HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006-date)

Report to the Minister for Health

Dr James Reilly TD

From

Dr Tony Holohan
Chief Medical Officer

24 February 2014

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Preface

This is a preliminary Report to the Minister for Health relating to the issues that arose following a *Primetime Investigates* programme relating to Portlaoise Hospital Maternity Services on 30th January 2014.

I approached the task on the basis that it was in the interests of the patients and families alike to come to as early a view as possible on findings and recommendations while pointing to areas that would require more time for further consideration or analysis. The Report does not purport to say, therefore, that all facts have been established given the time frame in which it was completed.

The first interactions I had were with some of the families involved. The stories of Katelyn Keenan, Joshua Keyes-Cornally, Mark Molloy and Nathan Molyneaux made a significant impression on me. The bravery and commitment of their parents in making sure their stories were heard, so that they could benefit other people, is the reason we have this Report. They have created this opportunity to improve our services. I hope I have done some justice to them and in some small way helped their parents to ensure that Katelyn, Joshua, Mark and Nathan have a legacy of which they can be proud.

I am acutely conscious that there is enormous pressure on the staff of the Portlaoise Hospital Maternity Service. Not only do they have to cope with the significant adverse publicity, the real impact it has on their lives in the communities in which they live and the prospect of more investigation, they are also the ones who must continue to provide the service that the local population needs. Recent hospital management initiatives to strengthen governance are acknowledged. It is my view, however, that they cannot be expected to do that alone, without guidance and mentoring and without reconfiguration of the governance of the service in a way which secures its future for the people of Portlaoise and its environs in a safe and sustainable manner.

In preparing this Report, I was supported by a small team of people whom I reassigned from their day-to-day work to allow this Report to be completed speedily. The Team was headed by Dr Kathleen Mac Lellan, Director of Clinical Effectiveness. I am indebted to her and her team for their work. I am also very grateful to Dr Siobhan O'Halloran, Chief Nursing Officer for her support particularly into the issues relating to midwifery staffing, leadership and development.

Dr Tony Holohan,
Chief Medical Officer
24 February 2014

Executive Summary

Introduction

Patients who use our services have a right to good care and to kind and compassionate treatment. They also have a right to expect that the healthcare professionals who provide that care and the system they work in do their best, in every sense of that term, to deliver high quality care. High quality care means care which is evidence based, appropriate, timely, efficient, effective and patient-centred. It implies that, even when things go wrong, the professionals and the system will do the right thing.

It is the action or inaction of senior responsible medical and nursing/midwifery staff in the immediate aftermath of events such as those that are the subject of this Report that make all the difference to effective management. It is vital to patient, public and staff confidence and morale that at the most challenging of times, the healthcare system performs to its highest standard. It is imperative, therefore, that we continue to strengthen policy and practice in respect of patient safety and in particular our capacity to learn lessons derived from monitoring and analysis of adverse events.

Background

With these issues in mind, the Minister for Health requested the Chief Medical Officer to prepare a Report for him on issues that arose following a *Primetime Investigates* programme relating to Portlaoise Hospital Maternity Services (PHMS) on 30th January 2014.

This Report provides a preliminary assessment of PHMS focusing on perinatal deaths (2006-date) and related matters. Through a series of recommendations it sets out the need for further examination or actions where the findings of this preliminary assessment suggest such a need. It also makes clear who should be responsible for these further examinations or actions.

Methodology

The critical initial question which this Report sought to address is whether the service provided by PHMS can be said to be safe from now on and into the future given the events that were reported in public and Portlaoise Hospital's response to these events.

In order to inform the preparation of this Report, meetings were held with some of the families involved, Patient Focus, the senior management team at Portlaoise Hospital, representation from the obstetric and midwifery team at PHMS, the National Clinical lead for the Obstetrics and Gynaecology programme, the HSE Quality and Patient Safety Directorate, the HSE Directorate, the State Claims Agency, HIQA and relevant regulatory bodies.

PHMS clinical activity and outcome data, investigation reports, incident reports and desktop reviews, all relating to the period 2006 to date, were examined. The analysis was further informed by a detailed examination of National Perinatal Surveillance Data from the various systems in existence that collect and report such data. In addition relevant HSE and Portlaoise Hospital policies and guidelines were reviewed.

Quantitative findings and assessment

The data we obtained, had it been collated and examined, could have shown that there was good reason to suspect that there may have been an on-going problem with outcomes of care experienced by people using the service in PHMS i.e.

- Birth rates had risen very quickly over a short period
- There was a number of what would now be defined as 'never events'
- A number of other serious adverse events occurred
- There was a rise in notifications of adverse incidents
- There was a significant increase in transfers out of PHMS for both maternity and paediatric care to other centres
- There was a higher than expected rate of obstetric claims.

All of this data was available throughout the period in question. It is clear that local hospital analysis of this kind of data was not happening on a regular basis. While there was awareness that the service was under pressure, there does not appear to be any evidence that monitoring of how this might have been impacting on patient care was taking place. Using the available data on an on-going basis is a straightforward and useful way for maternity units to monitor trends, so areas of possible concern for the service can be identified early and actions taken as required.

We also conducted a detailed analysis of the various systems that collate and report data on perinatal mortality. We found some inconsistencies and some duplication. These are the subject of specific recommendations.

Qualitative findings

In the course of the work undertaken, a number of issues and themes emerged. These were organised into seven overall themes which are set out below together with the overall Report findings and the recommendations relating to them.

Theme One looks at the patient safety culture at PHMS, the services when dealing with a perinatal death, the response to patients and families following serious adverse incidents and the practices in respect of disclosure to patients of serious adverse events and of investigations.

Theme Two deals with the system of clinical governance at PHMS. This includes arrangements for risk management and adverse incident reporting and investigation in the context of the reviews undertaken by the hospital. In particular, it focuses on the time taken to conduct and complete reviews, the quality of reviews, the involvement of staff, the use of codes in reviews and the nomenclature utilised for incidents and for reviews. It also examines the implementation of recommendations from these reviews.

Theme Three looks at the arrangements for implementation of standards and guidelines in general with particular reference to escalation of care and clinical handover. It considers the need for some further specific national guidance based on the findings of the reviews undertaken by the hospital.

Theme Four considers the escalation of incidents outside of the hospital and role of national HSE. It considers this in the context of the events which took place in Portlaoise Hospital in 2007. It considers how the systems of escalation and support can be strengthened.

Theme Five deals with leadership, staffing and workforce planning with particular reference to the supports needed by front line service leaders. It considers how workforce planning and assessment of midwifery requirements might be improved given the findings in the Report.

Theme Six considers the infrastructure and equipment. It is based not only on the walk around conducted, but on specific findings in the reviews completed by the hospital that have relevance for medical equipment and also medical record management.

Finally, Theme Seven gives consideration to the role that the Coronial process (inquests) played in the cases reviewed. It also considers the issues of consent and confidentiality.

Conclusions

The overall conclusions in the Report are as follows:

1. Families and patients were treated in a poor and, at times, appalling manner with limited respect, kindness, courtesy and consideration.
2. Information that should have been given to families was withheld for no justifiable reason.
3. Poor outcomes that could likely have been prevented were identified and known by the hospital but not adequately and satisfactorily acted upon.
4. The PHMS 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. (See Overall Recommendation 3).
5. Many organisations, including PHMS, had partial information regarding the safety of PHMS that could have led to earlier intervention had it been brought together.
6. The external support and oversight from HSE should have been stronger and more proactive, given the issues identified in 2007.

Summary Recommendations

All recommendations, wherever they appear in the Report, are seen as critically important elements of the whole response. There are, however, 11 overall recommendations. Overall recommendations are given the notation O.R. (overall recommendation) and cross referenced, where relevant, to where they appear in the main Report.

Recommendation O.R.1: PHMS should apologise unreservedly to the patients concerned.

Recommendation O.R.2: An immediate assessment of the patient safety culture at Portlaoise Hospital should be undertaken by HIQA.

Recommendation O.R.3: A team should be appointed to run the PHMS pending implementation of Recommendation O.R.4 below.

Recommendation O.R.4: PHMS should become part of a Managed Clinical Network under a singular governance model with the Coombe Women & Infant University Hospital.

Recommendation O.R.5: Other small maternity services should be incorporated into managed clinical networks within the relevant hospital group.

Recommendation O.R.6: The HSE should address the implications of this Report for other services at Portlaoise Hospital.

Recommendation O.R.7: Support should be provided to the Portlaoise Hospital senior management team. This should lead to a wider programme of support for frontline leaders, particularly in smaller hospitals, to ensure that they can and do provide safe and effective care.

Recommendation O.R.8: HIQA should be requested to undertake an investigation in accordance with Section 9 (2) of the Health Act 2007.

Recommendation O.R.9: HIQA should develop national standards for the conduct of reviews of adverse incidents.

Recommendation O.R.10: The HSE should ensure that every maternity service (and later every health service provider) be required to complete a Patient Safety Statement which is published and updated monthly.

Recommendation O.R.11: A National Patient Safety Surveillance system should be established by HIQA.

Section 1 Introduction and background

1.1 Introduction

Patients who use our services have a right to good care and to kind and compassionate treatment. They also have a right to expect that the professionals who provide that care and the system they work in do their best, in every sense of that term, to deliver high quality care. High quality care means care which is evidence based, appropriate, timely, efficient, effective and patient centred. It implies that, even when things go wrong, the professionals and the system will do the right thing.

Delivery of healthcare is inherently risky. The science of medicine is not an exact one. Its scale and complexity is without parallel in other sectors and businesses. The technologies that are used do not yield perfect observations or outcomes. Furthermore, health services are delivered by humans who make mistakes.

While it is inevitable that things go wrong, there is much that can be done to prevent harm and error, to identify it when it occurs, to take actions to mitigate the effect of that harm or error and to learn lessons from the investigation of harms/errors or groups of harms/errors that allow actions to be taken to minimise the risk of recurrence.

One cardinal lesson from patient safety practice is that honesty and openness are essential elements of patient trust and confidence which in turn are integral to the effective response to errors when they occur. Once this trust is broken, it is almost impossible to re-establish. Patients and families experience distress at the fact of an error which can then be compounded by mistrust, lack of confidence and hurt that can understandably be felt when healthcare professionals and providers appear to, or do, withdraw from engagement, fail to communicate and act defensively.

It is the action or inaction of senior responsible medical and nursing/midwifery staff in the immediate aftermath of events such as those that are the subject of this Report that make all the difference to effective management. Serious adverse events and incidents are not everyday occurrences. Furthermore, effectively managing a major adverse incident and the response to it is a complex task. In many institutions, there may be little direct experience which challenges the expectation of a consistent competent response.

It is vital to patient, public and staff confidence and morale that at the most challenging of times, the health system performs to its highest standard. It is imperative, therefore, that we continue to strengthen policy and practice in respect of patient safety and in particular our capacity to learn lessons derived from monitoring and analysis of adverse events.

1.2 Background

With these issues in mind, the Minister for Health requested the Chief Medical Officer to prepare a Report for him on issues that arose following a *Primetime Investigates* programme relating to Portlaoise Hospital Maternity Services (PHMS) on 30th January 2014.

This Report provides a preliminary assessment of PHMS focusing on perinatal deaths (2006-date) and related matters. Through a series of recommendations it sets out the need for further examination or actions where the findings of this preliminary assessment suggest such a need. It also makes clear who should be responsible for these further examinations or actions.

This Report is presented in the context of the implementation of a series of patient safety initiatives in Ireland that have emerged from the *Report of the Commission on Patient Safety and Quality Assurance* (2008)[1]. In addition, the Health Information and Quality Authority (HIQA) has identified that as part of their Business Plan for 2014, and in line with their programme for the monitoring of the *National*

[1] http://www.dohc.ie/publications/pdf/en_patientsafety.pdf?direct=1

Standards for Safer Better Healthcare[2], they will be conducting a governance review of HSE Midlands Regional Hospital Portlaoise[3].

1.3 Patient safety policy

Patient safety has become both a national and international imperative in recent years, with increased emphasis on patient safety in policy reform, legislative changes and development of standards of care driven by quality improvement initiatives. The Commission on Patient Safety and Quality Assurance was established in Ireland in January 2007 and published its report in August 2008[4]. The Commission's report provides the roadmap to developing a national culture of patient safety and recommends increased leadership and accountability throughout the service through new governance, management and reporting structures. A number of other important recommendations, relevant to this Report, were made including:

- legislation on licensing of all public and private healthcare providers
- mandatory adverse incident reporting
- open disclosure on patient safety incidents
- participation of clinicians in a national programme of clinical audit
- improved research, education and training on patient safety and
- patient involvement in service review and planning.

A National Patient Safety Advisory Group was established in 2011 by the Minister for Health. It provides a forum at national level for the maintenance of dialogue and interaction between key stakeholders in relation to the patient safety agenda and provides leadership, direction and policy advice for on-going work under the *Patient Safety First*[5] initiative. Key structural healthcare reforms include the establishment of the Patient Safety Unit within the Department of Health (2006), Health Information and Quality Authority (HIQA) (2007), the Quality and Patient Safety Directorate in the Health Service Executive (HSE) (2011) and the strengthening and reform of regulatory frameworks for healthcare providers and healthcare professionals.

Legislative proposals are at an advanced stage of development by the Department of Health for the introduction of a national licensing system. This will provide for a mandatory system of licensing for public and private health service providers. It will be designed to improve patient safety by ensuring that healthcare providers do not operate below core standards which are applied in a consistent and systematic way.

Much of the legislation governing healthcare professionals has been extensively updated and amended in recent years with the publication of a number of relevant Acts including the Medical Practitioners Act 2007 and the Nurses and Midwives Act 2011.

Patient safety has been made a priority within the HSE Annual Service Plan 2014[6] through specific measures focused on quality and patient safety including healthcare acquired infections (HCAIs), medication safety and implementation of early warning score systems. Clinical effectiveness is a key component of safe, quality care. To this end the Minister for Health established the National Clinical Effectiveness Committee (NCEC) in 2010 to provide a framework for national endorsement of clinical guidelines and audit.

A new Patient Safety Agency (PSA) is to be established. The Agency will be established initially on an administrative basis within the HSE structures in 2014.

Many of these patient safety initiatives have made significant progress in terms of legislative, regulatory and structural changes. Changing culture and developing processes for patient safety are

[2] http://www.hiqa.ie/publications/national-standards-safer-better-healthcare
[3] From this point onward in the Report HSE Midlands Regional Hospital Portlaoise will be referred to as Portlaoise Hospital
[4] http://www.dohc.ie/publications/pdf/en_patientsafety.pdf?direct=1
[5] http://www.patientsafetyfirst.ie/
[6] http://www.hse.ie/eng/services/Publications/corporate/serviceplan2014/

critical to delivery of quality safe healthcare service. A quality and safety culture ensures that quality and safety is seen as fundamental to every person working within that service, including clinical and non-clinical staff, healthcare managers and the Board, or equivalent, of an organisation.

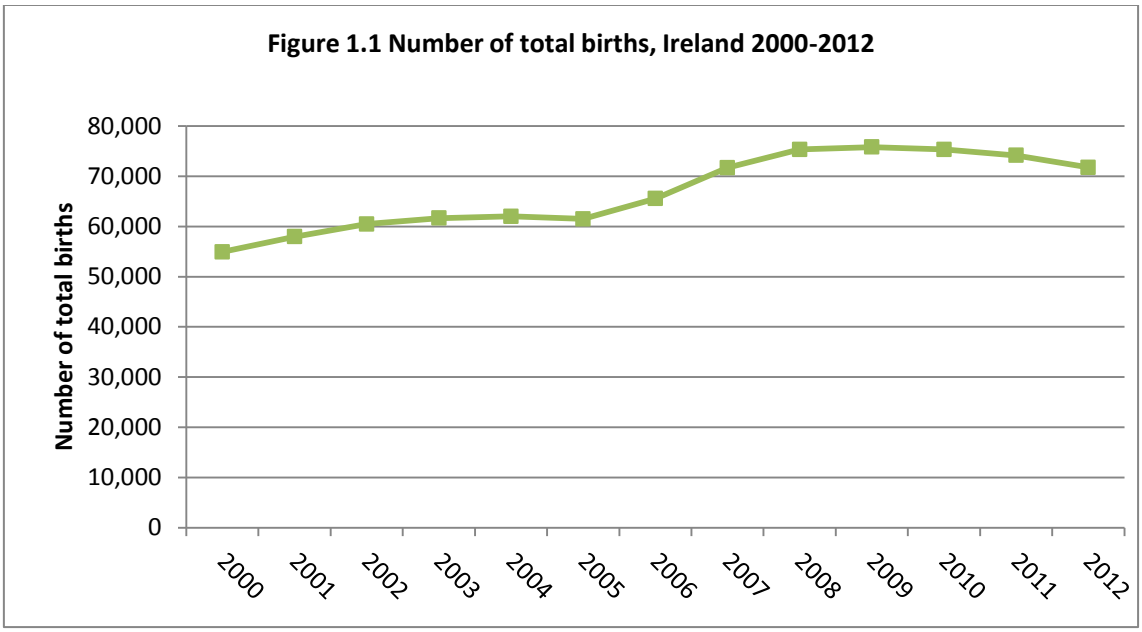
1.4 Maternity services in Ireland

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 registered with the scheme and hospital obstetricians working within the public maternity services. The HSE is the national agency accountable for the planning and delivery of healthcare services including maternity services. Public and private maternity services are provided in 19 maternity hospitals/units around the country (Table 1.1).

Table 1.1 Irish maternity services 2013

	Maternity Service	Births
Dublin	Coombe Women & Infant University Hospital	8,209
	National Maternity Hospital, Holles Street	8,994
	Rotunda Hospital	8,843
	Total	**26,046**
South and South East	Cork University Maternity Hospital	8,344
	Kerry General Hospital, Tralee	1,500
	South Tipperary General Hospital	1,202
	St Luke's General Hospital, Kilkenny	1,815
	Waterford Regional Hospital	2,215
	Wexford General Hospital	1,990
	Total	**17,066**
West and North West	Galway University Hospital	3,141
	Letterkenny General Hospital	1,798
	Mayo General Hospital, Castlebar	1,697
	Portiuncula Hospital, Ballinasloe	2,044
	Sligo General Hospital	1,544
	Total	**10,224**
Mid West	University Maternity Hospital, Limerick	4,652
	Total	**4,652**
North East	Cavan / Monaghan Hospital Group	1,915
	Our Lady Of Lourdes Hospital, Drogheda	3,648
	Total	**5,563**
Midlands	Midland Regional Hospital, Mullingar	2,461
	Midland Regional Hospital, Portlaoise	1,983
	Total	**4,444**
Total		**67,995**

While numbers of births nationally increased substantially from 2000 to 2009, since 2010 there has been a gradual decrease (Figure 1.1).



A new National Maternity Services Strategy will be developed this year which will provide the strategic direction for the optimal development of maternity services to ensure that women in Ireland have access to safe, high quality maternity care in a setting most appropriate to their needs. The Department of Health will oversee the development of this strategy which it plans will be finalised by the end of the year. The recommendations in this Report will inform the strategy.

Section 2 Methodology

2.1 Introduction

The critical initial question which this Report sought to address is whether the service provided by PHMS can be said to be safe from now and into the future given the events that were reported in public and Portlaoise Hospital's response to these events.

In order to address this, we examined:

1. The extent to which there was verifiable implementation of:
    a. recommendations made into any incidents that PHMS had investigated
    b. relevant national policies.
2. The extent to which the clinical governance arrangements would enable reliable identification and reporting of serious adverse incidents, their speedy and effective investigation, the implementation of the resultant learnings and the arrangements for monitoring and assurance.

While this cannot provide an absolute guarantee of safety, we took the view that a high standard of achievement or performance relative to the criteria set out above would allow a reasonable conclusion to be drawn regarding safety.

Portlaoise Hospital was requested to provide detail of all adverse events and serious incident reviews that occurred 2006 to date in PHMS. In order to be able to make an expedient deliberation in terms of PHMS a detailed examination of a reasonable sample of perinatal and related events 2006 to date was conducted. In addition, the data and information was utilised to create an overall impression of the patient safety and risk management processes in place in PHMS and the oversight and support being provided by the HSE Directorate.

The preliminary assessment of risk managment and patient safety at PHMS which was conducted, ascertained (from 2006 onwards) the number of:

- perinatal deaths
- early neonatal and maternal transfers to other maternity hospitals, and
- the number of perinatal incidents declared to be adverse events by the hospital as evidenced by reports, reviews or investigations.

The HSE designated the Regional Director of Performance and Integration (RDPI) to act as HSE liaison between the PHMS and the Department of Health team.

2.2 Meetings

In order to obtain other information and perspectives, meetings were held with some of the families involved, Patient Focus, the senior management team at Portlaoise Hospital, representation from the obstetric and midwifery team at PHMS, the Director of the National Clinical Programme for Obstetrics and Gynaecology, the HSE Quality and Patient Safety Directorate, the HSE Directorate, the State Claims Agency, HIQA and regulatory bodies (Table 2.1).

Table 2.1 Meetings with key informants

Date	Key informant meetings
4th Feb 2014	Patient Focus
4th Feb 2014	Family meetings
5th Feb 2014	Family meetings
5th Feb 2014	RDPI and senior management team Portlaoise Hospital
6th Feb 2014	Director National Clinical Programme for Obstetrics and Gynaecology
6th Feb 2014	National Director for Clinical Strategy and Programmes
6th Feb 2014	Chief Nursing Officer, Department of Health
6th Feb 2014	National State Claims Agency
6th Feb 2014	HSE Quality and Patient Safety Directorate
6th Feb 2014	Assistant Secretary, Acute Hospitals, Department of Health
7th Feb 2014	Nursing and Midwifery Board, Ireland
7th Feb 2014	Irish Medical Council
11th Feb 2014	HIQA
12th Feb 2014	RDPI, senior management team, representatives from obstetrics and midwifery, Portlaoise Hospital
14th Feb 2014	Assistant Secretary, Acute Hospitals, Department of Health
14th Feb 2014	HSE Directorate
14th Feb 2014	Chief Nursing Officer, Department of Health
18th Feb 2014	Assistant Secretary, Acute Hospitals, Department of Health
18th Feb 2014	HIQA
20th Feb 2014	Family Meetings and Patient Focus
20th Feb 2014	RDPI and senior management team Portlaoise Hospital

Patient Focus is an advocacy agency which is operating a Helpline for families. Its commitment to providing valuable support and information to those affected by the issue is acknowledged. Patient Focus facilitated the Department of Health in terms of working with families and providing valuable information and insights.

Contact was made with the Irish Medicines Board (IMB) to ascertain if there was any national sales data for Oxytocin[7] which might provide additional information. The IMB indicated that there are two authorised Oxytocin containing products in use in Ireland. These are: Syntocinon (dosages of Oxytocin 5IU/ML and 10IU/ML) and Syntometrine (Oxytocin 5IU and Ergometrine 500mcg/ml 500mcg/ml). The product sales history, however, does not indicate usage nor does it indicate whether the use of these products was appropriate.

In addition, a walk around of the maternity unit was conducted on 12th February 2014.

2.3 Examination of national perinatal data

A detailed examination of national perinatal data was undertaken. This required both verbal and written correspondence with PHMS as well as three of the agencies involved with perinatal surveillance data. These agencies are the General Register Office (GRO), the National Perinatal Reporting System (NPRS) and the National Perinatal Epidemiology Centre (NPEC). All agencies provided the requested data in a prompt and thorough manner which enabled the analysis in Section 4 to be carried out.

[7] Oxytocin is a drug utilised for labour induction

2.4 PHMS risk management data and processes

In order to create a view of Portlaoise Hospital's own assessment of its safety and risk profile, an examination of relevant PHMS investigation reports, incident reports and desktop reviews conducted (2006 to date) was made. Table 2.2 sets out the numbers of each of these that were made available to us. The co-operation of Portlaoise Hospital in providing this information in a timely manner is acknowledged. In addition, three meetings were held with the Portlaoise Hospital senior management team.

Table 2.2 PHMS safety and risk reports reviewed

Category	Number
Serious adverse incident review reports	6
National Incident Management Team (NIMT) review	1
Desktop reviews	10
Incident forms	2,380 (Approximately)

In addition, relevant HSE and Portlaoise Hospital policies and guidelines were reviewed (Appendix 1).

This process considered Portlaoise Hospital's general approach to risk management and patient safety issues and whether the full cycle of implementation of recommendations from the various reports (Table 2.2) was completed in a timely manner by Portlaoise Hospital.

