ Recommendations from national clinical programmes were not comprehensively acted upon in order to proactively improve the quality and safety of service.</li> <li>■ The HSE did not address the persistent failure of Portlaoise Hospital to comply with national key performance indicators in relation to complaints management.</li> <li>■ The HSE did not ensure that learning from complaints and concerns was effectively disseminated.</li> </ul>

Standard number	National Standard	HSE finding
5.11	<b>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.</b>	<ul style="list-style-type: none"> <li>■ The HSE did not fully consider and implement the findings and recommendations made by the Authority in previous statutory investigations and reviews.</li> </ul>
6.1	<b>Service providers plan, organise and manage their workforce to achieve the service objectives for high-quality, safe and reliable healthcare.</b>	<ul style="list-style-type: none"> <li>■ The HSE did not ensure that Portlaoise Hospital had enough staff with the requisite qualifications, skills and experience to ensure the safe and effective delivery of a model-3 hospital service at all times.</li> </ul>
6.2	<b>Service providers recruit people with the required competencies to provide high-quality, safe and reliable healthcare.</b>	<ul style="list-style-type: none"> <li>■ The HSE did not monitor and evaluate the effectiveness of recruitment processes and the arrangements in place for Portlaoise Hospital.</li> </ul>
7.1	<b>Service providers plan and manage the use of resources to deliver high-quality, safe and reliable healthcare efficiently and sustainably.</b>	<ul style="list-style-type: none"> <li>■ The HSE did not regularly monitor the services at Portlaoise Hospital to ensure that the hospital had the resources necessary to continue delivering their model of service safely and effectively.</li> </ul>
8.1	<b>Service providers use information as a resource in planning, delivering, managing and improving the quality, safety and reliability of healthcare.</b>	<ul style="list-style-type: none"> <li>■ High-quality information was not available to inform the planning, management and delivery of services at Portlaoise Hospital.</li> </ul>

## Glossary of terms and abbreviations used in this report

<p><b>Accountability:</b> being answerable to another person or organisation for decisions, behaviour and any consequences.</p>
<p><b>Adverse event:</b> an incident that results in harm to a patient.</p>
<p><b>Advocacy:</b> 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.</p>
<p><b>Allied health practitioners:</b> encompasses clinical support specialties such as physiotherapy, occupational therapy, social work, speech and language therapy and clinical nutrition.</p>
<p><b>Ambulance bypass protocol:</b> patients with specified conditions are taken by ambulance directly to larger nominated facilities better equipped to provide the healthcare intervention required, rather than to smaller local hospitals.</p>
<p><b>Anaesthetic:</b> a substance that produces partial or complete loss of sensation.</p>
<p><b>Anaesthetist:</b> a medical specialist who administers an anaesthetic to a patient before a medical procedure or surgery.</p>
<p><b>Antenatal care:</b> care provided to a pregnant woman during her pregnancy.</p>
<p><b>Audio visual separation:</b> in emergency departments which cater for both adults and children, audio visual separation means preventing in as much as possible children being able to see and hear distressed adult patients and adult patients being able to see and hear children receiving care.</p>
<p><b>Benchmarking:</b> a process of measuring and comparing care and services with similar service providers.</p>
<p><b>Best available evidence:</b> the consistent and systematic identification, analysis and selection of data and information to evaluate options and make decisions in relation to a specific question.</p>
<p><b>Caesarean section:</b> a surgical procedure used to deliver a baby through incisions created in the mother's abdomen and uterus.</p>
<p><b>Cardiotocography:</b> an electronic means of recording the fetal heart beat and the uterine contractions during pregnancy. A cardiotocograph machine produces a trace known as a cardiotocograph which illustrates the fetal heart rate and uterine activity.</p>

**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.

**Clean utility:** a 'clean' utility room is a room that holds clean materials and supplies.

**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 primary role of a clinical director is to manage and plan how services are delivered and contribute to the process of strategic planning, influencing and responding to organisational priorities. This will involve responsibility for agreeing an annual directorate service plan, identifying service development priorities and working to aligning directorate service plans with hospital or network plans.

**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. See Clinical audit.

**Clinical guidelines:** systematically developed statements to assist healthcare professionals and patients' decisions about appropriate healthcare for specific circumstances.

