Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Background document to support the development of National Standards for Safer Better Maternity Services

December 2016

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services –** Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.

- **Regulation –** Registering and inspecting designated centres.

- **Monitoring Children's Services –** Monitoring and inspecting children's social services.

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

- **Health Technology Assessment –** Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.

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

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Introduction

Overview

Pregnancy and childbirth are normal physiological life-changing events. While most women are healthy and well and have a straightforward pregnancy, some women require additional care and support. Maternity services must be responsive to the needs of all women. Good maternal health and safe, high-quality maternity care impacts on the health and life chances of newborn babies, their healthy development and their long-term health. Promoting and supporting the health of mothers and babies is vital to ensure the health and wellbeing of future generations.

The Health Service Executive (HSE) is the national agency accountable for the planning and delivery of the national health services, including maternity services. All pregnant women who are resident in Ireland are entitled to receive public maternity care under the 1954 Maternity and Infant Scheme. This care is provided by general practitioners (GPs) registered with the scheme, and hospital obstetricians and midwives working within the maternity services. The public maternity services are part of the Acute Hospitals Division of the HSE. The HSE's National Director of Acute Services is the senior HSE manager with responsibility for this division. The National Director of Acute Services is a member of the HSE directorate and reports directly to the Director General of the HSE. Maternity services are provided in 19 maternity units around the country.[1]

The model of maternity services in Ireland is predominantly a medical model of maternity care, which has been in place for over 60 years. Maternity services are typically consultant-led, with pregnant women and mothers attending the hospital for antenatal, delivery and postnatal care. GPs also provide antenatal and postnatal care in the community.[1]

Background to the Standards

HIQA launched the *National Standards for Safer Better Healthcare* in June 2012 These standards outline a vision for safe, high-quality healthcare. While these National Standards cover all healthcare settings a need was identified to develop service-specific standards for maternity services in Ireland. Recent reviews and investigations of maternity services in Ireland, undertaken by HIQA, the Health Service Executive (HSE) and the Department of Health, have identified the need to develop standards which are specific to maternity services. HIQA reports have raised significant concerns about inconsistencies in the safety and quality of maternity services and recommended that all women should have access to the appropriate level of maternity care at any given time. HIQA's 2015 Portlaoise investigation report[1] and its 2013 Galway investigation report[2] both identified the need for a national maternity services strategy to be agreed and implemented. A need was also identified for this strategy to be supported by nationally mandated maternity standards.

Ireland's first National Maternity Strategy (Creating a Better Future Together)(2) was launched in January 2016. The National Maternity Strategy and the *National Standards for Safer Better Maternity Services*, when implemented, represent the necessary building blocks to providing a consistently safe, high-quality maternity service, which will work towards restoring public confidence in the service.

Purpose of the Standards

The *National Standards for Safer Better Maternity Services* describe what safe, high-quality maternity services should look like. For women, giving birth to a healthy baby should be one of the most normal, rewarding and positive life experiences. The Standards aim to help maternity services achieve this for women and have been

[1] Report of the investigation into the safety, quality and standards of service provided by the Health Service Executive to patients in the Midlands Regional Hospital, Portlaoise.
[2] Investigation into the safety, quality and standards of service provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration, including those provided in University Hospital Galway, and as reflected in the care and treatment of Savita Halappanavar.

designed in such a way that they can be implemented in all maternity services. The Standards sit within the overarching framework of the *National Standards for Safer Better Healthcare* with the aim of promoting improvements in conjunction with the new National Maternity Strategy.

Standards development process

A review of international and national literature was undertaken and used to inform the development of the National Standards. This review took account of published research, reviews and investigations of maternity services in Ireland, standards and guidelines currently in place both in Ireland and in other countries, Government policy (including the National Maternity Strategy) and expert opinion.

The Standards were developed using the framework of the *National Standards for Safer Better Healthcare.* Figure 1 illustrates the eight themes under which the National Standards are presented. The four themes on the upper half of the circle relate to the dimensions of safety and quality in a service, while the four on the lower portion of the circle relate to the key areas of a service's capacity and capability.

Figure 1. Themes for safety and quality

The four dimensions of safety and quality are:

- **Person-centred Care and Support** – how services place the woman and her baby at the centre of their delivery of care. This includes the concept of access, equity and protection of rights.
- **Effective Care and Support** – how services deliver best achievable outcomes for women and their babies in the context of that service, reflecting best available evidence and information. This includes the concepts of service design and sustainability.

- **Safe Care and Support** – how services avoid, prevent and minimize harm to women and their babies and learn from when things go wrong.
- **Better Health and Wellbeing** – how services work in partnership with women to improve their health and wellbeing and that of their babies.

Delivering improvements within these quality dimensions depends on service providers having capacity and capability in four key areas, as follows:

- **Leadership, Governance and Management –** the arrangements put in place by a service for clear accountability, decision-making and risk management as well as meeting its strategic, statutory and financial obligations.
- **Workforce –** planning, recruiting, managing and organizing a workforce with the necessary numbers, skills and competencies.
- **Use of Resources –** using resources effectively and efficiently to deliver best possible outcomes for women and their babies.
- **Use of Information –** actively using information as a resource for planning, delivering, monitoring, managing and improving care.

The findings from the documents reviewed were grouped by these themes and informed the content of the standards and features within the individual themes. More information was available in relation to some themes than others, for example, the literature review identified most evidence in relation to theme 2 (Effective Care and Support) and yielded little return in relation to theme 7 (Use of Resources). Much information was available in the area of person-centred care and support in both the national and international documents reviewed but less so in relation to leadership, governance and management. Where information was not readily available, or deficiencies within specific themes were identified, expert opinion and advice was sought through extensive engagement with stakeholders. HIQA employed the following methods of engagement:

- HIQA convened a standards advisory Group which included women who had recently used maternity services, patient advocates, healthcare professionals and representatives from the Department of Health and the HSE.
- HIQA conducted a series of focus groups with women and their partners and with frontline staff working in maternity services. The team held 12 focus groups in six locations nationally, meeting with 138 participants to discuss their experience of maternity services and obtain their opinions as to what national maternity standards should address. The team also met with a number of senior administrative staff while on site in the various locations.
- HIQA undertook an eight-week public consultation process from 21 March to 16 May 2016 and received 127 submissions as part of this process. All submissions were reviewed and considered when revising the draft standards.

Structure of this report

This document sets out the findings of the research undertaken to inform the development of the National Standards for Safer Better Maternity Care. It includes:

- Chapter 1: a review of frameworks, standards and guidelines in place internationally
- Chapter 2: an overview of the Irish context including the National Maternity Strategy, standards and guidelines and reviews of investigations of Irish maternity services
- Chapter 3: the findings of a systematic literature review undertaken to identify and document recently published evidence in relation to standards in maternity services.

All documents were reviewed and assessed for inclusion in the evidence base to inform the development of the *National Standards for Safer Better Maternity Services*.

Chapter 1: International Review

1. Overview of international review

This section provides an overview of strategies, frameworks, standards and guidance that are available for maternity services internationally. International standards and country-specific frameworks, standards and guidelines are documented. The jurisdictions reviewed include:

- England
- Northern Ireland
- Scotland
- Wales
- Australia
- New Zealand
- Canada
- British Columbia.

These jurisdictions were chosen following a desktop review which identified relevant developments in maternity services in terms of recent strategies being developed, reviews of maternity services being undertaken or countries that have standards in place for maternity services. An overview of international standards is provided in section 1.1 with each individual jurisdictions explored in detail thereafter.

1.1 International standards

It is recognised internationally that the setting and implementation of quality standards are levers to improve care. Standards help to set public, provider and professional expectations and enable services to safeguard people using their services and to improve the quality of care they provide. Some work has already taken place internationally on developing standards for maternity care.

1.1.1 Standards for Maternal and Neonatal Care, WHO

The World Health Organization (WHO) published *Standards for Maternal and Neonatal Care*[3] in 2007 outlining key recommendations on the delivery of maternal and neonatal care in health facilities, starting from the first point of care. The nine standard statements cover antenatal, intrapartum and postnatal care. Each standard statement is accompanied by an aim, requirements, application, audit, including input indicators and process and output indicators, and a rationale. Immunization prior to pregnancy is included but otherwise pre-pregnancy care is not covered in the standards statements or requirements. These standards are more applicable to low-income countries with high maternal, perinatal and neonatal mortality. The purpose of the standards is to assist programme managers and health care providers to[3]:

- Develop evidence-based national and sub-national standards on maternal and neonatal health care
- Introduce standards setting and a quality improvement process at facility level as a means to improve access and quality of maternal and neonatal health services
- Provide effective maternal and neonatal health services
- Use existing resources to achieve the optimal health care outcomes
- Improve individuals', families' and community's satisfaction and utilisation of maternal and neonatal health services.

1.1.2 European Board and College of Obstetrics and Gynaecology

The European Board and College of Obstetrics and Gynaecology (EBCOG) aims to improve the health of women and their babies by promoting the highest possible standards of care in all European countries. Thirty-six countries, including the European Union (EU) 28 member states, are members of the EBCOG. Maternal and infant morbidity and mortality rates have declined significantly across the EU28 member states but inequalities in access to women's healthcare still exist. In 2014, the EBCOG published *Standards of Care for Obstetric and Neonatal Services*. These standards cover

maternity care from pre-pregnancy through intrapartum care to the postnatal period, including care of the newborn.

These standards have been developed for 36 countries with different maternity care models, levels of safety and quality as well as widely varying rates of adverse perinatal outcomes. There are few EU-wide agreed health indicators or guidelines for the care of women during pregnancy and labour and for the care of the newborn, nor are there uniform standards for data collection systems across the member states for meaningful comparisons.

The EBCOG document includes 18 standards which address similar areas as other international standards including:

- Pre-pregnancy services
- Care of pregnant women with pre-existing medical conditions and or special needs
- Intrapartum care
- Postnatal care of the mother
- Supporting families who experience pregnancy bereavement, early pregnancy loss or stillbirth.

Clinical standards, training standards and auditable indicators have been developed for each of the standards.

1.1.3 Standards of Maternity Care for Australia and New Zealand

The Royal Australian and New Zealand College of Obstetrics and Gynaecologists published an agreed set of *Standards of Maternity Care for Australia and New Zealand* in March 2014. The standards are structured around the organisation of maternity care and the process of maternity care for pre-pregnancy, during pregnancy and in the postnatal (the period of six weeks after birth) and neonatal period. A revised version was published in March 2016 with the addition of one new standard about antenatal

screening under the category of care during pregnancy. The standards are organised into five groups with 26 categories of standards for maternity care and are documented in Table 1. The categories were used to inform the categorisation of information retrieved in the literature review documented in Chapter 3 of this report.

Table 1. Five groups of Standards of Maternity Care for Australia and New Zealand

Organisation of maternity care	▪ Provision of choice for women and their families ▪ Planning appropriate maternity services for local communities ▪ Appropriate staffing for maternity services ▪ Provision of care in maternity units with service limitations ▪ Training and maintenance of professional competence in maternity units ▪ Inter-professional communication ▪ Clinical governance of maternity services ▪ Documentation and confidentiality ▪ Infection prevention and control
Pre-pregnancy care	▪ Preparation for pregnancy ▪ Pre-pregnancy care for women with existing medical conditions, or significant family or obstetric history
Care during pregnancy	▪ Access to maternity services ▪ Early pregnancy services ▪ Maternity booking and planning of care ▪ Pre-existing medical conditions in pregnancy, including mental health issues ▪ Women with social needs ▪ Antenatal screening ▪ Routine antenatal care ▪ Specific pregnancy-related conditions
Care during birth	▪ Intrapartum care

Care in the puerperium and neonatal period	▪ Neonatal care and assessment ▪ Postnatal assessment and care of the mother, including breastfeeding ▪ Care of babies requiring additional support, including babies born preterm ▪ Promotion of healthy parent-infant relationships ▪ Transition to parenthood ▪ Supporting families who experience bereavement, pregnancy loss, stillbirth or early neonatal death.

Many of these categories are similar to the categories of the Royal College of Obstetricians and Gynaecologists (RCOG) UK standards and some have been combined. There are 200 standards under each of the 26 categories. Apart from the category of appropriate staffing for maternity services which has 24 standards, the number of standards for each of the categories ranges from one to 15. Unlike the RCOG standards, audit indicators have not been developed for each category of standard.

1.2 England

In England, maternity services are provided by 136 National Health Service (NHS) trusts and 15 mother and baby units provided by mental health trusts. There are four broad types of settings for care in labour and birth: at home, freestanding midwifery units, midwifery units and hospital obstetric units.[4] In 2012, 87% of births took place in NHS obstetric units. Although 96% of NHS trusts offered home births, only 2.4% of births were at home.[5]

The department of health UK outlined its main objectives for maternity services as follows[5]:

- to improve performance against quality and safety indicators
- for mothers to report a good experience
- to encourage normality in births by reducing unnecessary interventions

- to promote public health with a focus on reducing inequalities[3]
- to improve diagnosis and services for women with pregnancy-related mental health problems.

The department of health outlined its strategy for maternity services in 2007 in *Maternity Matters*.(6) It intended to achieve its aims by offering choice in where and how women have their baby, providing continuity of care and ensuring an integrated service through networks and agreed care pathways. *Maternity Matters* sets out a strategy that puts women and their partners at the centre of their local maternity service provision. It highlights how commissioners, providers, maternity professionals and user representatives could use the health reform agenda to shape service provision to meet the needs of women and their families.(6)

This section sets out findings from a recent maternity services survey, the most recent maternity strategy for England, findings and learning from the recent Morecambe Investigation, standards developed by the Royal College of Obstetricians and Gynaecologists, and NICE Quality Standards. It also reviews the Leeds Maternity Strategy which sets out a framework for maternity services from 2015 – 2020.

1.2.1 Maternity Services Survey

The Care Quality Commission (CQC) is the independent regulator of health and social care in England. The CQC undertakes an annual survey looking at the experiences of people using maternity services. All women who have had a live birth in a hospital, birth centre, maternity unit or at home are eligible to participate in the survey. The CQC uses the results from the surveys in the regulation, monitoring and inspection of acute trusts in England. The results of the latest survey undertaken in 2015 are available on the CQC website.(7)

[3] While reducing inequalities is a specific focus of the public health aim as a general aim of the NHS, reducing inequalities is also inherent in other maternity aims.

The most recent findings into women's experiences of maternity services in England show that more attention needs to be paid to provision of good information, support around physical and emotional wellbeing, and involvement in decision-making, as well as practical issues such as feeding.[4] The surveys show evidence of particular challenges around postnatal care. For example, with regard to antenatal appointments, 15% of women said that midwives were not aware of their medical history, compared with 22% at the postnatal stage.[4] The survey also showed that women who saw the same midwife for each appointment tended to report a better experience of care. This demonstrates the value of having an ongoing relationship with a single practitioner as a means of ensuring continuity of care. While there will be occasions where people need to see different midwives due to changes in staffing, personal circumstances, or preferences, it is important for as many women as possible to be given the opportunity to see the same midwife throughout their maternity care if they choose to do so.

1.2.2 Better Births: Improving outcomes of maternity services in England: A five Year Forward View for maternity care (2016)

Twenty-two years after the initial publication of *Changing Childbirth* (1993), the *Better Births: Improving outcomes for maternity services in England* (2016)[8] review was commissioned by NHS England in 2015 to examine what change was necessary to maternity services in order to meet the needs of the population. The *Better Births: Improving outcomes for maternity services in England* review of maternity services was announced as part of the *NHS Five Year Forward View*.[4] The review aimed to assess current maternity care provision and consider how services should be developed to meet the changing needs of women and babies. Drawing on wide-ranging evidence, and in consultation with women and their families as well as a wide range of stakeholders including NHS staff, the review published its findings in February 2016.[8]

Measuring maternity services from conception through to six weeks after birth, the maternity review sets out conclusions and identifies recommendations developed upon three key sources of evidence; quality assessment, an independent evidence review

commissioned from the National Perinatal Epidemiology Unit at Oxford University and failings found in the final report of the Morecambe Bay investigation (2015) to ensure that what was learned from the investigation is embedded throughout the NHS. The review found two fundamental principles as highlighted by feedback findings from women and their families which included the importance of women being able to make choices about their care, and the safety of the mother and baby being paramount.

The review team carried out an extensive programme of engagement with the public, service users, staff and other stakeholders to ensure that the findings and conclusions took into account the opinions, expertise and perspectives of a wide range of people. The review covered all regions, and specifically sought to gather views from across rural, urban and suburban areas.[8]

Quality Assessment

Quality was assessed through a broad range of data including regulating inspections and national audits. Visits were also carried out to a selection of units to assess the views of frontline staff. The assessment of quality put particular focus on antenatal care, care during labour and birth, and postnatal care. This examined care across three dimensions of quality including safety, effectiveness and experience. In relation to the assessment of safety, the review describes areas of suggested improvement. Under-reporting of safety incidents is widespread and an improvement in reporting within this area is a necessity.

In relation to the assessment of effectiveness of services and identifying outcomes, the review also describes how there is scope for improvement. The review identified that the number of perinatal deaths is related to geographical region. Areas with deprived populations and greater proportions of older or younger mothers show a higher number of perinatal deaths. While controlling for the effects of such deprivation and maternal age on perinatal death between geographical regions, there is still a marked variation which can be associated with effectiveness of care. Maternal mortality has declined progressively over time. However, in an enquiry by MBRRACE-UK in 2015, half of

maternal death would have led to a different outcome if better care had been provided.[9] With depression and anxiety affecting 15-20% of women in the first year after childbirth, almost one in five women stated that they were not asked about their emotional state, or mental health, at the time of booking their maternity care. [10]. The review found that there is scope for significant improvement and a need for a more consistent approach to learning and improvement.

Areas for suggested improvement include assessment of experience and the workforce. The majority of women report positive maternity experiences. However, 16% of respondents reporting in a CQC Maternity Survey (2015) said that they had no choice. One in four respondents reporting in a National Perinatal Epidemiology unit (NPEU) Safely Delivered National Survey (2014) said they were not aware of possible choices, with 14% of respondents not being provided with enough information to enable a choice of where to have their baby.[10] 40% of women stated that they had not met the midwives previous to them coming to the woman's home for visits, with 32% stating that they saw three or more different midwives, and 77% of women stated that they did not have the name and telephone number of a named midwife or health visitor. Midwives reported feeling pressured at work, with half of midwives stating that they have previously suffered from work-related stress.

Evidence by the National Perinatal Epidemiology unit (NPEU)

The National Perinatal Epidemiology unit (NPEU) commissioned an independent evidence report to the Better Births review team on the following areas of maternity care in England:

- safety of place of birth
- effectiveness of 24/7 consultant labour ward cover in large units
- factors which influence a woman's choice of planned place of birth
- international evidence on the delivery of and outcomes from maternity services.

When considering places of birth and safety, midwifery services can provide sufficient care for low-risk women having their second or subsequent baby, planning a birth at home or in a midwifery-led unit and where the chances of transfer are low. The report found that a woman's ethnicity and level of deprivation does not affect the birth outcome, and that transfer chances may increase with age. The report states that freestanding units have a decreased chance of intervention. Low-risk women having their first baby however, have a higher chance of transfer and a small increased chance of an adverse outcome for the baby than women who have had a baby previously.

The report concluded that women should be provided with unbiased information so that they are able to make decisions regarding place of birth. This information should include intervention chances, on-site availability of obstetric and neonatal services, availability of pain management, and the frequency and likely duration of transfer. Similar to emphasis placed within the *Irish National Maternity Strategy* (2016-2026) and the *Strategy for Maternity Care in Northern Ireland* (2012-2018), the review states that all information provided to women needs to be personalised according to the woman's individual circumstances.

There is insufficient evidence to support a 24-hour resident approach of consultant presence on the labour ward. This is compared to other models of consultant care and based on birth outcomes. The review recommends that a 24-hour residence for doctors, or doctors with appropriate training, be utilised instead of a 24-hour resident consultant presence. The presence of these doctors should be based on workload.

Learning from the Morecambe Bay Investigation report

In part, the *Better Births: Improving outcomes for maternity services in England* (2016) review was commissioned to ensure that lessons from the Morecambe Bay investigation are learnt throughout the maternity care system. The review states that key areas where such lessons need to be addressed across maternity care include developing the right culture through effective leadership and commitment from all health professionals as well as senior management, ensuring that small units do not operate in isolation, and

ensuring a culture of professional relationships between obstetricians, paediatricians and midwives. The Morecambe Bay investigation is explored in greater detail later in this section

What the review heard

Based on feedback from women and their families, healthcare professionals and providers and commissioners, the review discovered a number of areas within maternity care that are of high importance to the stakeholders involved. For women and their families, important areas of maternity care included:

- safe and personalised care
- quality and consistent communication between healthcare professionals and women, and between healthcare professionals themselves
- care when a baby dies, including healthcare provider compassion, appropriate facilities and environment, and time for parents to come to terms with their loss and to make appropriate decisions
- care when complications arise which affect the health of the mother and or their baby
- care for women with different backgrounds
- postnatal care including support services to help women with issues around breastfeeding and mental health support such as continued counselling and therapy sessions.

Feedback from healthcare professionals in relation to important areas of maternity care included:

- teamwork and respect between professions
- professional support and workload, including more creative workforce design and better communication between healthcare providers and commissioners to develop stronger workforce planning
- role of general practice, including more inclusion of general practice in maternity services

- continuity of care through limiting caseload numbers at a manageable level, flexible working such as midwives managing their own diary, a culture of shared trust and responsibility, and rotation of midwives between community and acute-care settings to ensure skills are maintained and a continuity model of care is promoted.

Feedback from provider organisations and commissioners highlighted the need for:

- mental health support
- payment systems that are sensitive to the costs of providing different types of care, as the current maternity tariff system may prevent choice of care
- Provision of services for rural populations.

1.2.3 Royal College of Obstetricians and Gynaecologists Standards for Maternity Care

In June 2008, a joint working party published the *Royal College of Obstetricians and Gynaecologists Standards for Maternity Care* with the purpose of providing guidance for the development of equitable, high-quality services across the United Kingdom (UK). The Royal College of Midwives, the Royal College of Obstetricians and Gynaecologists, the Royal College of Paediatrics and Child Health and the Royal College of Anaesthetists worked together to agree 30 categories of standards for maternity care. These include:

- looking forward to pregnancy
- maternity booking and planning of care
- pre-existing medical conditions in pregnancy
- women with social needs
- pregnancy-related conditions
- postnatal assessment and care of the mother
- supporting infant feeding
- promotion of healthy parent-infant relationships
- transition to parenthood

- support families who experience bereavement, pregnancy loss, stillbirth or early neonatal death
- training and professional competence
- staffing.

1.2.4 NICE Quality Standards

The National Institute for Health and Care Excellence (NICE) quality standards are a concise set of priority statements designed to drive measurable quality improvements within a particular area of healthcare. NICE quality standards are derived from high-quality guidance, such as that from NICE or other sources accredited by NICE. Each quality standard defines clinical best practice within the specific topic area. A quality standard provides specific, concise quality statements, measures and audience descriptors to provide the public, health and social care professionals, commissioners and service providers with definitions of high-quality care.

Antenatal Care, NICE Quality Standard, 22 September 2012

The quality standard for antenatal care requires that services should be commissioned from and coordinated across all relevant agencies encompassing the antenatal care part of the maternity pathway.[11] An integrated approach to provision of services is fundamental to the delivery of high-quality care to pregnant women. The theme of this quality standard is that pregnancy is a normal physiological process. Women should have the opportunity to make informed decisions about their care and treatment based on the current available evidence, in partnership with healthcare professionals. It addresses routine antenatal care, including screening tests for complications in pregnancy, but it does not address the additional care needed to manage these complications if they arise.

Intrapartum Care, NICE quality standard, December 2015

This quality standard covers the care of women who go into labour at term (37^{+0} weeks to 41^{+6} weeks)[4] and care of their babies during labour and immediately after birth.(12) It covers both women who go into labour at low risk of intrapartum complications and women who go on to develop complications. The standard states that it is important that a woman is given information and advice about all available birth settings when she is deciding where to have her baby, so that she can make a fully-informed decision. This includes information about outcomes for the different birth settings. Uncertainty and inconsistency of care for women giving birth has been identified in a number of areas, such as choosing place of birth, care during the latent first stage of labour, fetal assessment and monitoring during labour (particularly cardiotocography compared with intermittent auscultation), and management of the third stage of labour. The quality standard sets out seven quality statements for intrapartum care and is expected to contribute to improvements in the following outcomes(12):

- maternal mortality and morbidity
- neonatal mortality and morbidity
- breastfeeding uptake
- positive experience of and satisfaction with care
- treating and caring for people in a safe environment and protecting them from unavoidable harm.

A NICE guideline on the intrapartum care of women at high risk of complications is under development and is due to be published in 2017, at which point the intrapartum care quality standard will be updated.

Postnatal Care, NICE quality standard 37, issued July 2013 and modified June 2015

This quality standard covers postnatal care, including the core care and support that every woman, their baby and, if appropriate, their partner and family should receive

[4] 37 weeks and 0 days gestation to 41 weeks and 6 days gestation

during the postnatal period.[13] This includes recognising women and babies with additional care needs and referring them to specialist services. Although the postnatal period is uncomplicated for most women and babies, care during this period needs to address any variation from expected recovery after birth. For the majority of women, babies and families, the postnatal period ends six-to-eight weeks after birth. However, for some women and babies, the postnatal period should be extended in order to meet their needs. This is particularly important where a woman or baby has developed complications and remains vulnerable to adverse outcomes. For example, this could include women who have poor support networks, have developed a postnatal infection or other health problem that is continuing to impact on their daily lives, or women who are at risk of mental health problems or infant attachment problems.