We then sought to establish the extent of both escalation to or monitoring by HSE at regional and/or national level of adverse incidents as well as the extent of external support and guidance provided to the Portlaoise Hospital over the time period in question.

2.5 Report findings – meetings with families and Portlaoise Hospital

Prior to finalising the Report, an overview of findings and recommendations was presented firstly to the families and secondly to the Portlaoise Hospital senior management team. Feedback from both meetings informed the final findings and text of this Report.

Section 3 Portlaoise Hospital

3.1 Portlaoise Hospital governance structures

Tullamore, Mullingar and Portlaoise Hospitals make up the Midland Hospitals and governance across these hospitals relates directly back to the previous structure of the Midland Health Board prior to the establishment of the HSE in 2005.

This arrangement evolved with the creation of the HSE Integrated Services Directorate in late 2009. Overall management responsibility for the three hospitals rested with the General Manager, Midlands Hospitals who reported to the Network Manager. Each hospital had a Grade VIII Hospital Manager, Director of Nursing and each Consultant had a reporting relationship to the General Manager. Finance, human resource (HR) and risk management were provided through this centralised service. Formal monthly meetings were held with the General Manager and Network Manager. Quality and risk were agenda items at these meetings.

From late 2009, the Network Manager reported to a Regional Director of Operations (RDO). By the end of 2010, the Network Manager, General Manager and Risk Manager who had dedicated time in the hospital (two days per week) retired. None of these posts was replaced. In early 2011, an Assistant National Director was redeployed within the system to take overall charge of the three Midland Hospitals. All previous reporting relationships to the General Manager now reported to this postholder who in turn reported to the RDO.

A Clinical Director was appointed to Portlaoise Hospital as part of the national roll out of the Clinical Directorate structures in 2010. From 2011 onward, the Assistant National Director conducted monthly meetings with the three Midland Hospital management teams where quality and risk was an agenda item. He was also a member of the Dublin-Mid Leinster (DML) regional managment team.

Quality and risk management support has been accessed through the broader Midlands management service rather than being provided in the hospital itself. However, dedicated access to this resource diminished from 2010 due to retirements and the broadening of the remit of this service to cover the entire Dublin Mid-Leinster region. A dedicated risk manager/risk co-ordinator was appointed in July/August 2013 in Portlaoise Hospital as a result of concerns in relation to the implementation of risk reviews.

Over the last two years the hospital has made significant changes to the managment of incidents and risks. There are now seven quality and safety specialty departments in the hospital including one for obstetrics and gynaecology. Each has a clinical lead and monthly meeting are held driven by the *National Standards for Safer Better Healthcare*[8]. The departmental groups feed into the monthly quality and safety executive meetings.

During 2012, and on foot of concerns expressed by HIQA in relation to the governance arrangements of Portlaoise Hospital, the RDO instructed the Assistant National Director to attend at the hospital for at least two days per week.

In July 2013, the HSE structures changed and the Regional Director of Performance and Integration (RDPI) replaced the RDO.

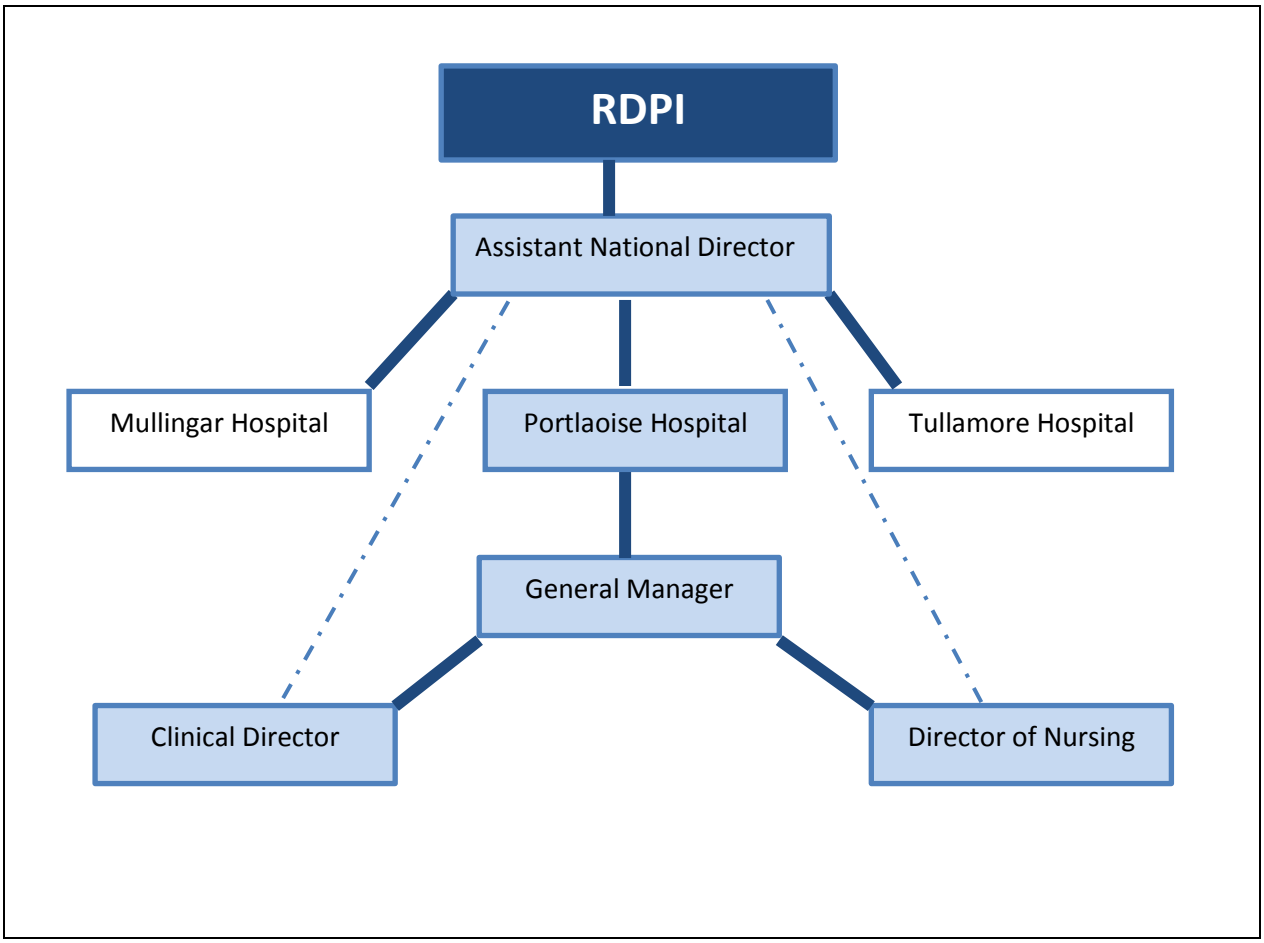
Current governance structure

The current governance arrangements were described by the RDPI as follows. The Hospital Manager has overall operational responsibility for the hospital and, in that respect, both the Clinical Director and Director of Nursing report to her in relation to day-to-day running of the hospital. Together the Hospital Manager, Clinical Director and Director of Nursing comprise the hospital management team and report to the Assistant National Director both collectively as the management team, as well as individually with regards to their respective roles. The Clinical Director has responsiblity for all medical

[8] http://www.hiqa.ie/publications/national-standards-safer-better-healthcare

matters and the Director of Nursing for all nursing matters. The Assistant National Director reports to the RDPI.

Figure 3.1 Portlaoise Hospital governance structure



The HSE Quality and Patient Safety Directorate is developing a clinical governance framework and a series of resource documents. The RDO nominated five hospitals to work with the resources. Each hospital established a multidisciplinary project team led by the clinical director, with a local project manager and agreed terms of reference. Each team used the resources to undertake a gap analysis; the findings of which helped them prioritise and plan quality improvement actions to strengthen quality and safety structures and processes. Portlaoise Hospital became a pilot site in September 2013.

3.2 Portlaoise Hospital Maternity Services

Portlaoise Hospital is a 200-bed hospital servicing the catchment areas of Laois, Offaly, Kildare, Carlow and Tipperary with in-patient, day cases, emergency and outpatient services. The obstetric and gynaecology service is a consultant-led service which has delivered 17,025 births since 2006.

The obstetric and gynaecology department consists of a 30 bed in-patient ward, three room assessment unit, three labour rooms and a nine-bed special care baby unit. The hospital maintains a five day 9am-5pm obstetric and gynaecology emergency department including an early pregnancy assessment unit. Outside of these hours, all attendances are facilitated through a three room assessment unit.

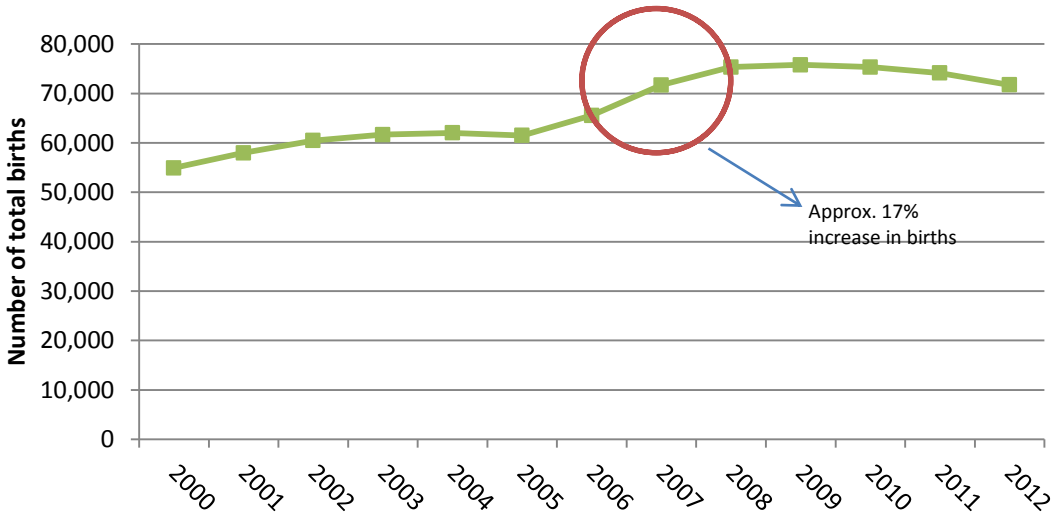
PHMS is not a training location for midwifery nor is it recognised as a training location by the Institute of Obstetrics and Gynaecology in Ireland for the training of junior doctors.

Section 4 Quantitative findings: Analysis of perinatal data

4.1 Births

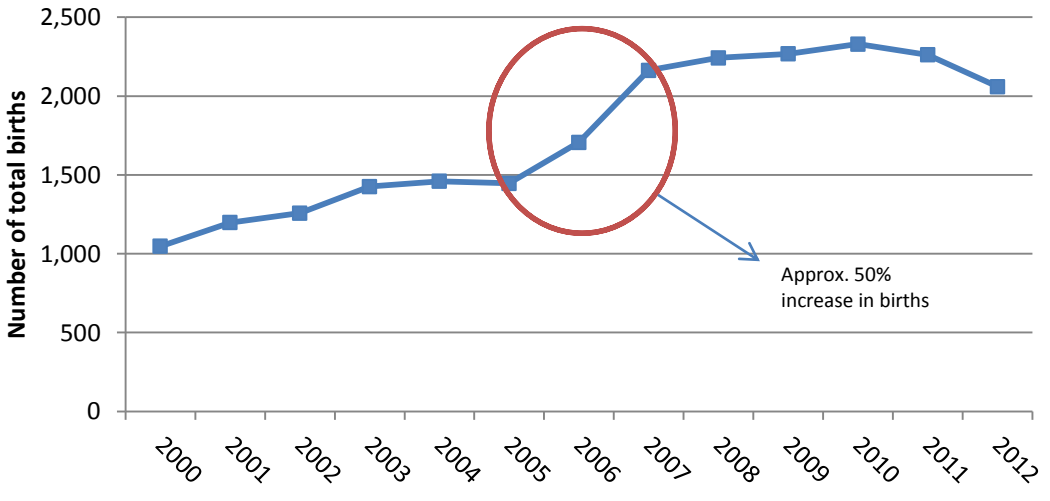
From 2000 to 2012, there was been a significant increase in national births of approximately 30%. The rate of increase was greatest from 2005 to 2007 (Figure 4.1).

Figure 4.1 Number of total births, Ireland 2000-2012



In comparison to national figures, from 2000 to 2012, PHMS, shows a much greater increase in births of almost 100% (1,047 births in 2000 compared with 2,059 births in 2012). In addition, from 2005 to 2007 there was approximately a 50% increase in PHMS compared to a 17% increase nationally in the same time period (Figure 4.2). In the seven years to 2007, the number of births in PHMS doubled. Births in PHMS have remained at this level ever since.

Figure 4.2 Number of total births PHMS 2000-2012



4.2 Perinatal deaths

Perinatal mortality statistics are complex and reporting on these rates is hampered by different definitions of stillbirth both nationally and internationally. In Ireland, four different agencies are involved in the compilation and reporting of perinatal mortality data. This results in discrepancies in reported rates of perinatal mortality and needs to be addressed. It was surprising the degree of complexity involved in ascertaining the numbers and underlying processes used to generate a perinatal mortality rate. The sections below set out the current situation and offer suggestions as to how these issues can be improved. This examination was of a complex nature and required several days of analysis by a public health specialist and statistician.

The four agencies that are involved in the collecting and reporting on perinatal data are the General Register Office (GRO), the National Perinatal Reporting System (NPRS), the National Perinatal Epidemiology Centre (NPEC)[9] and the Central Statistics Office (CSO).

NPRS	NPEC	GRO	CSO
•The National Perinatal Reporting System (NPRS) has the principal aim of the provision of national statistics on perinatal events including birth rate and perinatal mortality. All maternity hospitals/departments and independent midwives report to the NPRS.	•This centre was established after the findings of the Lourdes Hospital Inquiry Report •Collects from 19 maternity units, evaluates and publishes perinatal mortality and severe maternal morbidity data on an annual basis.	•The General Register Office is the central civil repository for records relating to births, stillbirths, deaths, marriages, civil partnerships and adoptions in Ireland.	•Vital statistics releases and publications are prepared on behalf of the Minister for Social Protection in accordance with the provision of section 2 of the Vital Statistics and Births, Deaths and Marriages, Registration Act 1952 and Section 73 of the Civil Registration Act 2004.

There are two components to the process of legal documentation of a birth, as follows:

1. The notification of the birth and
2. The registration of the birth.

Notification Process

All births, both live and stillbirth **(which is defined by the Civil Registration Act 2004 as weighing not less than 500g or has a gestational age of not less than 24 weeks and shows no sign of life)** should be notified using the quadruplicate birth notification form (Form BNF/01) that is usually completed with the parent(s) by hospital staff (in the case of hospital births) or by a doctor or midwife (in domiciliary births). The relevant copy of the form is sent to:

White Copy:	the Registrar of Births (GRO), as soon after birth as possible
Yellow Copy:	the local director of Public Health and Medicine
Green Copy:	the National Perinatal Reporting System (NPRS), from day eight after birth.
Pink Copy:	for hospital's own record.

On this form, details of type of birth (live, still) are recorded. This means that the Registrar of Births (General Register Office – GRO) and the NPRS should both receive the same details on numbers of live and stillbirths (as per the definition above) that took place. The NPEC collect data from the 19 maternity units specifically on perinatal mortality using their own bespoke online form. The CSO do not collect their own data but simply report on the registered birth and death information they receive

[9] This centre was established after the findings of the Lourdes Hospital Inquiry Report (http://www.dohc.ie/publications/pdf/lourdes.pdf?direct=10).

from the GRO. This multiple process of collection and reporting of perinatal data adds to the workload for maternity units and is an additional strain on current scarce health service resources.

Registration Process

The GRO receives the white copy of the birth notification form to indicate births that will require registration. As this white copy is completed and sent to the GRO soon after the birth, details of later neonatal death may not be recorded on the notification form at that time.

The completion of a Birth Notification Form is NOT sufficient to register a birth or stillbirth and the parent(s) or other qualified informant must attend the registrar's office in person to complete the registration process.

Collection and reporting definitions

The definition of stillbirth for collection of data is defined as weighing 500 grams or more or a gestational age of 24 weeks or more. This definition originated in the Stillbirth Registration Act 1994 and still applies today as per the Civil Registration Act 2004.

In terms of reporting, the NPRS only report on stillbirths having a weight of 500g and greater, which is in line with World Health Organization (WHO) recommendations[10]. The CSO and NPEC (since 2011) both report on the broader definition of 500g and greater or a gestational age of 24 weeks or more. In addition, the NPRS and NPEC report on notified stillbirths whereas the CSO report on registered stillbirths.

Legal requirements of notification and registration

The Civil Registration Act 2004 also states that all live births and stillbirths must be *notified* to the GRO as soon as is practical after a birth has occurred. While it is mandatory to notify the GRO of a stillbirth, it is not mandatory to *register* a stillbirth. While the legislation allows for the registration of the stillbirth within 12 months, if the registration does not take place within this timeframe, the GRO *may* request the medical practitioner or hospital to complete the registration process. However, in practice this does not occur due to the understandable sensitivity surrounding stillbirths.

The Act does not require notification of an early neonatal death (*a death that occurs up to and including day seven after birth*). However it is mandatory to *register* all deaths and this would include early neonatal deaths.

Historically Part 3 of this quadruplicate form is also to be returned to the NPRS after day eight of birth so that any data on an early neonatal death can also be recorded on the returned part 3. The NPRS in turn validates the information returned from the maternity units/healthcare professional; however, there is no legal basis in the Civil Registration Act 2004 to notify the NPRS specifically. Table 4.1 summarises the processes of data collection and reporting that the four agencies use for perinatal mortality statistics. The difference in returns of birth notifications to the GRO and the NPRS is discussed further below (Figure 4.3).

[10] http://whqlibdoc.who.int/publications/2006/9241563206_eng.pdf

Table 4.1 Summary of perinatal data collection and reporting processes

Agency	Collects data	Reports on data	Mandatory status	Manages notified data	Manages registered data
GRO Stillbirths	Yes. Through form 1 of the Birth Notification Form (to be returned as soon as practical after a birth takes place).	No.	Yes. For notification of births and stillbirths.	Yes. Collects birth notifications through form 1 of the Birth Notification Form.	Yes. Collects stillbirth registration data.
GRO Neonatal Death	No.	No.	Yes. For registration of deaths.	No.	Yes. Death registration process.
NPRS Stillbirths	Yes. Through form 3 of the Birth Notification Form (to be returned from the eighth day of birth).	Yes. Using data from form 3 of the Birth Notification Form (to be returned from the eighth day of birth).	No. However, historically the return of form 3 of the Birth Notification Form has always occurred and the returns are validated by the NPRS.	Yes. Collects birth notifications through form 3 of the Birth Notification Form which has information on stillbirths.	No.
NPRS Neonatal Death	Yes. Through form 3 of the Birth Notification Form (to be returned from the eighth day of birth).	Yes. Using data from form 3 of the Birth Notification Form (to be returned from the eighth day of birth).	No. However, historically the return of form 3 of the Birth Notification Form has always occurred and the returns are validated by the NPRS.	Yes. Collects birth notifications through form 3 of the Birth Notification Form which has information on early neonatal deaths.	No.
NPEC Stillbirths	Yes. Through their bespoke online Perinatal Death notification form.	Yes. Using data collected from their bespoke online Perinatal Death notification form.	No. The information returned to the NPEC from the maternity units is voluntary.	Yes. Using data collected from their bespoke online Perinatal Death notification form.	No.
NPEC Neonatal Death	Yes. Through their bespoke online Perinatal Death notification form.	Yes. Using data collected from their bespoke online Perinatal Death notification form.	No. The information returned to the NPEC from the maternity units is voluntary.	Yes. Using data collected from their bespoke online Perinatal Death notification form.	No.
CSO Stillbirths	No.	Yes. Using stillbirth registration data received from the GRO.	Not applicable as the CSO do not collect primary data.	No.	Yes. Reports on registered stillbirths.
CSO Neonatal Death	No.	Yes. Using death registration data received from the GRO.	Not applicable as the CSO do not collect primary data.	No.	Yes. Reports on registered deaths.

Finding/Assessment

When examining the details of the following Tables, it is important to bear in mind the complexities in perinatal mortality data, as outlined above. In the following section, perinatal mortality numbers for Portlaoise Hospital and nationally are presented.

In Table 4.2 using the definition "Stillbirths weighing >=500g or gestational age >= 24 weeks plus early neonatal deaths", numbers of perinatal deaths derived directly from Portlaoise Hospital records for the purposes of this Report, show a slight under recording of cases in the hospital records for some years. However, the NPRS notified cases (data that was received from returns by PHMS to the NPRS) show slightly more perinatal death notifications for some years than were reported by the hospital. The NPEC used the above definition in 2011 onwards and show the same numbers of perinatal deaths as direct data from Portlaoise Hospital in 2011 and 2012.

Table 4.2 Perinatal mortality (Stillbirths weighing >=500 g or gestational age >= 24 weeks plus early neonatal deaths) numbers, Portlaoise Hospital 2006-2012 by source of data

	2006	2007	2008	2009	2010	2011	2012
Portlaoise Direct	10	12	13	17	8*	12*	7
NPRS	11	16	14	17	9	13	7
NPEC#	-	-	-	-	-	12	7

*Unable to classify 1 perinatal death in each of 2010 and 2011 from hospital data received therefore not included in the first row of the Table

#NPEC used this definition of stillbirth from 2011 onwards

If perinatal mortality is defined as stillbirths weighing >500g only (as recommended by the WHO for reporting purposes) plus early neonatal death, Table 4.3 shows a variation in cases classified as perinatal deaths compared with Table 4.2. The different definition has an effect on the numbers that are recorded as perinatal deaths.

Table 4.3 Perinatal mortality (Stillbirths weighing >=500 g plus early neonatal deaths) numbers, Portlaoise Hospital 2006-2012 by source of data

	2006	2007	2008	2009	2010	2011	2012
Portlaoise Direct	10	10	12	16	8	11*	5
NPRS	11	16	13	16	8	13	6
NPEC#	-	-	9	16	8	-	-

*Unable to classify three perinatal deaths for 2011 from hospital data received due to no weight recorded, therefore, not included in the first row of the Table

#NPEC used this definition of stillbirth from 2008 to 2010

Table 4.4 National perinatal deaths^ 2006-2012 by source of data

	2006	2007	2008	2009	2010	2011	2012
NPRS	493	557	565	572	550	493	458
NPEC	-	-	-	-	-	456	444
GRO* and CSO combined	515	560	624	587	574	542	N/A

^(Stillbirths weighing >=500g or gestational age >= 24 weeks plus early neonatal deaths)

*Data for GRO refer to stillbirth notifications and for CSO refer to registered neonatal deaths

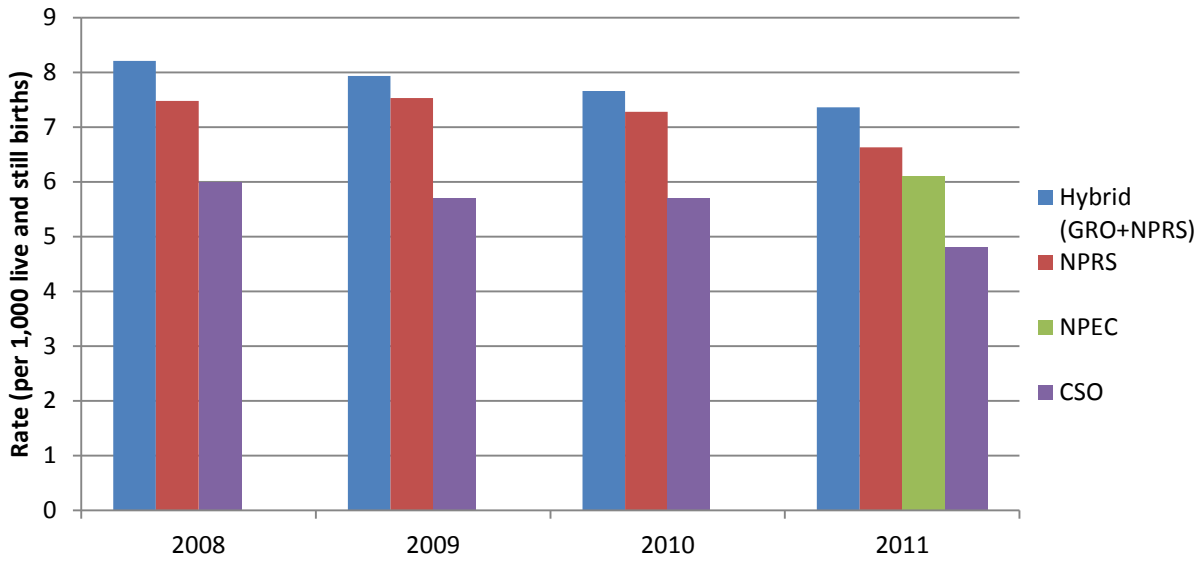
N/A: Not available

Turning to the national situation, there are variations in the number of perinatal deaths collected as shown in Table 4.4. These variations depend on several factors including the agencies from which the numbers are derived:

- The NPRS - data derived from the non-mandatory part of the Birth Notification Form that is returned after day eight which should include any details of a stillbirth or an early neonatal death
- The NPEC - data derived from the non-mandatory bespoke online Perinatal Mortality notification form and provided by the maternity units on a voluntary basis
- The GRO and CSO - mandatory Birth Notification Form 1 and mandatory death registration data.