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

**Clinical nurse manager (CNM):** refers to nurses who undertake first-line nursing management posts with responsibility for professional leadership, staffing and staff development, resource management and facilitating communication. There are three grades of first-line nurse management: CNM 1, CNM 2 and CNM 3. A CNM 1 reports to a CNM 2; a CNM 2 is in charge of a ward or unit of care and reports to a CNM 3; a CNM 3 is in charge of a department and reports to an assistant director of nursing.

**Clinical midwife manager (CMM):** refers to midwives who undertake first-line midwife management posts with responsibility for professional leadership, staffing and staff development, resource management and facilitating communication. There are three grades of first-line midwife management: CMM 1, CMM 2 and CMM 3. A CMM 1 reports to a CMM 2; a CMM 2 is in charge of a ward or unit of care and reports to a CMM 3; a CMM 3 is in charge of a department and reports to an assistant director of midwifery.

**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 hospital consultant is a registered medical practitioner in hospital practice who, by reason of his or her training, skill and experience in a designated specialty, is consulted by other registered medical practitioners and assumes full clinical responsibility for patients in his or her care, or that aspect of care on which he or she has been consulted, without supervision in professional matters by any other person. Consultants include surgeons, physicians, anaesthetists, pathologists, radiologists, oncologists and others.

**Continuous veno-venous haemofiltration:** a short-term treatment used in an intensive care unit (see ICU) for patients with acute or chronic kidney failure, to facilitate the removal of waste products from the bloodstream.

**Core hours:** core working hours refer to the hours when a department or area is fully functional and historically was 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.

**CT:** computed tomography is a computerised X-ray imaging technique which is used to generate cross-sectional and three-dimensional images of internal organs and structures of the body.

**Culture:** the shared attitudes, beliefs and values that define a group or groups of people and shape and influence perceptions and behaviours.

**Dirty utility:** a 'dirty' utility room is a temporary holding area for soiled and or contaminated equipment, materials or waste prior to their disposal, cleaning or treatment.

**Dublin Midlands Hospitals Group:** this hospital group was previously called the Health Dublin Midlands Group. It will comprise: St James's Hospital, Dublin; Tallaght Hospital, Dublin; Midland Regional Hospital Tullamore; Naas General Hospital; Midland Regional Hospital, Portlaoise; and the Coombe Women and Infants University Hospital, Dublin. Its primary academic partner will be Trinity College Dublin (TCD).

**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 planned by the patient and the surgeon or a physician at a time that is advantageous to the patient. It is not usually urgent.

**Emergency care:** the branch of medicine that deals with evaluation and initial treatment of medical conditions caused by trauma or sudden illness.

**Endocrinology:** the study of hormones, their receptors, the intracellular signalling pathways they invoke, and the diseases and conditions associated with them.

**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.

**Full dilatation Caesarean section:** a Caesarean section performed when the cervix is fully dilated as opposed to earlier on in the labour.

**Gastrointestinal endoscopy:** an examination of the inside lining of the digestive tract including the oesophagus, stomach, and upper small intestine using an endoscope, which is a flexible fibre optic tube with a tiny camera at the end.

**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.

**Gynaecology:** the branch of medicine particularly concerned with the health of the female organs of reproduction and diseases of these organs.

**Haematology:** the diagnosis, treatment, and prevention of diseases of the blood and bone marrow as well as of the immunologic (concerned with the structure and function of the immune system), haemostatic (blood clotting) and vascular systems.

**Haematologist:** a medical doctor who has specialised in the area of haematology

**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, or preserving or improving the health of service users.

**Healthcare record:** all 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 patients.

**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 in Irish acute hospitals. Information is provided by the hospitals to a central system, formerly administered by the Economic and Social Research Institute (ESRI) and now administered by the HSE.

**HSE:** The Health Service Executive, established under the Health Act 2004, is the statutory body responsible for providing health and social care services to everyone living in 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.

**Irish Maternal Early Warning System (IMEWS):** a system for the early detection of illness during pregnancy and after a woman has had a baby. Previously referred to as I-MEWS in national guidelines.