1.2.5 The Report of the Morecambe Bay Investigation (2015)

The Report of the Morecambe Bay Investigation highlights high-profile failings of care in maternity services and the necessity to ensure learning from such failings results in improved care.[14] After a series of maternity care incidents raised concern in the University Hospitals of Morecambe Bay NHS Foundation Trust, an investigation was launched to examine the occurrence of the incidents between 2004 and 2013. The investigation discovered a series of failures at almost every level, from the maternity unit to those responsible for regulating and monitoring the Foundation Trust.

The investigation describes how the origin of problems lay in the seriously dysfunctional nature of maternity service, including substandard clinical competence, deficient skills and knowledge, poor working relationships between staff members such as midwives, obstetricians and paediatricians, failures of risk assessment and care plans that resulted in inappropriate and unsafe care, and deficient responses to adverse incidents resulting in poor investigation and no lessons learned. Instances of significant failures of care were found within the investigation and were associated with three maternal deaths and the deaths of 16 babies either at or a short time after birth.[14]

Following a series of missed opportunities to identify problems and prevent recurrence of failures in care, an intense period of intervention from 2011 and 2012 occurred and from 2012 onwards a new senior management team was put in place within the Foundation Trust and a new approach to maternity care was implemented. The investigation describes how they perceived welcoming signs of significant improvement within its maternity services, and governance specifically, with the use of external services, such as the Care Quality Commission (CQC), to identify failed services and intervene. The investigation emphasises the necessity of continuous change and progress, and developed recommendations for both the Foundation Trust and the NHS that if implemented will result in safe, quality healthcare.[14]

1.2.6 Maternity Strategy for Leeds 2015-2020

In addition to the national strategy, *Better Births: Improving outcomes for maternity services in England,* a number of regions, such as Leeds, have developed individual maternity strategies. The *Maternity Strategy for Leeds 2015-2020* is a five-year maternity strategy that sets out the vision and ambition for high-quality, safe and personalised maternity services in the city of Leeds.[15] The delivery of this strategy is integral to the delivery of the *Best Start Plan*,[16] which sets out how services in Leeds can support children and parents from conception. Support from conception is a key priority in both the *Children and Young People's Plan* (2015 – 2019) and the *Leeds Joint Health and Wellbeing Strategy* (2016).

A Maternity Strategy Group led the development of the Leeds strategy, working together with the organisations and professional groups involved in the delivery of pregnancy and early postnatal services across Leeds. The strategy was strongly informed by the Leeds 'Maternity Health Needs Assessment'[17], as well as local and national policy, clinical evidence and the input of women and families of Leeds. The Maternity Strategy Group consulted with a large number of women about their maternity experiences through direct face-to-face conversations with women at events and workshops, and a survey where more than 800 responses were received. The

Maternity Services Liaison Committee (MSLC), which is a group that brings service users together with maternity providers and commissioners, was involved in every aspect of this work.

The strategy contains nine key priorities for how services in Leeds can provide safe, high-quality maternity care to support children and parents from conception to birth and beyond[15]:

1. **Personalised care -** All women will receive care that is personal to their needs, where professionals work with them to plan and deliver care throughout pregnancy, birth and after the baby is born.
2. **Integrated care -** Every woman feels that each stage of her care is coordinated, consistent and delivered in an integrated way.
3. **Access -** Services will be easy to access to help women have their first midwife appointment early in pregnancy and to continue to receive all the care and support that they need throughout their pregnancy.
4. **Emotional health -** The emotional and mental wellbeing of women who are pregnant will be supported and those who experience any emotional problems during and after their pregnancy are well supported and offered the best care.
5. **Preparation for parenthood -** All parents will be supported to have a healthy pregnancy and to feel well-prepared and confident for the birth and subsequent care of their baby.
6. **Choice -** Women and their partners will have all the information that they need to make informed choices about their pregnancy and care.
7. **Targeted support -** Families who need it will receive targeted support during their pregnancy and after the baby is born.
8. **Quality and safety -** Services will strive to ensure that all women receive high-quality, safe and responsive maternity care throughout their pregnancy, birth and postnatal care.

9. **Staffing -** Services will work in partnership to provide well-prepared, trained and confident staff in all services to meet the needs of women and families.

A Maternity Programme Board will oversee the delivery of the nine priorities of the strategy, as well as measuring and reporting its progress, over the next five years.

1.3 Northern Ireland

A strategy for maternity care in Northern Ireland from 2012 to 2018 was published in July 2012. This section sets out the detail of that strategy through the four stages of pre-pregnancy care, antenatal care, intrapartum care and postnatal care. It also documents the implementation plan for the strategy.

1.3.1 A Strategy for Maternity Care in Northern Ireland 2012-2018

Exploring a number of outcomes, and 22 associated objectives, *A Strategy for Maternity Care in Northern Ireland (2012-2018)*[18] focuses on promoting and protecting the health and wellbeing of every mother, baby, father and family. It focuses on investing in early intervention, prevention and support, and advises on integration and effective communication pathways between primary, community and secondary sectors to enable the delivery of high-quality care. Similar to the Irish National Maternity Strategy (2016-2026), care and services are outlined and recommended throughout all stages of pregnancy. Pre-conception care and support is promoted, risk assessment in antenatal care is addressed to allow either midwife or obstetrician to lead, and the need for effective support and information provided throughout the postnatal period, with particular emphasises on community care, is highlighted. The strategy also places awareness on the normalisation of birth, with the aim to reduce unnecessary interventions and improve the experience of giving birth for each parent, baby and family member. The aim of the strategy is to provide safe, high-quality sustainable and appropriate services with the aim of giving every baby and family the best start in life.

The six outcomes within the strategy are[18]:

- to give every baby and family the best start in life
- effective communication and high-quality maternity care
- healthier women at the start of pregnancy (pre-conception care)
- effective, locally accessible, antenatal care and a positive experience for prospective parents
- safe labour and birth (intrapartum) care, with improved experiences for mothers and babies
- appropriate advice, and support for parents and babies after birth.

The strategy identifies the roles and responsibilities of each maternity healthcare professional. It recognises the need for effective communication and partnership between teams of clinicians such as midwives, obstetricians, anaesthetists, neonatologists and paediatricians, while highlighting the inclusions of services from GPs, pharmacists, physiotherapists, dieticians, dentists and ambulance service personnel.[18] Table 2 presents a list of maternity care requirements within the strategy for successful maternity care.

Table 2. Maternity care requirements recorded in A Strategy for Maternity Care in Northern Ireland 2012-2018.

Successful maternity care requires
Effective clinical leadership and clear communication pathways between all involved in maternity care
A skilled workforce which understands specific roles and responsibilities
A sustainable configuration of service provision
A focus on improving clinical outcomes supported by data collection and analysis of quality indicators

Appropriate Information Communication Technology (ICT) support which continues to develop to meet regional and local needs

The strategy promotes good clinical leadership and communication in maternity care. It advises that clinicians must be competent leaders, experts in their own field and know and understand all team members' responsibilities. It also highlights the necessity of good communication between all staff members. Similar to the Irish National Maternity Strategy, the *Strategy for Maternity Care in Northern Ireland* identifies the necessity of workforce training and development. The strategy advises that commissioners should ensure that providers of care review their current service provision to examine how maternity care is being delivered. This should also include community care. Emphasis is also placed on the necessity of a medical workforce where workload is maintained at a suitable level and sustainable skills within job plans are developed. The strategy states that to achieve this each team of doctors within obstetrics and gynaecological services should conduct skills analysis and workforce planning.

The strategy also makes reference to an increased focus on quality improvement and measurement using a maternity dashboard which will monitor activity and outcomes. It also makes reference to the necessity of IT improvement in relation to sharing patient medical history data between health service IT systems and improvement in ease of information entry, system access ability within community settings and audit support through retrieval of unit level data.

All stages of pregnancy are discussed within the *Strategy for Maternity Care Northern Ireland* where recommendations are provided for safe, high-quality care. Similar to the Irish National Maternity Strategy, pre-conception care, antenatal care, intrapartum care and postnatal care are outlined.

Pre-pregnancy Care

Aiming for healthier women at the start of pregnancy, pre-conception care advises on:

- a healthy lifestyle
- weight management
- folic acid
- rubella immunity
- sexual health
- pre-existing familial conditions
- pre-existing clinical conditions
- previous poor obstetric history
- social care support
- access to maternity care.

Identifying that pre-conception care is generally provided in family-planning clinics and GP clinics, the strategy provides recommendations on healthy living to give to women who are planning to become pregnant. This includes advice on the management of addictions, such as smoking, alcohol and other recreational drugs, as well as advice on maintenance of long-term conditions such as diabetes, high blood pressure and depression. The strategy states that NICE[19] provides guidelines on mental health, diabetes and hypertension within pre-pregnancy care and also states that GP practices should use disease registers to assist them in the identification of those women who will benefit from pre-conception care.

The strategy also discusses unplanned pregnancy and the need to ensure that, in the future, pregnancy planning advice should be given to women who are not actively planning a pregnancy.

Antenatal Care

The outcome of antenatal care is described within the strategy as care that is effective, locally accessible and a positive experience for prospective parents. It describes that during the antenatal period, a woman will experience her first contact of maternity care

with a GP or midwife to confirm the pregnancy, a booking visit, an antenatal visit, and or antenatal education class. Emphasis is put on choice for women during the antenatal stage of pregnancy, allowing women to make informed decisions, with their healthcare professional, based on their needs. The strategy also highlighted that there is a need to ensure a safer, consistent approach to antenatal care. This is to ensure care, at the correct time, by the correct person and in the correct place is given.

The strategy emphasises the necessity of clear communication between the GP, midwife and all healthcare professionals involved in the woman's maternity care. It asserts that at the start of pregnancy, the GP should provide all medical, obstetric and social history to the maternity team and the maternity team should provide all necessary information back to the GP at the end of the woman's maternity care.

After the initial booking visit and risk assessment have been carried out, the woman, along with her maternity healthcare provider, makes a choice as to the type of care she will receive. This is similar to the *Irish National Maternity Strategy (2016-2026)* in which emphasis is placed on choice for women and their families when deciding on care pathways, such as, between a supported care pathway, an assisted care pathway, and a specialised care pathway. It is intended in the future that antenatal care in Northern Ireland will be determined by the needs of the woman and baby rather than perpetuating a pattern of care.

The strategy identifies that the antenatal care pathway for straightforward pregnancies should be based on the NICE antenatal care guidelines[(11)] and should consist of early and continuous assessment of physical, mental and social risk factors. The strategy advises on the development of agreed integrated care pathways for complex pregnancies. These should be developed upon the identification of the complication. Clear protocols and rapid referral between disciplines should occur and the GP should be kept informed. Evidence-based care should be ensured and co-orientated across relevant professionals. The strategy also identifies antenatal education as a way in which information on pregnancy, labour and parenting can be provided. It states that

antenatal education can reduce health inequalities and prepare both women and their partners for parenthood.

Intrapartum Care

The outcome of intrapartum care is described within the strategy as care that results in safe labour and birth with improved experiences for mother and baby. While the strategy highlights that protocols should exist for clear communication between all healthcare professionals involved in a woman's maternity care, it also ensures that women should be fully informed of both benefits and risks when deciding on a place of birth.

The strategy also makes reference to support for women who experience stillbirth or neonatal death. It is recommended that all staff, including medical staff, receive bereavement training as part of their role.

Postnatal Care

The outcome of postnatal care is described within the strategy as appropriate advice, and support for all parents and baby after birth. The strategy states that the timing of transfer, from a hospital or midwifery-led unit, to the woman's home depends on the clinical need of the woman and her baby. It states that hospital care is generally provided by midwives in which the woman's clinical condition is monitored and advice and support given. Women who experienced a more complex pregnancy and remain within the hospital for more than 24 hours, generally receive care from midwives and medical staff.

Following transfer from hospital, postnatal care should be provided by a primary healthcare team including community midwives, GPs, and health visitors. Care is provided in the woman's home within the first 10 days after birth by the community midwife and the timing of transfer over to the health visitor can vary depending on the woman and baby and their clinical needs. The strategy highlights that as more women are transferring home within hours of giving birth, the role of the community midwife is

becoming more significant. The strategy states that trusts should focus more on community-based care as a result. Postnatal support should be provided by the midwife in relation to breastfeeding support and encouragement to breastfeed up to six months and beyond, parenting advice and general care of the baby. The midwife should also support and monitor the mother's mental health and inform each parent of the importance of parental interaction and attachment for strong neurological development of the baby.

Implementation

To implement the *Strategy for Maternity Care in Northern Ireland*[18], the Department of Health in the UK set up a working partnership with the Health and Social Care Board and the Public Health Agency to co-lead the implementation. The strategy states that with the development of integrated care partnerships, provider organisations would have an opportunity to work together to improve outcomes for each woman and their baby. Similar to the *Irish National Maternity Strategy (2016-2026)*, strong emphasis is placed on proactive leadership. *A Strategy for Maternity Care Northern Ireland* states that a lead individual will be nominated and joint responsibility between the HSCB and the Public Health Agency will be taken to ensure implementation of the strategy. An individual within each health trust will be named to co-ordinate action. The Strategy proposes that a regional action plan and formal implementation process be utilised.

For each of the six outcomes and 22 objectives detailed throughout the strategy, action plans are recommended to be incorporated for each. It is suggested that this will allow for an opportunity to document timeframes for actions relevant to the objective and continuous progress could be demonstrated through outcome measurement. The strategy states that all outcomes and related objectives should be accompanied by performance measures. It is advised that these should be reported upon as part of a short annual report on implementation progress.

1.4 Scotland

Similar to the Northern Ireland strategy, a framework for maternity care in Scotland comprising the four stages from pre-pregnancy to postnatal care was launched in 2011. This section outlines the background to the framework and some of its components as well as the details of a review of maternity and neonatal services undertaken in 2015 and two national programmes, The Keeping Childbirth Natural and Dynamic Programme and Pathways for Maternity Care.

Framework for Maternity Care

The *Refreshed Framework for Maternity Care in Scotland* [20] outlines the principles which govern maternity services from pre-pregnancy, through pregnancy, childbirth, postnatal care and into parenthood in Scotland. The document is intended as an update of the national Framework for Maternity Services in Scotland, originally published in 2001.

The key drivers for refreshing the framework were:

- the need to reduce inequalities in maternal and infant health outcomes at birth and across the life course,
- the need to measure improved access, care and experience for all women, prioritising improvements for those at risk of poor health outcomes,
- the need to develop tailored, proportionate, universal provision that identifies and facilitates access to specialist provision where needed,
- the need to strengthen communication and collaboration between services providing maternity care,
- the need to use women's experience of care to drive service improvement,
- the importance of strengthening NHS Board planning of maternity care at regional level; within local children and adult service planning processes and within local community planning partnerships,

- and the fundamental and critical importance of workforce planning and development to ensure that all women and their babies are cared for by the right team of people, with the right skills, in the right place, every time.

Strengthening the role of maternity care services in promoting and supporting improvements in maternal and infant wellbeing is the key aim of the framework. The objective of refreshing the framework is to ensure that pathways of care are person-centred. This requires safe and effective communication and collaboration between maternity services, primary care and public health nursing studies.

The framework includes service descriptors for each part of the journey through maternity care as follows:

Pre-pregnancy Care:

- Specific pre-pregnancy services are available to women who need them (for example, poor obstetric or medical history, previous poor fetal or obstetric outcomes, or where there is a family history of significant illness or disease).

Pregnancy and Antenatal Care

- All women who experience complications in early pregnancy have access to an early pregnancy assessment service.
- All women have early and timely access to appropriate, safe and effective antenatal care.
- An evidence-based, tailored and proportionate health improvement programme is provided by maternity care services throughout the antenatal period.
- A high quality antenatal screening, diagnostic and follow up service is available and offered to all women in line with national guidance.
- A lead professional is identified for all women with antenatal care.

Labour and Birth

- The decision of where and how to give birth should be reached using a process of decision-making where the clinician and the woman are partners in ensuring the woman and baby are as safe as possible.
- Maternity services provide a fully integrated person-centred, high-quality childbirth service that is safe and effective.
- Women should be assessed on presenting for care and in labour and offered an appropriate birth care pathway, avoiding unnecessary intervention, regardless of the birth setting.

Postnatal Care

- All women and their babies are provided with person-centred, safe and effective postnatal care.
- A high-quality postnatal screening service is available and offered to all women and their babies in line with national guidance.
- A named professional and where necessary a lead professional is identified for all women and babies during postnatal care.
- An evidence-based, tailored and proportionate health improvement programme is provided by maternity care services throughout the postnatal period.
- Postnatal discharge planning processes and mechanisms are person-centred, safe and effective.

The Review of the Maternity and Neonatal Services

In 2015 the Scottish Government set out to assess the latest evidence and best practice in maternity and neonatal services in order to enhance services and increase the choice available to pregnant women across Scotland's NHS. The review focused on creating a refreshed model of care and approach to maternity and neonatal services, and aimed to examine choice, quality and safety of maternity and neonatal services in light of current evidence and best practice, in consultation with the workforce, NHS boards and service users.[21]

An expert review group, supported by four subgroups, was established to devise a series of recommendations and proposals that seek to enhance services. The review group and subgroups examined recent examples of innovation and best practice and considered the levels and type of services available, as well as examining new evidence about the benefits of different birth settings for mothers and babies. The review group will report its findings to Scottish government ministers by the end of Summer 2016 for approval, after which a final report will be then be published.[21]

The Keeping Childbirth Natural and Dynamic Programme

The Keeping Childbirth Natural and Dynamic programme is a national programme established to ensure the implementation of maternity policy in practice. It promotes multi-professional working and is progressing in partnership with women's representatives, professional Royal Colleges and NHS boards.[22]

The Keeping Childbirth Natural and Dynamic programme aims to ensure all women:

- have a robust assessment of their needs in early pregnancy
- are offered the most appropriate care pathway for their need
- have care provided by the most appropriately skilled maternity professional.

The three objectives of the Keeping Childbirth Natural and Dynamic programme are:

1. **Implementation of national multi-professional care pathways**. These pathways are now in place across NHS Scotland, which will facilitate robust risk assessment in early pregnancy and timely intervention for women and families with additional medical or social needs. The pathways identify the most appropriate care pathway for individual need and the most appropriately skilled professional to deliver that care.
2. **Implementation of the lead maternity professional based on risk.** Normally a midwife has responsibility for the care of women experiencing a normal pregnancy and an obstetrician, supported by the maternity team, for

women with factors that could adversely affect the outcome for mother and or their baby. A woman's general practitioner (GP) will continue to look after her general medical care and participate in antenatal care as desired.

3. **Implementation of the midwife to act as first point of professional contact in pregnancy.** To facilitate seamless access to maternity services, all pregnant women have been offered the option of seeing a midwife as their first contact from December 2009. This is in place in most NHS boards; however, any woman who wishes to continue to see her GP should be supported to do so.

A key objective of the 2011 Refreshed Framework for Maternity Care in Scotland[20] was to ensure that pathways of care are person-centred. This requires safe and effective communication and collaboration between maternity services, primary care and public health nursing services. The Keeping Childbirth Natural and Dynamic programme was established to identify the most appropriate care pathway for individual need and the most appropriately skilled professional to deliver that care as early as possible in pregnancy.

Both the Keeping Childbirth Natural and Dynamic programme and the 2009 pathways for maternity care have been developed to facilitate robust risk assessment in early pregnancy and ensure timely proportionate support for women and their babies throughout their maternity care journey.

Pathways for Maternity Care 2009

Pathways for Maternity Care was published by NHS Quality Improvement Scotland in March 2009.[23] It is a part of the Keeping Childbirth Natural and Dynamic programme to facilitate ongoing risk assessment and to ensure evidence-based care by the appropriate professional for all women accessing maternity care across Scotland. The ethos of the pathway is that pregnancy and childbirth are normal physiological processes and unnecessary intervention should be avoided. This pathway is the first in a series of pathways for maternity care.[23]

The philosophy of the Pathways

A key principle of the Pathways is the right of pregnant women to be provided with current evidence-based information and to be involved with decisions regarding their care and that of their baby. The Pathways state that good communication between the multi-professional team and women is essential. Women and their families should be treated with respect, dignity and kindness with their views and beliefs being sought and respected at all times.[24]

The following principles are outlined in Pathways for Maternity Care to enable midwives to deliver maternity care that embraces the normality of pregnancy[24]:

- The way midwives practice protects and maintains normality.
- The midwife is the lead professional for healthy women with uncomplicated pregnancies.
- There is consistent high-quality communication with women, providing relevant information at appropriate times.
- Discussion with all women is facilitated to enable them to make decisions regarding care and birth preferences, including place of birth, and to encourage women to document these preferences in their handheld record.
- Women are supported to take a central, active role in their own care during pregnancy, labour and the postnatal period.
- There is recognition of the impact of inequality and social exclusion on health and it is ensured that appropriate information, support and referral are provided to all women based on need.

The three Pathways

There are three Pathways that a woman can take during pregnancy, birth and the postnatal period.[24]

- **Green** care is for healthy women with uncomplicated pregnancies who will be offered a midwife as their lead professional. It should be acknowledged, however, that a woman may still choose to see her GP and or obstetrician.

- **Amber** care is for women who require assessment. The woman may have a potential medical, obstetric or social risk factor that requires the appropriate health professional to provide further assessment and or support. Following assessment, women may return to the green pathway, but also may move to the red pathway.
- **Red** care is for women with significant medical or obstetric factors that should have a consultant obstetrician as their lead professional, who would share care with other professionals such as midwives, anaesthetists, and neonatologists, for example.

The pathway for normal maternity care requires women to have continuous risk assessment throughout the pregnancy, labour and the postnatal period taking into account that risk status is dynamic and may change over time. It is anticipated that women may move between different care packages, in both directions, as a result of clinical recommendation or maternal choice. The pathway is intended to apply in the majority of, but not all cases. It is a guidance document to be used in conjunction with clinical judgement when deciding when it is not appropriate to follow care recommendations.[24]

1.5 Wales

In September 2011 the Welsh government published *A Strategic Vision for Maternity Services in Wales.*[25] This document focuses on continuing to improve maternity services in Wales beyond those achievements made by the *National Service Framework for Children, Young People and Maternity Services* 2005.[26]

This strategy clearly sets out the Welsh government's vision and the desired outcomes at population level, as well as outlining its expectations of NHS Wales. The strategy aimed to promote pregnancy and childbirth as an event of social and emotional significance where women and their families are treated with dignity and respect. Tackling inequities in terms of access to and the outcomes from maternity services in

Wales is also the cornerstone of this strategy, given the high level of social inequality in Wales.

Directed primarily at the NHS and its partners to inform the planning and delivery of its maternity services, the strategy outlines five key areas for action for NHS Wales to transform maternity services in Wales [25]:

1. Placing the needs of the mother and family at the centre of care so that pregnancy and childbirth is a safe and positive experience and women are treated with dignity and respect.
2. Promoting healthy lifestyles for pregnant women that have a positive impact on women and their family's health.
3. Providing a range of safe, high-quality choices of care, from midwife to consultant-led services
4. Employing a highly trained workforce which delivers high-quality services.
5. Maternity services are constantly reviewed and improved.

The Welsh government also established an All-Wales Maternity Services Implementation Group which is co-chaired by a service user and the Chief Nursing Officer. The group is made up of health professionals and Local Health Board Executive Leads for Maternity Services. The group developed a formal set of indicators for measuring the effectiveness and quality of maternity services in terms of clinical outcomes and women's experience. These indicators, based around the five key areas for action, formed the basis of a monitoring tool for local health boards to monitor their own services and to report performance against. Annual progress reports based on these indicators are published at regular intervals and are reviewed by executive management in NHS Wales and the Welsh government to monitor progress on delivering the strategic vision for maternity services in Wales.

1.6 Australia

Maternity care in Australia is provided in a variety of public and private settings, and is supported by service capability frameworks, workforce, funding, information and data, and technological infrastructure.[27] Australia has made significant gains in improving the safety of pregnancy and childbirth over the last century. However, the Australian department of health acknowledges that this is not the case for Aboriginal and Torres Strait Islander people, who continue to experience substantially poorer maternal and perinatal outcomes. This section outlines the 2010 Australian Maternity Services Plan in detail. The other initiative of relevance to Australia is the *Standards of Maternity Care in Australia and New Zealand*[28] as documented in section 1.1.3.

National Maternity Service Plan 2010

The National Maternity Services Plan[29] recognises the importance of maternity services within the health system and provides a strategic national framework to guide policy and programme development across Australia for a five-year period. Against a backdrop of general review and reform of national healthcare services, all jurisdictions have shown their commitment to providing high-quality, woman-focused maternity care within available resources. The National Maternity Services Plan builds on this work to reflect a joint understanding and commitment on ways to develop and improve maternity services in Australia, within the context of wide-ranging changes in the healthcare landscape. The plan focuses on primary maternity services during the antenatal, intrapartum and six-week postnatal periods for women and babies. While recognising the importance of links for women to a range of specialist services, it does not specifically address these specialist services.

A National Maternity Services Review,[30] published in February 2009, canvassed a wide range of issues relevant to maternity services, including antenatal services, birthing options, postnatal services up to six weeks after birth, and peer and social support for women in the perinatal period. The consultation process consisted of stakeholder

submissions and roundtable forums. The review culminated in the release of *Improving Maternity Services in Australia: the Report of the Maternity Services Review.*[30] This report made 18 recommendations in the areas of:

- safety and quality
- access to a range of models of care
- inequality of outcomes and access
- information and support for women and their families
- the maternity workforce
- financing arrangements.