The following graph (Figure 4.3) displays the perinatal mortality rate using notified data from the NPRS, NPEC and registered data from the CSO. The graph also shows a hybrid perinatal mortality rate which would be calculated if one was to use GRO notified birth notification data for stillbirths in conjunction with the numbers of neonatal deaths notified to the NPRS through the non-mandatory part of the Birth Notification Form.

Figure 4.3 National perinatal mortality rate (stillbirths plus early neonatal deaths) 2008-2011



Note: Stillbirths in this graph refer to those weighing 500g or more or at a gestational age of 24 weeks or greater.

A hybrid rate was generated for the purposes of this Report to show that the GRO receive a higher number of stillbirth notifications than the NPRS. The reverse seems to be the case for early neonatal deaths with NPRS receiving more early neonatal death notifications than are registered with the GRO. The hybrid rate shows that the current perinatal mortality rate calculated to date may be an underestimate of the true value of perinatal mortality in Ireland.

Table 4.5 below shows the formulae used in the various calculations of perinatal mortality rates that currently exist (1-3) and a hybrid calculation (4).

Table 4.5 Calculation methods for perinatal mortality rate

1. **NPRS** 1000 x (non-mandatory notified stillbirths + non-mandatory notified early neonatal deaths) / Number of non-mandatory notified live births and stillbirths
2. **NPEC** 1000 x (non-mandatory notified stillbirths + non-mandatory notified early neonatal deaths) / Number of non-mandatory notified live births and stillbirths
3. **CSO** 1000 x (registered stillbirths + registered early neonatal deaths) / Number of registered live births and stillbirths
4. **Hybrid** 1000 x (mandatory notified stillbirths + non-mandatory notified early neonatal deaths) / (Number of registered live births + mandatory notified stillbirths)

As seen in Figure 4.4, there are differences in the numbers of stillbirths collected by the NPRS and GRO, even though data used by the NPRS and GRO come from the same Birth Notification Form. There are more stillbirths notified to the GRO than the NPRS. The non-mandatory nature of birth notification to the NPRS may have a bearing on the reduced numbers of stillbirths notified to the NPRS compared with the numbers notified to the GRO. It may also reflect on administrative errors with the return of the Birth Notification Form to the correct agencies.

In addition, the numbers of early neonatal deaths recorded by the two agencies also shows a difference. The NPRS show slightly higher reports of early neonatal deaths (even though the return of this data is non-mandatory) than the GRO which keep registered data on early neonatal deaths. This shows under-*registration* of early neonatal death. This difference is also illustrated in Figure 4.5.

Figure 4.4 The number of stillbirths and early neonatal deaths notified to the GRO and NPRS, 2006-2011

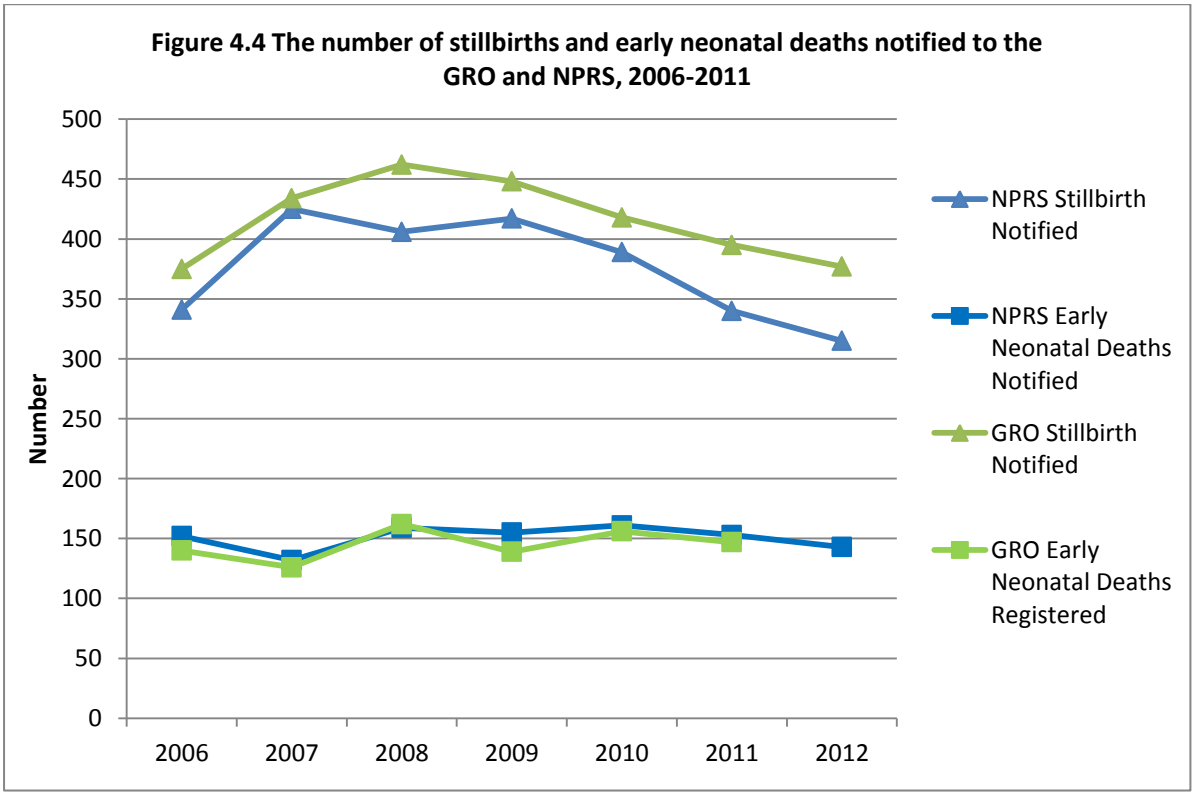
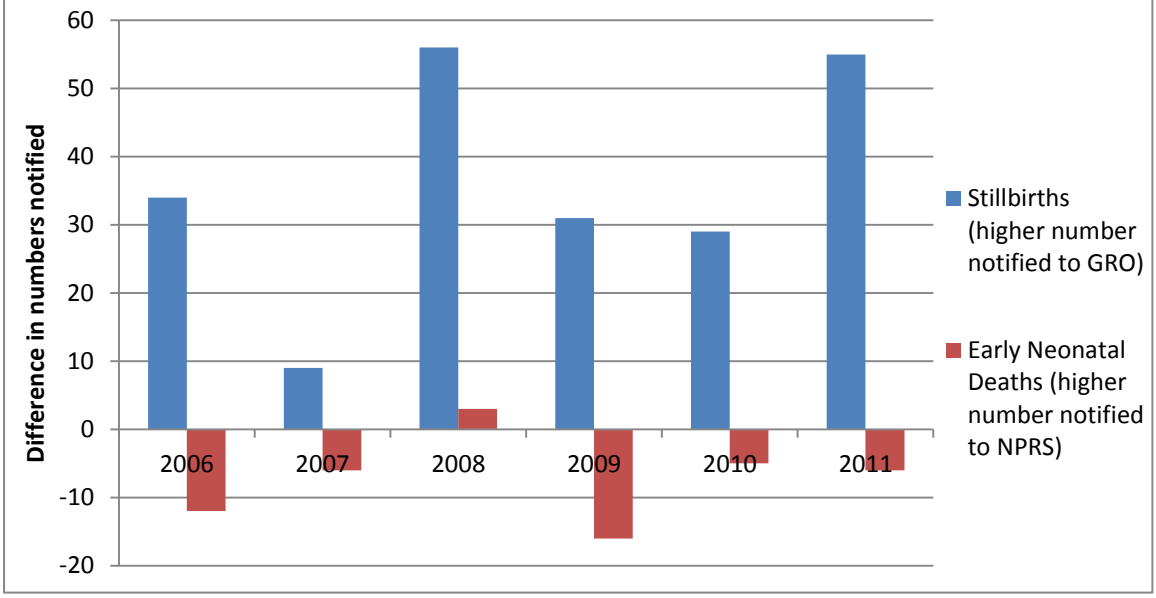
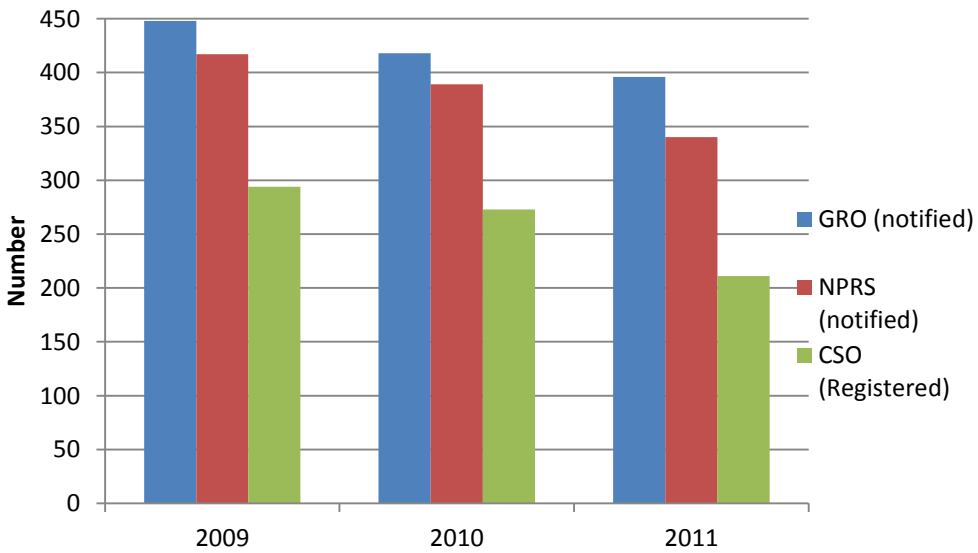


Figure 4.5 Difference between stillbirths and early neonatal deaths notified to the GRO and NPRS, 2006-2011



The mandatory GRO notified numbers of stillbirths are higher than the non-mandatory notified NPRS stillbirth numbers which are in turn higher than the CSO reported registered numbers. This is illustrated in Figure 4.6.

Figure 4.6 Number of stillbirths notified to the GRO and NPRS, and the numbers registered and reported by the CSO, 2009-2011



Note: Stillbirths in this graph refer to those weighing 500g or more or at a gestational age of 24 weeks or greater.

Taking into consideration the complexities of different definitions, the impact of mandatory notification and the issue of under-registration of stillbirths and neonatal deaths, a common perinatal mortality rate calculation is proposed. The recommended Official National Perinatal Mortality Rate Calculation based on the findings of this review should be as follows;

$$\frac{1000 \text{ X (mandatory notified stillbirths + mandatory notified early neonatal deaths)}}{\text{(Number of registered live births + mandatory notified stillbirths)}}$$

This analysis shows that there are weaknesses and inconsistencies in perinatal data collection, collation and reporting. This gives rise to inaccuracies and also to inconsistencies in the data reported – depending on the source used. The aim of the recommendations in this Report is to facilitate the presentation of the most accurate and consistent reflection of perinatal mortality in Ireland. The current disparate nature of reporting of perinatal data in Ireland leads to confusion, adds to the workload for maternity units and is an additional strain on current scarce health service resources. There is, therefore, a considerable case to be made for the consolidation of these systems to avoid the duplication and occasional confusion that arises at present.

Recommendation 1:

The Department of Health should work with the Department of Social Protection to ensure that all official perinatal mortality rates should be calculated using a common definition.

Responsibility:	Department of Health and Department of Social Protection
Timeframe:	Common definition in use by 2015

The recommended Official National Perinatal Mortality Rate Calculation based on the findings of this review should be as follows:

> 1000 x (mandatory notified stillbirths + mandatory notified early neonatal deaths) / (Number of registered live births + mandatory notified stillbirths).

It should be noted that stillbirths in this calculation refer to those weighing 500g or more or at a gestational age of 24 weeks or greater.

The Department of Health should engage with the Department of Social Protection to make them aware of this Report and of the implication of the findings in the context of the provisions of the Civil Registration Act 2004. The new calculation will require mandatory notification of early neonatal deaths. This should also allow for a review of the current definition of stillbirth in the Civil Registration Act 2004. Any change can be made by way of amendment to the Civil Registration Act 2004 along with the proposed change to the notification of early neonatal death as detailed in Recommendation 2.

Recommendation 2:

The Civil Registration Act 2004 should be amended to include a duty to notify early neonatal death to the General Register Office.

Responsibility:	Department of Health and Department of Social Protection
Timeframe:	Commence formal engagement between Departments immediately

There appears to be under registration of early neonatal deaths. An amendment to the Civil Registration Act 2004 to require notification of early neonatal death would ensure the capture of this information. The Department of Health should engage with the Department of Social Protection to make them aware of this Report and of the implication of the findings in the context of the provisions of the Civil Registration Act 2004.

Recommendation 3:	
The General Register Office should ensure that all notified early neonatal deaths are registered.	
Responsibility:	General Register Office
Timeframe:	End Quarter 1, 2014
There are differences in the numbers of stillbirths collected by the NPRS and GRO, even though data used by the NPRS and GRO come from the same Birth Notification Form. There are more stillbirths notified to the GRO than the NPRS. The non-mandatory nature of birth notification to the NPRS may have a bearing on the reduced numbers of stillbirths notified to the NPRS compared with the numbers notified to the GRO. It also may reflect on administrative errors with the return of the Birth Notification Form to the correct agencies. In addition, the numbers of early neonatal deaths recorded by the two agencies also shows a difference. The NPRS show slightly higher reports of early neonatal deaths (even though the return of this data is non-mandatory) than the GRO which keep registered data on early neonatal deaths. This shows under-registration of early neonatal death.	

The opportunity should be taken for rationalisation of current, various data collection streams to a single point. Data should be collected once and used several times. This can be achieved by the development of electronic transmission of the Birth Notification Form used for the reporting of perinatal events. Paper transmission of the Birth Notification Form should be phased out.

Recommendation 4:	
The HSE should ensure that the NPRS and NPEC are consolidated to create a single national reporting system for official statistics on perinatal events in Ireland.	
Responsibility:	HSE
Timeframe:	End Quarter 4, 2014
There is a multiplicity of recording and reporting systems in relation to perinatal data creating confusion and represents duplication and a waste of limited resources. In particular, the continued operation of the NPRS and the NPEC, both with HSE funding, should be addressed. In order to consolidate them, a review of the functions of each, and a plan based on that review, to have one single amended system should be undertaken.	

4.3 'Never events'

The term 'never event' was first introduced in 2001 by Ken Kizer, MD, Former CEO of the US National Quality Forum.[11] It particularly refers to concerning medical errors (such as wrong-site surgery) that should never occur. Over time, this list has been extended to include significant adverse events that are clearly identifiable, serious (resulting in death or significant disability) and usually preventable.

This Report is recommending that perinatal death or serious injury of a neonate associated with labour or delivery in a low-risk pregnancy and maternal death are listed as perinatal 'never events' for Ireland. See Recommendation 21.

[11] http://psnet.ahrq.gov/primer.aspx?primerID=3

If these definitions of perinatal 'never events' in addition to a definition of a surgical 'never event'[12] were in place in PHMS from the period 2006-2013 six such events would have occurred (Table 4.6).

Table 4.6 PHMS 'never events' (Source Portlaoise Hospital)

	2006	2007	2008	2009	2010	2011	2012	2013
Neonatal deaths low-risk pregnancy	1		1	1			1	
Unintended retention of a foreign object						2		

'Never events' are by their nature sufficiently serious and uncommon that they should immediately raise a flag for an organisation to examine the circumstances leading up the event and to take immediate actions as required. PHMS did not appear to have such processes in place. No reassurance can be derived from summary statistics such as perinatal mortality rates in circumstances where there are 'never events' are taking place.

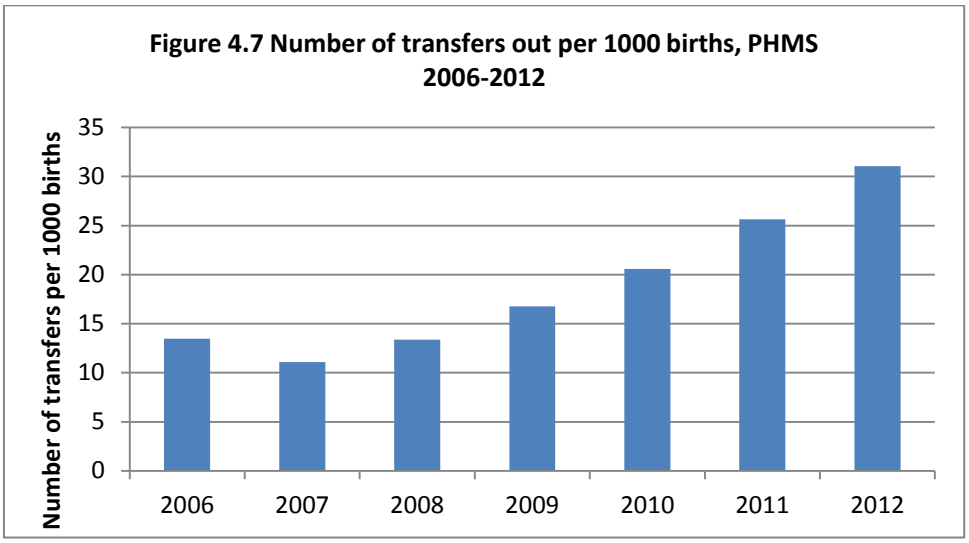
4.4 Perinatal and maternal transfers

Table 4.7 shows data made available by Portlaoise Hospital on the number of transfers from PHMS out to other centres in the early neonatal period. We adjusted the total number to create a rate per 1,000 births in the unit and this is shown in Figure 4.7. It shows an almost three-fold increase in transfer rate out of PHMS over the time period in question. We believe that the hospital was unaware of these trends until we shared our analysis of their data with them. The manner in which these data were recorded and initially presented to us meant that we could not determine the reason for transfer, time frame for transfer, whether it was a neonatal or maternal transfer or whether the transfer was direct from the labour ward or of the neonate from the Special Care Baby Unit (SCBU).

Table 4.7 Transfer rate out of PHMS per 1000 births, 2006 to 2012

Year	2006	2007	2008	2009	2010	2011	2012
Transfer rate per 1000 births, PHMS	13.46	11.08	13.38	16.76	20.58	25.64	31.07

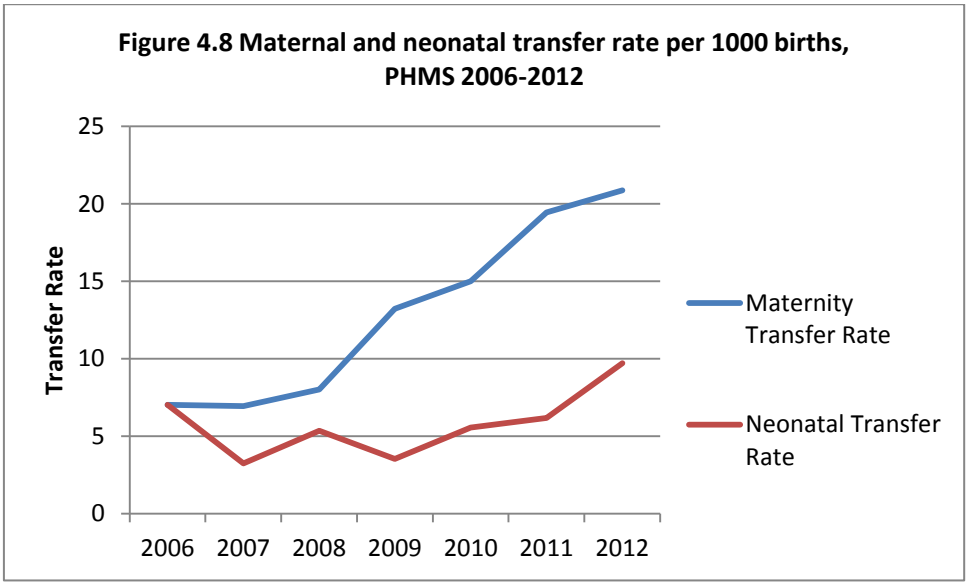
[12] 'Unintended retention of a foreign object in a patient after surgery or other procedure'



Once Portlaoise Hospital was asked for its perinatal transfer rate they provided other data detailing types of transfer. Table 4.8 and Figure 4.8 show that both the rate of maternal and neonatal transfer rate increased from 2009. While this Report does not investigate the exact reasons for this increase in transfer rate the fact that data on changing maternity unit activity was easily available and had not been examined by the Portlaoise Hospital is an important observation. The data in itself does not provide any answers but raises questions that should have been followed up.

Table 4.8 PHMS transfers out 2006-2013 (Source Portlaoise Hospital)

	2006	2007	2008	2009	2010	2011	2012	2013
SCBU	12	7	12	8	13	14	20	19
Maternity	12	15	18	30	35	44	43	38
Total	24	22	30	38	48	58	63	57

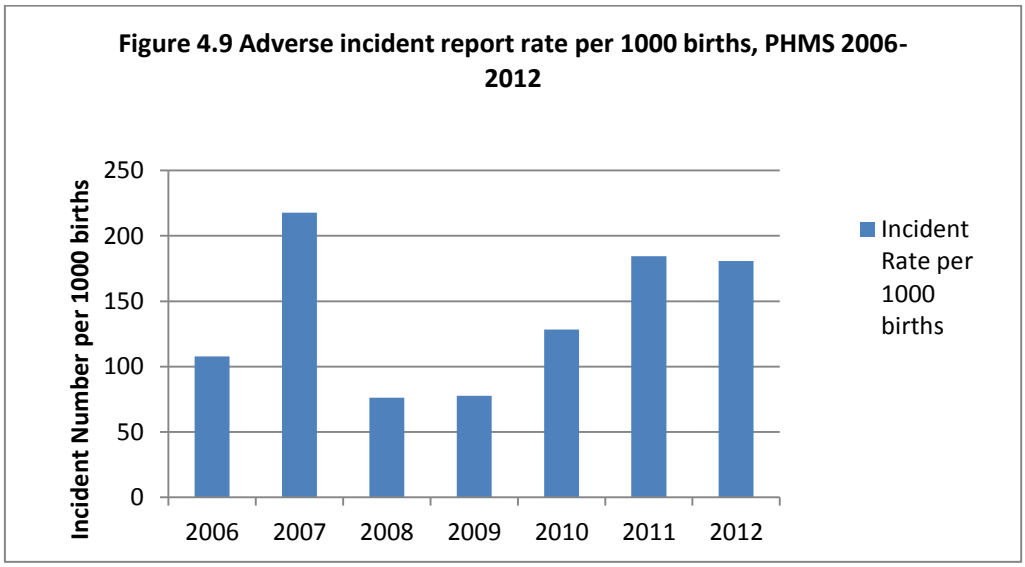


4.5 Adverse incident report forms

Approximately 2,380 incident report forms 2006 to date were made available by PHMS. There was significant variabilty in quality and completeness of the incident report forms. In addition, the severity of incident varied from a fall/slip to missing documentation to serious clinical incidents. Examination of adverse incident reporting rate per 1000 births shows that there is a persistant rise in obstetric incidents reported by PHMS over the years 2006 to 2012 (Figure 4.9). In 2007, there was a very high overall number which appears to be contributed to by multiple notifications of individual events, specifically staffing level concerns among midwives.

These reports are sent off-site to the regional risk office for collation. There was no indication that regular trend reports are run in order that the PHMS can track its trends and make changes or take remedial actions as required.