**Key performance indicator (KPI):** specific and measurable elements of practice that can be used to assess quality and safety of care.

**Locum:** a healthcare professional, with the required competencies, who is employed to temporarily cover the duties of another healthcare professional who is on leave.

**Manchester triage system:** this is an assessment system used in emergency departments to rapidly place patients into categories, according to the type of treatment they need and how quickly they need it.

**Master of a maternity hospital:** master is a term from the 19th Century when the Rotunda, the Coombe and National Maternity hospitals in Dublin were each granted the power to appoint a lead doctor to take control of all aspects of the hospitals' clinical and administrative areas.

**Methodology:** a system of methods, rules and procedures used for the delivery of a project.

**Model of service:** the way a health service is delivered. It can be applied to a single service unit, to an organisation or a national service.

**Model 1, 2, 3 and 4 hospitals:** in 2010, the HSE's National Acute Medicine Programme described four generic acute hospital models (model 1, 2, 3 and 4). Their purpose was to define the level of service that can be safely provided at acute hospitals within the constraints of available facilities, staff, resources and local factors.

**Model-1 hospitals** are community and or district hospitals and do not have surgery, emergency care, acute medicine (other than a select group of low-risk patients) or critical care.

**Model-2 hospitals** can provide the majority of hospital activity including extended day surgery, selected acute medicine, local injuries, a large range of diagnostic services, including endoscopy, laboratory medicine, point-of-care testing, and radiology – computed tomography (CT), ultrasound and plain-film X-ray – specialist rehabilitation medicine and palliative care.

**Model-3 hospitals** admit undifferentiated acute medical patients; provide 24-seven acute surgery, acute medicine, and critical care.

**Model-4 hospitals** are tertiary hospitals and are similar to model-3 hospitals but also provide tertiary care and, in certain locations, supra-regional care.

**Monitoring:** systematic process of gathering information and tracking change over time. Monitoring provides a verification of progress towards achievement of objectives and goals.

**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 patient by a team of healthcare professionals who work together to provide integrated care.

**National Integrated Medical Imaging System:** a new, central computer-based system for storing and examining X-rays and scans, managed and controlled by the Health Service Executive (HSE).

**NAEMS:** National Adverse Event Management System is replacing the STARSweb system as a national web-based database for the reporting of adverse clinical incidents and 'near misses'. See STARSweb.\*

**NEWS:** National Early Warning Score. This is a nationally agreed early warning score for the early recognition and management of acutely ill adult patients.

**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-elective or unscheduled cases:** people who require or who perceive the need for advice, care, treatment or diagnosis that is not planned or pre-booked. Non-elective or unscheduled care is available every day and should receive a prompt response depending on the urgency of the clinical need of the patient.

**Obstetrics:** the branch of medicine concerned with pregnancy and childbirth.

**Obstetrician:** a doctor who has specialised in the area of obstetrics.

**On call:** the provision or availability of clinical advice in addition to or outside of core working hours.

**Oncology:** the branch of medicine that deals with tumours and cancers, including the study of their development, diagnosis, treatment and prevention.

**Oncologist:** a doctor who has specialised in the area of treating patients with 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.

**Ophthalmology:** the branch of medicine concerned with the study and treatment of disorders and diseases of the eye.

**Out of hours:** outside the core working hours of 9am to 5pm, Monday to Friday. See Core hours.

**Outpatient department (OPD):** a hospital department which is primarily designed to enable hospital 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 who had previously attended the OPD.

**Outpatient:** a patient who receives treatment at a hospital (at an emergency department or a clinic) but is not hospitalised.

**Paediatrics:** the branch of medicine concerned with the treatment of infants and children.

**Paediatrician:** a specialist in paediatrics.

**Patient safety incident or 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 discernible harm to the patient (no harm event).

**Pathology:** a branch of medical science primarily concerning the examination of organs, tissues, and bodily fluids in order to make a diagnosis of disease.

**Pathologist:** a specialist in the area of pathology.

**Perinatal death:** the death of a baby in the weeks before or after birth.

**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.

**Performance management and or performance monitoring:** process which includes activities that ensure that goals are consistently being met in an effective and efficient manner. Performance management can, for example, focus on the performance of an organisation, a department, service, or the processes to deliver a service.