The review identified improved choices and information about maternity care for pregnant women as a priority, while maintaining the existing high standards of safety and quality. Support for a collaborative maternity workforce was also highlighted, with a particular emphasis on maximising the capacity of appropriately skilled midwives in the provision of maternity care. Access issues for rural and remote women, as well as Aboriginal and Torres Strait Islander women, were also identified as priority areas for improvement in Australian maternity services.

The five-year vision for Australian maternity services as set out in the 2010 National Maternity Service Plan[29] is that maternity care will be woman-centred, reflecting the needs of each woman within a safe and sustainable quality system. All Australian women will have access to high-quality, evidence-based, culturally competent maternity care in a range of settings close to where they live. Provision of maternity care will contribute to closing the gap between the health outcomes of Aboriginal and Torres Strait Islander people and non-indigenous Australians. Appropriately trained and qualified maternity health professionals will be available to provide continuous maternity care to all women.

The plan is underpinned by 10 principles for maternity care that build on principles previously agreed by health ministers for the provision of primary maternity services in

Primary Maternity Services in Australia: A Framework for Implementation(2008).[31] The 10 principles are:

1. Maternity care places the woman at the centre of her own care. Such care is coordinated according to the woman's needs, including her cultural, emotional, psychosocial and clinical needs, close to where she lives.
2. Maternity care enables all women and their families to make informed and timely choices in accordance with their individual needs. The planning and provision of maternity care is informed by women and their families.
3. Women and families in rural and remote Australia have improved and sustainable access to high-quality, safe, evidence-based maternity care that incorporates access to appropriate medical care when complications arise.
4. Governments and health services work to reduce the health inequalities faced by Aboriginal and Torres Strait Islander mothers and babies and other disadvantaged populations.
5. Maternity services offer continuity of care across the pregnancy and birthing continuum as a key element of quality maternity care for all women and their babies.
6. Maternity care will be provided for all women and their babies within a wellness paradigm, utilising primary healthcare principles while recognising the need to respond to emerging complications in an appropriate manner.
7. The potential of maternity health professionals is maximised to enable the full scope of their specific knowledge, skills and attributes to contribute to women's maternity care.
8. Maternity services provide high-quality, safe, evidence-based maternity care within an expanded range of sustainable maternity care models.
9. Maternity services are staffed by an appropriately trained and qualified maternity workforce sufficient to sustain contemporary evidence-based maternity care.
10. Maternity services operate within a national system for monitoring performance and outcomes and guiding quality improvement.

Four priorities including access, service delivery, workforce and infrastructure were identified. The components of these priorities are as follows:

Access:

- increase access for Australian women and their family members to information that supports their needs for maternity care
- increase access for Australian women and their family members to local maternity care by expanding the range of models of care
- increase access for Australian women and their family members in rural Australia to high-quality maternity care
- increase access for Australian women and their family members in remote Australia to high-quality maternity care.

Service delivery:

- ensure Australian maternity services provide high-quality, evidence-based maternity care
- develop and expand culturally competent maternity care for Aboriginal and Torres Strait Islander people
- develop and expand appropriate maternity care for women who may be vulnerable due to medical, socio-economic and other risk factors.

Workforce:

- plan and resource to provide an appropriately trained and qualified maternity workforce that provides clinically safe, woman-centred maternity care within a wellness paradigm
- develop and support an Aboriginal and Torres Strait Islander maternity workforce
- develop and support a rural and remote maternity workforce.
- facilitate a culture of interdisciplinary collaboration in maternity care

Infrastructure:

- ensure all maternity care is provided within a safety and quality system

- ensure maternity service planning, design and implementation is woman-centred.

1.7 New Zealand

Similar to Australia, a key development in New Zealand has been the *Standards of Maternity Care in Australia and New Zealand*[28] as documented in section 1.1.3. Another initiative of note is the Maternity Quality and Safety Programme and the development and use of maternity clinical indicators.

In 2009 the New Zealand government agreed to the development of the Maternity Quality Initiative, which included the establishment of a Maternity Quality and Safety Programme. This occurred in response to recommendations from the Perinatal and Maternal Mortality Review Committee, the Health and Disability Commissioner and the Minister of Health. It was agreed that in addition to standards, there was a need to have nationally consistent clinical guidelines for the maternity sector. This guidance was intended to enable and encourage consistency of clinical maternity practice for particular topics identified as areas of variability within the sector. The service specifications for district health boards providing maternity services require the service to adopt any applicable national clinical guidelines that are endorsed by the professional colleges.

The New Zealand Maternity Clinical Indicators 2012 report,[32] published in October 2014 presents 15 maternity clinical indicators by maternity facility and district health board region for births in 2012 and shows trends in these indicators since 2009. Since 2012, district health boards and maternity stakeholders have used the indicators in their local maternity quality and safety programmes to identify areas warranting further investigation at a local level. The original 12 indicators were revised in 2013. In addition to improving the quality and completeness of the original 12 indicators, a further three indicators were added that reflect care during pregnancy, care in the postnatal period and severe maternal morbidity.

The purpose of the indicators is to:

- highlight areas where quality can be improved at a national level
- support local quality improvement by helping district health boards to identify focus areas for local clinical review of maternity services
- provide a broader picture of maternity outcomes in New Zealand than that obtainable from maternal and perinatal mortality data alone
- provide standardised data allowing district health boards to evaluate their maternity services over time and against the national average
- improve national consistency and quality in maternity data reporting.

The indicators are evidence-based and cover a range of procedures and outcomes for mothers and their babies. Where possible, the indicators are aligned with international maternity indicators to enable international comparison.

1.8 Canada

This section sets out key initiatives in Canada beginning with the 2008 National Birthing Initiative and the background to its development. It documents the role of the Society of Obstetricians and Gynaecologists of Canada in producing national clinical guidelines and the work of the Canadian Perinatal Surveillance System in measuring and reporting on perinatal health indicators. This section then explores developments in British Columbia, specifically clinical guidelines developed by Perinatal Services British Columbia and the Maternity Care Pathway Guideline developed by the British Columbia Perinatal Health Program.

A National Birthing Initiative

Over half of respondents to a maternal experiences survey undertaken by Public Health Canada said they were satisfied with their birthing experiences. Despite these positive responses, there were warning signs that the quality and scope of maternity care in Canada was diminishing. Human resources in maternity care were drastically diminishing with over one in three (36%) obstetricians and gynaecologists in Canada

planning to retire within the next five years. In the Maternal Experiences Survey, women expressed the desire to engage a midwife for prenatal, antenatal and postnatal care, and yet only five provinces and one territory in Canada allowed this to happen. There was no consistent system-wide approach to guide the evolution of the maternity care system in the future and some provinces and territories were ill-prepared to manage the current situation and future challenges. Many of the solutions identified by provincial and territorial governments and various stakeholders have been difficult to implement because of the lack of a national framework to guide the process. In response to the results of the survey, the Society of Obstetricians and Gynaecologists of Canada developed *A National Birthing Initiative*[33] in cooperation with the College of Family Physicians of Canada, the Canadian Association of Midwives, the Association of Women's Health, Obstetric and Neonatal Nurses and the Society of Rural Physicians of Canada.[33]

A national strategy was recognised as necessary in order to address the fundamental system-wide changes required to ensure the sustainability of maternity and newborn care services and to provide leadership and support to provinces and territories during this transition. The pan-Canadian strategy aims to provide a framework to address human resource shortages in health, promote communities of practice, establish inter-professional education initiatives, integrate multidisciplinary collaborative maternity care teams and implement patient safety initiatives.

The development of A National Birthing Initiative for Canada was based on a set of fundamental guiding principles, as follows[33]:

- respect for the needs, goals and values of women and their families quality maternity care based on equity of access to, and integration of, services, continuity of care, patient safety, and valuing different providers' expertise
- care based on best available evidence and practice guidelines
- education based on communities of practice

- commitment to multidisciplinary collaborative maternity care
- shared values, goals and visions
- honest, open and continuous communication
- responsibility and accountability of the people and organisations that provide or receive maternity care
- understanding of, and respect for, different professions' scope of practice
- importance of common protocols for clinical and administrative purposes
- support for collaborative integrative action by healthcare providers, the public and federal, provincial and territorial governments.

The Society of Obstetricians and Gynaecologists of Canada

The Society of Obstetricians and Gynaecologists of Canada (SOGC) is one of Canada's oldest national specialty organisations. The society's mission is to promote excellence in the practice of obstetrics and gynaecology and to advance the health of women through leadership, advocacy, collaboration, and education. A leading authority on reproductive healthcare, the SOGC produces national clinical guidelines for both public and medical education on important women's health issues.

The SOGC's mission is to promote excellence in the practice of obstetrics and gynaecology and to advance the health of women through leadership, advocacy, collaboration, and education. The SOGC believes that:

- Women should have equitable access to optimal, comprehensive, culturally-safe healthcare provided with integrity and compassion.
- Women should have the knowledge they need to make informed choices about their health.
- Society of Obstetricians and Gynaecologists of Canada (SOGC) members have the right to practice in a safe and supportive environment.
- The practice of obstetrics and gynaecology must be based on the best scientific evidence available.

- The SOGC has a responsibility to facilitate change in relation to health system issues affecting the practice of obstetrics and gynaecology.
- Every woman has the right to optimal care during pregnancy and childbirth to ensure the health and safety of both the mother and her baby.

The Canadian Perinatal Surveillance System

The Canadian Perinatal Surveillance System is part of Health Canada's initiative to strengthen national health surveillance capacity.[34] The Canadian Perinatal Surveillance System is an ongoing national health surveillance programme delivered through the Maternal and Infant Health Section in the Public Health Agency of Canada. Its mission is to contribute to improved health for pregnant women, mothers and infants in Canada. The Canadian Perinatal Surveillance System is guided by a multidisciplinary and multi-sectoral steering committee that provides guidance to the Maternal and Infant Health Section with respect to the development and operation of the Canadian Perinatal Surveillance System. Steering committee members include expert representatives of national health professional associations, the provincial and territorial governments, consumer and advocacy groups and federal government departments, as well as Canadian and international experts in perinatal health and epidemiology. The surveillance system is based on the concept of health surveillance as a systematic, ongoing process that provides timely, relevant information about trends and patterns in the health status of a population and the factors that influence health status. The components of surveillance are data collection, expert analysis and interpretation, and response (communication of information for action).

The Canadian Perinatal Surveillance System has identified 52 perinatal health indicators, consisting of measures of maternal, fetal and infant health determinants and outcomes.[34] The Canadian Perinatal Surveillance System is currently reporting on 27 perinatal health indicators.

The aim of the Canadian Perinatal Surveillance System is to collect and analyse data on all recognised pregnancies, regardless of their outcome – abortion, ectopic pregnancy,

stillbirth or live birth – and on the health of the baby during the first year of life.[35] The long-term goal of the Canadian Perinatal Surveillance System is to establish a comprehensive national perinatal database through electronic transfer of data from vital event registration, hospital services and community-based services. Communication of information will serve as an evidence base for action to improve the effectiveness and efficiency of clinical care and guide the development of public health policies and programmes for maternal and infant health. The mechanisms and vehicles for information dissemination will vary according to the target audience, such as policy makers, healthcare providers, the public and researchers, and will take the form of national reports, fact sheets, peer-reviewed publications and the internet.[35]

1.8.1 British Columbia

Perinatal Services British Columbia

Perinatal Services British Columbia develops evidence-based, clinical guidelines that include recommendations for the care of the woman during pregnancy, labour, birth and after birth for women and newborns in British Columbia. These guidelines assist the practitioner and patient in making decisions about healthcare choices to ensure better patient care across healthcare settings.[36] It is expected that each health authority in British Columbia, as well as individual healthcare providers, will implement recommendations from current provincial guidelines and consider how the local practice context and resource availability may influence the adaptation of the guideline. The adoption of a guideline, in full or in part, should be clearly set out in the institutional policy and clearly communicated to all members of the healthcare team. Where there are variations from the provincial guideline as a result of local adaptation, these practices must be identified so outcomes can be interpreted accurately. It is expected that healthcare providers in British Columbia discuss all relevant information required to make a duly informed choice with women and parents. If a woman makes a care decision that is different from the recommendations, after discussion with and

counselling by her care provider, then that discussion should be clearly documented in the clinical record.(37)

Practice standards outline the expectations for practitioners and contribute to public protection. They inform care providers of their accountabilities and the public of what to expect regardless of where care is provided or received. Practice standards are detail the desired and achievable level of performance against which actual performance can be compared. It provides a benchmark below which performance is unacceptable. The goal is to ensure a consistent level of care throughout the province for specified practice. Perinatal Services British Columbia supports a philosophy of interdisciplinary education and all perinatal guidelines and standards have been developed, distributed and implemented within a multidisciplinary context.(38)

British Columbia Maternity Care Pathway Guideline

The British Columbia Perinatal Health Program developed a Maternity Care Pathway Guideline(39) in 2010 as a reference for best practice for routine prenatal care for all women in British Columbia. It was developed in response to recommendations of the 2004 British Columbia Maternity Care Enhancement Project. The purpose of the pathway is to inform all care providers of the current evidence-based recommendations for routine care in pregnancy to ensure that all women receive the same high standard of care regardless of their residence, service provider or special needs. The guideline is intended for use by physicians, midwives, nurses and other healthcare professionals who care for pregnant women. It does not include guidelines for additional care that may be required by some women. The overarching philosophy represented in the guideline is that pregnancy is a normal physiological process and therefore any interventions offered should have known benefits and be acceptable to pregnant women. The guidance represents the view reached by the British Columbia Perinatal Health Program following careful consideration of the available evidence. It does not override the individual responsibility of healthcare professionals to make decisions

appropriate to the circumstances of the individual patient, in consultation with the patient, guardian or carer.

The pathway states that women-centred services for maternity care should occur in the context of primary care. This recognises that for the majority of women, pregnancy and childbirth are normal life events. The mother and baby are placed at the centre of care with services planned and provided to meet their needs. Providing women-centred services relies on understanding women's preferences and needs with respect to care. It also involves engaging women and their families (as defined by the woman) as partners in the processes of planning, delivering and evaluating services.[40]

The pathway states that the core principles of woman-centred care include respect, information sharing, participation and collaboration. Women, their partners and their families should always be treated with kindness, respect and dignity. The views, beliefs and values of the woman and her family in relation to her care and that of her baby should be sought and respected at all times. Women should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals.[11]

The pathway outlines seven guiding principles[39] for care of pregnant women as documented in Table 3.

Table 3. Seven guiding principles for care of pregnant women, British Columbia Maternity Care Pathway Guideline

Access	Provide a flexible, diversity-sensitive, high-quality, accessible service. Women with limited social or financial means or geographic barriers to access, should be supported through innovative models of prenatal care.
Normal birth	Support and encourage confidence in normal birth and practices that promote minimal intervention.

Provider choice	Give information about local services and the care provided by family, physicians, midwives, and obstetrician, and of where the option of home birth is available. Support women's right to choose her care provider.
Shared decision making	Enable women to make informed decisions based on their needs in partnership with their care providers in all aspects of pregnancy and fetal health. Respect and encourage women's own awareness of their health and of the wellbeing of their fetus. Assist women to make decisions and clarify the right of a woman to accept or decline any test or procedure.
Choice of location and method of birth	Support women's right to choose how and where they give birth in consultation with care providers based on best evidence and available local resources.
Continuity of care	Provide care by one person or a small team whenever possible. When possible, allow women the opportunity to meet other care providers who may attend the birth. When specialist consultation or transfer of care occurs, ensure complete and effective sharing of patient information between care providers with a system of explicit referral and communication pathways.
Team work	Foster an interdisciplinary collaborative model of care with a clear understanding of all professional roles to maximise the quality and comprehensiveness of care.

It is stated in the pathway that information should be provided to women that:

- can be easily understood by all women, including those with additional needs such as physical, sensory, or learning disabilities and women who do not speak or read English
- is balanced and unbiased
- reflects current evidence

- is supported by written information and via different formats if available
- is applicable to each woman's circumstances and setting for care
- provides enough time and opportunity for discussion and questions to ensure the woman understands
- informs women of the purpose of any test or intervention before it is performed
- enables women to make informed decisions
- fosters collaborative decision-making between the woman and the care provider
- respects a woman's decisions and choices, even if they differ from the caregiver's recommendations.

The following care pathways have also been developed:

- Prenatal Care Pathway[41]
- Postpartum Nursing Care Pathway[42]
- Newborn Nursing Care Pathway.[43]

1.9 Summary of International Review

The review of international strategies, frameworks, standards and guidance demonstrated similarities with the Irish context – specifically in relation to the Irish National Maternity Strategy. In most cases, the frameworks span the pre-conception period, identifying the importance of health and wellbeing at this stage, through to pregnancy, labour, birth and the postnatal period. This has been reflected in the scope of the *National Standards for Safer Better Maternity Services* which cover pre-pregnancy, pregnancy, labour, birth and postnatal care for both the mother and the baby up to six weeks after birth.

The underlying principles of the frameworks, standards, guidance, pathways and indicators being used in the different jurisdictions centre on making the woman the focus of the service, improving access to services and choices for women, and focusing on pregnancy and birth as a normal physiological process. These mirror the principles outlined in the Irish National Maternity Strategy and reflect the findings and

recommendations of reviews and investigations of Irish maternity services as documented in Chapter 2.

The Australia and New Zealand maternity standards and those developed by the Royal College of Obstetricians and Gynaecologists in the UK are similar and a number of the categories within both of these standards were used in identify sub-themes by which to structure the findings of the systematic literature review documented in Chapter 3 of this document.

Chapter 2: summary of existing standards, guidelines and reviews and investigations of Irish maternity services

2. Overview

This chapter provides the context for national maternity standards in Ireland, outlining maternity services at the time of drafting the standards. An important development during preparation of the standards was the launch of Ireland's first national maternity strategy. A number of members of HIQA's Standards Advisory Group were also members of the steering group for the national maternity strategy. The *National Standards for Safer Better Maternity Services* are aligned to the principles and care pathways outlined in the national strategy.

The project team took account of existing standards and guidelines when drafting the standards, including the Practice Standards for Midwives and National, guidelines developed by the National Clinical Effectiveness Committee and other bodies. At the time of drafting the standards, work was also ongoing in preparing a set of national standards for bereavement care following pregnancy loss and perinatal care, to which the national maternity standards are also aligned. A high-level summary of each of these areas is included in Chapter 2. This chapter also contains a summary of reviews and investigations of maternity services that have been undertaken in recent years to provide insight into the issues and challenges that exist. The recommendations of each of these reports were reviewed and considered in terms of what is necessary to provide safe high quality maternity care for inclusion in the *National Standards for Safer Better Maternity Services.* The recommendations were mapped to the individual themes of the *National Standards for Safer Better Healthcare* in order to inform the drafting of standards and features within each corresponding theme of the *National Standards for Safer Better Maternity Services.*

2.1 The National Maternity Strategy

Ireland's first National Maternity Strategy[2] (*Creating a Better Future Together)* was launched by the Minister for Health in January 2016. The strategy aims to improve the safety and quality of maternity services and to standardise care across maternity services and is underpinned by the principle of multidisciplinary team working. The vision for maternity services, articulated in the strategy, is an Ireland where women and babies have access to safe, high-quality care in a setting that is most appropriate to their needs; women and families are placed at the centre of all services, and are treated with dignity, respect and compassion; parents are supported before, during and after pregnancy to allow them to give their child the best possible start in life. The strategy identifies four strategic priorities to do this:

1. A health and wellbeing approach should be adopted to ensure that babies get the best start in life. Mothers and families should be supported and empowered to improve their own health and wellbeing.
2. Women have access to safe, high-quality, nationally consistent, woman-centred maternity care.
3. Pregnancy and birth is recognised as a normal physiological process, and insofar as it is safe to do so, a woman's choice in pregnancy and birth is facilitated.
4. Maternity services are appropriately resourced, underpinned by strong and effective leadership, governance and management arrangements, and delivered by a competent workforce, in partnership with women.

The strategy is aimed at being a framework for a new and better maternity service which governs maternity care from pre-pregnancy, through antenatal and childbirth care, to postnatal care. Using the four strategic priorities listed above, the strategy allows for high-quality, safe care and choice for women and their families, which places them at the centre of Irish maternity services, and where dignity, compassion,

evidence-based and multidisciplinary team-based care and support are shown to each individual woman, baby and partner throughout all stages of pregnancy.

The strategy recognises that all women need a certain level of support, but some need more specialised care. The strategy proposes an integrated care model that encompasses all the necessary safety nets in line with patient safety principles, which delivers care at the lowest level of complexity, yet has the capacity and the ability to provide specialised and complex care quickly, as required. The strategy classifies women and babies into three risk groups: normal-risk, medium-risk (requiring a higher level of oversight), and high-risk (requiring a more intensive level of care, either throughout or at a particular stage of care). The strategy specifies that a choice of three maternity care pathways (supported, assisted and specialised) are available based on the risk profile of the woman and baby. Across all risk levels there is the potential need for an increased level of care, and the importance of a smooth transfer between care pathways is recognised. The strategy states that each woman will be supported to make an informed choice with regard to her care pathway and will have her care delivered by a particular team. It states that all pathways should support the normalization of pregnancy and birth.

Supported care pathway
The supported care pathway is intended for mothers and babies who are considered to be at normal-risk, with midwives leading and delivering care in a multidisciplinary framework. Responsibility for the coordination of a woman's care will be assigned to a named clinical midwife manager, and care will be delivered by the community midwifery team, with most antenatal and postnatal care being provided in the community and home settings. The woman can exercise a choice with her healthcare professional about the birth setting, which may be in an alongside birth centre in a maternity unit, a maternity hospital, or at home. An alongside birth centre is a birth centre situated in the immediate vicinity of a specialized birth centre, that is to say, a delivery suite in an Irish maternity unit or maternity hospital. A woman may need to transfer, either temporarily or permanently, to another model of care because of an emerging

risk. She may also choose to transfer to another care pathway, for example if she wants and epidural or she chooses to be under the care of a consultant obstetrician.

Assisted care pathway

The assisted care pathway is intended for mothers and babies who are considered to be at medium-risk, and for women at normal-risk who choose an obstetric service. Care will be led by a named obstetrician, and care will be delivered by obstetricians and midwives as part of a multidisciplinary team. Care will be provided across the maternity unit or maternity hospital and the community, and births will take place in a specialised birth centre. Postnatal care will start in the maternity unit or maternity hospital and move to the community on discharge.

Specialised care pathway

The specialised care pathway is intended for mothers and babies who are considered to be at high-risk and will be led by a named obstetrician. Care will be delivered by obstetricians and midwives as part of a multidisciplinary team. Care will, in the main, be provided in the maternity unit or in the maternity hospital, and births will take place in a specialised birth centre.

An individualised, multidisciplinary, multi-specialty approach to care and care planning (for both the maternity unit or maternity hospital and the woman) should be used. Where possible, antenatal care should be provided in the community. Postnatal care will start in the maternity unit or maternity hospital and transition to the community on discharge.

The strategy will be implemented on an incremental basis, however, it is acknowledged that certain challenges such as resource constraints may interfere with its implementation. The strategy emphasises the significance of proactive leadership at corporate and clinical level in the Health Service Executive (HSE) in relation to implementation. It is planned that the National Women and Infants Health Programme will provide effective management structures and leadership at a system level to

implement the strategy. The programme will work alongside maternity networks and maternity units to ensure the remodelling of maternity services in line with the strategy. A culture of lifelong learning and continuous development is also to be promoted. It is anticipated that the programme will identify short-term and long-term goals, addressing actions that can be initiated in the short-term while working towards longer-term goals.

The Department of Health in Ireland will maintain overall responsibility for overseeing the implementation of the strategy. Implementation progress will be measured against key performance indicators developed in consultation with the Department of Health and the National Women and Infants Health Programme. The strategy states that the National Women and Infants Health Programme will also be obligated to submit an annual report to the Minister for Health detailing:

- The progress made against the implementation plan in each maternity network.
- The extent to which initiatives have been achieved.
- How existing resources have been reconfigured in support of the strategy and how new funding allocated for the implementation of the strategy has been utilised.
- Any barriers to progress that require coordinated action.
- Any policy implications which should be considered by the Department of Health.
- The plan and resource requirements for the coming year.

2.2 Existing Standards

2.2.1 National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death

In August 2016 the Minister for Health, Mr Simon Harris launched the Health Service Executive (HSE) *National Standards for Bereavement Care* following Pregnancy Loss and Perinatal Death.[44] The standards clearly define the care parents and families can expect to receive following a pregnancy loss or perinatal death. It is planned that the standards will be implemented and applied across the health service in all appropriate

settings.[45] The standards were developed in response to recommendations in both the HSE's investigation report into the death of Savita Halappanavar and the report of Dr Peter Boylan following his review of maternity cases at Portlaoise Hospital. Providing bereavement care is an integral part of a maternity service. It is important that such bereavement care is integrated with the hospital's overall medical and clinical care response to parents. The four standards for bereavement care are:

- Bereavement care is central to the mission of the hospital and is offered in accordance with the religious, secular, ethnic, social and cultural values of the parents who have experienced a pregnancy loss or perinatal death.
- The hospital has systems in place to ensure that bereavement care and end-of-life care for babies is central to the mission of the hospital and is organised around the needs of babies and their families.
- Each baby and family receives high-quality palliative and end-of-life care that is appropriate to their needs and to the wishes of their parents.
- All hospital staff have access to education and training opportunities in the delivery of compassionate bereavement and end-of-life care in accordance with their roles and responsibilities.