Figure 4.9 Adverse incident report rate per 1000 births, PHMS 2006-2012



4.6 Obstetric claims

The Clinical Indemnity Scheme (CIS), which is operated by the State Claims Agency (SCA), was established in 2002 in order to rationalise pre-existing medical indemnity arrangements by transferring to the State, via the HSE, hospitals and other healthcare agencies, responsibility for managing clinical negligence claims and associated risks. Under the CIS, the State assumes full responsibility for the indemnification and management of all clinical negligence claims, including those which are birth-related. Claims made under the scheme are managed by the team of clinical claims managers within the Agency. The SCA's 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.

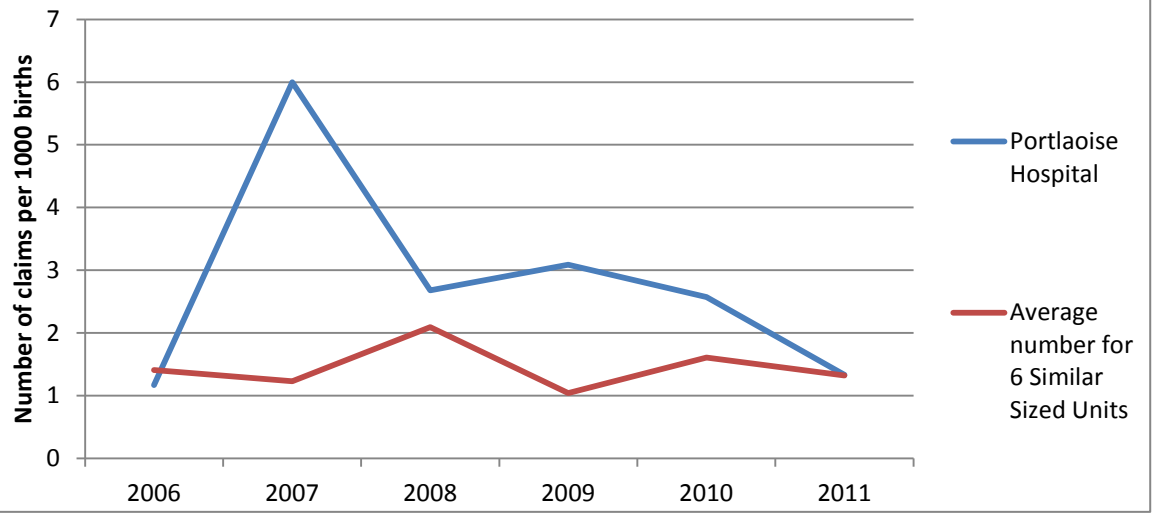
The SCA provided reports which were run to record all claims relating to 4 specific neonatal categories, reported to the National Adverse Event Reporting System (NAEMS) as having occurred during the period Jan 1st 2006-December 31st 2013. The categories examined were:

- Neonatal death
- Stillbirth
- Cerebral Irritability
- Apgar <5 @1 etc.

The specialty of Obstetrics consistently accounts for approximately 25% of claims and almost 60% of cost of claims managed by the SCA.

On examination of the perinatal claims made from Portlaoise Hospital to the SCA and compared with the average number of claims per year of six similarly sized maternity units, it can be seen that there was a sharp increase in the number of claims made in 2007 (Figure 4.10.). Of note, this coincides with the sharp increase in births that occurred in Portlaoise Hospital in the same time period as seen in Figure 4.2.

Figure 4.10 Number of claims to the State Claims Agency per 1000 births PHMS and 6 similar sized units, 2006-2011



4.7 Conclusions

The data in this section, had it been collated and examined, could have shown that there was good reason to suspect that there may have been an on-going problem with outcomes of care experienced by people using the service in PHMS i.e.:

- Birth rates had risen very quickly over a short period
- There were a number of what would now be defined as 'never events'
- A number of other serious adverse events occurred
- There was a rise in notifications of adverse incidents
- There was a significant increase in transfers out of PHMS for both maternity and paediatric care to other centres
- There was a higher than expected rate of obstetric claims.

All this simple data was available throughout the period in question. It does not require significant time or effort to collate it. It is clear that local hospital analysis of this kind of data was not happening on a regular basis. While there was awareness that the service was under pressure, there does not appear to be any evidence that monitoring of how this might have been impacting on patient care was taking place. Using the available data on an ongoing basis is a straightforward and useful way for maternity units to monitor trends, so areas of possible concern for the service can be identified early and actions taken as required.

Section 5 Qualitative findings: Analysis of discussion, reports and written material

In the course of the work undertaken, a number of issues and themes emerged. In this section, these issues are considered, findings or assessments are set out and recommendations made.

5.1 Theme One: Patient-Centredness

5.1.1 Culture at PHMS

The term "culture" in the context of patient safety has a specific meaning. It can be defined as follows: *The patient safety culture of an organisation is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management.*

A culture of quality and of safe care is one in which there is open, kind, transparent and sensitive care, effective team communications and a commitment to prevention of harm. A positive patient safety culture is focused on enhancing every aspect of the experience of a patient. It should be borne in mind that it is well established in evidence that culture and behaviour are critical components of safe and effective care.

In the preparation of this Report a number of issues of concern emerged through meetings with families and others. There were clear descriptions where patients felt backs were being turned; honest accounts were not given; and unprofessional behaviours and language were frequent. Insensitivity and a lack of empathy were common themes. Younger patients were not so much spoken to directly as through their mothers and had the feeling of being "judged" by staff. There were even accounts of senior clinical staff (more than one) inviting families to "sue". There was also a lack of cultural sensitivity. These accounts were not just applicable to the PHMS but also to the paediatric unit.

The specific descriptions provided of the care in the immediate aftermath of perinatal deaths added to the distress rather than support of the families. These accounts were powerful, clear and consistent. While we cannot say that they in fact typify the experience patients have in PHMS, they indicate a culture which is not consistent with good patient safety outcomes.

These personal accounts from the families were consistent with findings that are set out in PHMS's own investigation reports where issues of clinical handover, supervision, clinical leadership and the effectiveness of escalation procedures were consistently raised.

When these facts are considered with the unacceptable instances of non-disclosure of harm or of investigations being conducted into harm, an overall concern about the culture of care in the hospital must be raised. We met with Portlaoise Hospital on three occasions. We did not hear enough to satisfy us that this concern should not be raised in the Report. In fact, some of the interactions have added to the concern we have about the extent to which the culture has really changed as a result of the lessons derived from the learning from previous adverse event reports.

Recommendation 5:	
An assessment of the patient safety culture in Portlaoise Hospital should be conducted by HIQA.	
Responsibility:	HIQA
Timeframe:	End Quarter 2, 2014
While the focus of this Report is PHMS only, assurance is needed with regard to the patient safety cultural factors in the other services in the hospital. It is recognised that the HSE Quality and Patient Safety Directorate has done considerable work in this area. There are a number of tools in use internationally that allow detailed assessment to be made of the patient safety culture of a hospital to be undertaken and to inform the necessary remediation which can take the form of training, teambuilding, improved policies and procedures and on-going measurement and assurance of improvements in culture and behaviour. (See Section 6, Overall Recommendation O.R.2)	

Recommendation 6:	
HIQA should be requested 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.	
Responsibility:	HIQA
Timeframe:	End Quarter 4, 2014
A standard national patient safety culture and team-working assessment tool which can be utilised across the system will provide for local and national patient safety culture information. This will ensure that all hospitals and health service providers regularly measure and trend their culture allowing for planning of any necessary remediation. HIQA will ensure its implementation through its monitoring of the *Standards for Safer Better Health Care*.	

5.1.2 Dealing with a perinatal death

The immediate aftermath of a perinatal death is the only time that parents will have with their child. There may be little that staff can say or do that will help to reduce their trauma and sense of acute pain at the loss of their child. However, insensitive words and actions can make the trauma much worse.

Recognition of the emotions and issues that arise for families in these circumstances in general is much greater than in the past and there are a number of organisations, particularly the A Little Lifetime Foundation (formerly Irish Sudden Infant and Neonatal Death Society (ISANDS)), who provide practical and sensitive advice.

Meetings with a number of the families provided an opportunity to explore in detail the care of the recently deceased baby. It was clear that inadequate facilities and equipment added to the trauma. It is also apparent that there was no procedure or protocol to guide staff in their dealings and interactions with bereaved families. Mothers were not necessarily accommodated away from other mothers who had delivered babies; practices with regard to handling, holding, dressing, bathing, and photographing their infants were at best variable; appropriately sized coffins were not always made available. The transport of infants in the boot of taxis to Tullamore Hospital for post mortem examination was one especially distressing finding. Some of the comments attributed to staff who dealt with the families in these circumstances also added to the distress.

Recommendation 7: **The HSE should conduct a review in PHMS in respect of services for the infant and family following a perinatal death.**	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014
The HSE should undertake a review of services for the infant and family to ensure that facilities, equipment, training and procedures are fit for purpose and consistent with an appropriate external or national standard. This targeted review should identify any gaps and arrange for remedial action to be taken as necessary. It is recommended that A Little Lifetime Foundation (formerly ISANDS) provide advice and support for the review and subsequent actions.	

Following a perinatal death, autopsy examination can provide answers to important questions that families have. Access to a speedy service and diagnosis provided in a sensitive manner are each important in helping families to deal with the loss.

It also appears that further familial distress resulted from delays that occurred in accessing neonatal pathology services when they were required. Portlaoise Hospital indicated that the majority of such services are provided by two retired neonatal pathologists from Dublin. Another contributing factor is the fact that such post mortem examinations are not carried out in Portlaoise which necessitates transport of the infant to and from the pathology department in Tullamore Hospital.

It is recognised that PHMS is too small to require an in-house neonatal pathology service. It does, however, require timely and reliable access to such a service. Families anguish will be increased unnecessarily if absences or delays in such a service occur.

Recommendation 8: **The HSE should conduct a review of neonatal pathology service requirements and arrangements as they relate to PHMS.**	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014
PHMS neonatal pathology services are not carried out in Portlaoise Hospital which necessitates transport of the infant to and from the pathology department in Tullamore Hospital. It is recognised that PHMS is too small to require an in-house neonatal pathology service. It does, however, require timely and reliable access to such a service. The HSE should undertake a review of this aspect of maternity services to ensure that facilities, equipment, training and procedures are fit for purpose and consistent with an appropriate external or national standard.	

5.1.3 Response to patients and families following serious adverse incidents

A common factor in each of the serious adverse incident reviews is that they were conducted in a less than timely manner, often well after the incident had taken place. There is no evidence from the reports that senior medical and nursing staff responded in such a way as to step up interactions with the families in order to effectively communicate, to explain and to sensitively provide answers to the very real and reasonable concerns and questions that the families had or may have had. The fact that there was also failure to disclose the harms appropriately, or at all, is further evidence that the culture in the hospital was not one which leads to the right people stepping in and stepping up at the right times. These inferences that can be reasonably taken from the investigation reports are entirely consistent with the direct accounts of care that were received from the families concerned.

Recommendation 9:	
The HSE should ensure that systems are in place in order that a senior consultant and a senior nurse/midwife take responsibility for dealing with serious adverse events when they occur.	
Responsibility:	HSE and Local Hospital Management
Timeframe:	End Quarter 2, 2014
Once an adverse event takes place which results in significant harm to a patient, it is imperative that the service and its most senior personnel see and accept a duty of care to those affected. Patients and families in these circumstances will often be dealing with bereavement, ill-health and the emotional and psychological effects. This may be compounded by the circumstances that may have caused the harm. It is not likely that they will understand or even hear all information delivered in the acute stage and in the initial consultation. A sustained and continuing engagement dictated by the patient's needs and understanding is what is necessary. This should include the establishment of any review process which might be necessary. The words chosen by staff are all-important. This should be led by a senior consultant and a senior nurse/midwife.	

Recommendation 10:	
Training should be provided by the HSE for senior clinical staff in dealing appropriately with patients in the context of serious adverse events.	
Responsibility:	HSE and Local Hospital Management
Timeframe:	End Quarter 2, 2014
The provision of training for senior clinical staff will build their knowledge and competence in the management of serious adverse events and dealing appropriately with patients, families and staff.	

5.1.4 Open disclosure

There were clear and unacceptable failures to disclose to patients either that a serious adverse event had taken place or that reports had been completed into serious adverse incidents in their care. There is clear evidence available to us that information was available to the hospital to show that they knew that adverse events had occurred and that this was withheld from the families concerned. In some cases this led to families believing that other factors, for which they might have had responsibility, explained the deaths of their children. Families blamed themselves for events in which they had no responsibility. They were allowed to go on not knowing even when the hospital had more information.

These are failures in the duty of care of Portlaoise Hospital and the staff charged with the care of the patients. It is a most basic breach of the trust that is so essential to the delivery of good quality patient-centred care.

There are two aspects of open disclosure that arose in preparing this Report. First is the question of disclosure of the fact of harm, potential harm or suspected harm as a result of an adverse event to a patient and/or family. This is an absolute obligation. Second is the question of disclosure of the fact that a person's record/care has been reviewed but where no harm to the patient has arisen, or is likely to arise.

It is recognised that in certain circumstances, reviews of care do not always lead to a finding of an adverse event or harm. In some cases their purpose may not necessarily be a suspicion of harm to that specific patient. Look backs, desk-top reviews, clinical audit, multidisciplinary team reviews all take place, and need to take place, in the delivery of quality and patient-centred care. In this case, disclosure need not take place and in fact might impede participation in necessary quality assurance practices such as clinical audit were it to take place.

However, it is clear from the interviews and examinations undertaken in preparing this Report that there is a widespread confusion as to the intended meaning of these terms and how they are applied, the actual conduct of such reviews of care and in the practice of disclosure to patients.

In relation to the issue of disclosure of the fact that a person's record/care has been reviewed but where no harm to the patient has, or will, arise there is a need to have more consistency of understanding and practice. In many respects, this deepening of understanding should provide more assurance and confidence to healthcare professionals as to their obligations to disclose in such circumstances. In turn, this will enable more, rather than less, audit and quality assurance practices. The forthcoming Health Information Bill will bring more assurance for professionals in relation to disclosure.

The Health Information Bill being prepared by the Department of Health will be designed to foster and support a culture of open disclosure in the health service. In this context, work will also continue between the Department of Health and Department of Justice and Equality to ensure the Bill will be complementary to legislation currently being prepared by the Minister for Justice and Equality.

Recommendation 11: **The HSE National Open Disclosure Policy should be implemented in full.**	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014
The HSE National Open Disclosure Policy, launched by the Minister of Health in November 2013 was reviewed in the context of considering the issues concerning disclosure of adverse events and harm that arose in PHMS in mind to determine if its effective implementation would prevent these failures from occurring. It is clear from this that the National Open Disclosure Policy is a high quality policy which is informed by, and consistent with, best practice on open disclosure of adverse events around the world. It is not yet in place. It has been successfully piloted in two large teaching hospitals. Assurance of compliance should be provided through a Quality and Patient Safety Accountability Framework (Recommendation 18).	

Recommendation 12 **The HSE should develop a national policy on disclosure where no harm arises.**	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014
The process that led to the HSE National Open Disclosure Policy should develop a policy in relation to the requirement, or not, for disclosure of the fact that a person's record/care has been reviewed but where no harm to the patient has or will arise. The purpose of this will be to have more consistency of understanding and practice – in a manner which can maintain the confidence and trust of patients and professionals alike.	

Section 48 of the Health Act, 2004 deals with matters excluded from the right to complain and a number of issues are identified where a person is not entitled to make a complaint. The families of those affected by Portlaoise Hospital perinatal deaths (2006-date) raised a perceived issue regarding the implications of Section 48, Health Act 2004. This issue is in terms of the continuation of investigations by the HSE once legal proceedings have commenced.

Recommendation 13:	
The HSE should issue direction to the system on the appropriate interpretation of Section 48 of the Health Act, 2004.	
Responsibility:	HSE
Timeframe:	End Quarter 1, 2014
Section 48 of the Health Act, 2004 deals with matters excluded from the right to complain and a number of issues are identified where a person is not entitled to make a complaint. The issue is whether following the initiation of legal proceedings by a family following an adverse event the HSE must (a) not commence any new investigation into the event and (b) cease any investigation that is underway into the event.	

5.2 Theme Two: Clinical governance at PHMS

5.2.1 Risk management

Risk management and audit for Portlaoise Hospital are managed off-site at the HSE Regional Health Office (Tullamore). This includes risk management advice, support and co-ordination of incident forms for the hospital. Portlaoise Hospital provided copies of their processes for incidents/near misses, complaints management, open disclosure and details of their risk register.

The evolution of governance processes in Portlaoise Hospital is evident with a number of recent initiatives aiming to strengthen overall hospital governance. These efforts have been supported by the HSE Directorate and are acknowledged as creating the basis for stronger governance foundations for the future. These include, more recently, processes that have been put in place in PHMS such as regular obstetric patient safety meetings and monthly perinatal morbidity and mortality meetings.

Portlaoise Hospital senior management team outlined their on-going dissatisfaction at the regional structural arrangements for risk management and audit in that it is not integrated into their overall hospital governance. They stated that this arrangement hasn't worked for them. They have recently appointed a risk coordinator in the hospital which they believe has improved the hospital's visibility of risks at clinical and senior management level.

The senior management team pointed to the absence of a risk management committee reporting to a Board or senior management which is common in the larger national hospitals. This is a significant gap in terms of having formalised structures and processes in place to examine the risk profile of the hospital and promote organisational learning from reviews of adverse events.

On the other hand there was an apparent over-emphasis on the risk management process when some senior clinical leadership and judgement was needed to ensure that the focus on risk management did not obscure the real safety and quality lessons that were evident in the various adverse event reports.

The lack of on-site expertise and poor tracking and monitoring systems for risk is unhelpful. While systems have been strengthened recently, the overall picture is unsatisfactory and is not likely to be sustainable over time. In particular, the re-establishment of self-confidence and control among the Portlaoise Hospital's senior management team on site without external guidance and support will be very challenging indeed.

There were difficulties in establishing the baseline of adverse event reviews and desktop reviews. Even though copies of all investigations inclusive of desktop reviews in relation to maternity care in addition to specific perinatal deaths were requested additional cases not provided were identified following information from families. This highlights significant weaknesses in the logging and monitoring of adverse events in Portlaoise Hospital. The local-level information made available by PHMS does not portray a picture of safety at hospital level. That represents a real and on-going safety concern.

5.2.2 Adverse incident reporting and investigation

The HSE operates an Incident Management Policy which outlines that all incidents identified should be immediately managed in accordance with this Policy. It is HSE policy that all incidents are identified, reported, communicated and investigated to ensure that the health and safety of those affected is the primary focus of attention and that incidents are acted upon effectively and with an appropriate level of urgency. The policy details that where appropriate, incidents are to be managed and resolved locally and lessons that are applicable nationally should be applied nationally. All hospital managers are obliged to monitor incidents and the management of these incidents in order to allow the HSE as a whole to learn from incidents and continually improve. Where deemed necessary, notification to other statutory agencies and escalation to the National Incident Management Team (NIMT) must take place/be initiated.

A national incident management process is in place to support services in the management of incidents that may require expertise and support beyond that available at a local level. Those incidents that require direct HSE Directorate support are escalated further to NIMT.

Under the National Treasury Management Agency (NTMA) (Amendment) Act 2000, State authorities are obliged to report adverse incidents promptly to the SCA. This allows the SCA, in conjunction with State authorities, to identify and analyse developing trends and patterns and to work with the State authorities concerned to develop and implement risk mitigation strategies.

There is a statutory obligation on the HSE to notify adverse events to the SCA. A national confidential web-based clinical incident reporting system, STARSWeb has been developed and rolled out nationally by the Clinical Indemnity Scheme. This system is designed to capture all clinical adverse events and near-misses occurring in enterprises covered by the scheme. It is currently being upgraded to the National Adverse Event Management System (NAEMS).

It is clear that there are a number of significant challenges with the operation of patient-centred incident and risk reviews as conducted by Portlaoise Hospital in the aftermath of the clinical incidents that were examined for the purposes of this Report.

Time taken to conduct and complete reviews

Table 5.1 shows the time that elapsed before the commencement of a review and the time taken to complete the review. For some reviews this time period is over two years. Delays of this nature deny families answers to critical questions and deny healthcare systems both locally and nationally the opportunity to derive learning and to implement recommendations. The clearly stated aim of each of the reviews conducted by PHMS was undermined by these very significant delays.

Table 5.1 PHMS – completed risk management reports

Risk Management Report	Incident Date	Review commenced	Risk Management Report completed	Family informed
RM065	09/2006	11/2006	06/2007	*
RM062	11/2006	07/2007	06/2009	01/2014
RM087	07/2008	*	08/2011	12/2013
Midwife A Report	11/2006, 10/2009, 01/2010	08/2010	03/2012	Case X - 01/2014 Case Y - 09/2013
NIMP50069	01/2012	03/2012	09/2013	Draft ToR sent to family 03/2012

*Information requested from PHMS but not received

Ten desktop reviews were made available (Table 5.2). Very few had been completed in spite of the passage of time. The quality of the desktop reviews is highly variable and generally poor. No reference numbers were assigned, in a number of cases the date of event was not completed, and the level of detail including 'what happened' and 'information source' varies greatly.

Table 5.2 PHMS – desktop reviews per date of incident (source Portlaoise Hospital)

	2006	2007	2008	2009	2010	2011	2012	2013
Desktop reviews	0	0	0	0	0	3	5	2
Completed reviews	0	0	0	0	0	0	1	1

Variable quality of reviews

When each of the incident reports is reviewed, an obvious variation in their quality is evident. Many state that the London Protocol for incident review is followed. However, there is significant variation in the depth and detail of the recommendations, the composition of the review teams, the specificity and clarity of the recommendations even to the point that it is not clear in some cases what is meant by a recommendation. There are errors in many of the reports in wording, numbering of sections and dates. For example, in one report two recommendations are recorded in the body of the report but do not appear in composite list of recommendations in an appendix and, as a result, are not included in any progress reports. In another report, the chronology of dates is incorrect with the incident recorded as '2006' at one point and '2007' at another point.

This variation in the standard of incident reviews impedes effective implementation of recommendations and learning from the reviews.

Involvement of staff

Many of the reviews included interviews with staff. It is not clear that these interviews were cross referenced with all written records e.g. midwifery records. In a number of cases, statements from families were at variance with review statements. It has been alleged that evidence provided by some members of staff during inquest proceedings was at significant variation with their written and oral input to a given review. While this Report cannot adjudicate on such matters, the suggestion that such a scenario might have taken place should be regarded as a most serious matter by the management of Portlaoise Hospital and the HSE.

It was also noted with concern that investigative processes were delayed by the non-availability of key staff to provide input. This is a very serious matter. There is a duty of care to all patients current and future which is not served by delays in reporting and failure or delays of participation in review processes - the stated purpose of which is to learn lessons that can improve care and protect patients.

Using codes in reviews

It is necessary that reviews protect the confidentiality of patients, families and staff. Most of the reviews that were examined for the purposes of this Report were anonymised. However, the system of anonymisation was very confusing. Most individual patients were assigned a code of "Patient X" with the result that there were quite a number with the identity "Patient X". A similar issue arose with "Midwife A". In responding to issues identified and recommendations made in the various reviews, there is real potential for errors in implementation and assurance to occur when non-unique identification codes are used – this would be amplified at the national level if other regions were to also use "non-unique" assignment of codes.

Nomenclature utilised for incident reviews

It was evident that there is confusion with regard to terms and subsequent system requirements related to incident reviews. A lack of clarity with regard to expectations required for the various types of reviews that can be conducted following an incident appeared to hinder the timeliness and process utilised to conduct incident reviews. A single system using defined nomenclature for the types of reviews e.g. incident review, look backs, report etc. is required. This is required in order to provide clarity and to differentiate between a lack of understanding of the differences and requirements between a full incident review with harm and a review for the purposes of improving quality of care.

Recommendation 14:	
HIQA should develop national standards for the conduct of reviews of adverse incidents.	
Responsibility:	HIQA
Timeframe:	End Quarter 4, 2014
National standards for the conduct of reviews of adverse incidents should be developed by HIQA as per the standards provided for under the Health Act, 2007. This should set definitions for the classification of incidents (error, harm, adverse event, serious adverse event etc.), types of reviews required for different incidents (look backs, reviews, audits, desk-top reviews etc.), time limits, methods and procedures for unique anonymisation. The monitoring arrangements for the standards for safer better healthcare should be used as a means of assuring implementation. The governance framework for the health service providers should require that hospital and health service CEOs be accountable for the effective implementation of these standards. (See Section 6, Overall Recommendation O.R.6)	

Recommendation 15:	
The HSE should ensure consistency of adverse event terminology across its documentation and guidance.	
Responsibility:	HSE
Timeframe:	End Quarter 1, 2014
A brief examination of HSE documentation (Appendix 2) gives some examples of the different terms, and explanations for those terms, being utilised across the HSE. Pending the finalisation of standards recommended above (see Recommendation 14), the HSE should issue clear direction to the system to ensure consistency of use in all circumstances.	