**Policies, procedures, protocols and guidelines:** 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 giving birth 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.

**Productive ward initiative:** a national programme which aims to empower front-line staff to promote changes and improvements in how healthcare is delivered.

**PROMPT:** Practical Obstetric Multi-Professional Training (PROMPT) is an evidence-based multi-professional training package for obstetric emergencies. It is associated with direct improvements in perinatal outcome and has been proven to improve knowledge, clinical skills and team working.

**Protected disclosure:** any communication made in good faith that discloses or demonstrates an intention to disclose information that may provide evidence of improper conduct which poses a significant risk to public health or safety.

**Protocol:** in healthcare, 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.

**Radiologist:** a doctor who has specialised in the area of radiology.

**Radiology:** is a medical specialty that uses imaging (such as X-rays and scans) to diagnose and treat disease seen within the body.

**RDO:** a regional director of operations, HSE. From 2009, RDOs were the senior managers on regional HSE management teams. Regional directors of performance and integration (RDPIs) replaced the RDOs in 2013 as managers of performance and integration across hospital and community services.

**RDPI:** a regional director for performance and integration, 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.

**Scheduled care:** describes the care which patients receive on a planned basis.

**Safety walk-rounds:** a safety initiative which involves structured visits by senior managers to clinical areas within their hospital to have conversations with front-line staff for the purpose of preventing, detecting and mitigating harm to patients and staff.

<p><b>Service:</b> 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, and so on.</p>
<p><b>Service level agreement (SLA):</b> a framework for the provision of services, including details of quality and governance requirements.</p>
<p><b>Service provider:</b> 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 Health Service Executive (HSE).</p>
<p><b>Service user:</b> 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] or commissioning hospital laboratory services); parents, guardians, carers and family and potential users of healthcare services. The term service user is used in this document, but occasionally the term patient is also used where it is more appropriate.</p>
<p><b>Skill mix:</b> 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.</p>
<p><b>Stakeholder:</b> a person, group or organisation that affects or can be affected by the actions of, or has an interest in, the services provided.</p>
<p><b>STARSWeb:</b> a national web-based database established and maintained by the State Claims Agency to record adverse incidents and 'near misses' reported by hospitals, which is being replaced by NAEMS. See NAEMS.</p>
<p><b>Stroke:</b> occurs when a blood vessel, carrying oxygen and nutrients to the brain, bursts or is blocked by a clot, causing an interruption of the blood supply to part of the brain.</p>
<p><b>Supra-regional care:</b> complex healthcare which is not available in all areas, as it requires a multidisciplinary approach. For example, heart and liver transplant surgeons and a range of experts with advanced skills who usually work in tertiary care centres, which are usually large urban hospitals. Referrals by hospital consultants and local hospitals from all over the country can be made to supra-regional services.</p>
<p><b>Surgery:</b> medical treatment in which a doctor cuts into someone's body in order to repair or remove damaged or diseased parts.</p>
<p><b>Surgeon:</b> a specialist doctor in surgery.</p>

**Terms of reference:** a set of terms that describe the purpose and structure of a project, committee or meeting.

**Tertiary care:** specialised consultative healthcare, usually for inpatients and on referral from a primary or secondary health professional, in a facility that has personnel and facilities for advanced medical investigation and treatment, such as a tertiary level hospital.

**The Authority:** the Health Information and Quality Authority, or HIQA.

**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.

**Trial of forceps:** a trial of instrumental vaginal birth using either obstetric forceps or a vacuum instrument conducted in an operating theatre with preparations made for proceeding to Caesarean section. This technique is used in a small proportion of anticipated difficult births. See Caesarean section.

**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.

**Undifferentiated patients:** all types of patients with any degree of seriousness or severity of illness or injury.

**Urology:** the medical and surgical specialty that involves the urinary tracts of males and females and the reproductive system of males.

**Whole-time equivalent (WTE):** one whole-time equivalent employee is an employee who works the total number of hours possible for their grade. WTEs are not the same as staff numbers as many staff work reduced hours, for example, two nurses working 19 hours per week each would be 1 WTE as full-time hours for nursing staff are 39 hours per week.

**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 or patient.



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