The purpose of the standards is to enhance bereavement care services for parents who experience a pregnancy loss or perinatal death. The standards cover all pregnancy loss situations that women and parents may experience, from early pregnancy loss to perinatal death, as well as situations where there is a diagnosis of fetal anomaly that will be life-limiting or may be fatal. The standards are a resource for both parents and professionals, and are intended to promote multidisciplinary staff involvement in preparing and delivering a comprehensive range of bereavement care services that address the immediate and long-term needs of parents bereaved while under the care of maternity services. It is anticipated that the standards will guide and direct bereavement care staff on how to lead, develop and improve hospital response to parents who experience the loss of a pregnancy or a baby and will assist staff to

develop care pathways that will facilitate the hospital's response to the grief experienced by parents and their families.[43]

The standards can be used by parents, families, staff and support organisations to understand the range of hospital responses that the HSE are aiming to put in place. They are intended for use in conjunction with current clinical guidelines, professional codes of practice, government policy and relevant legislation.

2.2.2 Practice Standards for Midwives

In May 2015 the Nursing and Midwifery Board of Ireland (NMBI), the statutory regulator for the nursing and midwifery professions, launched new practice standards for midwives. As stated in the Nurses and Midwives Act 2011, the NMBI has two main objectives:

- to protect the public
- to ensure the integrity of nursing and midwifery practices.

The NMBI aims to achieve these objectives by promoting high standards of professional education, training and practice, and professional conduct among nurses and midwives.

The *Practice Standards for Midwives* were developed after the Minister for Health called for the regulator to explore how to improve competency and the development of skills in midwifery following the report by the Chief Medical Officer on Midland Regional Hospital, Portlaoise 2014. The document sets out the standard of midwifery care which would be expected from someone who practices as a registered midwife in Ireland. They also make registered midwives aware of the legislation and guidelines defining their role and describing their scope of practice. Registered midwives in Ireland must comply with these standards, as well as any other developments that impact or inform the evidence-based practice of midwifery in Ireland.

The Practice Standards for Midwives are employed in order to:

- Set out the standards of midwifery care which would be expected from someone who practices as a registered midwife in Ireland.
- Make registered midwives aware of the legislation and guidelines defining their role and describing their scope of practice.

The *Practice Standards for Midwives*, published in 2015, aim to provide the benchmark for safe, high-quality, evidence-based midwifery practice. Aligned with the principles included in the Code of Professional Conduct and Ethics 2014, they facilitate the support that midwives provide for women and ensure the best possible start in life for their babies. The standards include five practice standards:

1. Midwifery practice is underpinned by a philosophy that protects and promotes the safety and autonomy of the woman and respects her experiences, choices, priorities, beliefs and values.
2. Midwives practice in line with legislation and professional guidance and are responsible and accountable within their scope of midwifery practice. This encompasses the full range of activities of the midwife as set out in European Commission (EC) Directive 2005/36/EC and the adapted Definition of the Midwife International Confederation of Midwives 2011.
3. Midwives use comprehensive professional knowledge and skills to provide safe, competent, kind, compassionate and respectful care. Midwives keep up to date with midwifery practice by undertaking relevant continuing professional development.
4. Midwives work in equal partnership with the woman and her family and establish a relationship of trust and confidentiality.
5. Midwives communicate and collaborate effectively with women, women's families and with the multidisciplinary healthcare team.

2.3 Existing guidelines in Ireland

2.3.1 The National Clinical Effectiveness Committee

The National Clinical Effectiveness Committee (NCEC) is a Ministerial committee established as part of the Patient Safety First initiative. The role of the NCEC is to prioritise and quality assure National Clinical Guidelines and National Clinical Audit so as to recommend them to the Minister for Health to become part of a suite of National Clinical Guidelines and National Clinical Audit. National Clinical Guidelines which have been quality assured and recommended by NCEC for implementation provide robust evidence-based approaches to underpin or define models of care as appropriate. They provide guidance and standards for improving the quality, safety and cost-effectiveness of healthcare in Ireland. The implementation of guidance and audit can improve health outcomes, reduce variation in practice and improve the quality of clinical decisions.

In response to the *HIQA Patient Safety investigation Report into Services at University Hospital Galway* (2013), the NCEC was requested by the Minister for Health to commission and quality assure a number of National Clinical Guidelines. The National Clinical Guideline for a maternity early warning system is one such guideline. The Irish Maternity Early Warning System has been quality assured by NCEC and endorsed by the Minister for Health for implementation in the Irish health system.

The Irish Maternity Early Warning system (IMEWS) – National Clinical Guideline No. 4

The Irish Maternity Early Warning System (IMEWS) is a physiological track and trigger system which is a bedside tool developed for use in maternity care to assess basic maternal physiological parameters, and in doing so, assist in the identification of women with developing, established or deteriorating critical illness. The purpose of this guideline is to improve the management of the in-patient care of a woman with a confirmed clinical pregnancy and up to 42 days in the postnatal period through the use of a standard maternity early warning system. IMEWS prompts frontline clinical staff to

request a medical review at specific trigger points, using a structured communication tool while following a definitive escalation plan.

The guideline has been prepared to promote and facilitate standardisation and consistency of practice using a multidisciplinary approach across all hospital maternity services in Ireland. A standard national patient observation chart and escalation triggers are recommended. The guideline is designed to guide clinical judgement but not replace it. In individual cases, a healthcare professional may, after careful consideration, decide not to follow guideline recommendations if it is deemed to be in the best interests of the woman. Clinical decisions and therapeutic options should be discussed with a senior clinician on a case-by-case basis as necessary.

Communication (Clinical Handover) in Maternity Services – National Clinical Guideline No. 5

Clinical handover refers to the transfer of professional responsibility and accountability for some or all aspects of care for a patient, or group of patients, to another person or professional group on a temporary or permanent basis. This guideline describes the elements that are essential for timely, accurate, complete, unambiguous and focused communication of information in maternity hospital services in Ireland, relating to the patient's condition. The guideline is intended to be relevant to all healthcare staff involved in the clinical handover of patient care in maternity services. It outlines the general and specific measures for clear and focused communication of information relating to the patient's condition, both urgent and routine, for in-patients and patients attending maternity hospital services in Ireland. This includes both stand-alone maternity hospitals and co-located maternity units in Ireland.

In response to the *HIQA Patient Safety Investigation Report into Services at University Hospital Galway* (2013), the NCEC was requested by the Minister for Health to commission and quality assure the National Clinical Guideline – Communication (Clinical Handover) in Maternity Services. This guideline was then endorsed by the Minister for

Health for implementation in the Irish health system. The guideline aims to describe the elements that are essential for timely, accurate, complete, unambiguous and focused communication of information in maternity hospital services in Ireland, relating to the patient's condition, both urgent and routine. These elements include:

- professional consultations such as:
    - team-to-team
    - one professional to another
    - laboratory to team
    - radiology to team
- deterioration in a patient's condition
- transitions of care such as:
    - clinical handover of patient care at a change of shift
    - clinical handover to and from a higher level of care (for example, ambulance staff to ED/AMAU staff, Model 2/3 hospital to Model 4 hospital, ward to ICU/CCU, ICU/CCU to ward)
    - communication with patients and or their relatives, to ensure that a treatment plan is readily explained and understood.

The expected outcome is that all clinical handover between healthcare staff in maternity hospitals will be conducted using a structured communication tool, promoting standardisation of practice and minimisation of variability. In turn, this reduces risk for patients. The guideline makes recommendations on the process of clinical handover and the content of clinical handover of patients between healthcare staff, and between healthcare staff and patients or relatives for in-patients, and patients attending maternity hospital services in Ireland.

Sepsis Management – National Clinical Guideline No. 6

Sepsis, severe sepsis and septic shock are used to describe the systemic inflammatory response of patients to infection, as a continuum of progressive and life-threatening

severity. Sepsis is the clinical syndrome defined by the presence of both infection and a systemic inflammatory response. The aim of this guideline is to facilitate the early recognition and appropriate treatment of sepsis in Ireland in order to maximise survival opportunity and minimise the burden of chronic sequelae. The NCEC guideline development group recommends the *Surviving Sepsis Campaign Guidelines* and the Sepsis 6 bundle as the guide to the management of sepsis in Ireland.

In response to the *HIQA Patient Safety Investigation Report into Services at University Hospital Galway* (2013),[46] the NCEC was requested by the Minister for Health to commission and quality assure The National Clinical Guideline – Sepsis Management. The guideline was then endorsed by the Minister for Health for implementation in the Irish health system. The guideline is intended to be relevant to all healthcare staff involved in the care of patients who have sepsis. Definitions of sepsis, severe sepsis and septic shock are included in the clinical guideline. The aim of the guideline is to facilitate the early recognition and appropriate treatment of sepsis in Ireland in order to maximise survival opportunity and minimise the burden of chronic sequelae.

2.3.2 National Clinical Programme for Obstetrics and Gynaecology

The National Clinical Programme for Obstetrics and Gynaecology was set up in 2010 as a joint initiative between HSE Clinical Strategy and Programmes Division and Institute of Obstetrics and Gynaecologists, Royal College of Physicians of Ireland. Professor Michael Turner of the University College Dublin (UCD) Centre for Human Reproduction at the Coombe Women and Infants University Hospital is the clinical lead, and the overarching aim of the national programme is to 'improve choices in women's healthcare'.

The programme takes direction and guidance from the clinical advisory group, a select group of Obstetricians and Gynaecologists from the Institute of Obstetricians and Gynaecologists . This group is chaired by Professor Robbie Harrison, and meets at least four times each year. The programme reports to the Clinical Strategy Programmes Division in the HSE, which is led by Dr Aine Carroll. The programme established a

multidisciplinary national working group to harvest the views of and gain consensus from a range of healthcare providers associated with maternity services, including midwifery, obstetrics, gynaecology, anaesthesia and allied health professionals. Examples of guidelines developed by the National Clinical Programme for Obstetrics and Gynaecology include:

- Guideline for the Critically Ill Woman in Obstetrics[47] (August 2014)
- Clinical Practice Guideline: Resuscitation for the Pregnant Woman[48] (October 2014)
- Clinical Guidelines: The Management of Second Trimester Miscarriage[49] (July 2014)
- Clinical Practice Guideline: the Diagnosis and Management of Ectopic Pregnancy[50] (November 2014)
- Clinical Practice Guideline: Bacterial Infections Specific to Pregnancy[51] (February 2015).

2.3.3 National Clinical Programme for Paediatrics and Neonatology

The National Clinical Programme for Paediatrics and Neonatology was established in 2011 as a joint clinical initiative between the HSE and the Faculty of Paediatrics, Royal College of Physicians of Ireland. Two clinical leads were appointed, one for paediatrics and one for neonatology. The objectives of the programme are focused on the areas of quality, access and value.

The programme reports to the Faculty of Paediatrics in the Royal College of Physicians of Ireland and the National Director for Clinical Strategy and Programmes, HSE. Within the Faculty of Paediatrics there are two clinical advisory groups associated with the programme – the Paediatric Clinical Advisory Group and the Neonatal Clinical Advisory Group. Both groups meet every two months. The programme also has a multidisciplinary working group, which meets approximately every six-to-eight weeks. The multidisciplinary working group is involved in strategy development, providing a

forum for advice of clinical and operational activities, advising on and supporting implementation projects, and as a channel for communications to relevant professional groups and other stakeholders from the programme. All recommendations of the working group are approved by the clinical advisory groups and other stakeholders as appropriate prior to implementation.

The programme has developed a number of algorithms for use in clinical care settings including[52]:

- Apnoea of Prematurity
- Developmental Dysplasia of the Hip (DDH)
- Pulse Oximetry Screening for Newborn Congenital Heart Disease
- Term Infant with Neonatal Jaundice on the Postnatal Ward.

2.4 Reviews and investigations of maternity services in Ireland

A number of investigations and reviews of maternity services in Ireland have been undertaken by HIQA, the HSE and others.[1;46;53-57] This section sets out the background to these reviews, their key findings and subsequent recommendations. These reviews detail what the current starting point is in maternity services and documents where areas requiring improvements have been identified. The findings and recommendations in these reviews informed the development of the *National Standards for Safer Better Maternity Services*. The reviews considered in this section are listed in chronological order in Table 5.

Table 5. Reviews and investigations of maternity services in Ireland

Name	Organisation and year published	Background to report
The Lourdes Hospital Inquiry: An inquiry into peripartum hysterectomy at Our Lady of Lourdes Hospital, Drogheda. Report of Judge Maureen Harding Clark S.C.	Inquiry established by the Government, 2006	The Medical Council received complaints from 15 patients treated by Dr Michael Neary at Our Lady of Lourdes Hospital, Drogheda, between 1986 and 1998 including 10 complaints alleging unwarranted peripartum hysterectomies. Dr Neary was subsequently found guilty of professional misconduct and was struck off the Medical Register. Following the Medical Council's report, the government established a non-statutory inquiry – the Lourdes Hospital Inquiry – and appointed Judge Maureen Harding Clark as its chairperson.
Report into the circumstances pertaining to the death of Mrs Tania McCabe and her infant son Zach at Our Lady of Lourdes Hospital, Drogheda on Friday 9 March, 2007[54]	The Health Service Executive, 2008	A review team was commissioned by the Hospital Network Manager of HSE North East to examine the circumstances pertaining to the death of Mrs Tania McCabe and her infant son Zach at Our Lady of Lourdes Hospital, Drogheda on Friday 9 March, 2007. The review focused on the clinical management of both Tania and Zach, and also examined whether non-clinical factors influenced the care she received.
National Miscarriage Misdiagnosis Review[53]	The Health Service	In early June 2010, reports of cases of misdiagnosis of miscarriage appeared in Irish media, leading to widespread concern and public

	Executive, 2011	discussion about diagnosis of early pregnancy loss. The HSE responded to this issue as a serious incident and established the National Miscarriage Misdiagnosis Review to lead a national review of the cases identified.
Investigation into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration, including those provided in University Hospital Galway, and as reflected in the care and treatment provided to Savita Halappanavar[46]	The Health Information and Quality Authority, 2013	In carrying out this investigation, HIQA looked in detail at the safety, quality and standard of services provided by the HSE at University Hospital Galway to patients, including pregnant women, at risk of clinical deterioration and as reflected in, among other things, the care and treatment provided to Savita Halappanavar. This included a review of Savita Halappanavar's pathway of care as documented in her healthcare records. The investigation also considered the effectiveness of the HSE's role in planning and delivering maternity services nationally in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public.
HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006 – date)[58]	The Department of Health, 2014	The Minister for Health requested the Chief Medical Officer to prepare a report on issues that arose following an RTE *Primetime* programme relating to Portlaoise Hospital Maternity Services on 30 January 2014. The report provides a preliminary assessment of Portlaoise Hospital Maternity Services focusing on perinatal deaths from 2006 to 2014 and related matters.
Confidential Maternal Death	The Maternal	This second Maternal Death Enquiry Ireland report was published in the

Enquiry in Ireland – *Report for 2009 - 2012*[57]	Death Enquiry, Ireland (funded and endorsed by the HSE), 2015	wake of the first report incorporating Irish data in the long-established UK Confidential Enquiry into Maternal Deaths in December 2014. It covers the same timeframe as the UK enquiry, and provides further detail on Irish data included in the first Maternal Death Enquiry Ireland report published in August 2012[56]. For the future, the revised reporting and assessment procedures will be published in annual reports, resulting in earlier access to data and emerging trends.
Report of the investigation into the safety, quality and standards of services provided by the Health Service Executive to patients in the Midland Regional Hospital, Portlaoise[1]	The Health Information and Quality Authority, 2015	This report presents the findings of the investigation by HIQA into the governance and assurance arrangements that the HSE has in place to ensure the safety, quality and standard of services provided to patients in Portlaoise Hospital. The investigation examined the quality and safety of clinical services, and the governance arrangements in place for the maternity and the general healthcare services at Portlaoise Hospital and how these were governed by the HSE's relevant national directorate.
A Review of 28 Maternity Case Notes by A Clinical Review Team Undertaken at the Request of the Health Service Executive	Undertaken at the request of the Health Service Executive, May 2015	The report is a clinical review of 28 case notes from three maternity units, Midland Regional Hospital Portlaoise (23 cases), University Maternity Hospital Limerick (three cases) and Midland Regional Hospital Mullingar (two cases) by a team of obstetricians referred to as the Clinical Review Team. The review was requested by the HSE as a consequence of patients contacting either a helpline, or the hospitals directly, following an RTE *Primetime* programme broadcast in January 2014 related to maternity services at Portlaoise. No time limit was set by the HSE regarding patients'

		care. The clinical review team only reviewed case notes provided to them by the HSE, relying on the HSE for the provision of all relevant records. The clinical review team did not meet with any patient, family or staff during the course of the review.
Flory Report	Commissioned by the HSE, 2015	The Flory Report is an assurance review conducted by an independent international expert on two HSE-run maternity units in Cavan General Hospital and South Tipperary General Hospital. The reviews were undertaken by Mr David Flory, an experienced senior executive from the NHS in England.
Baby Molloy Report	Health Service Executive, 2015	This report was published following a systems-analysis review into the death of Baby Mark Molloy who died in the Midlands Regional Hospital, Portlaoise in January 2012. The report identifies a number of significant failings into the death of Baby Mark.
Midland Hospital Portlaoise Systems Analysis Review Report: Review of the Care of Shauna Keyes	Health Service Executive, 2016	This report documents the findings of an independent review in relation to the care of Shauna Keyes and her baby Joshua at the Midlands Regional Hospital Portlaoise. The report highlighted four key areas of concern in Shauna's care including the management of her labour, the caesarean section, the resuscitation of her baby and the care and support provided to Shauna following Joshua's death.

2.4.1 The Lourdes Hospital Inquiry

The Lourdes Hospital Inquiry was an inquiry undertaken by Judge Maureen Harding Clark S.C. into peripartum hysterectomy at Our Lady of Lourdes Hospital, Drogheda.[59] The Medical Council received complaints from 15 patients treated by Dr Michael Neary at Our Lady of Lourdes Hospital, Drogheda between 1986 and 1998, including 10 complaints alleging unwarranted peripartum hysterectomies**. The Council commenced an inquiry in June 2000. In July 2003 the council's fitness to practise committee found that the facts in the 10 complaints of unwarranted peripartum hysterectomy were proven. Dr Neary was found guilty of professional misconduct and was struck off the Medical Register in September 2003. Following the Medical Council's report, the government decided to establish a non-statutory inquiry in April 2004 with Judge Maureen Harding Clark appointed as its chairperson.[59]

The purpose of the inquiry was to determine how many caesarean and peripartum hysterectomies were carried out at Our Lady of Lourdes Hospital, and to compare that rate with other similarly sized units throughout the State. The inquiry aimed to determine whether the medical culture in Our Lady of Lourdes Hospital was different to that in other hospitals, and how the standards of maternity care were allowed to fall below what should be expected. It sought to determine whether the obstetricians and their practices were protected by any parties who knew or ought to have known of these practices. It tried to determine the extent of missing records and how these records came to be missing. Finally, the inquiry would review the adequacy of the systems in place to prevent a recurrence of the events at Our Lady of Lourdes Hospital.

** A peripartum hysterectomy is an operation to remove the womb within six weeks of delivery. It includes caesarean hysterectomy performed during caesarean section after the baby has been removed, and hysterectomy following vaginal delivery.

The inquiry found that[59]:

- Any isolated institution which fails to have a process of outcome review by peers and benchmark comparators in place can produce similar scandals as those which occurred in the Hospital.
- Support systems must be in place to conduct regular and obligatory audit.
- There must be mandatory continuing professional development and skills assessment at all levels of healthcare.
- Staff need to attend updating of skills and methods programmes, and should be able to recognise that procedures change in accordance with evidence based research.
- Outdated and unnecessary practices ought to be recognised as such and changed as soon as information is available.
- Hospital management should have more authority and training, and should have medical input.
- Clinical independence should no longer be interpreted as a licence for arrogance, disregard for patient choice, dignity and need or freedom from accountability.

In summary, the Inquiry found a maternity unit that was "*to some extent caught in a time warp*" and that "*there was no badness to cover up*". The inquiry found it highly probable that some mothers' lives were saved when hysterectomy was the only procedure to stop intractable haemorrhage.[59]

The inquiry stated there is a need for functioning monitoring bodies and noted that while the numbers of the procedures undertaken in Our Lady of Lourdes maternity unit may be startling, they have to be understood in the context in which they occurred. The report states that good hardworking decent people can unwittingly enable bad practice when support and safety systems are not in place. Judge Clark concluded, based on the cooperation received from witnesses, that a private non-adversarial inquiry can be effective.

The findings of the review informed the development of the following themes within the *National Standards for Safer Better Maternity Services:*

- Effective Care and Support
- Safe Care and Support
- Leadership, Governance and Management
- Workforce
- Use of Information.

2.4.2 Tania McCabe Report

The *Report into the circumstances pertaining to the death of Mrs Tania McCabe and her infant son Zach at Our Lady of Lourdes Hospital, Drogheda on Friday 9 March, 2007* documents the circumstances pertaining to the death of Mrs Tania McCabe and her infant son Zach at Our Lady of Lourdes Hospital, Drogheda on Friday 9 March, 2007.[(54)] The report was published by the Health Service Executive (HSE) in 2008 following a review commission by the Hospital Network Manger of HSE North East. The review focused on the clinical management of Tania and Zach, and also examined to what extent non-clinical factors may have influenced the care both received.

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

The review team identified two care management problems:

- a working diagnosis of ruptured membranes was not made during Tania's first admission to hospital
- septic shock was not recognised or diagnosed following her second admission and caesarean section.

The review team analysed the incident using the Incident Decision Tree (NPSA, 2004). Based on this, the team were satisfied it was system failure that led to Tania's death. On the basis of the findings 27 recommendations were made.

The findings and associated recommendations informed the development of the following themes within the *National Standards for Safer Better Maternity Services:*

- Person-centred Care and Support
- Effective Care and Support
- Safe Care and Support
- Leadership, Governance and Management
- Workforce.

2.4.3 National Miscarriage Misdiagnosis Review

In early June 2010, reports of two cases of misdiagnosis of miscarriage appeared in the Irish media, leading to widespread concern and public discussion about diagnosis of early pregnancy loss. Medical or surgical intervention was recommended to women who had a diagnosis of miscarriage, but subsequently it was found that the pregnancy was viable and the women went on to continue their pregnancies. The diagnosis of miscarriage had been made in error. Over the following weeks, several other women raised similar concerns with their hospitals.

The HSE responded to the issue as a serious incident and set up a National Miscarriage Misdiagnosis Review to manage the incident and examine any similar cases that had occurred over the previous five years where drug or surgical treatment was recommended following a diagnosis of miscarriage, and where subsequent information demonstrated that the pregnancy was viable. The National Miscarriage Misdiagnosis Review was tasked with providing an analysis of all of the cases involved in this incident.

A five-year timeframe, from 18 June 2005 to 18 June 2010, was agreed by the review team as being likely to encompass all cases that would be relevant to current

practice. The five-year timeframe would allow the team to identify trends and patterns in the systematic causes of miscarriage misdiagnoses. The review team also considered any cases specifically submitted by patients that fell outside of the five-year timeframe, and cases identified through the Clinical Indemnity Scheme, where the case informed the work of the review team and the development of national standards. A total of 32 cases were identified for review, 24 of which met the terms of reference for the review. Of the 24 confirmed cases, 18 of the cases occurred within the specified five-year timeframe. A database was compiled to allow comparison of findings and identify patterns of practice that led to the possible misdiagnoses of miscarriage.

The report aimed to aggregate the outcomes of the reported cases in order to identify trends about the causes of the misdiagnoses. The analysis allowed the development of national recommendations for improvements. The findings from each hospital's individual systems analysis investigation, together with the findings from the national review of cases, were used to develop a series of recommendations for overall improvement in maternity services.

Recommendations were made in the areas of guidance, facilities and equipment, clinical management, education, training and accreditation and support for women. The recommendations informed the development of the following themes within the *National Standards for Safer Better Maternity Services:*

- Person-centred Care and Support
- Effective Care and Support
- Workforce.

2.4.4 HIQA's 2013 Galway Report

In October 2013 the Health Information and Quality Authority (HIQA) published the report of its *Investigation into the safety, quality and standards of services provided by the Health Service Executive (HSE) to patients, including pregnant women, at risk*

of clinical deterioration, including those provided in University Hospital Galway (UHG) and as reflected in, among other things, the care and treatment provided to Savita Halappanavar.[46] The investigation found a failure in the provision of the most basic elements of patient care to Savita Halappanavar. HIQA identified a failure to recognise that she was developing an infection and then a failure to act on the signs of her clinical deterioration in a timely and appropriate manner. The investigation also identified a number of missed opportunities to intervene in her care which, if they had been acted upon, may have resulted in a different outcome for Savita Halappanavar.

Some of the key findings from the investigation were as follows[46]:

- HIQA found no nationally agreed definition of maternal sepsis and also found inconsistencies in the recoding and reporting of maternal sepsis.
- There are a number of data collection sources involved in the collection of maternal morbidity and mortality data in Ireland; however, there is no centralised and consistent approach to reporting this.
- There is wide variation in the local clinical and corporate governance arrangements in place across the 19 public maternity hospitals or maternity units nationally. This makes it impossible to properly assess the performance and quality of the maternity service nationally.
- There has been no national review or national population-based needs assessment undertaken to date to identify the appropriate allocation of resources including multidisciplinary workforce arrangements, or the models of care required to ensure that all pregnant women have appropriate choices and access to the right level of care and support at the right time in Ireland.
- In order to provide assurances that pregnant women are receiving safe, high-quality and reliable care during and after their pregnancy, maternity services must collect, monitor and manage quality and safety performance measures to evaluate the performance of their clinicians and the outcomes for patients.

These measures should be primarily focused on assessing quality and safety outcomes for patients.