Recommendation 16:	
All staff should be obliged to participate honestly and openly in all investigation processes.	
Responsibility:	HSE and Local Hospital Management
Timeframe:	Immediate
When an investigation into an incident is taking place, it is imperative that all staff participate in a manner which enables early and effective completion so that learning can be derived and applied that may of benefit for the management of other patients. The forthcoming Code of Conduct for employers as detailed in Section 7 will make this obligation clear. It should be a clear imperative from a Human Resources point of view that health service management takes every negotiating opportunity to embed this obligation explicitly into contracts of employment for all staff.	

Recommendation 17:	
There should be an appropriately resourced special support team that is deployed from the HSE, Quality and Patient Safety Directorate to guide a consistent response to major adverse events.	
Responsibility:	HSE
Timeframe:	End Quarter 1, 2014
Institutions, particularly smaller ones with more limited experience of serious adverse events and with less expertise and capacity, may need help and support to guide the response and to ensure that there is a consistent high standard in dealing with it. This should take the form of a deployment of a trained and experienced team with appropriate specialist expertise, knowledge and authority. It is important that its role would be to guide and support rather than to take responsibility from people at the local level who must maintain engagement and continuity. In addition to direct issues that arise in relation to the incident itself, an incident often has a profound effect on staff who may need assessment and counselling. It must be remembered that these staff are the people expected to maintain continuity of services. It can be particularly challenging if the incident is the subject of external/media scrutiny and exposure.	

5.2.3 Applying the learning: Implementation of recommendations

No common process for development of recommendations was evident across the adverse incident reports. There was an absence of timeframes, identification of responsibility and accountability and evidence of completion for implementation of recommendations. Recommendations were not cross referenced across reports and, subsequently, were repeated over timeframes without any reference being made to their implementation. For example, the requirement for specific guidelines emerges across reports from 2006 to 2012. The requirement for such guidelines is treated as isolated to each report rather than a process of quality improvement which tracks evidence of development or implementation of such guidelines over time.

There was little clarity as to the actual responsibility for implementation of reports or individual recommendations when the material supplied by the PHMS is reviewed. Many recommendations were not implemented while others were declared to be un-implementable. It is not clear that there was any process to measure, manage or mitigate any risk that might have arisen from a delay or non-implementation of any recommendation. In short, there appears to be no clear system of governance and assurance around the effective and expedient implementation of recommendations, many of which were to deal with known risks to patients.

Portlaoise Hospital senior management team are satisfied that the results and frequency of audits completed were acceptable in providing to them an indication of completion of implementation of recommendations. However, evidence of implementation of recommendations, in the main, focuses on the availability of specific guidelines, training or completion of audits. It was not clear whether audit results confirmed implementation of guidelines or that training has provided assurance of competency attainment for relevant skills.

The investigation reports, in the main, followed a general style of a series of recommendations related to addressing the care management issues that emerged from the PHMS's or the HSE assessment of the incident. It was anticipated that in line with best practice there would be a closed loop cycle to confirm implementation of all recommendations related to care management issues identified.

Appendix 3 provides an overview of the review of implementation of recommendations from a sample of serious adverse incident reports provided from PHMS. The information provided from Portlaoise Hospital indicates that many, though not all of the recommendations, are now implemented. It is noted in particular that workforce planning issues including midwifery staffing are the subject of on-going work.

It was not possible to ascertain the timeliness of implementation of recommendations as all updates provided were dated 2014. The Portlaoise Hospital senior management team indicated that there is an IT system in place which was established to track implementation of recommendations from such reports. However this system was not viewed by the Portlaoise Hospital's senior management team as supporting their requirements for monitoring implementation of recommendations. Additionally, they outlined the repetitive nature of recommendations over time from reports. This, they considered, gave an impression that no recommendations were implemented when they asserted many recommendations either had been implemented or were in the process of implementation.

The utilisation of a quality and safety accountability framework which is explicit (clear requirements and timelines), coherent (connection between recommendations and expected outcomes) and credible (evidence-based and realistic) will promote timely implementation of reports.

It is essential that responsibility and accountability is clearly set out in relation to recommendations that arise from reviews of incidents. This also needs to include monitoring and assurance in relation to implementation of recommendations. Such a system is urgently needed to bring clarity to the roles of managers and clinical leaders (where, it has to be acknowledged, there is some confusion) as to patient safety matters. It will have to conform to, and be consistent with, other systems of accountability in such a way as to ensure that matters of quality and safety, which are integral to patient care and patient experience, are given a weighting and consideration in management and leadership that is consistent with their importance. It should allow for a clear system which can be used to implement effectively, expediently and consistently in relation to any initiatives that relate to quality and patient safety.

Recommendation 18: **A Quality and Patient Safety Accountability Framework should be developed and implemented by the HSE.**	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014
The Quality and Patient Safety Accountability Framework should be implemented for the management of assurance statements of implementation of patient safety and quality initiatives to include the implementation of recommendations from incident reviews, national HSE policies, recommendations of National Clinical Guidelines etc. The core components of the accountability framework should provide for: • Identification of who has responsibility and accountability for stewardship of implementation • Identification of responsibility and accountability for implementation at national, hospital group, hospital, unit level etc. as appropriate • Timeframes for implementation • Detail of processes and/or key data required at identified time points for assurance of implementation e.g. KPIs, audit, competencies etc • Identification of any risks to implementation.	

5.3 Theme Three: Clinical effectiveness at PHMS

Internationally, the provision of evidence-based healthcare is recognised as essential to the delivery of high quality safe patient care. Clinical effectiveness involves a number of processes, but primary among these are the development or adaptation and implementation of clinical guidelines to support evidence-based practice, key performance indicators and the utilisation of clinical audit.

A clinical effectiveness approach incorporating national and international best available evidence in guidance for the healthcare system promotes the delivery of safe effective care.

The National Clinical Effectiveness Committee (NCEC) is a Ministerial Committee with multi-disciplinary representation which was established to prioritise and quality assure national clinical guidelines and national audit and to create a mandate in relation to their implementation. National Clinical Guidelines are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and service users' decisions about appropriate healthcare for specific clinical circumstances across the entire clinical system. It is important that the methodology utilised to develop a clinical guideline is robust and transparent and that accountability frameworks to monitor the implementation of guideline recommendations are in place.

There are a number of elements to clinical effectiveness which emerged in the preparation of this Report. A description is provided for each of these elements.

5.3.1 Clinical practice guidance

Many of the reviews conducted into PHMS make recommendations for clinical practice guidance to support or standardise care delivery. Clinical practice guidance refers to a number of items such as guidelines, checklists, procedures, clinical guidance, clinical protocols etc. There is no rationale given as to why one level of guidance is recommended over another. While the HSE has a procedure for developing policies, procedures, protocols and guidelines, this focus is primarily on style and format. There is an absence of direction to the system in terms of the criteria for the most appropriate guidance to utilise for specific clinical circumstances, the methodology to develop this guidance and the approval processes for the guidance.

The reviews do not refer to any accountability frameworks for implementation of clinical practice guidance. It is essential that inherent in the development of such guidance is a process for review of guidance and assurance of sustained implementation through an accountability framework. National, local and unit responsibilities and timeframes for implementation of recommendations should be defined.

Recommendation 19: **The National Clinical Effectiveness Committee should develop standards for clinical practice guidance.**	
Responsibility:	National Clinical Effectiveness Committee
Timeframe:	End Quarter 4, 2014
Standard definitions and criteria should be developed in relation to the various forms of clinical practice guidance such as guidelines, checklists, procedures, clinical guidance, clinical protocols etc. This will ensure consistency of approach and utilisation of appropriate methodology to develop clinical practice guidance nationally.	

In particular, the importance of standardised criteria for the use of oxytocin[13] in PHMS, and nationally emerged. The development of a guideline on induction of labour practices which could incorporate a specific protocol/instruction on the use of synthetic oxytocin (for example syntocinon) would facilitate

[13] Oxytocin is a drug utilised for labour induction. Synthetic oxytocin is sold as proprietary medication under the trade name Syntocinon.

the appropriate use of oxytocin administration. This is in line with the UK process for providing guidance on induction of labour.[14]

Recommendation 20: **A national guideline for the induction of labour should be developed by the HSE.**	
Responsibility:	HSE
Timeframe:	End Quarter 4, 2014
The development of a guideline on induction of labour practices that incorporates a specific protocol/instruction on the use of synthetic oxytocin would facilitate the appropriate use of syntocinon administration. The guideline should be developed to National Clinical Effectiveness Committee (NCEC) standards and submitted for NCEC quality assurance.	

5.3.2 Clinical handover

Clinical handover is defined as the transfer of professional responsibility and accountability for some or all aspects of care of a patient, or group of patients, to another person or professional group on a temporary or permanent basis (ACSQHC 2010[15], BMA, 2012[16]). This involves both written and verbal communication. Clinical handover is an integral part of clinical care in all healthcare settings. It is an essential part of care of a patient. Relevant up-to-date information needs to be handed over from each shift and between various clinical teams and departments. This transfer of information should follow a structured format. Clinical handover is recognised as a high risk area for patient safety with much variation in practice.

It was evident within the review of PHMS incident reports that the way in which information passed between clinical staff between shifts, on transfer across the hospital and when escalation of care was required, was not carried out in a standardised way.

In response to the *Patient Safety Investigation Report into Services at University Hospital Galway*[17], the NCEC has been requested by the Minister for Health to commission and quality assure a National Clinical Handover Guideline. Development of this guideline has commenced.

5.3.4 Escalation of care

Delivery of healthcare carries with it some element of risk and errors can happen. The ability to recognise clinical symptoms of patient deterioration and to know when to escalate care are two crucial healthcare professional skills that help to minimise risks and errors. Escalation of care is based on a number of principles. These include:

- The categorisation of the severity of a patients' illness
- The early detection of that deterioration
- The use of a standardised and structured communication tool such as ISBAR (Identify, Situation, Background, Assessment and Recommendation)
- Early medical review that is prompted by evidence-based trigger points
- A definitive escalation plan in place that is monitored and audited on a regular basis.

[14] http://www.nice.org.uk/nicemedia/live/12012/41255/41255.pdf
[15] Australian Commission on Safety and Quality in Healthcare (2010) The OSSIE Guide to Clinical Handover Improvement. Available at: http://www.safetyandquality.gov.au/wp-content/uploads/2012/01/ossie.pdf
[16] British Medical Association (2012) Safe handover: safe patients Guidance on clinical handover for clinicians and managers. BMA. Available at: http://bma.org.uk/search?query=safe%20handover
[17] http://www.hiqa.ie/publications/patient-safety-investigation-report-services-university-hospital-galway-uhg-and-reflect

At several points in the assessment of care at PHMS, it became clear that there was a delay in acting on clinically significant signs and symptoms of the patient. At some points there was failure to recognise the deterioration of the patient condition such as the non-recognition of foetal distress evident on CTG monitoring[18]. This meant that escalation of care was not triggered due to failure to recognise that escalation was needed. At other times, even when the need for escalation of care was recognised and acted upon, either a misjudged clinical decision was taken such as the inappropriate use of oxytocin when labour was progressing with efficient uterine contractions or senior staff were not contacted or were unavailable for urgent review of patients who were deteriorating.

Primary responsibility for the care of the patient lies with the medical practitioner or medical 'team'. However an escalation protocol describes the supporting actions that must be in place for the management of all patients. It is the responsibility of each acute hospital service to clearly outline their escalation protocol. All escalation protocols should support the clinician at the bedside to escalate care until he/she is satisfied that an effective response has been made. The escalation process should be tailored to match the characteristics of the acute hospital setting. Consideration of the size and role of the hospital, the location, available resources and the potential need for transfer to another facility will all need to be accounted for in the escalation protocol. An example of a system of escalation of clinical care is the National Clinical Guideline (Early Warning Score) which was quality assured by the NCEC and endorsed by the Minister for Health in February 2013. The guideline is now implemented in all acute hospitals for adult non-pregnant patients.[19]

In response to the *Patient Safety Investigation Report into Services at University Hospital Galway*[20] the NCEC has been requested by the Minister for Health in October 2013 to commission and quality assure a National Clinical Guideline for paediatric and maternity early warning score systems. This work has commenced.

5.4 Theme Four. Escalation of incidents and role of national HSE

Up to this point, the focus of the Report has been on the issues that arise within Portlaoise Hospital and any implications they might have elsewhere. This section is focused on the extent of oversight, monitoring and support that existed for the hospital or its maternity service from outside.

The section is informed by discussions with a number of national organisations including the HSE at Directorate level. Reports completed into the issues relating to symptomatic breast disease services (Doherty and FitzGerald reports, 2008[21] [22]) as well as 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 the hospital as it dealt with the legacy of those issues and as it sought to address the core deficiencies that were evident in its capability and reliability at that time.

In 2007, there was clear evidence that Portlaoise Hospital had weak systems of clinical governance and management arising in the context of symptomatic breast disease services. One comparable feature is that the service itself on each occasion was not aware of the number of cases of serious adverse incidents until external review processes were undertaken.

It should be pointed out that the time period over which the issues that are the subject of this Report arose overlapped significantly with the emergence of difficulties in relation to symptomatic breast disease and to the planning of the response to those issues at the time.

The principal outcome of the response to the issues regarding symptomatic breast disease services in 2007 was the establishment of the serious incident management protocol and its allocation by way of

[18] Cardiotocography (CTG) is the process of monitoring the foetal heart rate and uterine contractions during labour. The machine used to perform the monitoring is called a cardiotocograph, more commonly known as an electronic foetal monitor (EFM).
[19] http://www.hse.ie/go/nationalearlywarningscore/
[20] http://www.hiqa.ie/publications/patient-safety-investigation-report-services-university-hospital-galway-uhg-and-reflect
[21] http://www.dohc.ie/publications/pdf/doherty_report.pdf?direct=1
[22] http://www.dohc.ie/publications/pdf/fitzgerald_report.pdf?direct=1

responsibility to a senior manager at the national level. This has led on to the national incident management process that is in place today. Essentially, these provide for an appropriate escalation of issues upwards when they come to attention at a local level. In the event that no issues are raised locally, there is no other means of creating intelligence about patient safety incidents within the HSE system. This is now an apparent weakness in patient safety reporting and assurance in that it relies on a hospital or healthcare provider to "self declare" issues of concern.

There was clear evidence that one of the cases (NM0069) was escalated upwards with the result that NIMT took over the conduct of a review that had started locally. We were provided with no evidence that any other specific event or case was escalated upwards through the NIMT system to National HSE at any stage prior to the RTE *Primetime Investigates Programme* of 30 January 2014.

It does not appear that there was any other process in place over the time period in question which would have been capable of assessing the Portlaoise Hospital's performance in relation to the issues around breast care which arose there in 2007 or indeed that was specific to the kinds of events that have now emerged.

The SCA process of notification of adverse events did create a flow of information out from the hospital that might have informed questions of safety. This was not made available to the HSE at the national level. It would be important that SCA information including information related to voluntary providers is made available to the HSE Quality and Patient Safety Directorate in the future. It has been indicated to us, however, the SCA did indeed raise concerns it had in 2007 and 2008 about maternity services in Portlaoise on the basis of the notifications of incidents it was receiving. It was further indicated to us that the response from the hospital was inadequate to none at all.

In addition, since 2011, on the basis of specific pieces of information that came into its possession from members of the public, HIQA has been raising concerns about PHMS with the hospital itself. It indicated to us that it is concerned about the nature of the response from the hospital to the extent it decided to escalate the issues to the national level during the second half of 2013. It is understood from HIQA that its commitment in its 2014 business plan to conduct a governance review of the hospital is in part related to difficulties in getting sufficient assurances to date from local or national HSE.

As described in Section 4 of this Report perinatal death or serious injury resulting from death or serious injury of a neonate associated with labour or delivery in a low-risk pregnancy and maternal death should be listed as 'never events' for Ireland.

Recommendation 21:

The HSE should issue a directive to all providers to require them to notify the director of quality and patient safety and HIQA of all 'never events' .

Responsibility:	HSE
Timeframe:	End Quarter 1, 2014

The HSE should issue a directive to all providers to require them to notify the director of quality and patient safety and HIQA of all 'never events'. It must include death or serious injury of a neonate associated with labour or delivery in a low-risk pregnancy and maternal death. The Health Information Bill is at an advanced stage of drafting and already contains provision to make mandatory the notification of such events. The items on the list should be those contained in the draft Health Information Bill. Once the Health Information Bill is enacted, reporting in this manner will be legally mandated.

Reporting of 'never events' should help to increase awareness at the hospital level of the seriousness of these events and the automatic need they should trigger for an effective and speedy analysis of all

factors. Such an arrangement would also create a flow of information to the HSE Directorate where an assessment can be made of the need to deploy a support team to the hospital to ensure that there is an effective and speedy response that conforms to appropriate policies and guidance.

One of the core findings of this Report was that the full picture as it relates to safety over the period of time in question was not apparent to anyone. The primary responsibility for creating that picture must be at the local level. This is where all the data originates – with the possible exception of claims numbers from the SCA.

Recommendation 22: **The HSE should ensure that every maternity service (and later every health service provider) should be required to complete a Patient Safety Statement which is published and updated monthly.**	
Responsibility:	HSE
Timeframe:	End Quarter 1, 2014
A patient safety statement can provide up to date information on key patient safety issues. The precise format of the patient safety statement and the data it should contain will need to be defined. The patient safety statement should be updated each month and become a core element of clinical governance arrangements. In particular it should be discussed at the senior management team meeting each month and at the Board level each month as a standing agenda item. It should set out activity, interventions, complaints, adverse incidents, serious incidents, never events, transfers, staffing and any other appropriate information from the perspective of patient safety and quality. This model should quickly be applied to all services rather than just maternity services. (See Appendix 4 for an example of the types of information that should be considered for inclusion in a patient safety statement.) (See Section 6, Overall Recommendation O.R.10)	

Recommendation 23: **The Patient Safety Statement should be a requirement of hospital licensing.**	
Responsibility:	Department of Health, Licensing Bill
Timeframe:	General Scheme to be published by end Quarter 1, 2014
The forthcoming legislation to provide for licensing of health services should incorporate a clear mandate for the preparation of Patient Safety Statements by each provider. In the meantime, HIQA can be requested to ensure that compliance with the development and use of the patient safety statement in its programme of monitoring of Standards for Safer Better Healthcare. (See Section 6, Overall Recommendation O.R.10)	

A composite outline of the patient safety risk profile of hospitals in general and for PHMS specifically was not available in the preparation of this Report. It became apparent however during the course of preparing this Report that the availability of such profiles where information is available would be helpful in the longer term for the governance of patient safety in Ireland.

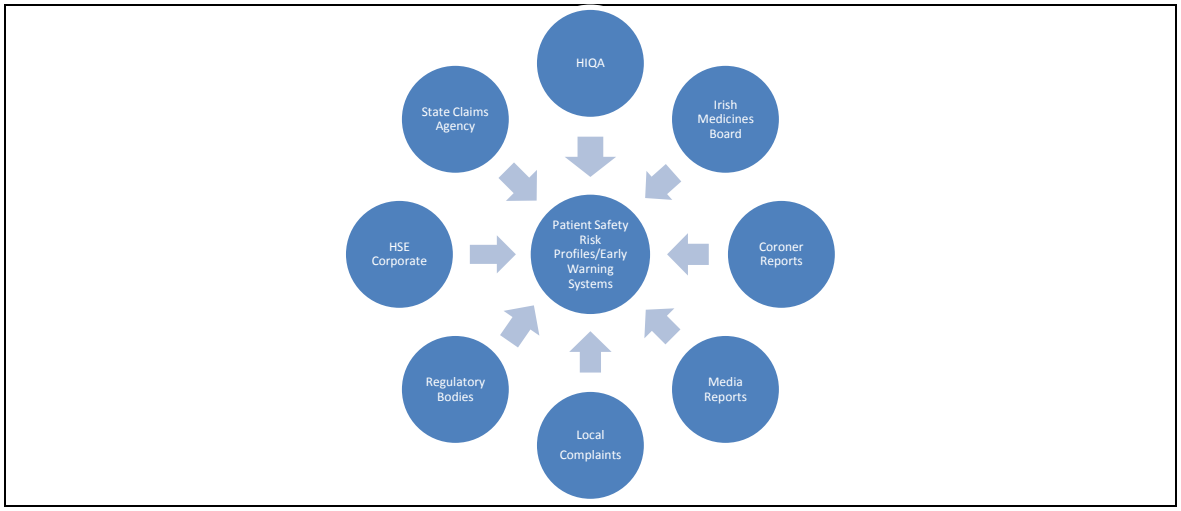
Enquires to various agencies revealed the availability of valuable patient safety information indicative of risk from a number of sources. Some of this information can be described as 'soft' information and some more factual which in combination could potentially provide useful trends in terms of early warning systems for patient safety issues and hospital risk profiles in the future.

At this time, no single agency or body had responsibility for oversight of the risk management and patient safety issues that emerge for numerous single agencies. This means that the intelligence gathering of single agencies does not form part of an overall process of pooling of risk information intelligence in order to create a composite risk profile for the healthcare system.

The diffusion of this information is clearly a lost opportunity as such a system could provide early warning signals to HIQA, the Department of Health and the HSE of potential patient safety issues and risks to the system. Examples of the types of information available from agencies/bodies (see Figure 5.1) include incident reports, complaints, fitness to practice issues, morbidity and mortality statistics etc.

HIQA has the national statutory role to monitor standards of quality and safety in the health services and to investigate as necessary serious concerns about the health and welfare of service users. In addition, HIQA 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* (2012)[23] describe high quality safe healthcare and because of the interdependence of the standards should be regarded and implemented together as a complete system.

Figure 5.1 Potential agencies/bodies with patient safety intelligence
(Note: this is not an exhaustive list)



Recommendation 24:	
A National Patient Safety Surveillance system should be established by HIQA.	
Responsibility:	HIQA and Department of Health
Timeframe:	End Quarter 4, 2014
It is recommended that a new National Patient Safety Surveillance system be established with responsibility assigned to HIQA. The requirement to pool information that may exist across agencies to create better risk and safety profiling of services be considered further as a critical gap in our patient safety functions nationally with a view to any new function becoming a function of HIQA. This will also require other organisations to share their information and intelligence with HIQA. This may require amendments to the Health Act 2007 and will have to be examined in some more detail by the Department of Health. HIQA will use this information for risk stratification and guiding the targeting of their standards monitoring programme.	

[23] http://www.hiqa.ie/standards/health/safer-better-healthcare

5.5 Theme Five: Leadership, staffing and workforce planning

5.5.1 Leadership

Leadership is essential to fostering a culture of patient safety and quality and providing strategic direction in terms of maintaining a balanced competent workforce. It is critical to the appropriate management of resources and staff in order for hospitals to have the capacity to meet demand. The management team and clinical leads within hospitals through working together can drive excellence in care and militate against risk. At a national level the clinical programmes are developing the most effective best practice models of care.

Acute hospitals are complex and challenging places to lead and manage. Strong and effective leadership and management are essential to create and sustain a successful hospital with good outcomes for patients. Those who occupy critical leadership positions in a hospital, and most particularly the Chief Executive/General Manager, the Clinical Director and the Director of Nursing/Midwifery, are placed in what is often an exceptionally difficult situation, without necessarily being given the support they need to fulfil these roles effectively. Many of those who take on these roles are experiencing high levels of stress, often caused by expectations that are beyond their capability, capacity or authority to meet; or by lack of the fundamental supports that they need to fulfil their roles and responsibilities; or indeed by a sense of isolation in their role.

Each member of a senior management team requires specific complementary skills and competencies. The Department of Health is developing a "Code of Conduct" for employers (Section 7). The Chief Executive (or equivalent) of all health and social care organisations will be accountable for the implementation of this Code. This will provide direction in terms of expectations for patient safety and quality within hospitals.

In general in health care settings, it is known that explanations for patient harm vary between scepticism of the data, justifications based on resources and staffing to outright indifference and detachment. The last is the most concerning. It is more likely in individuals who are isolated professionally and vocationally in roles that they see as unchanging or unchangeable. This is compounded by unrealistic clinical and administrative workloads, with no structured or even informal mentoring or leadership structure through which grievances, concerns about mental health, work competence of colleagues and patient safety can be relayed.