- There are significant deficits in how relevant learning, particularly in the areas of maternity services and clinically deteriorating patients, has been adopted and implemented locally and nationally following previous investigations and inquiries both within Ireland and internationally.
- Responsibility for implementing learning is not clearly owned meaning that learning does not happen. The responsibility and accountability to ensure learning happens sits locally with the boards and executives of healthcare facilities, and nationally with the HSE and other corporate bodies providing health services. The circumstances of the death of Tania McCabe and her son Zach have a disturbing resemblance to the case of Savita Halappanavar. Six years on from the publication of the HSE's Tania McCabe report in 2007, only five out of the 19 public maternity hospitals or maternity units were able to provide a detailed status report on the implementation of the report's recommendations.

As a result of the findings of the investigation HIQA made 34 recommendations that focus on the improvements required in University Hospital Galway and across all maternity hospitals in Ireland, as well as at national level. One of the key recommendations arising from the investigation was the need for the development and implementation of a National Maternity Services Strategy as a step towards a demonstrable, high-quality, safe and best-practice model of maternity care across the country. A strategy was published in January 2016. HIQA's recommendations in this report informed the development of the following themes within the *National Standards for Safer Better Maternity Services:*

- Effective Care and Support
- Safe Care and Support
- Leadership, Governance and Management
- Workforce

- Use of Information.

2.4.5 HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006 – 2014)

This report, undertaken by the Chief Medical Officer, was a preliminary report to the Minister for Health relating to the issues that arose following an RTE *Primetime* programme on Midland Regional Hospital Portlaoise (Portlaoise Hospital) maternity services which aired on 30 January 2014. A review was requested by the Minister for Health. The report provides a preliminary assessment of maternity services in Portlaoise Hospital focusing on perinatal deaths between 2006 and 2014 and related matters.[60] Through a series of recommendations it sets out the need for further examination or actions where the findings of the preliminary assessment suggest such a need. It also makes clear who should be responsible for these further examinations or actions.

The report sought to address whether the service provided by Portlaoise Hospital is safe at the time of the review and in 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 the report, meetings were held with some of the families involved, patient advocacy group Patient Focus, the senior management team at Portlaoise Hospital, 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.

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

The overall conclusions of the report are as follows:

- Families and patients were treated in a poor and, at times, appalling manner with limited respect, kindness, courtesy and consideration.
- Information that should have been given to families was withheld for no justifiable reason.
- Poor outcomes that could likely have been prevented were indentified and known by the hospital but not adequately and satisfactorily acted upon.
- Portlaoise Hospital maternity services 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.
- Many organisations, including Portlaoise Hospital, had partial information regarding the safety of the services that could have led to earlier intervention had the information been compiled.
- External support and oversight from the HSE should have been stronger and more proactive, given the issues identified in 2007.

The recommendations informed the development of the following themes within the *National Standards for Safer Better Maternity Services:*

- Person-centred Care and Support
- Safe Care and Support
- Leadership, Governance and Management
- Workforce
- Use of Information.

2.4.6 Confidential Maternal Death Enquiry in Ireland

Since its inception in 2009, Maternal Death Enquiry Ireland has carried out confidential enquiries into maternal deaths in Ireland using the UK model[††]. Funded and endorsed by the Health Service Executive (HSE), the Maternal Death Enquiry is a based in the National Perinatal Epidemiology Centre, Cork. The Maternal Death Enquiry aims to investigate why some women die during or shortly after pregnancy, and to learn how such tragedies can be avoided in the future to ensure that all pregnant and recently delivered women receive safe, high-quality care in appropriate settings.(56)

Given the number of pregnancies reported annually in Ireland and with due regard to confidentiality, it became imperative for Maternal Death Enquiry Ireland to join a larger cohort in order to maintain anonymity. A larger cohort also allows for more meaningful analysis and recommendations. The UK Maternal Death Enquiry has a respected and validated research methodology and recommendations from previous Maternal Death Enquiry UK reports have historically informed Irish healthcare professionals in ensuring continued improvement in Irish maternity services. In July 2007, a Maternal Mortality in Ireland Working Group was established with the stated objective of linking Ireland with the UK based Confidential Enquiries into Maternal and Child Health (CEMACH). The working group was a joint collaboration between Institute of Obstetricians and Gynaecologists and HSE. Following consultation with relevant advisory authorities, including the Data Protection Commissioner and the General Register Office, funding for CEMACH Ireland was secured from the HSE. In April 2009, Maternal Death Enquiry Ireland was established with the support of the Department of Health and Children and the State Claims Agency.

[††] The Confidential Maternal Death Enquiry (MDE) was initiated in England and Wales in 1952 and became UK-wide in the 1980s. Ireland became a participant in 2009. For many years the MDE UK enquiry has been acknowledged globally as a gold standard for a confidential maternal death enquiry.

Confidential Maternal Death Enquiry in Ireland – Report for 2009 – 2012 (Published February 2015)

Between 2009 and 2012, a total number of 38 maternal deaths[‡‡] occurring during or within 42 days of pregnancy end, were reported to Maternal Death Enquiry Ireland. Of these 38 deaths, 10 were classified as direct maternal deaths (due to obstetric causes, for example a pulmonary embolism), 21 as indirect maternal deaths (due to pre-existing medical or mental disorders which were exacerbated by pregnancy, for example cardiovascular disease), and the remaining seven were attributed to coincidental causes (not due to direct or indirect causes, for example a road traffic accident). There was no evidence of clustering in any one maternity unit.(57)

The report found a number of specific lessons for the Irish context for the period 2009 to 2012.(57)

Ethnicity and nationality

Maternal mortality was proportionally higher among minority ethnic groups of women who were not born in Ireland. Two in five, or 40%, of all maternal deaths identified between 2009 and 2012 by Maternal Death Enquiry Ireland occurred in women who were not born in Ireland. The higher proportion of deaths raises issues with how women who were not born in Ireland engage with Irish maternity services, such as, the availability of interpretative services. A particular concern was the issue of engagement with the services by non-national patients in receipt of alternative medical advice from outside the country.

Maternal age and BMI

While the numbers of maternal deaths in specific age groups were small, there was a suggestion of an increasing maternal mortality rate in women 30 years of age and

[‡‡]For the years 2009 to 2012, case ascertainment by Maternal Death Enquiry Ireland (direct, indirect and coincidental) was four times that of the civil death registration system. This issue is not unique to Ireland as underestimation of maternal deaths using civil death registration systems, even in developed countries, has been acknowledged by the World Health Organization (WHO).

above compared with younger women. Overall, the distribution of maternal deaths in Ireland did not suggest an association with increased BMI. However, of the maternal deaths attributed to cardiac disease in the period 2009 – 2012 (eight deaths), half of the women were either overweight or obese.[57]

First hospital booking appointment

The number of indirect maternal deaths (due to pre-existing medical or mental disorders which were exacerbated by pregnancy) underlines the importance of a comprehensive booking interview. The report states that there is a particular importance in ascertaining any history of previous medical or mental disorders, and substance abuse. It also highlights that previous involvement with social services requires follow up.[57]

Mental illness

Women who had a previous history of mental illness were engaged with the mental health services, and good communication between maternity services and mental health services was apparent. The absence of a mother and baby unit was identified as a continuing and regrettable deficiency in the Irish health service and it was noted that stand-alone psychiatric units are poorly equipped to look after women with medical and obstetric complications.

Pre-conception counselling

The importance of pre-conception counselling and patient compliance was evident in cases of pre-existing disease. Ideally, women should have management of their medical conditions optimised prior to becoming pregnant. Prospectively, there may be opportunities for improvement in relation to anti-epileptic and anti-depressant medication compliance in the pre-conception period.

Immunisation programmes: influenza

The recent MBRACE-UK report describes maternal deaths due to a novel strain of influenza A/H1N1/09 (commonly referred to as H1N1 or 'swine flu') occurring during

a global pandemic declared by WHO in 2009. Two such cases occurred in Ireland between 2009 and 2012. The importance of immunisation against seasonal and pandemic influenza for pregnant women is a key recommendation both in the recent MBRACE-UK report and Immunisation Guidelines issued by the National Immunisation Advisory Committee of the Royal College of Physicians of Ireland.

A fundamental component of the UK Maternal Death Enquiry process is dissemination of recommendations from the enquiry's reports to inform health professionals and to improve maternity services. Since its inception, Maternal Death Enquiry Ireland has promoted this element of the audit cycle through a series of organised educational events. Feedback from attending delegates has indicated a heightened awareness among health professionals of both the maternal death enquiry process in Ireland and recommendations contained in previous enquiry reports from the UK. Revised reporting and assessment procedures have been put in place will result in annual reports, resulting in earlier access to data and emerging trends in the future.

The findings and associated recommendations informed the development of the following themes within the *National Standards for Safer Better Maternity Services:*

- Person-centred Care and Support
- Effective Care and Support
- Safe Care and Support
- Better Health and Wellbeing
- Use of Information.

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

On 30 January 2014, RTE broadcast a *Primetime* programme about the tragic deaths of newborn babies in Portlaoise Hospital and the subsequent management of patients and their families by the hospital and the HSE. Following the broadcast, the Minister

for Health asked the Chief Medical Officer of the Department of Health to conduct a preliminary assessment of perinatal deaths and related matters from 2006 to 2014 in the maternity services in Portlaoise Hospital. Following publication on 28 February 2014 of the Chief Medical Officer's report, the Board of HIQA considered and agreed to a request from the then Minister for Health to conduct an independent investigation into the services provided by the HSE at Portlaoise Hospital.

HIQA reviewed the progress that had been made in ensuring that the findings from previous investigations and reviews conducted by HIQA, the HSE, the Chief Medical Officer and others had been implemented. This included an assessment against the hospital's service model to assure the delivery of high-quality, safe and reliable care.

The HIQA investigation considered the views of a number of patients and families whose experience of care fell well below the standard expected in a modern acute hospital. The assessment of these patients' and families' experiences reflects their experience of care and its aftermath when they raised concerns at local and national levels of the HSE. The investigation examined the quality and safety of clinical services, and the governance arrangements in place for the maternity and general healthcare services at Portlaoise Hospital and how these were governed by the HSE's relevant national directorate.

Seven national investigations undertaken by HIQA, resulting in the publication of over 200 recommendations, had a number of recommendations for both the relevant hospitals and the HSE nationally which should have been used by all healthcare services as a learning tool to inform and improve practice, and to drive quality and safety. Had the relevance of investigation findings been reviewed in the context of Portlaoise Hospital, and the aligned recommendations been subsequently implemented, HIQA found that this could have vastly reduced the number of adverse findings identified throughout the Portlaoise investigation. In addition ,the report shows that risks in general hospital services and maternity services at Portlaoise

Hospital were already identified and known about at all levels of health service management.[1]

HIQA's 2013 Galway report noted the absence of comprehensive national data relevant to the maternity services which would allow the HSE to evaluate the quality and safety of the maternity services provided nationally. The progress achieved in implementing the recommendation to define and agree a dataset of quality metrics is acknowledged in HIQA's Portlaoise report. This recommendation is designed to support monitoring and evaluation of performance and management of crucial patient outcome and experience indicators. This dataset was shared with all 19 public maternity hospitals or units for implementation in July 2014.

The findings and associated recommendations informed the development of the following themes within the *National Standards for Safer Better Maternity Services:*

- Person-centred Care and Support
- Effective Care and Support
- Safe Care and Support
- Leadership, Governance and Management
- Workforce
- Use of information.

2.4.8 A Review of 28 Maternity Case Notes

In June 2015 the HSE published a report by Dr Peter Boylan and his clinical review team of six obstetricians titled *A Review of 28 Maternity Case Notes*. The review was requested by the HSE in response to concerns raised by maternity patients who contacted Patient Focus or the HSE helpline following the airing of an RTE *Primetime* programme relating to the maternity services at the Midlands Hospital, Portlaoise, in January 2014. Patients who made contact were then written to, requesting consent, if they wished their own healthcare records to be reviewed. By midsummer 2014, 28 patients had consented. The concerns and complaints raised by the patients were

varied and spanned both maternal and baby issues. The cases ranged from birth in 1985 to 2013, 23 of which related to Portlaoise, three to Limerick and two to Mullingar.[61] It is important to note that the review team only reviewed the case noted provided to them by the HSE. The review team did not meet with any patient, family or staff during the course of the review.

Subsequent to the implementation of Dr Boylan's clinical review, the HSE received consent from a further 103 patients for a clinical records review. In light of the volume of cases, it was requested that the hospital involved conduct a clinical records review of the individual cases.

None of the patient reports have been published. Only individual patients received their own report, and as such the findings from the review are not available. However, based on the review of the 28 maternity case notes, the clinical review team made recommendations that informed the development of the following themes within the *National Standards for Safer Better Maternity Services:*

- Person-centred Care and Support
- Effective Care and Support
- Safe Care and Support
- Leadership, Governance and Management
- Workforce
- Use of Information.

2.4.9 Flory Report

In September 2015 the HSE published two assurance review reports conducted by an independent expert on two HSE-run maternity units in Cavan/Monaghan Hospital and South Tipperary General Hospital.[62;63] The reviews of the governance of maternity services in both units focused on the systems and processes for assurance of service quality, risk management and patient safety primarily inside the hospitals, but also in the hospital group structures within which they operate. While these reviews focused

on a small sample of the country's maternity units, the findings provide important insights for considering governance of quality, safety and risk in other maternity units, and across hospitals and hospital groups more generally.

The report found that there was a need to ensure the ability of HSE services to effectively function, recover quickly from changes or significant challenges while at the same time planning for the medium and long-term sustainability of services within the new hospital groups. In particular, the report supports the current acute hospital reform programme by confirming that:[62;63]

- Smaller hospitals such as Cavan/Monaghan and South Tipperary cannot operate in isolation as stand-alone entities either clinically or financially. They cannot sustain the breadth and depth of clinical services that the populations they serve require, without formal links and networks as part of bigger, stronger, more specialist units. Likewise, they cannot afford to do everything independently and the connection and sharing of staff and facilities between units enables the available funds to go further.
- The role of the hospital group is crucial both in terms of building effective networks and also in providing direct support and filling some gaps in the operating model for smaller hospitals. In this way, the role of the hospital group must go beyond oversight and planning and into direct 'hands-on' responsibility for solving problems.
- The development of maternity networks needs to be fast tracked.

A number of factors emerged in the two units which other similarly sizes hospitals are likely to face in relation to staffing, networks involving voluntary hospitals and infrastructure, and capital investment. Affording, recruiting, and retaining a clinical and managerial workforce capable of delivering high-quality services safely and effectively is a struggle for small units. In this regard, the units rely on a relatively small number of key individuals in both clinical and managerial positions working beyond their contractual commitments and with a broader range of responsibilities

than their job titles describe to keep the unit running. While this is a great strength in the operation of the units, it also carries a significant risk if any of those individuals leave or are away.(62;63)

For maternity networks that involve voluntary hospitals, operational resilience in smaller services is strengthened through support from bigger units, which are often voluntary hospitals, operating in quite a different statutory and governance framework than the HSE public hospitals. The evidence from the two units reviewed found that this is not straightforward. In the former regional HSE structures the patient pathways which ensure higher risk patients go to the bigger, more specialist centres seemed to generally work well but there was little evidence of networked staff rotas or other forms of practical, cross-site operational support. In the early days of group structures, there is little evidence of practical networking in maternity services. The report states that there is a lot of talk about it and some preparation for it, but not much action as of yet.(62;63)

The findings and recommendations outlined in the reports informed the development of the following themes within the *National Standards for Safer Better Maternity Services:*

- Safe Care and Support
- Leadership, Governance and Management
- Workforce
- Use of Resources.

2.4.10 Molloy Report

In October 2015 the HSE published a report following a systems analysis review[§§] into the death of baby Mark Molloy who died in the Midlands Regional Hospital,

[§§] A systems analysis review (previously known as a root cause analysis) is a methodical investigation of an incident involving collection of data from literature, records (such as healthcare records), interviews with those involved and analysis of data to establish the chronology of events that led up to

Portlaoise in January 2012.[64] The report identifies a number of significant failings leading to the death of Mark Molloy. The systems analysis review, undertaken in 2013, is a methodical investigation of an incident to allow management to understand the key causal factors contributing to an adverse outcome. The reports from such reviews are used as tools for hospital management and are not typically published. The report of the review in this case was published at the request of the Molloy family. The HSE noted that at the time of publication, two years after the review's completion, the findings of the report and its 43 recommendations had been implemented in maternity services in Portlaoise and in other maternity units throughout the country.[64]

The aim of the review as outlined in the terms of reference was to[65]:

> "Establish precisely what happened so that the Health Service Executive – Dublin Mid-Leinster and the Midland Regional Hospital at Portlaoise can identify all lessons that can be learned from the experience such that the likelihood of a recurrence is removed or reduced; and so that Mr. and Mrs. Molloy can have access to an explanation of the events leading up to the death of their baby son, the systems causes, and the actions identified to prevent a recurrence of these issues".

The investigation identified two care delivery issues related to the care and management delivered to Mrs Molloy and baby Mark Molloy. These were[65]:

- failure to recognise and act on the signs of fetal distress
- failure to fully assess all sections of the cardiotocography (CTG) resulting in:
    - the inappropriate prescribing and administration of Syntocinon,
    - and a delay in the decision to transfer Mrs Molloy to the Theatre Department for an assisted delivery.

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the incident, identifying the key causal factors, and recommending control actions to address the contributory factors to prevent future harm arising, as far as is reasonably practicable.

The investigation aimed to identify the factors that contributed to the development of these care delivery issues and the recommendations required to prevent or to reduce the risk of recurrence. The report made 43 recommendations.

The HSE stated that the systems analysis review and the subsequent HIQA report on Portlaoise Hospital have resulted in improvements in the maternity unit. For example, new management and governance arrangements, a formalised management arrangement with the Coombe maternity hospital, the appointment of a clinical director to improve clinical integration of maternity services, and the appointment of additional midwifery and specialist nursing staff for maternity services. It was also stated that the report had been an important influence on the development of improved services in all units throughout Ireland.[64] Key developments in this regard are cited as:

- dissemination of a number of key clinical guidelines relating to obstetric services including sepsis management, management of a critically ill woman, clinical handover and management of miscarriage
- implementation in all hospitals of the National Early Warning Score (NEWS) and the Maternity Early Warning Score (MEWS)
- launch of standards on bereavement services for families affected by adverse outcomes
- development of mandatory CTG trace training
- the establishment of the Women and Infants programme and advertisement of key posts
- approval to appoint directors of midwifery to all 19 units to strengthen clinical governance and senior decision-making in all of the units
- reporting by the 19 maternity units on 30 quality assurance indicators since August 2014
- development of maternity safety statements on a monthly basis, with effect from October 2015.

The report informed the development of the following themes within the *National Standards for Safer Better Maternity Services:*

- Person-centred Care and Support
- Effective Care and Support
- Safe Care and Support
- Leadership, Governance and Management
- Workforce
- Use of Information.

2.4.11 Systems Analysis Review Report: Review of Care of Shauna Keyes

In October 2009, Shauna Keyes, a first time mother, was admitted to Midlands Regional Hospital Portlaoise after she was found to be in early labour.[66] After being given a Syntocinon drip to augment her labour and an epidural at her request, a series of issues occurred in Shauna's care resulting in the death of her baby Joshua. A systems analysis review report highlighted key areas of concern in Shauna's care relating to the interpretation of the CTG, the absence of fetal blood sampling, the delay in delivering Joshua, the absence of a formal bereavement service and a lack of support for relatives in relation to the coronial process.[66]

- Following the induction of labour, there was a delay in carrying out the caesarean section. Factors contributing to the delay included a lack of appropriate fetal monitoring, a failure to recognise in a timely manner the need to move to emergency caesarean section, a delay between time from decision to incision of caesarean section and a lack of education and training specifically in relation to a failure to identify and act on a concerning CTG.
- When the review team considered issues in Joshua's resuscitation, it was noted that he was born in poor condition. This was unexpected as the CTG recordings and fetal heart rates were within the normal range prior to delivery. The review states that as Joshua's condition was unexpected a resuscitation

process was applied and no deficits were noted in relation to the resuscitation process.

- In the immediate period following the death of Joshua, it was noted that the hospital failed to have a consistent, individualised approach to support given to Shauna and her family.
- Following her discharge from hospital, Shauna and her partner had a number of meetings with members of staff who had been involved in her care. Shauna raised concerns that their need for personal support was not addressed and that she did not feel assured in relation to actions to be taken on foot of her experience.
- An additional issue was identified in relation to the timing of Shauna's antenatal booking appointment. As her first antenatal booking appointment was at 25 weeks, it was not possible to determine an estimated delivery date. The review states that this was outside the hospital's control as there was no system in place to prioritise referrals to ensure that women were seen within the first trimester or if they were a late booker.

Recommendations were made in relation to each of these areas and informed the development of the following themes within the *National Standards for Safer Better Maternity Services:*

- Person-Centred Care and Support
- Effective Care and Support
- Safe Care and Support
- Leadership, Governance and Management
- Workforce.

2.5 Summary

Ireland's first National Maternity Strategy (*Creating a Better Future Together*)[2] was launched in January 2016. A number of members of the Maternity Strategy Steering Group were also members of HIQA's Maternity Standards Advisory Group and HIQA

worked with these members to ensure that both pieces of work were aligned and would complement each other. HIQA also engaged with the group responsible for developing the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death*[44] to ensure alignment with the principles of these standards which mark a significant move towards a more person-centred approach to care.

A need to improve Irish maternity services has been identified in a number of reviews and investigations, as documented in this chapter. It has been shown that women have faced serious failings in their maternity care and a series of significant deficits have been identified. This has undermined confidence in the maternity services and has also impacted significantly on staff morale.

The findings and recommendations of each of these reviews and investigations were examined and considered in drafting the *National Standards for Safer Better Maternity Services.* A number of the recommendations in the reports cited in this chapter have led to significant initiatives including the development of the National Maternity Strategy[2] and the clinical guidelines developed by the National Clinical Effectiveness Committee as documented in section 2.3.1.

The National Maternity Strategy[2] and the *National Standards for Safer Better Maternity Services,* when implemented, represent the necessary building blocks to providing a consistently safe, high-quality maternity service, which will in turn work towards restoring public confidence in the system.

Chapter 3: Systematic Literature Review

3.1 Overview of literature review

3.1.1 Introduction

The purpose of this systematic literature review was to retrieve and document recently published evidence in relation to standards in maternal health services as they relate to the eight themes set out in the *National Standards for Safer Better Healthcare* as follows:

- Person-centred care and support
- Effective care and support
- Safe care and support
- Better health and wellbeing
- Leadership, governance and management
- Workforce
- Use of resources
- Use of information.

The review was undertaken between April and September 2015, with additional articles of relevance included after the initial review, for example, articles suggested by members of Standards Advisory Group. Evidence gathered helped to inform the development of the *National Standards for Safer Better Maternity Services.*

3.1.2 Scope of the systematic literature review

This systematic literature review examined material published by the scientific community relating to standards in maternal health services. As the national maternity standards are underpinned by the *National Standards for Safer Better Healthcare*, the eight themes of the *National Standards for Safer Better Healthcare* were used to identify material by theme to inform the development of standards. The scope of the systematic literature review was from pre-pregnancy to six weeks after

birth. Literature on assisted human reproductive services were excluded from this review.

3.1.3 Systematic literature review objectives

The three objectives of this systematic literature review were:

1. to use online search databases to conduct a systematic literature review of the latest published medical science material supporting the development of standards, guidelines and best practice in maternal health services
2. to group retrieved search results under the eight themes of the *National Standards for Safer Better Healthcare*, to help guide subsequent development of service-specific national standards for maternity services.
3. to inform HIQA prior to engagement with key stakeholders involved in focus groups and the Standards Advisory Group.

3.1.4 Database search strategy methodology

The research question

Systematic literature reviews collate evidence without bias and should be reproducible, thorough and transparent. Formulating the right research question from the beginning is an essential part of producing an effective systematic literature review. The following research question was proposed:

> What evidence exists in recently published medico-science literature to support the development of maternal health service standards, guidelines or best practice in relation to:
>
> - Person-centred care and support
> - Effective care and support
> - Safe care and support
> - Better health and wellbeing
> - Leadership, governance and management

- Workforce
- Use of resources
- Use of information.

Database searching

The research question can be broken down into three key elements: the 'P' population element, the 'LQ' limiting query element, addressing standards, guidelines and best practice, and the 'O' outcome element which deals with the eight themes of the *National Standards for Safer Better Healthcare.* These elements were combined to formulate search queries and used in conjunction with search filters, limiters and qualifiers to search two major medical and health science search databases, Embase (Excerpta Medica database) and MEDLINE (Medical Literature Analysis and Retrieval System Online) using PubMed. The Cochrane Database of Systematic Reviews was also searched to source up-to-date clinical systematic reviews.

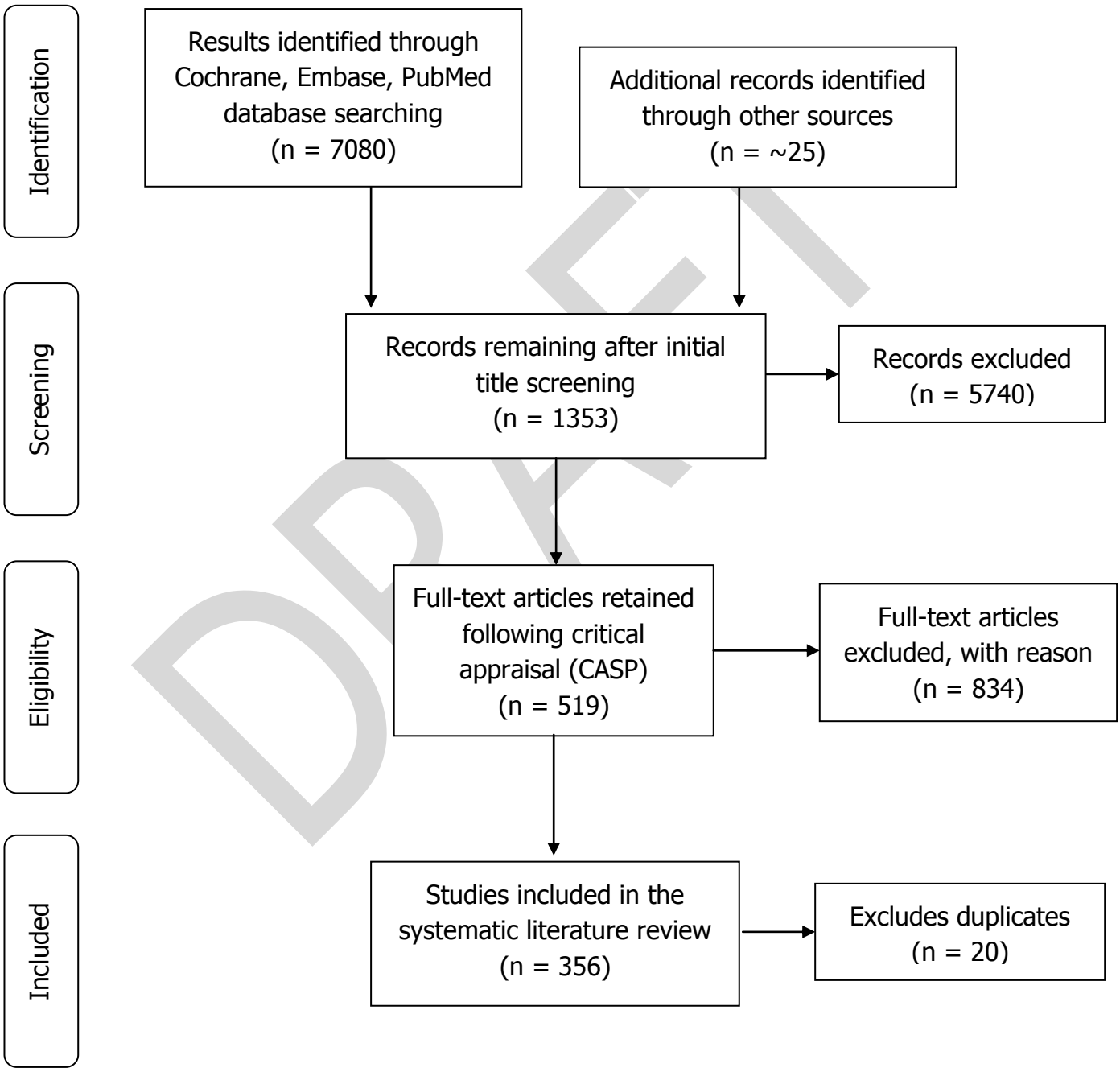
Natural language and controlled vocabulary descriptors or MeSH (Medical Subject Headings) terms were used to describe each element within a search query. MeSH terms were defined using Emtree in Embase and the MeSH database in PubMed and the Cochrane library. Additional limits placed on returned results included publication dates (from 2005 to 2015), the English language and human-based publications.

Summary of search results

Search queries identified a total of 7,080 articles (86 in Cochrane, 2,165 in Embase and 4,829 in PubMed). Titles of papers were reviewed and relevant papers were selected for abstract review. Following a review of abstracts, papers of interest were selected for retrieval and skim reading. The relevance, quality and transferability of information and studies, were evaluated using a CASP (Critical Appraisal Skills Programme) checklist. Publications that met all criteria (506) were stored in an online evidence library and exported using special bibliographic software, Reference Manager (see Figure 2). Findings from this evidence base are summarised and

presented under *National Standards for Safer Better Healthcare* themes in the next section.

Figure 2. Maternity standards systematic literature review flow diagram



3.1.5 Structure of the systematic literature review

The *National Standards for Safer Better Maternity Services* were developed using the framework of the *National Standards for Safer Better Healthcare*, launched by HIQA in 2012. The systematic literature review is presented under the eight themes under which the National Standards are presented:

- Person-centred care and support
- Effective care and support
- Safe care and support
- Better health and wellbeing
- Leadership, governance and management
- Workforce
- Use of resources
- Use of information

The systematic literature review is presented under these themes with sub themes covered within these as identified in the literature.

3.2 Person-centred Care and Support

3.2.1 Overview

Maternity services should respect the preferences, values and dignity of women and respond to their needs and rights. Provision of choice is central to this. Person-centred maternity care should engage, inform and listen to women. The following aspects of person-centred care and support, with regard to maternity services, are addressed in this section:

- Provision of choice through communication with women
- Shared decision-making
- Access to maternity care
- Homebirths

- Women with social needs
- Mental health issues
- Pregnancy loss.

3.2.2 Provision of choice to women through communication

The provision of choice is a hallmark of successful maternity services in well-resourced countries. Such choice places responsibility on maternity service providers to ensure women are enabled to make informed decisions about their own care. Women should be provided with sufficient information to allow them to understand the risks, benefits and consequences of decisions at each stage of the antenatal, intrapartum and postnatal periods.*** Access to information and counselling is particularly relevant for women with additional needs such as social needs, pre-existing medical conditions,[68] fertility issues,[69;70] or those dependent on prescription medication. A Swedish study found that women today have higher expectations regarding information than in the past.[71] Women in the UK are provided with evidence-based information addressing their individual needs and preferences to allow them to actively participate in their own care, if that is their choice.[72] A UK study published in 2010, found that 60% of women felt they were given choice in their care and 97% of women said they were talked to in a way that they could understand.[73] The UK government also ensures women's views are communicated to NHS Trusts offering maternity care by mandating that at least one in three of statutory maternity service committee members are women who use or have used maternity services. A Scottish study of women living in remote areas found that women preferred delivery in a maternity unit to homebirth, and consultant-led care to midwife-managed care.[74]

Weight stigma, which has a negative impact on psychological and physical health is pervasive in Western society and in healthcare settings.[75] Two Australian studies

*** The postnatal period begins immediately after the birth of the baby and extends up to six weeks, or 42 days, after birth.[67]

were conducted to examine the presence of weight stigma in maternity care from the perspective of women and care providers.[75] The first study investigated the association between pre-pregnancy body mass index (BMI) and experiences of maternity care from a state-wide, self-reported survey of 627 Australian women who gave birth in 2009. Women with a higher BMI were more likely to report negative experiences of care during pregnancy and after birth compared to lower weight women.The second study involved the administration of an online survey to 248 Australian midwifery and medical students, to investigate their perceptions of, and attitudes towards, providing care for pregnant women of differing body sizes. Midwifery and medical students perceived overweight and obese women as having poorer self-management behaviours. They reported less positive attitudes towards caring for overweight or obese pregnant women compared to women with a normal BMI. Those who reported few weight stigmatising attitudes responded less positively to overweight and obese pregnant women. Strategies to recognise and combat weight stigma need to be included in the training of midwives and doctors.

Single family rooms in neonatal intensive care units are more conducive to family-centred care, breastfeeding success and improved infant health than an open ward.[76]

3.2.3 Shared decision-making

Communication is key to shared decision-making in maternity care. Healthcare professionals should help women and their partners understand the consequence of the choices they make.[77] Clinical guidelines can prioritise safety and risk management but women's preferences must also be considered. Decision aids or decision support techniques including booklets, audio-guides, interactive computer programmes and structured counselling have been found to reduce decision-making regret, reduce indecision, and increase accuracy of risk perception.[78]

3.2.4 Access to maternity care

Many women from refugee backgrounds have complex medical and psychosocial needs. They may face multiple barriers that prevent them from accessing maternity care in either a timely manner or indeed at all. A large tertiary referral centre in Brisbane, Australia carried out a multifaceted project in order to develop a best practice model of refugee maternity care.(79) Models of care which took into account accessibility of services in terms of location, ease of transport and ease of childcare improved attendance and women's satisfaction.(79)

3.2.5 Homebirth

Planned homebirth rates are low in most high-income countries in Europe, apart from the Netherlands where about one in five women give birth at home.(80) In the Netherlands, labour is seen as essentially a normal physiological process and if pregnancy, childbirth and the postnatal period are uncomplicated, then women remain in the care of midwives.(81) Only women with high-risk profiles are cared for by obstetricians from the confirmation of the pregnancy. A list of obstetric indications designates the most appropriate care provider for women with defined medical or obstetric conditions. The list of Dutch high-risk maternal profiles has expanded from 39 in 1958 to 143 in 2003.(81) This may reflect the increasing complexity with increasing maternal age and rising rates of obesity and diabetes. Obstetrician involvement in the birth process increased from 24.7% in 1964 to 59.4% in 2002.

The rate of homebirths is in decline in Nordic countries. The prevalence of planned homebirths is between 1% and 2% in Denmark and Iceland, and about 0.1% in Sweden and Norway. In Denmark, homebirth is the only alternative to the maternity unit and a woman has the right to be attended by a midwife during homebirth. Iceland and Norway have freestanding midwife units and alongside midwife units (birth unit situated in a hospital with a maternity unit) in addition to the option of homebirths or birth in a maternity unit. Icelandic women have the right to choose homebirth in accordance with national guidelines for choice of place of birth. Sweden

has one alongside midwife unit in Stockholm and homebirth midwives are contracted privately.[82] Homebirths experienced a steady decline in the US between 1990 and 2004, but increased from 0.6% to 0.8% between 2004 and 2010.[83]

The relative benefits and risks of birth in different settings in high-income countries have been widely debated in recent years.[84] A woman's preference for homebirth may conflict with evidence-based practice. A Cochrane review published in 2012 compared planned hospital birth with planned home birth in selected low-risk women.[85] Two randomised control trials met the inclusion criteria, but only one very small trial (n=11) was included because it provided some outcome data. The evidence from this trial was of moderate quality and too small to allow conclusions to be drawn. A randomised controlled trial, the gold standard, is unlikely to be feasible, forcing women and healthcare professionals to rely on evidence from observational studies. Retrospective observational studies published over the last 20 years have conflicting results and have been criticised due to many methodological flaws.

The Birthplace in England study

The largest prospective cohort study to date, the Birthplace in England study, looked at perinatal outcome according to the planned place of birth at the start of care in labour.[84] The study, which took place between April 2008 and April 2010, aimed to collect data in every NHS trust in England providing home birth services, every freestanding midwifery unit, every alongside midwifery unit (midwife-led unit on a hospital site with an obstetric unit) and in a random sample of obstetric units, stratified by unit size and geographical region. This study only included women giving birth with midwives who were employed through the NHS. Women were classified as healthy women with low-risk pregnancies if, before the onset of labour, they were not known to have any of the medical or obstetric risk factors listed in the NICE intrapartum care guideline.

The primary objective of this study was to compare intrapartum and early neonatal mortality and specific neonatal morbidities of births planned at home, births in

freestanding midwifery units and births in alongside midwifery units with births planned in obstetric units, for babies of women judged to be at low risk of complications before the onset of labour. The primary outcome was a composite of perinatal mortality and specific neonatal morbidities: stillbirth after the start of care in labour, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus and fractured clavicle. Secondary outcomes included neonatal and maternal morbidities, maternal interventions and mode of birth. Women were analysed in the group in which they planned to give birth, with the obstetric unit group as the reference. Data was collected on 79,774 eligible women, 64,538 of whom were judged to be at low risk. The incidence of adverse perinatal outcomes was low in all birth settings. Overall, there was no significant difference in the primary outcome between any of the non-obstetric units compared with the obstetric units. Interventions during labour were substantially lower in all non-obstetric units compared with obstetric units. For nulliparous women, there was a significant increase in the incidence of the primary outcome for women who planned home births but not for either midwifery unit setting. For multiparous women there was no significant difference in the incidence of the primary outcome by planned place of birth. The rate of transfer of nulliparous women from non-obstetric units ranged from 36% to 45%. This ranged from 9% to 13% for multiparous women. The study acknowledged that the use of a composite primary outcome measure was a weakness of the study because of the low events rates for individual perinatal outcomes. The ability for the findings of this study to be generalised and applied to other settings is uncertain because care in other countries is provided very differently.

An economic evaluation of the Birthplace in England study found that planned homebirth was the most cost-effective option for women judged to be at low risk of complications.[86] Over one in four women were transferred from alongside midwifery units to obstetric units while one in five women were transferred from freestanding midwifery units to obstetric units.[87] Nulliparity, labour after 40 weeks' gestation and

or the presence of a complicating condition, was associated with a higher rate of transfer to an obstetric unit.[87]

Birthplace in the Netherlands studies

A prospective cohort study was carried out in the catchment area of the neonatal intensive care unit of the University Medical Centre in Utrecht to compare the incidence of perinatal mortality and severe perinatal morbidity between women with low-risk term pregnancies supervised in primary care by a midwife and women with high-risk term pregnancies supervised in secondary care by an obstetrician.[88] The main outcome measures were perinatal death (antepartum, intrapartum and neonatal) or admission to the neonatal intensive care unit. Infants of women at low risk whose labour started in primary care under the supervision of a midwife had a significantly increased risk of delivery-related perinatal death than infants of women at high risk whose labour started in secondary care under the supervision of an obstetrician. There was no difference in the rates of admission to the neonatal intensive care unit between the two groups. The authors acknowledged that the study was based on aggregated data from a national perinatal register, which made adjustment for confounders impossible which was a major limitation.

A nationwide retrospective cohort study compared perinatal mortality and morbidity outcomes between planned homebirths and planned hospital births in the Netherlands.[89] Intrapartum fetal death, neonatal death within 24 hours, neonatal death up to seven days after birth and admission to a neonatal intensive care unit were the study outcomes. The study was conducted between 1 January 2000 and 31 December 2006 and included 529,688 women considered to be at low risk and in primary midwife-led care at the start of labour. In the Netherlands, perinatal registration data is collected in three separate databases: one for primary care, one for secondary obstetric care and one for paediatric care. These databases were combined into one national perinatal database via a validated linkage method prior to the publication of this study in 2009. There was no significant difference in the risk of intrapartum fetal death, neonatal death within 24 hours, neonatal death up to seven

days after birth, or admission to a neonatal intensive care unit between planned homebirths and planned hospital births.[89] There was significant increase in the risk of admission to the neonatal intensive care unit for babies of each of the following subgroups of women who planned homebirth; nulliparous, aged 35 years or older, gave birth at 37 or 41 weeks' gestation, non-Dutch origin or had a low socio-economic status (based on the mean household income level of the neighbourhood), compared to women who planned a hospital birth. The large sample size allowed the study to detect differences in rates of rare adverse outcomes. Data was missing because this was a retrospective study. Planned place of birth was not recorded for 8.5% of women (n=45,120) and paediatric data of half of the non-academic hospitals were missing. The latter reduced the power of the study to find significant differences in admission to the neonatal intensive care unit (NICU).

3.2.6 Women with social needs

Despite decreasing perinatal mortality and maternal mortality rates in high-income countries, inequalities persist for women from lower socio-economic groups (such as, low education and income level), from specific ethnic groups and those living in deprived areas.[90] A systematic review, published in 2014, described disparities between immigrant and non-immigrant women's experiences of maternity services in Australia, Canada, Sweden, UK and the USA.[91] Immigrant women were less positive about their care than non-immigrant women. Communication problems and lack of familiarity with maternity care systems had a negative impact on their experiences, as did perceived discrimination and care which was not kind or respectful. A Norwegian study, published in 2007, found that immigrant women had an increased risk of stillbirth and sub-optimal care such as failure to act on non-reassuring fetal status or incorrect assessment of labour progression compared with non-immigrant women.[92] Inadequate communication was documented for almost half (47%) of immigrant women and an interpreter was used for 29% of these women.

Refugees comprise a vulnerable sub-group of immigrants. An Australian study published in 2012, described a best model of refugee maternity care that emphasised continuity of carer, quality interpreter services, educational strategies for both women and healthcare professionals, and the provision of psychosocial support to women from refugee backgrounds.[79] In the UK, maternal mortality due to ectopic pregnancy is falling; however, women from ethnic minority groups have a higher mortality rate than other women because of delay in accessing care and communication difficulties.[93]

A study of 27,107 pregnant adolescent women conducted over 10 years in the US found that they were more likely than adult women to suffer adverse outcomes during pregnancy such as anaemia, infection, hypertensive disease and depression.[94] Consequences extending beyond pregnancy also occurred, including, delayed or discontinued education, increased use of public assistance and depression in later life. A 2015 Australian study of pregnant adolescent women found that despite individualised care programmes, exposure to domestic violence and drug abuse had an impact on maternal attachment and assessment of infant temperament.[95] Specialised clinical and counselling strategies have been developed to assist healthcare professionals provide additional support to certain groups, such as teenagers, so that they can make a confident and effective transition to parenthood.[96]

Results are mixed regarding the effectiveness of home visiting programmes. A multi-centre UK trial arranged weekly home visits for vulnerable families from six months of pregnancy to 12 months postnatally.[97] This intervention led to an improvement in the sensitivity and adjustment of mothers to their infants, and to infant cooperativeness. In 2006 a systematic review of the literature on postnatal support reported that no randomised controlled trial evidence was found to endorse universal provision of postnatal support to improve parenting, maternal mental health, maternal quality of life, or maternal physical health. There was some evidence that populations at high risk may benefit from postnatal support.[98] The study found that

nulliparous women with low incomes and those at high risk for family dysfunction showed improvements in parenting knowledge, confidence, infant-child interaction and maternal mental health, using either nursing visits and case conferencing, or frequent paediatrician educational visits.

3.2.7 Perinatal mental health

Mental health problems occurring in pregnancy and the postnatal period are often similar to those occurring at other times in their nature, course and potential for relapse, but there can be differences.[19] The majority of mental health problems during pregnancy and the postnatal period are mild to moderate and can be treated in primary care. Mental health problems in pregnancy and the postnatal period often need more urgent intervention than they would at other times because of their potential effect on the baby and on the woman's physical health and her ability to function and care for her family. Mental health problems frequently go unrecognised and untreated in pregnancy and the postnatal period. Some women do not seek help because of fear of stigma, or fear of intervention by social services. The perinatal period can also present practical barriers to accessing treatment. The demands associated with the care of an infant may interfere with a woman's ability to attend treatment regularly. If mental health problems are left untreated, women can continue to have symptoms detrimental to their wellbeing, sometimes for many years. These problems can also affect their children and other family members. The recognition of risk factors, timely discussion, and the management of mental illness can greatly reduce the impact of mental illness during pregnancy and in the postnatal period.[99] Women at risk should be referred to a specialist perinatal mental healthcare professional for further assessment, intervention, and monitoring both during pregnancy and in the postnatal period. Apart from pharmacological interventions, guidelines recommend establishing specialised community perinatal teams to promote and monitor mental health. Mother and baby units that treat acutely-ill women enable mothers to remain with their baby in a supervised environment while receiving treatment for their psychiatric illness.

Perinatal depression

Depression and anxiety are the most common mental health problems occurring during pregnancy and in the first year after childbirth. Perinatal depression affects approximately 15% of women and begins during pregnancy or in the first four weeks.[99;100] Psychosocial risks for perinatal depression include low socio-economic status,[101] lack of social support and isolation, poor education, lone parenthood, and having a history of mental illness. A French study, which reported an antenatal depression rate of 12% in women, identified level of education, past psychiatric history, stress related to the health and viability of the fetus, relationship conflict and work difficulties as potential risk factors for antenatal depression.[102] A study of 95 women found that women who experienced psychological aggression by their partners during pregnancy had higher levels of depressive symptoms than women who did not.[103] Treatment of depression during pregnancy may be improved in a number of ways, for example, educating women with regard to antenatal depression, personalised care based on a woman's individual risk, dealing with relationship issues, and education around parenthood.[104]

There are risks associated with taking psychotropic medication in pregnancy and during breastfeeding but such a risk needs to be balanced against the potential to trigger or worsen an episode if medication is stopped. Some women choose to stop medication once the pregnancy has been confirmed, without medical advice or supervision. A systematic review published in 2010 examined the effects of gestational exposure to antidepressants on pregnancy, neonatal outcomes and longer-term developmental outcomes.[105] While 35 studies were included in this review, the studies varied in quality and many had insufficient numbers of participants to be able to detect rare events.[105] No randomised controlled trials on gestational exposure to antidepressants could be located for this literature review. The larger register studies were limited by lack of proof of drug exposure and difficulty with follow-up. Study design was a further issue of concern as all designs had multiple confounders and many lacked controls. The decision about how to treat

a pregnant woman with depression has to balance the overall benefits and risks to both mother and baby.

Screening for perinatal depression

Antenatal mental health assessment is becoming increasingly common in high-income countries.[106] There is currently no evidence from any well-designed and well-conducted randomised controlled trial that screening for depression in pregnancy or postnatally benefits women.[107] The 2014 NICE guideline on antenatal and postnatal mental health does not recommend routine screening for depression in pregnancy or the postnatal period.[108] However, the administration of two questions (Whooley questions)[†††] about depression at several points during pregnancy and the postnatal period is recommended instead. The Whooley questions and Arroll 'help' question are used in the UK at the booking appointment to identify women with possible depression, despite a lack of evidence of their validity and acceptability. A number of validated postnatal depression screening tools exist. The Edinburgh postnatal depression scale is the most popular of these because of its brevity, sensitivity and specificity.[100;109-111] The Marcé Society for Perinatal Mental Health, an international society established in 1980, does not recommend routine screening for perinatal depression because of the potential for false positive findings, costly referrals, diagnostic work-ups for women who are not depressed, and negative associations of labelling.[110] A survey of a subgroup of women from the cohort in the Australian Longitudinal Study on Women's Health was conducted over six months in 2011. Almost four out of five (1,835) women responded and completed a written questionnaire.[112] Significant emotional distress was experienced by 398 women antenatally and 380 women postnatally. Women who were not asked about their emotional health were less likely to seek any formal help during pregnancy or in the

[†††] The Whooley questions are: 'During the past month have you often been bothered by feeling down, depressed, or hopeless?' and 'During the past month have you been bothered by having little interest or pleasure in doing things?' This may be followed by the Arroll question, which asks whether help is needed.

postnatal period. Women who were asked about their emotional health but were not referred for additional support were also less likely to seek any formal help during both pregnancy and in the postnatal period.[112]

Women have an increased risk of relapse or developing a first episode of bipolar affective disorder during the early postnatal period than at any other time during their lives.[19] Approximately 60-70% of women with bipolar affective disorder experience a mood episode during the perinatal period.[113] Postnatal psychosis affects between one and two in 1,000 women. Women with pre-existing bipolar type 1 disorder are at particular risk, but postnatal psychosis can occur in women with no previous history of mental health problems.

Women with past or current psychiatric illness especially severe depression, anxiety,[114] substance-use disorder, intimate partner problems or puerperal psychosis are at an increased risk of suicide during the perinatal period.[115] Maternal death associated with psychosocial risk factors has become one of the leading causes of maternal deaths in high-income countries.[110;115] Between 2010 and 2012, 0.67 maternal deaths per 100,000 maternal deliveries in the UK and Ireland were due to psychiatric causes. This was an increase from 0.55 per 100,000 maternal deliveries between 2009 and 2011.[116]

3.2.8 Pregnancy loss

Women who experience pregnancy loss can experience grief similar in intensity to the grief of other types of major loss. Healthcare professionals should discuss with a woman whose baby is stillborn or dies soon after birth, and her partner and family, the options of seeing the baby, holding the baby, seeing a photograph of the baby, or having mementos of the baby. This should be followed-up with an appointment in primary care or in the maternity unit. If the baby is known to have died in-utero (in the womb), this discussion should take place before the delivery.[117] Healthcare professionals need to be aware that emotional support in addition to physical care is required at this time.[118]

3.3 Effective care and support

3.3.1 Overview

The findings from the literature review relating to effective care and support are presented in this section, predominantly under the care pathway sequence of antenatal, intrapartum and postnatal care. Articles sourced relating to pre-pregnancy care are discussed in section 3.5 under the theme of better health and wellbeing. Areas covered are:

- models of care
- clinical guidelines
- antenatal care
- intrapartum care
- postnatal care.

3.3.2 Models of care

Various models of care, both public and private, exist throughout the developed world. A case study was conducted in a midwifery-led birth centre in England to assess the impact of an adapted version of the recently implemented all-Wales care pathway for normal birth. [119] Twenty-six women participated having been recruited at their 36-week antenatal visit. Eighteen interviews were conducted with clinicians and women, including the women whose care was observed and the midwives who cared for them, senior midwifery managers and obstetricians. Interviews were also held with other key stakeholders from the study site. Qualitative data was content analysed and observations were undertaken of episodes of care during labour for four women. The implementation of the care pathway resulted in a number of anticipated benefits, including increased midwifery confidence in skills to support normal birth and the promotion of team working. There were also unintended consequences, including concerns about a lack of documentation of labour care and a negative impact on working relationships with obstetric and other midwifery

colleagues. Women were unaware their care was informed by a care pathway. The authors concluded that care pathways are complex interventions which generate a number of consequences for practice. Those considering introduction of care pathways need to ensure that all relevant stakeholders are engaged and robust evaluation strategies are developed to accompany implementation.

3.3.3 Clinical guidelines

Healthcare professionals depend on clinical guidelines to follow current evidence-based practice in the care of women and their babies.[120] In recent years, confidential maternal death enquiries have helped to identify areas where clinical guidelines are needed to ensure women receive the best possible maternity care, delivered in an appropriate setting, and in a way that meets their individual needs.[121] However, the evidence base supporting clinical guidelines is not always clear, leaving scope for judgment and interpretation.[122] Circumstances, values and preferences can also vary between countries, which is why guideline panels do not always reach the same consensus, using the same evidence base.