It is evident in this Report that the senior management team in Portlaoise Hospital is dealing with some apparent features of stress and isolation as described in the preceding paragraph. Given the hospital scale, this team requires immediate support to manage the current response to the families and staff following the serious incident events. In addition, leadership and support to build the capacity of the current governance structures are required.

In order to fairly hold people to account, then we must ensure that they have the tools, capabilities, authority and supports they need to be accountable. It is simply not good enough for the system to place people into such difficult and challenging roles without also putting in place the sustained supports they require to carry out their responsibilities.

As part of the reform of the health service it should now be an urgent priority to:

- Ensure that all senior leaders within hospitals have a clear and effective means by which urgent issues and risks can be meaningfully escalated and addressed where such issues are beyond the scope or authority of the individual to resolve locally
- Ensure that the expectations placed on hospital management are achievable (albeit always challenging) across the balance of their responsibilities including quality and safety, patient outcomes, working culture, and financial issues

- Establish a developmental programme whereby those aspiring to such leadership positions are provided with a long-term education and training pathway to enable them develop the skills and experiences they need to fulfil such roles
- Work with Universities and Professional Bodies including Medical Training Bodies to help incorporate such elements within undergraduate and postgraduate medical, nursing and allied professional training pathways
- Ensure that all newly appointed CEOs, General Managers, Directors of Nursing/Midwifery and Clinical Directors, are provided with a structured and intensive programme of support for the initial period of their appointment
- That all those in such positions are provided with access to high calibre coaching and mentoring as a basic support throughout their tenure
- Develop a framework to ensure that they are provided with a constructive and safe way to discuss and get feedback on their performance.

While some good work in these areas is underway, through for example the Quality Improvement Diploma, the Lead Clinical Director, the work of the Office of Nursing and Midwifery Services, and the work of the Leadership and Training Unit of the HSE; this is not sufficiently resourced, comprehensive or structured. This should now form a critical element of plans to reform the health service in the interests of patient safety and staff welfare and performance, which is fundamental to outcomes and experiences for patients.

Recommendation 25: **The HSE should provide support to the Portlaoise Hospital senior management team. This should lead to a wider programme of support for frontline leaders, particularly in smaller hospitals, to ensure that they can and do provide safe and effective care.**	
Responsibility:	HSE
Timeframe:	Immediate
The senior management team in Portlaoise Hospital will not be able to continue their existing roles while dealing with the issues that arise from this report and the recommendations it provides without support which is real, expert, timely and sustained in its provision. The critical roles of frontline clinical leaders as well as national clinical leaders need to be supported to ensure that they are roles that can be safely and effectively fulfilled and assured. This is especially important in smaller centres where critical mass is limited. Hospital Networks provide a real opportunity to develop the right support systems that ensure that there is fair accountability which is balanced with authority and responsibility.	

5.2.2 General workforce planning

Workforce planning should provide for a health workforce that is patient focussed, sustainable, appropriately skilled and flexible. Effective service delivery requires processes to ensure that sufficient staff will be available at the right time, with the right skills, diversity and flexibility to deliver high quality care i.e. appropriate skill mix. Workforce planning must be integrated with service and financial planning and encompass principles for guiding better workforce planning decisions.

Workforce planning forecasting requires consideration of population projections (demographics/epidemiology) and healthcare system 'demand' and 'capacity'. Best practice indicates that workforce decisions should be made with good quality data on patient mix (acuity/dependency) and service demands, current staffing (establishment/complement, staff in post and skill mix), factors that impinge on daily staffing levels (absence, vacancies, turnover, ward size and layout etc.) and evidence of the effectiveness of staffing – quality and safety patient outcomes indicators.

Evidence-based workforce planning tools and data systems are integral to supporting workforce planning. Principles and approaches are outlined in the *Integrated Workforce Planning Strategy for the Health Services* (DoHC & HSE 2009)[24] and the tool developed by the Labour Market Research and Skills Unit in FÁS[25].

Workforce Planning is a priority action in the Health Reform Programme. The effective management of human resources requires an approach to workforce planning and development that includes recruiting and retaining the right mix of staff, training and upskilling the workforce, providing for professional and career development and creating supportive and healthy workplaces. The Department of Health and the HSE have begun an exercise to assess the composition of the current workforce to ensure it meets service needs.

PHMS current workforce is outlined in Table 5.3. There are large gaps in terms of midwifery leadership positions due to non-filling of posts and long-term sick leave. The CNM III post has never been filled. These gaps diminish the day-to-day leadership and clinical supervision on the maternity unit. This long term lack of clinical midwifery leadership is a significant barrier to the development of a culture of patient safety and organisational learning.

Table 5.3 PHMS – workforce February 2013 (source Portlaoise Hospital)

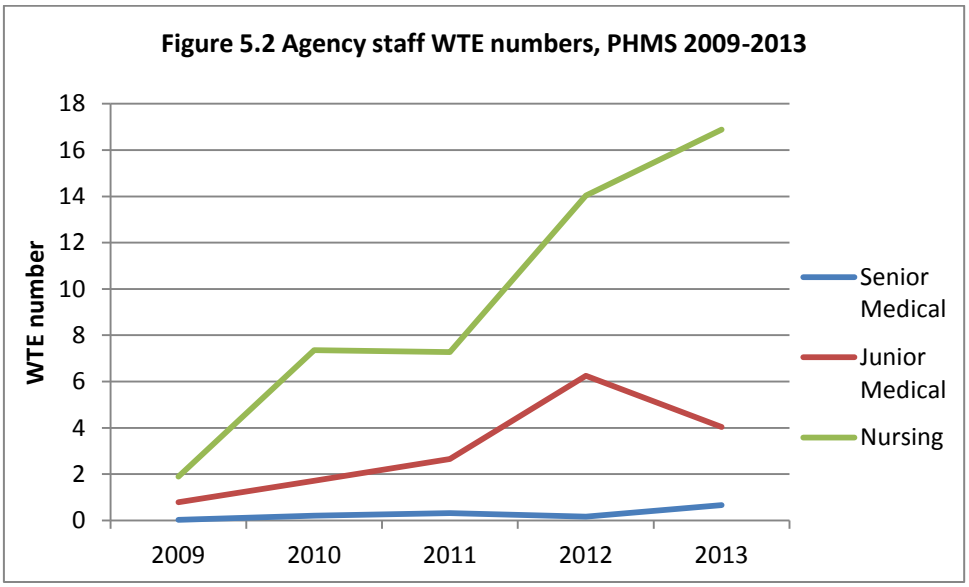
Medical staff	3 WTE Consultant Obstetricians 6 Registrars 6 Senior House Officers
Epidural Service	3 Consultant Anesthetists 5 Registrars
Special Care Baby Unit	3 WTE Consultant Paediatricians 4 Registrars 5 Senior House Officers
Nursing and Midwifery Management staff	Divisional Nurse Manager CNM III (vacant since post approval 2007) CNM II
Midwives (inc. CNM II and Shift Leaders)	29.57 WTE Establishment/Agreed staff complement - 39.42 WTEs Clinical Midwife Specialist (Lactation) (Vacant post) Clinical Skills Faciliator (new post – recruitment in process)

Both medical and midwifery staff appear to be operating with a 25% rate of agency utilisation on a weekly basis. Agency use and costs have increased significantly from 2009 to 2013. The extensive use of agency and locum staff (Table 5.4, Figure 5.2) raises concerns in relation to the stability of the workforce.

Table 5.4 PHMS – maternity agency costs (source Portlaoise Hospital)

	2006-2008	2009	2010	2011	2012	2013
Senior medical	No agency	€6,552	€41,008	€54,257	€29,942	€81,014
WTE		*0.03*	*0.21*	*0.31*	*0.17*	*0.66*
Junior medical	No agency	€51,756	€107,339	€165,447	€389,585	€251,505
WTE		*0.78*	*1.72*	*2.66*	*6.25*	*4.04*
Nursing	No agency	€80,256	€294,429	€290,960	€562,010	€608,364
WTE	No agency	*1.89*	*7.36*	*7.27*	*14.04*	*16.89*
Total		€138,564	€442,776	€510,664	€981,537	€940,883

[24] http://www.hse.ie/eng/staff/Resources/HR/An_Integrated_Workforce_Planning_Strategy_for_the_Health_Services_2009-2012.pdf
[25] Behan et al (2009) A Quantitative Tool for Workforce Planning in Healthcare: Example Simulations. Report by the Skills and Labour Market Research Unit, FÁS, on behalf of the Expert Group on Future Skills Needs. FÁS, Dublin.



5.5.3 Midwifery workforce planning

It is noted that the HSE is about to commence a *Midwifery workload and workforce review in Maternity Services in Ireland.* This project has been jointly commissioned by the HSE Office of Nursing and Midwifery Services Director and the Joint Standing Maternity Committee of the Dublin Maternity Hospitals with the approval of the Director of the HSE's Obstetrics and Gynaecology programme, National Director Clinical Strategy and Programmes Division, National Director Quality and Patient Safety and the support of the Chief Nursing Officer, Department of Health.

The model/models of maternity care and how these are organised will strongly influence the skill, grade and competence required together with the manner in how this resource is deployed. Currently, Birthrate Plus is the most widely used, and endorsed, workforce-planning tool in maternity care in the UK. It has also been used to inform staffing requirements in a number of Irish maternity units. In the short term and in order to provide an assurance that appropriate midwifery staffing levels are in place, the Department of Health, Chief Nursing Officer advised that consideration should be given to employing Birthrate Plus as the current workforce-planning tool of choice in tandem with analysis of gynecological, neonatal high dependency/intensive care and theatre requirements; and consideration of the development of national guidelines on rostering of midwifery staff.

Recommendation 26: **The HSE should develop evidence-based workforce planning tools and data systems for midwives and maternity care assistants (Birthrate Plus).**	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014
Workforce planning for midwives and maternity care assistants is important to forecast short and long-term staff requirements. The HSE should develop evidence-based workforce planning tools and data systems for midwives and maternity care assistants (Birthrate Plus) to support the workforce planning function, taking into account the pending National Strategy for Maternity Services. This should be complemented with analyses of gynaecological, neonatal high dependency/intensive care and theatre requirements	

Recommendation 27:	
The HSE should develop national guidelines on rostering of midwifery staff in maternity units based on best evidence.	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014
Well planned rosters linked with patient activity are important components of effective service delivery to ensure sufficient staff at the right time with the appropriate skills are on duty.	

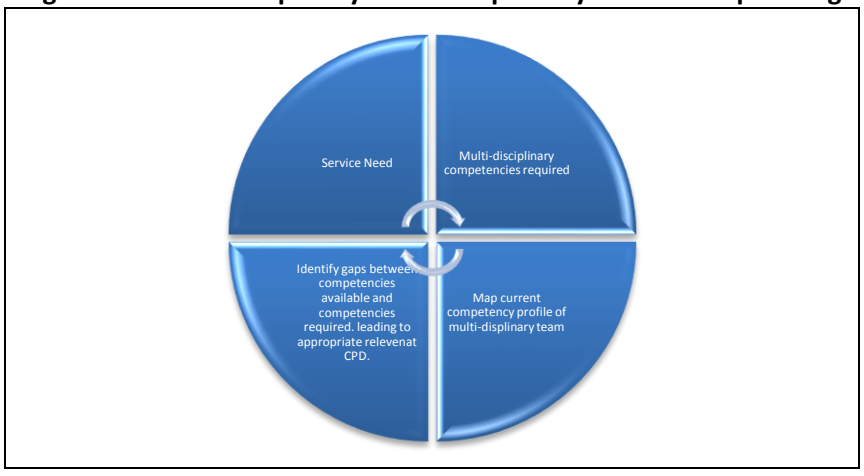
Recommendation 28:	
The HSE should undertake a comprehensive review of the potential role of maternity care assistants in Ireland, including training requirements, should be undertaken to identify the roles and responsibilities that could reasonably and safety be delegated by a midwife. This should include an economic analysis.	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014
Maternity care assistants are part of and add value to the overall maternity workforce in a number of countries.	

5.5.4 General continuing professional development

Continuing professional development (CPD) comprises a range of learning activities through which professionals maintain and develop throughout their career to ensure that they continue to be able to practise safely and effectively within their changing scope of practice, in line with service requirements. CPD is an on-going process to support competence development and competence maintenance. It encompasses a range of activities to increase knowledge and skills including formal education, participation in audit, skills development etc.

It is evident that effective clinical outcomes are influenced by the education and competence levels of clinicians. Consequently, competency determination and development is necessary for safe quality healthcare. Competency frameworks are collections of competencies that are central to, and set the standards of effective performance for a specific patient cohort. The Chief Nursing Officer, Department of Health provided advice regarding specific requirements for CPD related to midwives (Section 5.5.5).

Figure 5.3 Multi-disciplinary team competency framework planning



Appropriate CPD planning is crucial to ensure that healthcare professionals access CPD that is relevant to their individual learning needs and the needs of the service. CPD is an on-going cyclical process which should be planned formally by service providers and individuals.

Recommendation 29:	
The HSE should ensure that a culture of lifelong learning for healthcare professionals should be promoted and supported in line with individual learning needs and the needs of the service.	
Responsibility:	HSE and regulatory bodies
Timeframe:	End Quarter 1, 2014
The complexity of healthcare and influence of new developments and research require health professionals to engage in CPD as an on-going process to support competence development and competence maintenance. Appropriate CPD planning is crucial to ensure that healthcare professionals access CPD that is relevant to their individual learning needs and the needs of the service. Competency frameworks can support this process. Specific requirements for midwifery are referred to in Section 5.5.5 and 5.5.6.	

Recommendation 30:	
The HSE should ensure that healthcare professionals involved in foetal assessment including the interpretation of cardiotocography (CTG) should engage in regular multi-disciplinary training.	
Responsibility:	HSE
Timeframe:	End Quarter 1, 2014
The importance of regular CTG training which involves clinical hands on training is critical to ensuring the on-going competence of medical and midwifery staff in this important task.	

5.5.5 Continuing professional development - midwifery

- The competencies and expected standards of practice of a midwife are articulated in EU Directive 2005/36/EC on the minimum expectations of a midwife. These requirements underpin the standards of education and training of student midwives in Ireland but are only relevant in-so-far as they determine the requirements for entry level registration and do not address on-going training needs assessment for competency maintenance.

- The principal functions of a continuing competence framework are to act as a quality assurance mechanism; to ensure that healthcare professionals are competent in their practice and thereby protect the public (ANMC 2007[26]). Assessing competency is fraught with problems; not least the implications of competencies not being achieved and what implication decisions to manage this might have for services. One of the most successful competency based programmes in maternity care is the neonatal resuscitation programme. While competency is assessed, it operates on the basis of voluntarism and is non-punitive.

- The most extensive empirical evaluation of the continuing competence frameworks for nurses was conducted in New Zealand (2010[27]). This study found that a combination of hours of

[26] ANMC (2007) "Development of a national framework for the demonstration of continuing competence for nurses and midwives – literature review" Canberra Australia, Australian Nursing and Midwifery Council.
[27] Nursing Council of New Zealand, (2010) "Evaluation of the Continuing Competence Framework", New Zealand Council of Nursing, Wellington, October.

practice, CPD, random audit, portfolio documentation, peer assessment and competencies for the scope of practice was critical to assuring individuals were competent to practice.

- Best practice would indicate that competence requirements should be based on a combination of (i) care needs of women and babies, (ii) international best evidence e.g. NICE guidelines on antenatal care, (iii) evidence from audit etc. e.g. clinical indemnity processes, and individual and organisational professional development needs.

- Internationally competence assessment schemes for midwives typically are not aligned to performance management systems. Competence assessment schemes are linked to scope of practice and context of care/setting and thus the subject of regulation.

Recommendation 31:	
The Nursing and Midwifery Board should develop a process for continuously improving the Practice Standards for Midwives to ensure the skill set included is based on best evidence and service need.	
Responsibility:	Nursing and Midwifery Board, Ireland
Timeframe:	End Quarter 1, 2014
New developments and research in maternity care require ongoing vigilance to ensure their appropriate implementation into day-to-day practice.	

5.5.6 Midwifery training needs assessment

The Nursing and Midwifery Board of Ireland has published Practice Standards (2010)[28] for midwives that outline the scope of practice and core midwifery practice skills. These are scheduled to be reviewed in 2014. However currently there is no mechanism for the NMBI to determine if each midwife is compliant with these standards other than through Fitness to Practice. The NMBI currently has a process for approving short courses, conference and skills based workshops (n=74 for midwifery). Regional midwifery training needs are collated by the Boards of Management of the Centres of Nursing and Midwifery Education which have responsibility for providing on-going education.

A process for on-going midwifery training needs assessment can be linked with competency maintenance/CPD and clinical activity. The NMBI has a critical role in this given its responsibility in legislation for the maintenance of professional competence and the development of such scheme(s).

Recommendation 32:	
The Nursing and Midwifery Board in conjunction with the HSE should explore how a training needs assessment could be linked to maintenance of professional competence for midwives.	
Responsibility:	Nursing and Midwifery Board, Ireland
Timeframe:	End Quarter 1, 2014
A process for on-going midwifery training needs assessment can be linked with competency maintenance/CPD and clinical activity. The NMBI has a critical role in this given its responsibility in legislation for the maintenance of professional competence and the development of such scheme(s).	

[28] http://www.nursingboard.ie/en/publications_current.aspx?page=2

Recommendation 33:	
The Nursing and Midwifery Board should prioritise the development of Rules relating to a professional competence scheme, in accordance with Section 13 of the Nurses and Midwives Act 2011.	
Responsibility:	Nursing and Midwifery Board, Ireland
Timeframe:	Immediate
A professional competence scheme managed by the NMBI will promote high standards in competence maintenance for midwives. There is an urgency to progress this as speedily as possible.	

Recommendation 34:	
The Department of Health should commence Part 11 of the Nurses and Midwives Act 2011 to ensure that midwives maintain their professional competence within their scope of practice utilising a scheme to be determined by the NMBI.	
Responsibility:	Department of Health
Timeframe:	Urgent but dependent on Recommendation 33
It is important that once Rules are completed that the Department through Commencement Orders provides the necessary legislative supports.	

5.6 Theme Six: Infrastructure and equipment

5.6.1 Capital facility

PHMS comprises of 30 bed inpatient ward, three labour wards and a three room assessment on the 3rd floor. On the 2nd floor directly underneath are the theatres and a nine bed special care baby unit. The general layout of the services on the 3rd floor gave a sense of clutter and lack of space. The available single rooms have no en-suite facilities.

From a risk and patient safety management perspective, the location of theatre and the special care baby unit on a separate floor is not ideal. All staff should be aware of the shortest and fastest route to the theatre and regular emergency 'dry runs' should be conducted. At this time PHMS should engage in a process such as the productive ward or use of lean management methodologies to create as efficient and productive a space as possible.

Recommendation 35:	
The HSE should support PHMS to engage in the productive ward initiative.	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014
Engagement in the productive ward initiative will support the services to manage the delivery of care in the most efficient manner. This should include 'dry runs' of the shortest emergency route to theatre and the special care baby unit from the labour rooms.	

5.6.2 Healthcare records

Healthcare records refer to all information collected, processed and held in both manual and electronic formats pertaining to the service user and their care. Healthcare records include demographics, unique identification, clinical data, images, investigations, samples, correspondence and communications relating to the service user and his/her care.

The healthcare record is a legal document designed to provide an overview of the service user's state of health before, during, and after a particular therapy. It forms an essential part of care allowing communication between healthcare professionals and demonstrating that the practitioner's duty of care has been fulfilled. Effective timely healthcare record keeping is essential in order to inform the various clinical decisions required at patient care time-points.

The HSE has published *Standards and Recommended Practices for Healthcare Records Management* (2011)[29] as a guide to the standards of practice required in the management of healthcare records in the HSE, based on current legal requirements and professional best practice.

Many of the reviews referred to poor quality documentation, including retrospective entries, unsigned and untimed entries and examples of actions taken and care given, not documented. It is the responsibility of healthcare professionals to adhere to best practice in healthcare record management. It would appear that patient healthcare records were not managed in line with HSE standards.

Meetings with families identified that there were considerable delays in the release of healthcare records and that they were required to go through Freedom of Information processes to gain access to their healthcare records. This created unacceptable anguish and the practice is outside of the HSE stated standards for healthcare records management which identify that generally, access to an individual's own healthcare record should be provided administratively. This was confirmed by the HSE Directorate. The HSE standards require that as an exception access to a deceased person's records should be processed under the Freedom of Information Acts. It is unclear if the hospital was utilising this exception in the cases where there was a perinatal death.

Recommendation 36:	
Healthcare organisations should ensure, as a matter of priority, that they review and address any shortfall in the management of healthcare records in line with the HSE national policy.	
Responsibility:	Local Hospital Management
Timeframe:	End Quarter 1, 2014
Healthcare organisations should examine their own standards and processes against the standards set out by the HSE.	

Recommendation 37:	
The HSE should provide assurance that healthcare organisations are adhering to its national healthcare records management standards.	
Responsibility:	HSE
Timeframe:	End Quarter 1, 2014
The HSE *Standards and Recommended Practices for Healthcare Records Management* (2011) provides a comprehensive guide to required standards of practice and assurance of implementation across the healthcare system is essential. Assurance of compliance should be provided through a Patient Safety and Quality Accountability Framework (Recommendation 18).	

[29] http://www.hse.ie/eng/about/Who/qualityandpatientsafety/resourcesintelligence/Quality_and_Patient_Safety_Documents/v3.pdf

Recommendation 38:	
The HSE should review the National Maternity Healthcare Record to determine that it is fit for purpose.	
Responsibility:	HSE
Timeframe:	End Quarter 1, 2014
The HSE's recommended practice includes a National Maternity Healthcare Record, which is in use in PHMS. Issues were, however, raised in relation to the completeness of this record and the requirement for additional documentation processes to augment the detail in the National Maternity Healthcare Record.	

5.6.3 Medical devices

With advances in medical technology, the use of medical devices for the delivery of care to patients has become an integral part of the ability of healthcare institutions to monitor, treat and support the management of various medical conditions. The HSE has developed a formal system to manage the safe use of medical devices.[30] This policy is to ensure that uniform standards and procedures are in place to assure a coordinated approach to the management of medical devices and equipment throughout the organisation. The aim is to ensure the minimisation of the risk of harm to service users and employees associated with the use of medical devices and equipment.

The HSE Medical Devices and Equipment Standard is accompanied by a self-assessment tool. All service areas are required to conduct this self-assessment on an annual basis. The outcome of this self-assessment will determine the areas that require improvement.

The maintenance of CTG machines[31] was raised by some family members where they stated that the CTG machine audible alarms were switched off by staff during labour and hence, early indication of foetal distress was not acknowledged.

In addition, one of the families described how on transfer of their child the incubator was not working in the ambulance. The child was described as hypothermic on arrival at the transfer hospital. This was a particularly distressing event for the family. As part of this Report information on any investigation on this incident was sought from the HSE. No information or confirmation that an investigation occurred was provided. This is particularly unsatisfactory and the HSE has been requested to follow up this matter.

Recommendation 39:	
The HSE should provide assurance that healthcare organisations are adhering to its Medical Device Standards.	
Responsibility:	HSE
Timeframe:	End Quarter 1, 2014
The HSE Medical Devices and Equipment Standard provides a guide to required standards of practice, and assurance of its implementation across the healthcare system is essential. Assurance of compliance should be provided through a Patient Safety and Quality Accountability Framework (Recommendation 18).	

[30] Medical Devices/Equipment management Policy (Incorporating the Medical Devices Management Standard) HSE 2009. Available at, http://www.hse.ie/eng/services/Publications/corporate/Medicaldevicesequipment.pdf

[31] Cardiotocography (CTG) is the process of monitoring the foetal heart rate and uterine contractions during labour. The machine used to perform the monitoring is called a cardiotocograph, more commonly known as an electronic foetal monitor (EFM).

5.7 Theme Seven: Legal and ethical issues

5.7.1 Coronial process

A Coroner is an independent official with legal responsibility to enquire into the circumstances of sudden, unexplained, violent and unnatural deaths. This may require a post-mortem examination, sometimes followed by an inquest. The post-mortem is carried out by a pathologist, who acts as the Coroner's agent for this purpose.