3.3.4 Antenatal care

Early pregnancy services

Many women in early pregnancy experience complications. National Institute for Clinical Effectiveness (NICE) guidance on ectopic pregnancy and miscarriage, published in 2012, recommends that services are organised to provide an early pregnancy assessment service, also known as an early pregnancy assessment unit.[93] Timely decisions about effective care and management can then be made in an appropriate environment. Criteria for the diagnosis of miscarriage have been criticised for being unsupported by evidence and have resulted in controversy.[123] Guidance on diagnostic criteria for miscarriage in the UK was revised in 2012, following the publication of a multicentre prospective study.[123]

Maternity booking and planning of care

Healthcare professionals need to be aware of the risks associated with pregnancy in the later reproductive years so that women are given the appropriate level of care in order to prevent and allow for the early detection and appropriate management of complications. The likelihood of pre-existing medical conditions, antenatal complications and labour and birthing complications increases with advancing maternal age in nulliparous women.(124) Advanced maternal age is also independently associated with perinatal death.(124)

Pre-existing maternal conditions

1. Heart disease

Heart disease is a leading cause of indirect maternal death in developed countries. Most indirect maternal deaths are due to myocardial infarction, cardiomyopathy and congenital heart disease. Heart disease was the leading cause of indirect maternal death in the Confidential Maternal Death Enquiry in Ireland, Report for 2009 to 2012.(57) Pre-pregnancy assessment by a multidisciplinary team with experience in the management of their specific heart disease in pregnancy is recommended for women with pre-existing heart disease.(125) The level of care and surveillance required for each individual woman during pregnancy should be determined by a multidisciplinary team.(125) Effective care of women with systemic lupus erythematosus requires a multidisciplinary team approach with a well-defined management plan.(126) A recently published review article on the management of women with anti-phospholipid syndrome recommends management by a multidisciplinary team.(127)

2. Pre-existing diabetes

A systematic review of eight clinical guidelines about the management of women with gestational diabetes mellitus or pre-existing diabetes mellitus divided their recommendations into four domains:(128)

- screening for gestational diabetes mellitus

- glycaemic control
- antenatal care and care in labour
- pre-pregnancy counselling.

Advancing age, increasing parity, obesity, hypertension, smoking and drug abuse increase the risk of adverse pregnancy outcomes in women with pre-existing diabetes.[129] Obstetric risk factors include late booking, poor obstetric history, previous miscarriage, multiple pregnancy and nutritional deficiency. Women with pre-existing diabetes are also at increased risk of diabetes progression, spontaneous miscarriage, pre-eclampsia, polyhydramnios‡‡‡, macrosomia, operative delivery and stillbirth. Elevated blood glucose levels during labour and delivery increase the risk of non-reassuring fetal heart rate, birth asphyxia and neonatal hypoglycaemia.[130] Women with pre-existing diabetes require a multidisciplinary team approach from pre-pregnancy to the postnatal period.

3. Human immunodeficiency virus

There is limited data on the antenatal prevalence of HIV in Europe.[131] A study conducted to summarise national prevention of mother-to-child transmission guidelines in Europe in 2012 surveyed 25 European countries.[131] Nineteen countries, including Ireland, had national written guidelines. In all but one country, the policy was to recommend antenatal HIV screening for all pregnant women.[131] Sixteen (73%) countries, including Ireland, had an opt-out screening strategy.

4. Cancer

Given the recent trend in advancing maternal age, more women are diagnosed with cancer during pregnancy or inquire into the safety and possibility of pregnancy following a cancer diagnosis.[132] The care and management of women with cancer in pregnancy poses many challenges. In 2010, a European survey of the practice of physicians from a variety of specialities providing care for pregnant women with cancer was conducted.[133] The first study sample included 142 physicians. Over 130

‡‡‡ Excess amniotic fluid

respondents agreed that the management of women with cancer in pregnancy should be determined by a multidisciplinary team.[133] Inconsistencies were found in practice partly because of a lack of a multidisciplinary team approach. The authors concluded that a strict referral system was required in order to centralise specific clinical expertise.[133]

5. Disability

It has been estimated that 9.4% of women giving birth in the UK have one or more limiting longstanding illness which may cause disability affecting pregnancy, birth and early parenting.[134] Many women with disabilities have pre-existing medical conditions which can impact on their health and wellbeing during pregnancy.[134] Secondary analysis of data from a national anonymous postal survey (n=24,155) conducted in England in 2010 was used to determine women's experience of maternity care during pregnancy, labour and birth and in the postnatal period.[134] Overall, women with disabilities were as likely to access healthcare early in pregnancy as women without disabilities.[134] They were likely to have more antenatal checks and ultrasound scans, to be delivered by caesarean section, to have longer stays in hospital and were less likely to breastfeed than women without disabilities.[134] Women with disabilities appeared to use maternity services more often and more intensively than women without disabilities. The majority of women with disabilities were positive about their care and reported sufficient access and involvement. The study concluded that there was a need to improve aspects of maternity care for women with disabilities such as staff training, support, communication and infant feeding.[134]

6. Substance abuse

Substance abuse in women is correlated with stress, anxiety, depression, domestic violence, psychiatric disease, childhood abuse and adult sexual assault.[135] Women with substance use disorders are more likely to experience unplanned pregnancy, less likely to attend antenatal care, and have a higher incidence of infection with human immunodeficiency virus, hepatitis B, hepatitis C, and *Chlamydia*

trachomatis.[136] In pregnancy, women with substance abuse disorders have an increased risk of miscarriage, intrauterine growth restriction, placental abruption, preterm delivery, fetal intraventricular haemorrhage, intrauterine fetal demise, and neonatal abstinence syndrome.[137] Many challenges exist in the identification of women with substance abuse disorders in pregnancy and in the provision of care.[137] Opiates account for a substantial proportion of substances abused.[136] Maternity units should have protocols for the assessment and management of neonates exposed to opiates during pregnancy. A multidisciplinary approach has been shown to be most successful in providing comprehensive and effective care to women and their babies.[137]

Prenatal screening and diagnosis

In clinical practice, many complex ethical, legal and psychosocial issues need to be considered before offering prenatal screening and or prenatal diagnosis of fetal aneuploidy[§§§]. European guidelines on offering prenatal diagnosis were published in 2014.[138] These guidelines were developed in a way that allows individual values and beliefs, cultural norms and ethnicity to be taken into account. The principles of autonomous choice and informed consent underpin the guidelines. Pre- and post-test counselling needs to be provided by an appropriately trained health professional. Information should be provided in both verbal and written forms. Trained interpreters must be available if there are language difficulties. An individualised approach to each family should be taken within each country's local ethical and legal framework.[138]

Termination of pregnancy

According to official UK statistics, more than 4,000 women residing in Ireland travel to the UK for termination of pregnancy each year.[139] The cost of travelling and using services in the UK and other European countries are high, both emotionally and financially. These costs are potential barriers for many poor or otherwise

[§§§] An abnormal number of chromosomes in a cell.

marginalised women.[139] Women residing in Ireland who have to travel to other jurisdictions in order to undergo termination of pregnancy legally are at risk of deep psychological trauma.[139] In most countries, misoprostol, a drug which causes the uterus to contract, has not been approved for use in obstetrics and gynaecology. Misoprostol can be used to induce labour in all three trimesters of pregnancy with either a live or a dead baby or fetus.[140] Misoprostol has been used to carry out a high proportion of clandestine terminations of pregnancy in Latin American countries.[140;141]

Imaging

Ultrasound in pregnancy has had an excellent safety record in the last 50 years.[142;143] With advances in ultrasound and Doppler[****], it is important that this safety record is maintained. In 2008 the International Society of Ultrasound in Obstetrics and Gynecology published a consensus statement about fetal echocardiogram. [144] This includes guidance about:

- the timing of and indications for fetal echocardiography
- a definition of what constitutes a fetal echocardiogram
- a description of imaging modalities for fetal echocardiography
- the importance of multidisciplinary collaboration
- documentation of diagnostic findings and conclusions.

In 2014, a taskforce made up of representatives from relevant professional bodies in the US published a consensus report on the detailed fetal anatomic ultrasound examination.[145] This focused on indications and components of the examination as well as training, maintenance of competence and continuing medical education. In 2005, the American Institute of Ultrasound in Medicine stated that the use of three-dimensional (3D) ultrasound examination in conjunction with two-dimensional (2D) ultrasound examination increases the diagnostic and clinical value for select indications such as facial and skeletal anomalies.[146] 2D ultrasound examination

[****] A form of ultrasound which measures blood flow.

remains the "gold standard" in the detection of congenital anomalies.[147] 3D ultrasound examination should only be used to complement 2D ultrasound examination.

The use of magnetic resonance imaging (MRI) is considered safe during pregnancy but caution is advised.[148] Fetal MRI should not be used as a general screening tool. Its use is recommended to answer specific questions raised by ultrasound examination or in occasional specific high-risk situations.[143] Guidelines are available on the use of MRI and computed tomography (CT) imaging during pregnancy and lactation.[148]

Prescription drug use

Since 1979, the US Food and Drug Administration (FDA) mandated that drug labels describe a drug's potential to negatively affect pregnancy, fertility or harm a fetus.[149] In the US, the medical records of 1,626 pregnant women were reviewed between 2001 and 2003 to examine the use of prescription drugs and the use of category X drugs.[149] In the US, the use of category X drugs is contraindicated in pregnancy. Just over half (56%) were prescribed a prescription drug. One in 100 women was prescribed a category X drug. The most commonly prescribed drugs which were not mutually exclusive were antibiotics (62%), pain relief medication (18%), asthma medication (18%), and anti-emetic (anti-vomiting) medication (17%). The common use of prescription drugs during pregnancy suggests a need for systems to safeguard prescribing practices for women of reproductive age.[149]

The FDA implemented a new pregnancy and lactation labelling rule in 2014 which aimed to improve the risk-versus-benefit assessment of drugs used by pregnant and breastfeeding women.[150] The Centers for Disease Control and Prevention (CDC) introduced their own strategy for safer medication use during pregnancy looking at the comparative safety of different treatments during pregnancy.[151] Information is communicated in a factual way, without being alarmist. However, some pharmacists

argue that product information can be overly conservative with negative ramifications.[152]

Prevention of infection

Infections can negatively impact pregnancy outcomes. Vertically transmitted infections[††††], including cytomegalovirus, rubella, toxoplasmosis, syphilis or varicella, may lead to malformations, neurodevelopmental delay or long-term childhood consequences.[153] Women with syphilis experience a higher incidence of fetal loss and stillbirth (21%), neonatal deaths (9.3%) and prematurity or low birth weight (5.8%).[154] Maternal genital infections such as vaginal bacteriosis can also increase the risk of miscarriage and preterm birth. Group B streptococcus infection or genital herpes can cause neonatal infection through intrapartum transmission. Infection screening during pregnancy enables the early detection and treatment of maternal, fetal and neonatal infections to reduce pregnancy and neonatal complications.[153;155]

Vaccination during pregnancy

The risk of some types of infection during pregnancy can be controlled through vaccination. This prevents disease-related morbidity and mortality and adverse pregnancy outcomes, including fetal congenital anomalies, spontaneous miscarriage, preterm birth, and low birth weight. Vaccination provides direct fetal and neonatal benefit through passive immunity. Influenza, pertussis and tetanus vaccines are recommended during pregnancy.[156] Influenza during pregnancy is associated with an increased risk of serious respiratory disease and maternal death.[157] A pregnant woman who contracts influenza is at increased risk of obstetric complications such as miscarriage, preterm labour and birth and stillbirth.

Vaccination against influenza during pregnancy provides immunity against influenza infection to babies in the first six months of life. Vaccination against influenza is the most effective intervention to mitigate the burden of influenza disease during

[††††] Vertically transmitted infections are infections passed directly from mother to embryo, fetus or baby during pregnancy or childbirth.

pregnancy yet immunization rates during pregnancy remain suboptimal.[157] Data from the Centers for Disease Control and Prevention estimated influenza vaccination coverage to be approximately 50%.[157] Reported patient barriers to maternal influenza vaccination uptake include safety concerns, lack of knowledge about influenza and consequences for pregnancy, fear of needles, vaccination history, obstetrician-gynaecologists not viewed as vaccinators and issues surrounding access to care.[157] Interventions such as an education programme for medical practitioners and distribution of posters advertising the influenza vaccine, have been shown to increase the uptake of influenza vaccinations rates.[158] Other interventions include reminder and recall systems, immunization registries, standing orders for immunizations, immunization status review at each patient visit, regular assessment of immunization coverage rates within primary care centres and increasing demand for immunizations by improving the awareness of the public and healthcare professionals of recommended immunizations.[157]

Specific pregnancy related conditions

The leading causes of maternal mortality and morbidity worldwide include sepsis,[159] pre-eclampsia and eclampsia,[160] antepartum haemorrhage,[161] venous thromboembolism,[162] postpartum haemorrhage[163] and amniotic fluid embolism[164]. All conditions, apart from postpartum haemorrhage, are also associated with significant perinatal mortality and morbidity.

1. Sepsis

Non-obstetric risk factors for maternal sepsis in pregnancy include maternal age over 35 years, low socio-economic factors, minority ethnic group origin, obesity and maternal medical conditions.[159] Obstetric risk factors for maternal sepsis include preterm pre-labour rupture of the membranes, a history of group B streptococcal infection, vaginal trauma, vaginal haematoma and caesarean section. The management of sepsis in pregnancy presents challenges due to the physiological changes of pregnancy.[165] The initial symptoms and signs of sepsis may be masked in a young and previously healthy woman but a woman's condition can deteriorate

rapidly leading to sudden circulatory collapse. Early recognition, accurate diagnosis and aggressive appropriate treatment strategies may significantly improve outcomes.[159;165] Early involvement of the obstetrician, anaesthetist, intensive care medicine specialist and microbiologist is vital with timely admission to high-dependency care if there is clinical deterioration. Regular observations should be made using Modified Obstetric Early Warning Score systems.[159;165] Additional strategies in the management of sepsis include the implementation of sepsis-integrated care pathways and the use of the 'surviving sepsis resuscitation bundle' or similar protocols.[159] The awareness of healthcare professionals about the danger and risk factors for sepsis in pregnancy needs to be raised through education, development of clinical guidelines, skills and drills training and multidisciplinary team meetings.

2. Multiple pregnancy

The incidence of twin and triplet pregnancy has increased over the last 30 years due to advancing maternal age and increased use of assisted reproductive technology.[166] Twin and triplet pregnancies are associated with higher maternal and perinatal mortality and morbidity than singleton pregnancies.[166;167] In 2011, NICE guidance on antenatal care for twin and triplet pregnancies recommends multidisciplinary specialised team care due to the increase in maternal and perinatal mortality and morbidity. Each woman should have a care plan based on chorionicity that uses care pathways agreed on by maternity networks.[168]

3. Pre-eclampsia and eclampsia

Hypertensive disorders of pregnancy include chronic (pre-existing) hypertension, gestational hypertension, pre-eclampsia, eclampsia and haemolyis, elevated liver enzymes and low platelets (HELLP) syndrome.[160;169-171] The reported incidence of pre-eclampsia ranges between two and eight percent.[172] A summary of NICE guidance on the management of hypertensive disorders in pregnancy published in 2010 recommends empowering women by increasing their awareness about the

signs and symptoms of hypertensive disorders.[160] It also emphasises the need for escalation based on clinical assessment of the individual woman.[160]

4. Intrauterine growth restriction

Intrauterine growth restriction (IUGR)[‡‡‡‡] is a major public health problem because it is associated with increased perinatal morbidity and mortality. It is the most common cause of antepartum stillbirth in normally formed babies or fetuses.[173] The identification of intrauterine growth restriction remains a challenge which has been complicated by the emerging global obesity epidemic. Data from a mandatory population-based surveillance system in New South Wales, Australia was analysed in order to determine the odds of having a baby weighing less than the third percentile.[174] This population-based surveillance system included public and private hospital births and home births of 877,951 women with singleton pregnancies between 1994 and 2004. Socio-economic disadvantage was a significant predictor of Intrauterine growth restriction. Smoking patterns, inadequate antenatal care and clinical conditions accounted for some of the association.[174] Data from the Canadian Maternity Experiences Survey of 6,421 women was analysed retrospectively to identify maternal risk factors for small gestational age babies.[175] Risk factors included low pre-pregnancy BMI, smoking during pregnancy, being a recent immigrant and reporting life as 'very stressful' in the year prior to birth of the baby.

5. Venous thromboembolism

Thromboembolism was the leading cause of direct maternal death in the Confidential Maternal Death Enquiry in Ireland Report for 2009 to 2012.[57] The American College of Chest Physicians recommends a documented risk assessment for venous thromboembolism in early pregnancy.[176] This risk should be re-assessed at each episode of hospitalisation and again after delivery.[176] The prevention of death from

[‡‡‡‡] Intrauterine growth restriction, as defined by the National Clinical Programme for Obstetrics and Gynaecology, is a pathologically small fetus (estimated fetal weight less than the tenth percentile, oligohydramnios, abnormal umbilical artery Doppler, and or poor interval growth velocity and or estimated fetal weight less than the third percentile).

venous thromboembolism in pregnancy requires risk assessment, appropriate thromboprophylaxis, a high index of clinical suspicion followed by a timely and accurate diagnostic approach and appropriate anticoagulation.(177)

6. Preterm birth

Preterm birth is the leading cause of neonatal mortality and morbidity in normally formed infants in the developed world. Data from the Canadian Maternity Experiences Survey (n=6,421) was analysed retrospectively to identify maternal risk factors for preterm term birth.(175) Risk factors included education less than high school, having a previous medical condition, developing a new medical condition or health problem during pregnancy, being a primigravida, or being a multigravida with a previous preterm birth or a previous miscarriage or termination and reporting life as 'very stressful' in the year prior to birth of the baby. In recent decades, advances in neonatal care have led to the most of the decrease seen in neonatal mortality.(178) Successful obstetric strategies for the prevention of preterm birth include tobacco control, cautious use of fertility treatments, antenatal clinics dedicated to the prevention of preterm birth, supplementation with progesterone,(179;180) assessment of cervical length and cervical cerclage.(178)

7. Antepartum haemorrhage

Antepartum haemorrhage complicates three to five percent of pregnancies.(161) Placenta praevia and placental abruption, though not the most common, are the most serious causes of Antepartum haemorrhage. The rise in caesarean section rates in recent decades has been associated with an increase in the incidence of placenta accreta.(181) Placenta accreta ought to be considered in women with a placenta praevia overlying a scar on the uterus. Rising caesarean section rates have led to an increase in the number of peripartum hysterectomies performed because of placental bed pathology.(181) When an antenatal diagnosis of placenta accreta§§§§ is made, the

§§§§ Placenta accrete occurs when all or part of the placenta attaches abnormally to the muscle wall of the uterus.(182)

need for a peripartum hysterectomy should be anticipated and arrangements made for delivery in a maternity unit with appropriate clinical resources and facilities.

A 10-year retrospective population-based cohort study (n=34,695) was conducted in South Australia to determine the pregnancy outcomes of nulliparous women with singleton pregnancies who were greater than or equal to 35 years of age.[124] Although these women were less likely to smoke, have higher socio-economic status, were more likely to attend antenatal classes and maintain private health insurance than women aged between 25 and 29 years, being greater than or equal to 35 years was also associated with pre-existing medical conditions, obstetric complications, adverse labour and birth outcomes and complications. These included pre-existing hypertension, placenta praevia, suspected intrauterine growth restriction, gestational diabetes, preterm birth, induction of labour, breech presentation, planned and unplanned caesarean section and perinatal death.[183]

3.3.5 Intrapartum care

1. Continuous one-to-one care

A 2012 Cochrane review to assess the effect of continuous, one-to-one intrapartum support compared with usual care included 22 trials, with 15,288 women meeting the inclusion criteria.[184] Women who received continuous, one-to-one intrapartum support were significantly more likely to have a spontaneous vaginal birth, less likely to have intrapartum analgesia and less likely to report dissatisfaction than women assigned to usual care. They had shorter labours and were less likely to have a caesarean section, an instrumental vaginal birth or a baby with a low five minute Apgar score.

2. Fetal heart rate monitoring

International clinical guidelines recommend that a baby's heart rate is monitored during labour by either intermittent auscultation or continuous cardiotocography (CTG). CTG is open to misinterpretation by healthcare professionals which can result in unnecessary intervention or delay in providing necessary intervention. A

population-based case control study, conducted in Stockholm County between 2004 and 2006 of babies with an Apgar score of less than seven at five minutes, reported that some form of substandard care during labour occurred in two out of three cases and in one out of three controls.(185) The main reasons for substandard care were misinterpretation of the CTG, not acting on an abnormal CTG in a timely fashion and improper use of oxytocin. Obstetric litigation, with its huge costs and consequences is a growing problem.(186) This increase in obstetric litigation has contributed to a rise in caesarean section rates in recent decades. Regular mandatory training of healthcare professionals, appropriate to their scope of clinical practice, in CTG interpretation as well as good clinical practice based on evidence-based guidelines are recommended to reduce obstetric litigation.(186) Each maternity unit should have mechanisms in place to rapidly review adverse obstetric events and disseminate key learning points to healthcare professionals, appropriate to their scope of clinical practice.(186)

3. Induction of labour

Rates of induction of labour have increased in developed countries in recent decades. The rise in caesarean sections has in part been attributed to this increase. There are many indications for induction of labour but the timing of induction of labour at or beyond term has been the greatest source of debate. Research on this topic has produced conflicting evidence mainly due to methodological issues. Post-term pregnancy, defined as a pregnancy at or beyond 42^{+0} weeks' gestation (294 days), is associated with increased perinatal mortality (stillbirth and neonatal death) and perinatal morbidity but the absolute risk is small.

In 2012, a Cochrane systematic review of induction of labour at or beyond term for improving birth outcomes for women recruited 9,383 women to 22 trials.(187) The review recommended that women be provided with enough information to enable them to make an informed choice between induction of labour and expectant management.(187) Women should be told about the absolute risk and the relative risk of perinatal death at different gestational ages and in different groups of women.

Regular fetal monitoring should be advised if a woman chooses to wait for the spontaneous onset of labour, because longitudinal epidemiological studies suggest that the risk of perinatal death rises with increasing gestational age. The Cochrane review noted that women's experiences and opinions about these choices have not been adequately evaluated.

4. Caesarean section

The optimal caesarean section rate in high-income countries remains a matter of public and professional debate. A caesarean section should be performed only when there is clear benefit to the woman or her baby.[188] Caesarean birth on maternal request is defined as a first caesarean birth prior to the onset of labour in the absence of any maternal or fetal indications.[189] A Cochrane systematic review reported that there are no randomised controlled trials on which to base practice recommendations regarding planned caesarean section for non-medical indications at term.[190] NICE guidance on caesarean section recommends that the specific reasons for the request are explored, discussed and recorded and that the risks and benefits of caesarean section compared with planned vaginal birth are also discussed and recorded.[191] When a woman requests delivery by planned caesarean section because she is anxious about childbirth she should be offered referral to a healthcare professional with expertise in providing perinatal mental health support as well as the opportunity to attend an antenatal education programme.[191]

Many clinical guidelines on vaginal birth after caesarean section (VBAC) have been published [192;193] The usefulness of these guidelines is undermined by the wide variation in their recommendations.[193] High-quality evidence to guide clinical practice is lacking because no randomised controlled trials comparing planned VBAC with planned elective repeat caesarean section have been published.

The WHO recently proposed the use of the Robson classification system as the universal standard for assessing, monitoring and comparing caesarean section rates within and between maternity units over time.[194;195] This system classifies women

into one of 10 groups on the basis of five obstetric parameters: parity, past obstetric history, singleton or multiple pregnancy, fetal presentation, mode of onset of labour or no labour and gestational age. The groups are totally inclusive and mutually exclusive.

The Robson classification system allows standardised comparisons between maternity units over time and identifies which groups of women are contributing to rising caesarean section rates.[196] The WHO will guide and support countries in the implementation, use and interpretation of the classification system.[195] It is envisaged that the information arising from the use of the classification system will allow caesarean section rates to be compared in a meaningful, targeted, transparent and useful way and be a powerful tool to inform clinical practice.[195] The classification system will allow the assessment of caesarean section rates in relation to other measures and outcomes (for example, length of labour, rates of oxytocin usage, newborn outcomes and postpartum haemorrhage).

5. Obstetric anaesthesia

The number of maternal deaths attributable to general anaesthesia has fallen in recent decades.[197] A review of best practice of the types of anaesthesia for unplanned (emergency) caesarean section emphasised the need for clear communication between the obstetric team and the anaesthetic team.[198] The teams must discuss the urgency of the caesarean section so that the safest type of anaesthesia can be safely administered to the woman. General anaesthesia is rarely administered to women undergoing a planned caesarean section. This has led to a decrease in training opportunities in the administration of general anaesthesia to pregnant women. Best practice calls for competency-based training and assessment of all anaesthetists in maternity units.[198] It also emphasises that early post-operative maternal observations are key in the detection of both revealed and hidden postpartum haemorrhage.