The Coroner essentially establishes the "who, when, where and how" of unexplained death. A Coroner will not be involved in cases where a person died from a natural illness or disease for which the deceased was being treated by a doctor within one month prior to death. If death is due to unnatural causes, the Coroner is obliged to hold an inquest.

Three cases that were the subject of review for this Report had inquests conducted by the Coroner. The families seemed particularly angry at their treatment in the process - a process that they understood to be there to provide them with the answers to some of their questions. They described their surprise and discomfort at the extent of the adversarial nature of the process. They expressed further surprise at the scale and duration of attendance by members of staff of PHMS and at the size (and cost) of the legal teams that attended.

Another concern expressed was the length of time it took for some of the cases to be heard relative to the time of the death. Of most concern was an allegation that has not been substantiated, that one key witness simply did not attend.

In 2007 the Department of Justice and Equality published the Coroner's Bill 2007 which incorporates many of the recommendations made by a Working Review Group in 2000. That Bill was not enacted. While the time available in preparing this Report does not allow a detailed examination of the Coroner's process, or the review that was conducted into the service in 2000 which led to the 2007 Bill, it is reasonable to reflect on the submission from the families and as a result to raise a question about the extent to which patient and family interests are served by the current process. While this Report is not in a position to suggest an answer it is important to point to the need for more work to be done on this issue.

Recommendation 40:	
The HSE should develop guidelines for staff on attendance at inquests.	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014
Guidelines for staff should be developed which provide information on the inquest process, detail expected behaviours and requirements for attendance.	

Recommendation 41:	
The Department of Health should engage with the Department of Justice and Equality in respect of the coronial service.	
Responsibility:	Department of Health and Department of Justice and Equality
Timeframe:	Commence formal engagement between departments immediately
The Department of Health should engage with the Department of Justice and Equality in respect of the coronial service. A review was undertaken in 2000 and a Bill published in 2007 which should provide a basis for examination in context of the issues that arose in PHMS. In preparation the Department of Health should engage with the State Claims Agency and the HSE and others as appropriate to prepare a paper which would facilitate an informed engagement with the Department of Justice and Equality.	

5.7.2 Consent

Consent is the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication about the proposed intervention. The process of communication begins at the initial contact and continues through to the end of the service user's involvement in the treatment process, provision of social care or research study. Seeking consent is not merely getting a consent form signed; the consent form is just one means of documenting that a process of communication has occurred. The HSE published its National Consent Policy in 2013.[32]

For the consent to be valid, the service user must:

- have received sufficient information in a comprehensible manner about the nature, purpose, benefits and risks of an intervention/service or research project
- not be acting under duress; and
- have the capacity to make the particular decision.

The concept of informed consent is interconnected with the principles of autonomy and bodily integrity. Notwithstanding emergency situations, a medical intervention cannot be provided without the patient's informed consent. As such, informed consent is considered an essential prerequisite to the commencement of any healthcare intervention. However, consent must be considered valid, i.e. the individual should have the requisite capacity to make the decision; his/her choice should be voluntary; should be provided with appropriate information, in a format he/she can understand, regarding the benefits, risks, consequences and alternatives to the proposed treatment; and his/her decision should be accurately documented.

At a meeting with one of the families, there was confusion over the purpose of signing a written consent form. It is understandable that in an emergency situation such as those encountered in the adverse event review reports, time is limited; however, opportunities to provide sufficient information in a comprehensible manner should be taken.

Recommendation 42: **The HSE should provide assurance that healthcare organisations are adhering to its National Consent Policy.**	
Responsibility:	HSE
Timeframe:	End Quarter 1, 2014
The HSE Consent Policy provides extensive guidance on required standards of practice in relation to consent and assurance of its implementation across the healthcare system is essential. Assurance of compliance should be provided through a Patient Safety and Quality Accountability Framework (Recommendation 18).	

5.7.3 Confidentiality

Medical confidentiality is of particular ethical and moral importance. Healthcare professionals have long been accustomed to dealing with sensitive information regarding their patients.

The principle of confidentiality provides an assurance that personal information will not be disclosed to unauthorised persons, processes, or devices. Confidentiality refers to agreements made with subjects, through the consent process, about if and how information provided by individuals will be protected. The principle of confidentiality in Ireland is provided for under the Data Protection Acts 1988 and 2008, under which personal information must be obtained for a specified purpose, and must not be disclosed to any third party except in a manner compatible with that purpose.

[32] http://www.hse.ie/eng/services/list/3/nas/news/National_Consent_Policy.pdf

Service users have a right to expect that information about them will be held in confidence by those who provide health and social care services to them. Confidentiality is central to trust in this relationship. Staff are expected to comply with the provisions of the Data Protection Acts 1988 and 2003 which state that personal information obtained from service users for the purposes of informing care, treatment or service provision should not be disclosed to a third party unless the service user has consented or unless the specific requirements of the legislation are complied with. Healthcare professional regulatory bodies provide more explicit guidance.

Section 6 Overall conclusions and recommendations

6.1 Introduction

In order to inform the preparation of this Report, meetings were held with some of the families involved, Patient Focus, the senior management team at Portlaoise Hospital, representation from the obstetric and midwifery team at PHMS, the National Clinical lead for the Obstetrics and Gynaecology programme, the HSE Quality and Patient Safety Directorate, the HSE Directorate, the State Claims Agency, HIQA and regulatory bodies.

PHMS clinical activity and outcome data, investigation reports, incident reports and desktop reviews, all relating to the period 2006 to date, were examined. The analysis was further informed by a detailed examination of National Perinatal Surveillance Data from the various systems in existence that collect and report such data. In addition, relevant HSE and Portlaoise Hospital policies and guidelines were reviewed.

The earlier sections of the Report set out a qualitative and quantitative analysis of the issues that arise from the publicity surrounding PHMS. It is considered that these analyses support a number of overall conclusions and recommendations. These are set out below in relation to the patients, the service, the staff and the oversight.

6.2 Overall conclusions

6.2.1 The patients

1. Families and patients were treated in a poor and, at times, appalling manner with limited respect, kindness, courtesy and consideration.
2. Information that should have been given to families was withheld for no justifiable reason.

It is difficult to explain some of the behaviour that was attributed to staff by the patients as well as by some of the staff that we met. We have not sought to validate each statement made but we have no reason to doubt it. Nothing we came across could be regarded as providing an acceptable explanation.

There was an unacceptable lack of consideration of the views and experiences of patients. It is clear that there are some difficult cultural issues at play in PHMS which must be addressed. Issues in relation to the cohesion of the senior management and clinical teams and breakdown in relationships at times both within and between these teams was suggested to us and at times evident. This is in itself concerning as it raises a risk to the collective responsibility, accountability and subsequent management of patients following adverse events and increases safety risks for the hospital.

6.2.2 The service

3. Poor outcomes that could likely have been prevented were identified and known by the hospital but not adequately and satisfactorily acted upon.
4. The PHMS 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. (See Overall Recommendation 3).

Clear failures were identified in this preliminary risk and patient safety assessment of PHMS. These failures were at a number of levels, both local and national. It is not possible to conclude, based on the information in this Report, that PHMS is safe and sustainable. This conclusion is drawn from Portlaoise Hospital's own assessment of its risk management processes, the current risk management arrangements in place, and the monitoring of implementation of recommendations from the various investigations of adverse events in Portlaoise Hospital and the various findings we have made in relation to patient safety and patient care. It is also informed by the difficulties that the hospital has in

attracting and retaining the necessary staff, for many reasons, and its resultant increasing dependency on agency staffing.

It will be challenging for Portlaoise Hospital to re-establish its self-confidence and the confidence of the local people without significant help. As a small stand-alone service it is limited in the numbers of staff and the expertise it can be expected to have and to maintain. It is not a training location for midwifery nor is it recognised as a training location by the Institute of Obstetrics and Gynaecology in Ireland for the training of junior doctors. In short, it lacks many of the important criteria on a stand-alone basis to be a safe sustainable maternity service in the 21st century.

6.2.3 The staff

Many of the staff did their best in challenging circumstances. However it is evident that on occasions both standards of care and staff behaviours, particularly their interactions with families following adverse events, were less than acceptable. It is noted in this Report that circumstances including poor leadership outside of individual clinician control did not support or help lessen the risk of such events.

Leadership is essential to fostering a culture of patient safety and quality and providing strategic direction in terms of maintaining a balanced competent workforce. It is critical to the appropriate management of resources and staff in order for hospitals to have the capacity to provide this leadership. The management team and clinical leads within hospitals through working together and with the appropriate support are essential to the safe and effective provision of services in the hospital on an on-going basis.

The Department of Health is developing a 'Code of Conduct' for employers (Section 7). The Chief Executive (or equivalent) of all healthcare and social care organisations will be accountable for the implementation of this Code. This will provide direction in terms of expectations for patient safety and quality within hospitals.

Senior healthcare staff must receive support and mentorship to build their skills, competencies and confidence.

6.2.4 Oversight

5. Many organisations, including PHMS, had partial information regarding the safety of PHMS that could have led to earlier intervention had it been brought together.
6. The external support and oversight from HSE should have been stronger and more proactive, given the issues identified in 2007.

Dealing with issues of patient safety requires action on the basis of intelligence and evidence. A central finding of this Report was that a profile of safety of PHMS within the hospital could have been created from easily available information.

At this time, no single agency or body has overall 'line of sight' at the national level nor specific responsibility for the creation of such an oversight of the risk management and patient safety issues that emerge for numerous single agencies. This means that any intelligence gathered within single agencies does not become part of an overall pooling of risk information. It can be said that different pieces of the jigsaw are held by different organisations. Creating the full picture is, therefore, very challenging as was evidenced by the time and effort required to do just that for the purpose of this Report. This is a weakness in our system of patient safety. There must be a stronger system of using and sharing information that can be used to improve quality and safety for patients.

At a national level concerns about the governance of Portlaoise Hospital were known since 2007. As a small stand-alone service it is limited in the numbers of staff, the expertise it can be expected to have and to maintain. It would have benefited from more direct assistance. The final analysis of this Report identified fundamentally that problems arose from systemic weaknesses of governance, management,

and communication for dealing with critical situations such as arose in late August 2007. At the time it was detailed that these issues needed to be tackled to avoid a recurrence. Portlaoise Hospital does not appear to have been provided with the oversight and supports that could have reduced risk, increased patient safety and protected staff morale.

The HSE outlined the progression of patient safety and risk governance arrangements for Portlaoise Hospital over time. Following the Fitzgerald Report[33] the HSE implemented the national incident management policy (NIMP) and assigned responsibility to a member of the National Management Team. The development of the integrated service areas and regional director of operation positions from 2009 onwards are seen to have strengthened broader governance arrangements. These structural reforms were implemented in order to allow for some oversight and escalation of serious risks or adverse events at regional level. The system is however dependent on hospitals to examine their own risk and self-declare concerns.

6.3 Overall Recommendations

This section sets out summary recommendations. Some are recommendations from the main body of the Report that are restated here given their centrality to the appropriate response to the findings and conclusions set out in earlier chapters. That is not to say that recommendations that are in the main report and not restated here are of lower importance - they are not. All recommendations, wherever they appear in the Report, are seen as critically important elements of the whole response. Overall recommendations are given the notation O.R. (overall recommendation) and cross referenced where relevant to where they appear in the main Report.

6.3.1 The patients

Recommendation O.R.1: **PHMS should apologise unreservedly to the families and patients concerned.**	
Responsibility:	Portlaoise Hospital Maternity Services
Timeframe:	Immediate
It is known that apologies have been made to a number of families and patients. In the event that any family or patient has not yet received an apology from the hospital itself, that should happen without delay. The hospital should provide written assurance that it has done so.	

Recommendation O.R.2: **An immediate assessment of the patient safety culture at Portlaoise hospital should be undertaken by HIQA (See Recommendation 5).**	
Responsibility:	HIQA
Timeframe:	End Quarter 2, 2014
While the focus of this Report is PHMS only, it is reasonable to say that assurance is needed to ensure that the factors that lead to these recommendations do not also apply in the other services in the hospital. There are a number of tools in use internationally that allow detailed assessment to be made of the patient safety culture of a hospital to be undertaken and to inform the necessary remediation which can take the form of training, teambuilding, improved policies and procedures and on-going measurement and assurance of improvements in culture and behaviour. HIQA should be requested to make this assessment of patient safety culture and team-working.	

[33] http://www.dohc.ie/publications/pdf/fitzgerald_report.pdf?direct=1

6.3.2 The service

Recommendation O.R.3: **A team should be appointed to run the PHMS pending implementation of Recommendation O.R.4 below.**	
Responsibility:	HSE
Timeframe:	Immediate
In this regard the HSE should immediately put in place a transition team to take control of the service at PHMS and to oversee the planning and execution of the orderly implementation of the managed clinical network recommended below. The transition team should consist of appropriate clinical and managerial expertise.	

Recommendation O.R.4: **PHMS should become part of a Managed Clinical Network under a singular governance model with the Coombe Women & Infant University Hospital.**	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014. The HSE has already taken initial steps to implement this.

The number of births at PHMS shows that there is and will continue to be a need to have a maternity service at Portlaoise Hospital which meets the requirement of good safety, patient-centred and sustainable care. A decision to close the service would not be appropriate given the scale of activity. Neither is it an option to maintain and develop the service under its current governance arrangements given the findings and conclusions in this report.

Portlaoise Hospital is a constituent hospital of the Dublin Midlands Hospital Group. This Group also includes the Coombe Women & Infant University Hospital. The development of a managed clinical network within the Dublin Midlands Hospital Group, initially comprising the PHMS and the Coombe Women & Infant University Hospital provides a sustainable solution to the leadership, staffing, training, quality assurance, clinical standard and risk management issues identified in this report.

The implementation of the *Establishment of Hospital Groups*[34] will ensure that the future service needs of the whole population of each hospital group will be quantified and planned in a more integrated fashion. The overarching system of clinical governance and enhanced communication and cooperation between hospitals within the hospital group setting, will underpin the provision of quality and safe healthcare.

The managed clinical network should consist of the following features:

- A single clinical service under the governance, direction and authority of the Master of the Coombe
- Capacity for medical, midwifery and other staff to be appointed to the network and to rotate as required by service and training needs between sites
- Training for junior doctors and midwives to happen on both sites
- Common system of clinical governance i.e. policies, audit meetings, quality assurance, incident reporting, incident management etc. with pooling of all data to ensure that all quality assurance is on the basis of one single service- albeit operating on two sites
- Risk stratification of patients attending PHMS to ensure that higher risk pregnancies are dealt with at the Coombe site.

[34] http://www.dohc.ie/publications/IndHospTrusts.html

Recommendation O.R.5: **Other small maternity services should be incorporated into managed clinical networks within the relevant hospital group.**	
Responsibility:	HSE
Timeframe:	End Quarter 2, 2014
This Report recommends the urgent transition of Portlaoise Hospital as the first smaller hospital to become part of a managed clinical network under the clinical governance of a larger hospital, in this case, the Coombe Women & Infant University Hospital. A managed clinical network with the features described above would provide a number of advantages for smaller units. It can provide clinical governance, leadership, shared clinical guidance, shared training and processes for rapid referral. In these circumstances, other small maternity services in the country should be incorporated into a managed clinical network within the relevant hospital group. Given the findings of this Report which are in part the result of small size and the challenge of sustaining services by attracting and retaining staff, it is considered reasonable that work commence on integrating smaller maternity units into systems of common governance in line with the planned hospital networks. It should not await the outcome of further analysis by HIQA which is recommended below.	

Recommendation O.R.6: **The HSE should address the implications of this Report for other services at Portlaoise Hospital.**	
Responsibility:	HSE
Timeframe:	End Quarter 1, 2014
It would be unreasonable and unsafe to assume that some of the issues which arose in PHMS are not also issues for other services in the hospital. However, this was beyond the scope of this Report. The HSE should be asked to give consideration to this recommendation and to present the Minister for Health with a proposal for any necessary changes based on their assessment.	

6.3.3 The staff

Recommendation O.R.7: **Support should be provided to the Portlaoise Hospital senior management team. This should lead to a wider programme of support for frontline leaders, particularly in smaller hospitals, to ensure that they can and do provide safe and effective care (see Recommendation 25).**	
Responsibility:	HSE
Timeframe:	Immediate
The senior healthcare staff at Portlaoise Hospital cannot be expected to deal with the complexity of managing the serious adverse events dealt with in this Report on their own. The HSE should as a matter of urgency should examine the level and type of support most appropriate to build confidence and competence in order that the hospital can deliver a safe effective service. This support should be put in place immediately and thereafter considered for similar settings.	

6.3.4 Oversight

Recommendation O.R.8:	
HIQA should be requested to undertake an investigation in accordance with Section 9 (2) of the Health Act 2007.	
Responsibility:	HIQA
Timeframe:	Immediate commencement

HIQA should be required by the Minister for Health to undertake an investigation in accordance with section 9 (2) of the Health Act 2007. This will allow a number of the issues found in this review to be examined in more detail. HIQA have the relevant powers and authority to undertake such detailed analysis. HIQA will develop and publish terms of reference for any such investigation.

This 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*[35] (HIQA, 2013).

Recommendation O.R.9:	
HIQA should develop national standards for the conduct of reviews of adverse incidents (see Recommendation 14).	
Responsibility:	HIQA
Timeframe:	End Quarter 4, 2014

National standards for the conduct of reviews of adverse incidents should be developed by HIQA as per the standards provided for under the Health Act, 2007. This should set definitions for the classification of incidents (error, harm, adverse event, serious adverse event etc.), types of reviews required for different incidents (lookbacks, reviews, audits, desk-top reviews etc.), time limits, methods and procedures for unique anonymisation. The monitoring arrangements for the standards for safer better healthcare should be used as a means of assuring implementation. The governance framework for the health service providers should require that hospital and health service CEOs be accountable for the effective implementation of these standards.

[35] http://www.hiqa.ie/publications/patient-safety-investigation-report-services-university-hospital-galway-uhg-and-reflect

Recommendation O.R.10:

The HSE should ensure that every maternity service (and later every health service provider) be required to complete a Patient Safety Statement which is published and updated monthly.

Responsibility:	HSE
Timeframe:	End Quarter 1, 2014

Patient Safety Statements from maternity services initially and thereafter from all healthcare providers could be used with other available information to risk-rate services and to target quality improvement measures that enhance local ownership and capability. It is important that this is the first element of oversight as it will ensure that primary responsibility for oversight of safety and quality must remain with the service and those responsible for it. It will also have the advantage of creating a source of information that is much more accessible and transparent for the purposes of external scrutiny including by the public.

A patient safety statement can provide up to date information on key patient safety issues. The precise format of the patient safety statement and the data it should contain will need to be defined. The patient safety statement should be updated each month and become a core element of clinical governance arrangements. In particular it should be discussed at the management team meeting each month and at the Board level each month as a standing agenda item. It should set out activity, interventions, complaints, adverse incidents, serious incidents, never events, transfers, staffing and any other appropriate information from the perspective of patient safety and quality. This model should quickly be applied to all services rather than just maternity services.

(See Appendix 4 for an example of the types of information that should be considered for inclusion in a patient safety statement.)

Recommendation O.R.11:

A National Patient Safety Surveillance system should be established by HIQA.

Responsibility:	HIQA and Department of Health
Timeframe:	End Quarter 4, 2014

It is recommended that a new National Patient Safety Surveillance be established with responsibility assigned to HIQA. The requirement to pool information that may exist across agencies to create better risk and safety profiling of services be considered further as a critical gap in our patient safety functions nationally with a view to any new function becoming a function of HIQA. This will also require other organisations to share their information and intelligence with HIQA. This may require amendments to the Health Act 2007 and will have to be examined in some more detail by the Department of Health. HIQA will use this information for risk stratification and guiding the targeting of their standards monitoring programme.

Section 7 Reform and Policy Implications

7.1 National Maternity Services Strategy

In the context of the implementation of the Report on the Establishment of Hospital Groups[36], small maternity services around the country should be incorporated into a managed clinical network within the relevant hospital group. The roll out of managed clinical networks for maternity services should be considered in the context of the development of the new National Maternity Services Strategy. The experience gained from implementing such a network across part of the Dublin Midlands Hospital Group, will inform the Strategy and any consideration regarding the clinical governance of maternity services. The Department of Health will consider and provide policy direction in relation to overall governance of hospital groups and how the governance of maternity services and managed clinical networks will be integrated into the overall governance model.

The recommendations in this Report regarding quality assurance, clinical effectiveness, safety etc. should be incorporated into the National Maternity Services Strategy.

7.2 Hospital groups

Future Health - A Strategic Framework for Reform of the Health Service 2012-2015[37] provides the overarching policy framework for the re-organisation of public hospitals. Public hospitals will be reorganised into more efficient and accountable hospital groups that will harness the benefits of increased independence and a greater control at local level. This represents the most fundamental reform of the Irish acute hospital system in decades.

By working in groups, hospital services will be provided by the hospitals in each group, based on the evidence-based needs of their populations. Each group of hospitals will work together as single cohesive entities managed as one, to provide acute care for patients in their area, integrating with community and primary care. This will maximise the amount of care delivered locally, whilst ensuring complex care is safely provided in larger hospitals. Each group will comprise between six and eleven hospitals and will include at least one major teaching hospital. Each grouping will also include a primary academic partner in order to stimulate a culture of learning and openness to change within the hospital group. Robust governance and management structures will need to be put in place at group level.

Portlaoise Hospital is part of the Dublin Midlands Hospital Group. This group also includes the Coombe Women & Infant University Hospital. This arrangement allows for a managed clinical network as recommended earlier with clinical governance, leadership, shared clinical guidance, shared training and processes for rapid referral. Managed care networks should provide for a continuum of care across services within the network.

7.3 Patient Safety Agency

A new Patient Safety Agency (PSA) is to be established. The Agency will be established initially on an administrative basis within the HSE structures in 2014. The HSE is expected to establish a Board to oversee the PSA and to agree its initial governance and operational arrangements. The PSA will have an advocacy role in relation to patient complaints, supporting patients by directing them to the appropriate provider or agency so that they can secure a response regarding the issues they raise. Based on a detailed analysis of complaints throughout the system, the PSA will also provide national leadership for patient advocacy services, including the Health Service Charter *"You and Your Health Service"*[38]. It is intended that the PSA would progress to become an independent agency in time and engage on the broader quality improvement and patient safety agenda.

[36] http://www.dohc.ie/publications/IndHospTrusts.html
[37] http://www.dohc.ie/publications/pdf/Future_Health.pdf?direct=1
[38] http://www.hse.ie/eng/services/yourhealthservice/

7.4 Code of Conduct for employers

The Department of Health is developing a 'Code of Conduct' for employers that will clearly set out employers' responsibilities in relation to achieving an optimal safety culture, governance and performance of the organisation. It is intended that the Code will include the expected attributes, behaviours and responsibilities of all managers as representatives of the employer, and underpin their role and responsibility in achieving these aims. The Code of Conduct should also clearly articulate the duties and responsibilities on them in the regulation of health and social care professionals in their organisation, including referral of professionals to the appropriate regulatory body/bodies.

In addition, the Code of Conduct should be incorporated into the recruitment, appointment, job descriptions and performance review of managers in health and social care services. The Chief Executive (or equivalent) of all healthcare and social care organisations will be accountable for the implementation of this Code. As identified in the *Patient Safety Investigation Report into Services at University Hospital Galway*[39] HIQA will monitor compliance with this Code as part of its monitoring of National Standards.

Demonstration of compliance with the adherence to the Code of Conduct will complement and may provide part evidence for the proposed requirements in the forthcoming Licensing of Health Facilities Bill for applicants for a licence to provide evidence of fitness and competence to hold a licence.

7.5 Clinical effectiveness

A clinical effectiveness approach incorporating national and international best available evidence in guidance for the healthcare system promotes the delivery of safe effective care. Clinical effectiveness processes such as clinical guidelines and audit are essential for the transfer of evidence to practice.

The National Clinical Effectiveness Committee (NCEC) is in place to prioritise and quality assure national clinical guidelines and national audit and to create a mandate in relation to their implementation.

There are a number of elements to clinical effectiveness which emerged in the preparation of this Report. These included the extent of reference to different clinical practice guidance without rationale as to why one level of guidance is recommended over another, escalation of care and clinical handover. The NCEC will develop Standards for Clinical Practice Guidance (Recommendation 19).

In response to the *Patient Safety Investigation Report into Services at University Hospital Galway*[38] the NCEC has been requested by the Minister for Health to commission and quality assure a number of national clinical guidelines. This work has commenced.

As identified by international best evidence the promulgation of best practice across national healthcare services is dependent on well-developed quality assured national clinical guidelines and audit. It is recommended that NCEC will develop standards for clinical practice guidance (Recommendation 19).

[39] http://www.hiqa.ie/publications/patient-safety-investigation-report-services-university-hospital-galway-uhg-and-reflect

Section 8 List of Recommendations

Number	Recommendation	Responsible Body	Timeframe
Overall Recommendations			
O.R.1	PHMS should apologise unreservedly to the families and patients concerned.	PHMS	Immediate
O.R.2	An immediate assessment of the patient safety culture at Portlaoise hospital should be undertaken by HIQA.	HIQA	End Quarter 2, 2014
O.R.3	A team should be appointed to run the PHMS pending implementation of Recommendation O.R.4 below.	HSE	Immediate
O.R.4	PHMS should become part of a Managed Clinical Network under a singular governance model with the Coombe Women & Infant University Hospital.	HSE	End Quarter 2, 2014
O.R.5	Other small maternity services should be incorporated into managed clinical networks within the relevant hospital group.	HSE	End Quarter 2, 2014
O.R.6	The HSE should address the implications of this Report for other services at Portlaoise Hospital.	HSE	End Quarter 1, 2014
O.R.7	Support should be provided to the Portlaoise Hospital senior management team. This should lead to a wider programme of support for frontline leaders, particularly in smaller hospitals, to ensure that they can and do provide safe and effective care.	HSE	Immediate
O.R.8	HIQA should be requested to undertake an investigation in accordance with Section 9 (2) of the Health Act 2007.	HIQA	End Quarter 4, 2014
O.R.9	HIQA should develop national standards for the conduct of reviews of adverse incidents.	HIQA	End Quarter 4, 2014
O.R.10	Every maternity service (and later every health service provider) be required to complete a Patient Safety Statement which is published and updated monthly.	HSE	End Quarter 1, 2014
O.R.11	A National Patient Safety Surveillance system should be established by HIQA.	HIQA	End Quarter 4, 2014
Analysis of Perinatal Data			
R.1	The Department of Health should work with the Department of Social Protection to ensure that all official perinatal mortality rates should be calculated using a common definition.	Departments of Health and Social Protection	Common definition in use by 2015
R.2	The Civil Registration Act 2004 should be amended to include a duty to notify early neonatal death to the General Register Office.	Departments of Health and Social Protection	Commence formal engagement between departments immediately
R.3	The General Register Office should ensure that all notified early neonatal deaths are registered.	General Register Office	End Quarter 1, 2014
R.4	The HSE should ensure that the NPRS and NPEC are consolidated to create a single national reporting system for official statistics on perinatal events in Ireland.	HSE	End Quarter 4, 2014

Theme One: Patient-Centredness			
R.5	An assessment of the patient safety culture in Portlaoise Hospital should be conducted by HIQA. (See Recommendation O.R.2)	HIQA	End Quarter 2, 2014
R.6	HIQA should be requested 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.	HIQA	End Quarter 4, 2014
R.7	The HSE should conduct a review in PHMS in respect of services for the infant and family following a perinatal death.	HSE	End Quarter 2, 2014
R.8	The HSE should conduct a review of neonatal pathology service requirements and arrangements as they relate to PHMS.	HSE	End Quarter 2, 2014
R.9	The HSE should ensure that systems are in place in order that a senior consultant and a senior nurse/midwife take responsibility for dealing with serious adverse events when they occur.	HSE and local hospital management	End Quarter 2, 2014
R.10	Training should be provided by the HSE for senior clinical staff in dealing appropriately with patients in the context of serious adverse events.	HSE and local hospital management	End Quarter 2, 2014
R.11	The HSE National Open Disclosure Policy should be implemented in full.	HSE	End Quarter 2, 2014
R.12	The HSE should develop a national policy on disclosure where no harm arises.	HSE	End Quarter 2, 2014
R.13	The HSE should issue direction to the system on the appropriate interpretation of Section 48 of the Health Act, 2004.	HSE	End Quarter 1, 2014
Theme Two: Clinical Governance			
R.14	HIQA should develop national standards for the conduct of reviews of adverse incidents.	HIQA	End Quarter 4, 2014
R.15	The HSE should ensure consistency of adverse event terminology across its documentation and guidance.	HSE	End Quarter 1, 2014
R.16	All staff should be obliged to participate honestly and openly in all investigation processes.	HSE and local hospital management	Immediate
R.17	There should be an appropriately resourced special support team that is deployed from the HSE, Quality and Patient Safety Directorate to guide a consistent response to major adverse events.	HSE	End Quarter 1, 2014
R.18	A Quality and Patient Safety Accountability Framework should be developed and implemented by the HSE.	HSE	End Quarter 2, 2014
Theme Three: Clinical Effectiveness			
R.19	The National Clinical Effectiveness Committee should develop standards for clinical practice guidance.	NCEC	End Quarter 4, 2014
R.20	A national guideline for the induction of labour should be developed by the HSE.	HSE	End Quarter 4, 2014
Theme Four: Escalation of Incidents and Role of National HSE			
R.21	The HSE should issue a directive to all providers to require them to notify the director of quality and patient safety and HIQA of all 'never events'.	HSE	End Quarter 1, 2014

R.22	The HSE should ensure that every maternity service (and later every health service provider) should be required to complete a Patient Safety Statement which is published and updated monthly. (See Overall Recommendation O.R.10)	HSE	End Quarter 1, 2014
R.23	The Patient Safety Statement should be a requirement of hospital licensing. (See Overall Recommendation O.R.10)	Department of Health, Licensing Bill	Appropriate sections to be drafted and incorporated into the Bill by end Quarter 1, 2014.
R.24	A National Patient Safety Surveillance system should be established by HIQA. (See Overall Recommendation O.R.8)	HIQA and Department of Health	End Quarter 4, 2014
Theme Five: Leadership, Staffing and Workforce Planning			
R.25	The HSE should provide support to the Portlaoise Hospital senior management team. This should lead to a wider programme of support for frontline leaders, particularly in smaller hospitals, to ensure that they can and do provide safe and effective care	HSE	Immediate
R.26	The HSE should develop evidence-based workforce planning tools and data systems for midwives and maternity care assistants (Birthrate Plus).	HSE	End Quarter 2, 2014
R.27	The HSE should develop national guidelines on rostering of midwifery staff in maternity units based on best evidence.	HSE	End Quarter 2, 2014
R.28	The HSE should undertake a comprehensive review of the potential role of maternity care assistants in Ireland, including training requirements, should be undertaken to identify the roles and responsibilities that could reasonably and safety be delegated by a midwife. This should include an economic analysis.	HSE	End Quarter 2, 2014
R.29	The HSE should ensure that a culture of lifelong learning for healthcare professionals should be promoted and supported in line with individual learning needs and the needs of the service.	HSE and regulatory bodies	End Quarter 1, 2014
R.30	The HSE should ensure that healthcare professionals involved in foetal assessment including the interpretation of cardiotocography (CTG) should engage in regular multi-disciplinary training.	HSE	End Quarter 1, 2014
R.31	The Nursing and Midwifery Board should develop a process for continuously improving the Practice Standards for Midwives to ensure the skill set included is based on best evidence and service need.	NMBI	End Quarter 1, 2014
R.32	The Nursing and Midwifery Board in conjunction with the HSE should explore how a training needs assessment could be linked to maintenance of professional competence for midwives.	NMBI	End Quarter 1, 2014
R.33	The Nursing and Midwifery Board should prioritise the development of Rules relating to a professional competence scheme, in accordance with Section 13 of the Nurses and Midwives Act 2011.	NMBI	Immediate

R.34	The Department of Health should commence Part 11 of the Nurses and Midwives Act 2011 to ensure that midwives maintain their professional competence within their scope of practice utilising a scheme to be determined by the NMBI.	Department of Health	Urgent but dependent on Recommendation 33.
Theme Six: Infrastructure and Equipment			
R.35	The HSE should support PHMS to engage in the productive ward initiative.	HSE	End Quarter 2, 2014
R.36	Healthcare organisations should ensure, as a matter of priority, that they review and address any shortfall in the management of healthcare records in line with the HSE national policy.	Local Hospital Management	End Quarter 1, 2014
R.37	The HSE should provide assurance that healthcare organisations are adhering to its national healthcare records management standards.	Health Service Executive	End Quarter 1, 2014
R.38	The HSE should review the National Maternity Healthcare Record to determine that it is fit for purpose.	HSE	End Quarter 1, 2014
R.39	The HSE should provide assurance that healthcare organisations are adhering to its Medical Device Standards.	HSE	End Quarter 1, 2014
Theme Seven: Legal and Ethical Issues			
R.40	The HSE should develop guidelines for staff on attendance at inquests.	Health Service Executive	End Quarter 2, 2014
R.41	The Department of Health should engage with the Department of Justice and Equality in respect of the coronial service.	Department of Health and Department of Justice and Equality	Commence formal engagement between departments immediately
R.42	The HSE should provide assurance that healthcare organisations are adhering to its National Consent Policy.	HSE	End Quarter 1, 2014

Glossary of terms and abbreviations

ACSQHC	Australian Commission on Safety and Quality in Healthcare
BMA	British Medical Association
CEO	Chief Executive Officer
CIS	Clinical Indemnity Scheme
Clinician	A health professional, such as a physician, or nurse, involved in clinical practice.
CNM	Clinical Nurse Manager
CPD	Continuing Professional Development
CSO	Central Statistics Office
CTG	Cardiotocography
DML	Dublin Mid Leinster
DoH	Department of Health
GP	General Practitioner
GRO	General Register Office
HCAIs	Healthcare Acquired Infections
HIQA	Health Information and Quality Authority
HR	Human Resources
HSE	Health Service Executive
IMB	Irish Medicines Board
ISANDS	Irish Stillbirth and Neonatal Death Society
ISBAR	Identification, Situation, Background, Assessment, Recommendation
IT	Information Technology
KPI	Key Performance Indicator
MOET	Maternity Obstetrical Emergency Training
NAEMS	National Adverse Event Management System
NCEC	National Clinical Effectiveness Committee
NICE	National Institute for Health and Care Excellence
NIMT	National Incident Management Team
NMBI	The Nursing and Midwifery Board of Ireland
NPEC	National Perinatal Epidemiology Centre
NPRS	National Perinatal Reporting System
NTMA	National Treasury Management Agency
PHMS	Portlaoise Hospital Maternity Services
PSA	Patient Safety Agency
RDO	Regional Director of Operations
RDPI	Regional Director of Performance and Integration
SCBU	Special Care Baby Unit
SIMP	Serious Incident Management Policy
SCA	State Claims Agency
WHO	World Health Organisation
WTE	Whole Time Equivalent

Appendix 1 HSE and Portlaoise Hospital Documentation

Origin of Report	Name of Report	Document Reference Number	Approval Date	Revision Date
HSE	Guideline on Effective Clinical Handover for Midwives	PHOG003	July 2013	July 2015
HSE	Management of an expectant mother's Pain & Pain Relief during labour but not including Epidural Anaesthesia	PHOG017	November 2013	November 2015
HSE	Foetal Heart Rate Monitoring during labour in the Maternity Department	PHOG011	November 2013	November 2015
HSE/Institute of obstetricians & Gynaecologists	Clinical Practice Guideline: Intrapartum Foetal Heart Rate Monitoring	Guideline No.6	June 2012	April 2014
	Internal Staff Notice: Administration of Syntocinon	N/A	22nd November 2011	N/A
	Internal Staff Notice: Oxytocin infusion Regime for first and second stage of labour	N/A	18 July 2007	N/A
HSE	Syntocinon Infusion Guideline for Induction and Augmentation of Labour in the first and second stages of labour	PHOG010	July 2013	July 2015
HSE	Policy for the Provision of Statutory and Mandatory Training in the HSE DML	QPSDML4001	29 January 2013	January 2015
HSE	Incident/Near Miss Algorithm	N/A	27 January 2014	July 2014
HSE	Toolkit of documentation to Support the Health Services Executive Incident Management	OQR0008	March 2009	March 2010
HSE	HSE Incident Management Policy and Procedure	OQR006	September 2008	N/A
HSE	Serious Incident Management – Policy and Procedure (part 2)	N/A	N/A	N/A
HSE	Complaints and Incident Management and Investigation Guidelines (HSE Dublin Mid-Leinster)	HSEMARM006	November 2009	N/A
HSE	Complaints and Incident Management and Investigation Guidelines (HSE Midland Area)	HSEMARM006	19 August 2005	N/A
HSE MRHP	Membership of MRHP obstetrics/Gynaecology Quality & Safety Specialty committee	N/A	N/A	N/A
HSE MRHP	Agenda for Obs/Gynae Quality & Safety Specialty Committee Meeting	N/A	N/A	N/A
HSE MRHP	Clinical Specialty Lead Guidance Document	N/A	4 March 2013	N/A
HSE MRHP	Membership of MRHP Quality & safety Executive Committee	N/A	N/A	N/A
HSE MRHP	Organisation Chart 1 *(no title)*	N/A	20 May 2013	N/A
HSE MRHP	Organisation Chart 2 MRHP Consultant & NCHD structure	N/A	20 May 2013	N/A
HSE MRHP	Organisation Chart 3 MRHP Nursing, midwifery & Domestic Services Structure	N/A	10 May 2013	N/A

HSE MRHP	Organisation Chart 4 MRHP Business & Clinical Support	N/A	May 2013	N/A
HSE MRHP	Organisation Chart 5 MRHP Quality & Safety Committee Structure	N/A	22 January 2014	N/A
MRHP	Internal Note: Update (as at 5/2/14/) re Open Disclosure Initiative at MRHP	N/A	5 February 2014	N/A
HSE	Quality & Safety Clinical Governance Development Project	Newsletter Volume 1, Issue 4	2 December 2013	N/A
MRHP	Proposal (version 6) MRHP patient Partnership Group: Terms of Reference	N/A	20 January 2014	N/A
MRHP	Notes re Meeting re MRHP patient Partnership Group (PPG)	N/A	20 January 2014	N/A
MRHP	DML Quality Management System – Risk Register. Ob/Gynae Risk Register: Includes "open", "monitor" and "closed" risks	Various	5 February 2014	On-going updates
MRHP	DML Quality Management System – Risk Register. Ob/Gynae Risk Register: "open" risks	Various	5 February 2014	On-going updates
MRHP	DML Quality Management System – Risk Register.	Various	5 February 2014	On-going updates
HSE DML	Risk Register (with associated updates) DML Risk Register	Various	3 March 2011	On-going updates
HSE MRHP	DML Quality Management System – Risk Register. MRHP	Various	5 February 2014	On-going updates

MRHP – Midland Regional Hospital – Portlaoise HSE DML – HSE Dublin Mid Leinster

Appendix 2 Definitions

HSE (2013) Open Disclosure National Policy	**Error:** The failure of a planned action to be completed as intended or use of a wrong inappropriate or incorrect plan to achieve an aim. Adverse Event: An incident which results in harm to a person that may or may not be the result of an error. **Harm:** Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury. **Incident:** An event or circumstance which could have or did lead to unintended and/or unnecessary harm and/or a complaint loss or damage. **Near Miss Event:** An incident which could have resulted in harm but did not either by chance or timely intervention. **No Harm Event:** An incident occurs which reaches the service user but results in no injury to the service user. Harm is avoided by chance or because of mitigating circumstances.
HSE (2011) Policy Management of Adverse Clinical Events National Ambulance Service	**Error:** The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning). Errors may be errors of commission or omission, and usually reflect deficiencies in systems of care. **Adverse Event:** An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable. **Near Miss:** Serious error or mishap that has the potential to cause an adverse event, but fails to do so because of chance or because it is intercepted. **Adverse Drug Event:** a medication related adverse event. **Adverse Device Event:** an adverse event related to a medical device or equipment. **Significant/Serious Adverse Event:** an event that results in death or serious injury/illness to a patient, or with the potential to cause serious injury or illness to a patient. **Serious Incident:** means an incident which involved or is likely to cause extreme harm or is likely to become a matter of significant concern to service users, employees or the public (HSE, 2008).
HSE (2010) Risk and Incident Escalation Procedure http://www.hse.ie/eng/about/Who/qualityandpatientsafety/resourcesintelligence/Quality_and_Patient_Safety_Documents/escalation.pdf	**Risk**: means the chance of something happening that will have an impact on objectives (AS/NZS 4360:2004). **Incident:** means an event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage (WHO, 2009). **Patient Safety Incident:** means an event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a patient (WHO, 2009). **Serious Incident**: means an incident which involved or is likely to cause extreme harm or is likely to become a matter of significant concern to service users, employees or the public (HSE, 2008).
HSE (2008) Serious Incident Management – Policy and Procedure http://www.hse.ie/eng/about/Who/qualityandpatientsafety/incidentrisk/Riskmanagement/Incident%20management%20policy%202008.pdf	Each Incident must be assessed based on the individual circumstances, using local managers' experience and judgement, but the following definitions of incidents and harm are in line with internationally accepted healthcare risk systems. Incident: Any event that causes or has the potential to cause harm. Harm: A detrimental impact (including physical, psychological, financial, and environmental) on service users, employees and the public. Serious Incident: Any incident which involved or is likely to cause extreme harm or is likely to become a matter of significant concern to service users, employees or the public.
HSE (no date) Incident Management Training for Senior Managers http://www.hse.ie/eng/about/Who/qualityandpatientsafety/incidentrisk/Riskmanagement/bro	**An incident** is an event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm and near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention. **Incidents** can be clinical or non-clinical and include incidents associated with harm to: - Our patients, service users, staff and visitors

chureincmgy0912.pdf	- The attainment of HSE objectives - ICT systems - Data security e.g. data protection breaches - The environment. **Incidents** include complaints which are associated with harm and as such these complaints are service user or staff reported incidents.
HSE (no date) Serious Incident Management Team Guideline on Conducting Look-back Reviews	Look-back reviews are carried out when a hospital or other health service makes a decision to review the care or treatment provided to a specific group of people using our services. This re-examination is usually done when it is considered that the results delivered by either a service or an individual may not have been up to the standard which would be expected when benchmarked against international norms. The decision to carry out a look-back review is made (by the relevant National Director) following an incident investigation as part of the HSE Incident Management Policy and Procedure. Following a preliminary assessment of an incident, it may be considered that a look-back review is required. A look-back review may be required where: - A faulty batch of vaccines is identified - Equipment is found to be faulty or contaminated and there is a potential that patients have been placed at risk - There is a concern about the competence of a clinician - There is concern about the level of injury in a care setting

Appendix 3 Adverse Report Recommendations

FI: Fully implemented IP: Implementation in progress NPD: No progress detailed

Recommendation Themes	Evidence of Implementation
Date incident: September 2006 Date report: June 2007	
5 required new control measures - Clinical decision making - Communication - Clinical leadership	- No progress report
Date incident: November 2006 Date report: June 2009	
*13 recommendations (FI - **8**, IP - **3**, NPD - **2**)* - Guidelines: Foetal heart rate, Pain management - Workforce planning - Obstetric on-call cover - Escalation of care - Clinical leadership - Training needs assessment - Team performance management - Healthcare records management	*Date of update: No date on report* - Guideline (foetal heart rate April 2008. Audit 2013. - Guideline (Pain management) Audit late 2012. - Staffing review on-going. - Training needs analysis completed. Discussions on-going with the Coombe Hospital re formalised education links. - National Maternity Healthcare Record implemented. - Healthcare records training provided.
Date incident: July 2008 Date report: August 2011	
*16 recommendations (FI - **12**, IP - **4**)* - Monitoring of foetal heart rate - CTG training – 2 yearly - CPD for staff, staff competence assessment - Workforce planning - NCHD hours, location of obstetric on-call cover - Clinical guideline (syntocinon)[40] - Clinical leadership - Escalation of care - Foetal blood sampling	*Date of update: 05/02/2014* - Statements that audit completed. - Statements that training provided. - Staffing review on-going. - Clinical guideline (syntocinon) developed, implemented and audited. - Statement that guideline re ISBAR and IMEWS implemented with inbuilt escalation policy.
Date incidents: November 2006, September 2009, January 2010 Date of report: March 2012	
43 recommendations *(FI - **29,** IP - **9**, Closed - **5**)* - Specific midwife A recommendations - Guidelines: documentation, oxytocin, pain management - CTG policy and training - Healthcare records - Clinical leadership - Audit - CPD for staff - Workforce planning - Risk management	*Date of update: 15/01/2014* - Guidelines in place. - Workforce planning on-going. - Training in place. - Audits completed.
Date of incident: January 2012 Date of report: September 2013	
43 recommendations (+ 3 additional from Coroner's inquest) *(FI - **39,** IP - **7**, NPD - **2**)* - Guidelines: intrapartum care, pain relief - CTG policy and training - Use of syntocinon (Coroner's recommendation) - Escalation of care, clinical handover, communication - Foetal blood sampling - Equipment care - Healthcare records management - Clinical assessment, escalation of incidents - Workforce planning - CPD for staff, performance management system - Clinical leadership - Governance arrangements/infrastructure - Management of bereaved parents - Audit - Risk assessment for transfer from labour ward to theatre	*Date of update: 30/01/2014* - Guidelines in place. - Foetal blood sampling commenced. - CTG training mandatory annually. Monthly CTG discussions. - Statement that guideline re ISBAR and IMEWS developed with inbuilt escalation policy. Midwife training Mar/Apr 2013. - Clinical handover guideline updated. - Training needs analysis commenced. - Audit plan finalised. - Syntocinon audit completed.

[40] Oxytocin is a drug utilised for labour induction. Synthetic oxytocin is sold as proprietary medication under the trade name Syntocinon.

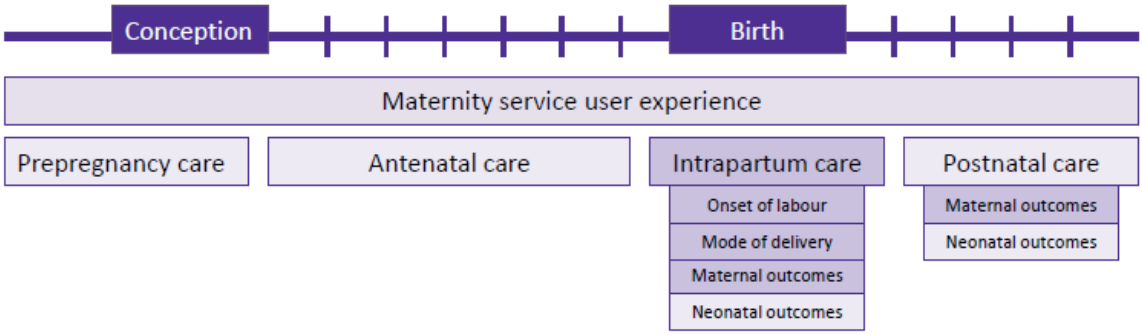
Appendix 4 Maternity Patient Safety Statement

(for illustrative purposes only)

A monthly patient safety statement is a powerful tool. It uses available data to inform on activity trends in a healthcare unit and focuses the attention on areas that are both performing well and areas that are underperforming. However, data needs to be analysed on a regular basis by those who have the capacity to interpret the data wisely and to implement necessary change for better patient outcomes.

In terms of monitoring maternity unit patient safety, it is important to first consider the pathway of the maternity service user. The various junctures of that maternity pathway are illustrated below.

Maternity service pathway[41]



When developing a maternity patient safety statement, the following data fields are some examples of information that would be useful to guide units on their safety performance.

- **Birth Rate**
- **Mode of delivery**: Vaginal, C-Section, Induced labour
- **Maternal outcome**: Transfers to another hospital, Emergency readmission within 30 days of delivery, death.
- **Perinatal outcome**: Transfers to another hospital, stillbirth numbers, early neonatal deaths (death within 7 days of birth), late neonatal deaths (from days 8 to 28 after birth).
- **Adverse events**: Classified as minor, moderate, major or extreme adverse events as per the risk impact table categorisation, Appendix 1 *HSE Incident and Management Policy and Procedure 2008*.
- **Obstetric claims**
- **Staffing level**: Senior, junior medical, nursing staff and permanent or agency level.

All of the above information should be readily available in all maternity units. The collection of this simple information should then be translated into rates for trend analysis that are monitored over time. Having this analysis not only informs on patient safety and early warning of a system failure but may also give useful feedback on the impact of any new interventions in a maternity unit.

[41] Patterns of Maternity Care in English NHS Hospitals 2011/2012. London School of Tropical Medicine, Royal College of Obstetricians and Gynaecologists, London School of Hygiene and Tropical Medicine.