6. Third stage of labour

Inaccurate estimation of blood loss may lead to misdiagnosis and inappropriate management of women with postpartum haemorrhage.[199] There has been a call for a single definition of postpartum haemorrhage, training of staff in the assessment of blood loss and improvement in the way data is collected.[163] Facilities delivering maternity services are encouraged to adopt formal protocols for the prevention and treatment of postpartum haemorrhage. [200]

The use of simulation in the training of staff is also recommended. Major postpartum haemorrhage is an obstetric emergency that requires a systematic and multidisciplinary team approach.[201] International clinical guidelines on postpartum haemorrhage published by WHO, the International Federation of Gynecology and Obstetrics and the American, British, Canadian and German Societies of Obstetricians and Gynaecologists differ in their recommendations. A systematic review of their impact on the prevention, diagnosis and treatment of postpartum haemorrhage found that they were effective in reducing the incidence of postpartum haemorrhage.[199]

7. Stillbirth

A systematic review which included 96 population-based studies conducted in five high-income countries (Australia, Canada, US, UK and the Netherlands) was published as part of the 2011 Lancet series on stillbirth prevention.[202] Stillbirth was defined as greater than 22 weeks' gestation or birthweight greater than 500g if gestation was unknown. Maternal weight, maternal smoking, maternal age, primiparity, small size for gestational age (less than the tenth percentile), placental abruption, and pre-existing maternal diabetes or hypertension were the most important risk factors for stillbirth in high-income countries. Maternal weight and maternal smoking are potentially modifiable risk factors. Maternal overweight and obesity (BMI greater than or equal to 25kg/m^2), was the highest ranking modifiable risk factor in the five countries. It was estimated that maternal smoking contributes to one in five stillbirths in disadvantaged populations. Maternal age greater than or

equal to 35 years was the next highest ranking risk factor after maternal overweight and obesity.

Small size for gestational age and abruption were the highest ranking medical or pregnancy-related disorders and complications. This highlights the important contribution of placental pathology to stillbirth in high-income countries and the need for expert perinatal pathology services. Pre-existing hypertension and pre-existing diabetes are also important contributors to stillbirth in high-income countries. Obesity increases the risk of development of type 2 diabetes and gestational diabetes which further increases the risk of stillbirth. In high-income countries, a woman living under adverse socio-economic circumstances has twice the risk of having a stillborn baby compared to a woman living without such disadvantage.[203] Improved access to appropriate antenatal care and programmes that increase the smoking cessation rate in pregnancy will help to reduce these health inequalities.

A retrospective population audit of two counties in Norway was conducted between 1998 and 2003 to find out if suboptimal factors in stillbirths were more frequent in non-Western women (from Eastern Europe, Turkey, Asia, south and central America and Africa) compared with Western women.[92] The audit reviewed 356 stillbirths after 23 weeks. Thirty-three (10.8%) stillbirths occurred during labour. Suboptimal factors were identified in over a third of all stillbirths (37%). Non-Western women were at increased risk of both stillbirth and suboptimal care compared with Western women.

Unidentified or inadequate management of intrauterine growth restriction (IUGR) or decreased fetal movements was a common failure of antenatal care in both groups of women. Inadequate communication was documented in almost half, 47%, of non-Western women. An interpreter was used for 29% of non-Western women. Increased vigilance in the care of non-Western women, a reduction in language barriers, better identification and management of IUGR for all women and

appropriate intervention in complicated vaginal births have the potential to reduce stillbirth rates.

Decreased fetal movement is associated with an increased risk of a poor pregnancy outcome. Monitoring of a baby's movements by the mother is recommended as a screening tool to reduce unexpected stillbirth in the third trimester but there is no consensus as to what constitutes normal fetal movement.[204] There is wide variation in the way women who report decreased fetal movements in the third trimester are managed because there is very little research to inform practice in the detection and management of decreased fetal movement.[204] There has been a call for large scale randomised controlled trials to determine the best screening and management options.[204]

8. Maternal mortality and morbidity

A system of confidential enquiry into maternal death in England and Wales was established in 1952. Reports were published every three years until 2014 and will be published once a year in future. This well-established system now includes Scotland, Northern Ireland and Ireland. Internationally, this system is considered the 'gold standard' for the review of maternal deaths.[121] An overview of confidential enquiries noted that findings need to be emphasised and team-based training needs to be reinforced.[121] Clinical guidelines need to be continuously updated with the development of new technologies, changes in the training and type of healthcare professionals, and the rise in obesity and unhealthy lifestyles of women.[121] In developed countries, severe maternal morbidity or maternal near-miss events are used as quality measures of maternity care, rather than maternal deaths which are rare.[197]

A prospective population-based cohort study was conducted between 2004 and 2006 to assess the incidence, case fatality rate, risk factors and substandard care in severe maternal morbidity in the Netherlands.[205] The cohort included 371,021 women. Five categories of severe maternal morbidity were used: admission to the intensive care

unit, uterine rupture, eclampsia and or HELLP syndrome, major obstetric haemorrhage and miscellaneous. The reported incidence of severe maternal morbidity was 7.1 per 1,000 deliveries. The case fatality rate was one in 53. The care of 63 women who experienced severe maternal morbidity was audited and it was found to be substandard in 39 cases (62.0%). Non-Western immigrant women had a 1.3 fold increased risk of severe maternal morbidity compared with Western women.

3.3.6 Postnatal care

Postnatal care of mother and baby

Postnatal care is best delivered in a primary care setting because most women return home and to the community within a few days of giving birth.[206] This care needs to be integrated into primary care. A systematic review of clinical guidelines for postnatal care of women and their babies in primary care was conducted between 2002 and 2012 in order to compare their scope, content and to assess their quality.[206] Six guidelines from Australia, the UK and the US were included. The scope of the guidelines varied greatly. Only one guideline, from the UK, provided comprehensive recommendations for the postnatal care of women and their babies. Guideline recommendations were generally consistent except for the use of the Edinburgh Postnatal Depression Scale for mood disorder screening and the suggested time of routine visits. Some recommendations lacked evidence to support them and levels or grades of evidence varied between guidelines.

Neonatal care

International clinical guidelines on neonatal resuscitation are available.[207] Relatively few babies require any resuscitation at birth, with most babies who need it only requiring help with lung inflation.[208] Neonatal jaundice is one of the most common conditions requiring medical attention in the newborn.[209]

About 60% of term and 80% of preterm babies develop jaundice in the first week of life, and about 10% of breast-fed babies are still jaundiced at one month old.[209] Neonatal jaundice is generally harmless, but high concentrations of unconjugated

bilirubin may occasionally cause kernicterus (permanent brain damage). This is a rare condition and sequelae include choreoathetoid cerebral palsy, deafness, and upgaze palsy. Jaundice can also be a sign of serious liver disease such as biliary atresia, the prognosis for which is better if it is treated before six weeks of age. Early recognition of jaundice is vital for treatment of any underlying condition and for the appropriate use of phototherapy, which can safely control bilirubin concentrations in most cases.

Group B streptococcus (*Streptococcus agalactiae*) is the most common cause of severe, early onset infection in newborn infants. Early onset infection occurs within seven days of birth. Infected neonates present with respiratory disease, sepsis without focus and meningitis.[210] In 2014, a Cochrane review was published on the effectiveness of intrapartum antibiotic prophylaxis for maternal Group B streptococcus colonization.[210] Intrapartum antibiotic prophylaxis significantly reduced the incidence of early onset Group B streptococcus infection. It did not significantly reduce all cause mortality, mortality from Group B streptococcus infection or mortality from infections caused by bacteria other than Group B streptococcus.

3.4 Safe Care and Support

3.4.1 Overview

One of the main conclusions of the 1999 Institute of Medicine report 'To Err is Human: Building a Safer Health System' is that the majority of medical errors do not result from individual recklessness or the actions of a particular group.[211] More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. This report introduced the concept that medical errors can be prevented by making the system safer. The Institute of Medicine's 2001 report 'Crossing the Quality Chasm: A New Health System for the 21st Century' provided a framework for healthcare system reform.[212] In line with this framework, maternity service providers should strive to achieve optimal health outcomes and experiences for women and their partners, through the provision of

person-centred care, grounded in evidence-based medicine, which makes the best use of resources.[213] Such care should be safe, effective, timely, efficient, and equitable for all women.

A safety culture is defined as the integration of safety thinking and practices into clinical activities.[214] A safety climate is the quantitative description of a safety culture. Safety climate can be assessed in several ways that include the examination of adverse events (outcomes measures), analysis of adherence to practices (process measures), or calibration of healthcare teams' attitudes about issues relevant to safety.[214]

Standardisation of maternity care is promoted through the use of protocols, checklists, guidelines, definitions, algorithms, care bundles, and care pathways.[119;215-217] Standardisation helps to reduce the likelihood of variability, system deficiencies, inadequate safety measures and the occurrence of error.

3.4.2 Patient safety programmes

Patient safety programmes reduce risk to improve the quality of care. Programmes aim to eliminate variability in the provision of care in order to standardise care. Patient safety programmes include the development of standardised protocols, the use of checklists instead of reliance on memory for critical procedures, and an approach to peer review and quality improvement that emphasises systems change to prevent error rather than a punitive approach to those in involved in adverse incidents.[216] Safe systems have a culture in which errors are openly discussed.

In a large tertiary medical centre in the US, a comprehensive perinatal safety initiative was incrementally introduced over two years with the aim of reducing adverse obstetrical outcomes.[218] Evidence-based protocols, formalized team training with emphasis on communication, standardisation of electronic fetal monitoring with required documentation of competence, a high-risk obstetrical emergency simulation programme, and an integrated educational programme among all healthcare

providers were introduced. Eleven adverse outcome measures were followed prospectively. The rates of birth trauma and return to theatre decreased significantly. There were significant improvements in staff perceptions of safety, in patient perceptions of whether staff worked together, in the management and documentation of abnormal fetal heart rate tracings and the documentation of obstetric haemorrhage. This study demonstrates that a comprehensive perinatal safety initiative can significantly reduce adverse obstetric outcomes, thereby improving patient safety and enhancing staff and patient experiences.

A patient safety programme was introduced in a university based obstetric service in the US from 2002 to 2006 to determine its effect on staff safety culture. The programme included guideline and protocol-based standardisation of practice, an obstetrics patient safety nurse, a continuing series of crew resource management seminars based on those of the airline and defence industries, an obstetrics hospitalist to provide a consistent system of inpatient coverage and resident supervision, oversight by a patient safety committee, and an anonymous event reporting system.(214) A Safety Attitude Questionnaire was administered to all labour and birth unit staff on four occasions over five years from 2004 to 2009 to assess teamwork and safety cultures, job satisfaction, working conditions, stress recognition and perceptions of management. There were significant increases in the proportion of staff members with favourable perceptions of teamwork culture (39% in 2004 to 63% in 2009), safety culture (33% to 63%), job satisfaction (39% to 53%), and management (10% to 37%).

A prospective cohort study was conducted to determine the impact of the implementation of a multi-factorial prevention strategy on rates of nosocomial infection in newborn infants weighing less than 1500g.(219) This patient safety programme included changes to antiseptic solutions, standardisation of devices and protocols, and staff education. One hundred and seventy-four newborns required 1,359 devices. There was a significant reduction in nosocomial bloodstream infections (21% in the control group and 9% in the intervention group). There was

no significant difference in length or stay, length of ventilation or mortality between the two groups.

Standardisation of practice alone can improve quality of care. A tertiary referral centre in British Columbia, Canada assessed the incidence of combined adverse maternal and perinatal outcomes in 295 women with pre-eclampsia before and 405 women after the introduction and implementation of standardised initial assessment and ongoing surveillance.[220] This was associated with a reduction in the incidence of adverse maternal outcomes without a change in the incidence of adverse perinatal outcomes.[220]

3.4.3 Patient safety tools

Various tools can be used to monitor the quality of maternity care. Some of these include indicators, checklists and warning systems.

Indicators

Healthcare improvement can be measured using quality indicators. These indicators look at how well care is delivered and the results achieved when compared with an ideal standard. They can also be used to detect inadequate quality performance and to assist the prioritisation of funding.[221] Maternity care indicators have been developed around 'maternal near miss' events and maternal death.[222;223]

Since September 2010, all births in Denmark have been monitored from a quality perspective with the Danish National Indicator Project in order to document and develop the quality of intrapartum care.[224] Registration is mandatory for all delivery units in Denmark. Indicators were selected based on relevance, scientific evidence, usefulness, applicability, acceptability and patient safety. Eight indicators were selected:

- anaesthesia and or pain relief
- continuous support for women in the delivery room
- delivery of a healthy child after uncomplicated delivery

- unplanned caesarean section
- severe fetal hypoxia
- skin-to-skin contact between mother and newborn
- postpartum haemorrhage and lacerations (third or fourth degree).

Maternity units receive feedback in the form of real-time monthly and quarterly standard reports, including unadjusted results that may be used for the unit's own internal monitoring and quality improvement.

In 2013, a multidisciplinary French speaking panel of 35 participants from five countries and 20 maternity units assessed 51 potential indicators extracted from scientific literature using the Delphi method.[20] Eighteen indicators were identified that could be used to assess the quality of maternity care[225]. These included:

- nuchal translucency measurement during the first trimester of pregnancy
- caesarean section before labour
- caesarean section before labour in low-risk women
- epidural analgesia use
- caesarean section during labour
- caesarean section during labour in low-risk women
- instrumental vaginal delivery
- intact perineum
- third and or fourth degree perineal tear
- uterine rupture
- rate of non-low birth weight neonates admitted to the neonatal intensive care unit
- babies at term with an Apgar of less than seven at five minutes
- blood transfusion during and or after delivery
- nosocomial infection of surgical site
- maternal transfer or admission to intensive care unit
- decision to breastfeed before discharge.

In 2014, the UK Care Quality Commission (CQC) introduced a set of 150 hospital indicators under a 'hospital intelligent monitoring' strategy.[226] Indicators were chosen based on national guidelines, care gaps, public health relevance, economic impact and quality of life. The CQC used testing protocols to check whether an indicator was valid, communicable, effective, reliable, objective, available, attributable, interpretable, comparable, actionable and repeatable. Testing protocols also looked at basic feasibility (relevance, reliability, variability, risk, data entry or collection) and clinical opinion. This set of indicators included medical specialties such as neonatal care. One was a composite indicator while the other measured neonatal non-elective readmissions within 28 days of delivery.

A population-based observational study was conducted to determine if there was an association between two perinatal-specific quality measures and severe maternal and neonatal morbidity.[23] All hospital births were identified using New York City discharge and birth certificate data sets from 2010.[23] Two quality measures were calculated for 115,742 women in 41 New York City hospitals: elective, non-medically indicated deliveries between 37 and 39 weeks' gestation and caesarean section performed in women considered to be at low risk. Quality indicator rates and maternal and neonatal complication rates varied widely between the hospitals. There was no correlation between the two quality indicators and severe maternal and neonatal morbidity. Current quality indicators may not be sufficiently comprehensive for guiding quality improvement in obstetric care.

An issue identified with using indicators to compare maternity units is that some indicators may need to be risk adjusted to account for clinical and socio-demographic factors.[227] There can also be differences in the accuracy, completeness and quality of data between maternity units.

Checklists

Adverse outcomes can occur when system deficiencies or inadequate safety measures fail to prevent error from causing harm. Checklists and protocols can

overcome system deficiencies and reduce harm to women and their babies through improved standardisation and communication.[228]

Warning systems

The 2003-2005 Confidential Enquiry into Maternal and Child Health report recommended the introduction of the modified early obstetric warning system for all obstetric inpatients to track maternal physiological parameters, and to aid the early recognition and treatment of the acutely ill woman.[197] A prospective study was conducted of all women between 20 weeks' gestation and six weeks postnatal who were admitted as inpatients to a London maternity unit over a two month period. The aim of the study was to evaluate the modified early obstetric warning system as a tool for predicting maternal morbidity. The modified early obstetric warning system chart was completed in 673 of 676 eligible women. Two hundred (30%) women were identified as requiring urgent medical assessment. Eighty-six women fitted the maternity unit's criteria for morbidity. The modified early obstetric warning system had a sensitivity of 89%, a specificity of 79%, a positive predictive value of 39% and a negative predictive value of 98%. This suggests that it is a useful bedside tool in the prediction of maternal morbidity.

3.4.4 Audit

A 2014 UK survey of obstetric anaesthetists reported all respondents now use an obstetric early warning system, compared with 19% when a similar survey was conducted in 2007.[229] Ireland has adopted the national Irish Maternity Early Warning System which consolidates the recording of a woman's vital signs on a dedicated chart.[230] Data entry omissions and trends showing clinical deterioration are easily identifiable. A clinical escalation process also exists in response to pre-defined triggers.

A number of audit tools are available to help assess quality of maternity care. These include tools for data collection (checklists, early warning systems, interviews, focus groups, observation, questionnaires, surveys), tools to describe processes (flow

charts, process mapping, cause–effect analysis, self-assessment guides) and tools for collaborative work (nominal group technique, supportive supervision, SWOT (strength, weakness, opportunities and threats) analysis and root-cause analysis.

Governance arrangements must be in place to ensure that the consolidation of services into larger healthcare systems allows for more subspecialty care, for example, maternal-fetal medicine.[231] The development of centres of excellence, which combine university women's hospitals with research institutes, helps communication and translation of research into clinical practice, advances expertise in subspecialties, and creates career opportunities for academics and medical students.[232] Centres of excellence also help build research networks linking interdisciplinary and multicentre research projects.

3.5 Better Health and Wellbeing

3.5.1 Overview

Healthy Ireland, the national framework for action to improve the health and wellbeing of the people of Ireland, adopts a life-course perspective.[233] This approaches health as an integrated continuum and acknowledges that what happens during early years of life has long-lasting effects. A fundamental goal of *Healthy Ireland* is to support people to enjoy a healthy and active life, starting in the uterus and continuing through childhood, adolescence, adulthood and older age. Healthy ageing is impacted before birth and is influenced throughout the life course. Pregnancy is a critical period during which maternal nutrition and lifestyle choices have major influences on both the mother and child's health.[234] The health of mothers and the health of their babies is strongly associated, as is the health of mothers and their socio-economic circumstances. The most effective time to intervene in terms of reducing health inequalities and improving health and wellbeing outcomes is before birth and in early childhood.

The 'Barker hypothesis', also known as the 'developmental origins of adult disease', the 'fetal origins hypothesis' and the 'developmental origins of health and disease' proposes that many common chronic conditions are the result of poor intrauterine health and poor postnatal health.[235] This challenges the widely accepted view that these conditions in Western countries are due to genetic inheritance and unhealthy lifestyles as adults. Much of human development is completed during the first 1,000 days after conception.

The developmental origins of health and disease provide justification, from a public health perspective, for investing finite resources in maternity services. The prevention of chronic disease globally lies in ensuring that the nutrition of girls and young women is protected. Not only will this prevent chronic disease but it will produce future generations with better health and wellbeing throughout their lives.[236] The raising of awareness and implementation of effective interventions for modifiable risk factors, such as overweight, obesity, maternal age and smoking are priorities.

Maternity service providers and women should ideally work together to improve the health and wellbeing of women and their babies.

This can be achieved by addressing the following areas:

- pre-pregnancy care and advice
- pregnancy care and advice
    - nutrition
    - lifestyle and exercise
    - weight gain and obesity
    - breastfeeding
    - smoking
    - alcohol
    - transition to parenthood.

Immunisation, pre-existing medical condition and pre-exisiting mental health conditions should be dealt with under pre-pregnancy care and advice. Nutrition, lifestyle, exercise, weight gain and obesity need to be addressed pre-pregnancy and on an on-going basis during the pregnancy. For the purposes of this document, these are included in the section on pregnancy.

3.5.2 Pre-pregnancy care and advice

Immunisation provides direct fetal and neonatal benefit through passive immunity. Infection with rubella during pregnancy can result in fetal congenital anomalies. Women known to be pregnant should not receive the measles, mumps and rubella (MMR) vaccine.[237] Non-pregnant women of childbearing age who do not have documentation of rubella vaccination, serologic evidence of rubella immunity, or laboratory confirmation of rubella disease should be vaccinated against MMR.[237] Vaccination with varicella vaccine is also recommended for non-pregnant women of childbearing age who are susceptible to infection.[238]

Approximately two to three in one hundred infants are born with major malformations, without any use of medication during pregnancy.[239] However, teratogenic and fetotoxic drugs have the potential to cause fetal malformation. Teratogenic drugs affect an embryo three to eight weeks after conception and fetotoxic drugs affect the fetus during the second and third trimester. Neonatal exposure to maternal medication from breast feeding is a fraction of the dose in utero. Two European projects, EUROCAT and EUROPLAN, have joined together to provide science-based recommendations for the prevention of fetal congenital anomalies through exposure to teratogenic or mutagenic risk factors.[240] Recommendations are made in the field of medical drugs, food, nutrition and lifestyle, health sciences and environmental pollution.

Much has been published on the use of anti-hypertensive medication in pregnancy.[160;169;170;241;242] Teratogenicity due to inadvertent exposure to anti-hypertensive medication remains a concern because half of pregnancies are

unplanned.[170] Pre-pregnancy counselling and advice about adequate contraception are necessary for women with chronic hypertension if teratogenicity is to be avoided.[170]

Counselling is recommended for all women of reproductive age with diabetes mellitus.[128] Women need to be provided with information about pregnancies complicated by diabetes mellitus. The importance of normal glucose values pre-pregnancy should be stressed in order to reduce the risk of fetal congenital anomalies. The hypoglycaemic agents being taken need to be evaluated in order to determine whether their use is safe during pregnancy. If not, then women planning a pregnancy need to be changed to hypoglycaemic agents that are safe during pregnancy.

3.5.3 Pregnancy care and advice

Nutrition

According to the 'Barker hypothesis', the mother's diet during pregnancy has little effect on the baby's birth weight, but it may permanently programme the structure and physiology of the baby.[236] The growth of a baby is determined by the nutrients and oxygen the baby receives from its mother. The birth weight of a baby depends not only on the mother's nutrition but also on the placenta's ability to transport nutrients from the mother to the baby. A mother's ability to nourish her baby is established during her own fetal life and by her nutritional experiences in childhood and adolescence, which determines her body size, composition and metabolism.[236] In contrast, the rates of growth in the first two to three years of life are dependent on the environment rather than genetic influences. Impaired growth in infancy and rapid childhood weight gain exacerbate the effects of impaired intrauterine growth.[236]

Many fetuses in the Western world today are receiving unbalanced and inadequate diets with insufficient micronutrients.[236] Good nutrition and a healthy lifestyle are recommended to reduce fetal congenital anomalies, suboptimal fetal development

and chronic diseases later in life such as coronary heart disease, hypertension, stroke and type two diabetes.[234;243] Factors important for a healthy pregnancy outcome include:

- a healthy pre-pregnancy weight
- consumption of a wide variety of foods
- appropriate vitamin and mineral supplementation
- avoidance of cigarettes, alcohol and other harmful substances
- appropriate physical activity
- appropriate weight gain
- safe food handling.

Inadequate levels of key nutrients during crucial periods of fetal development may lead to predisposing the infant to chronic conditions in later life.[234] Improving the wellbeing of mothers, infants, and children is essential to the health of the next generation.

Energy requirements from food remain unchanged during the first trimester of pregnancy, increasing to 340kcal and 452kcal per day in the second and third trimesters. This additional energy intake should be sourced from a variety of foods and ensure sufficient inclusion of folic acid, iron, vitamin D, choline, calcium, iodine and omega-3 fatty acids.

Folic acid supplementation before and during pregnancy has dramatically reduced the incidence of neural tube defects since it was first introduced in the 1960s.[244] Pregnant women should source folic acid from fortified foods, dietary supplements and natural food sources (600ug/day).[245] Over 60 countries, including Ireland, have made the fortification of flour with folic acid mandatory. This led to a decrease in pregnancies with neural tube defects of between 25-45% in Canada and the US.[234] Iron deficiency anaemia during the first two trimesters of pregnancy increases the risk of preterm labour and low birth weight. Iron deficiency also increases maternal susceptibility to infections.[243]

A 2012 meta-analysis found that antenatal maternal supplementation with multiple micronutrients (for example, zinc, vitamin A, thiamine, vitamin B6, niacin) resulted in a reduction in the incidence of low birth weight and small-for-gestational-age babies.[246] However, supplements should be taken from early pregnancy for benefits to take effect. The role of vitamin D during pregnancy has not been fully elucidated; however, it appears to affect fetal skeletal development, tooth enamel formation, and general fetal growth and development.[246-249] Sufficient vitamin D can be obtained through dietary intake, however, women with poor nutrition, or those living in northerly latitudes or institutions, or those with darker pigmentation may require supplementation.[249]

Choline is grouped within the B complex of vitamins and is an essential nutrient during pregnancy. Choline deficiency can interfere with normal fetal brain development. Calcium absorption increases during pregnancy to meet maternal and fetal bone requirements.[234] Iodine is required in greater amounts during pregnancy due to increased thyroid hormone production and increased fetal iodine requirements.[250] Iodine deficiency can lead to maternal and fetal goitre, intellectual impairment, neonatal hypothyroidism, increased risk of pregnancy loss and infant mortality. Omega-3 fatty acids, are associated with improved visual, cognitive and nervous system development. Postnatal dietary counselling can benefit both mother and baby. Deficiencies in omega-3 fatty acids, B vitamins, vitamin D and trace minerals such as zinc and selenium have been linked to the development of postnatal depression.[251]

Lifestyle and exercise

Many studies support physical activity during pregnancy.[252-255] Exercise during pregnancy is associated with:[256-260]

- improved cardiorespiratory fitness
- improved strength
- prevention of urinary incontinence
- decreased musculoskeletal discomfort

- reduced incidence of muscle cramps and lower limb oedema
- reduced symptoms of depression and mood stability
- improved body image
- improved sleep
- gestational weight gain control
- reduction in the risk of gestational diabetes mellitus
- reduction in the risk of pre-eclampsia.

Women who engage in physical exercise during pregnancy are at reduced risk of gestational diabetes mellitus and pre-eclampsia.[261] Physical exercise has not been shown to reduce birth weight or influence preterm birth rates, but fetal benefits have been proven, such as decreased fat mass, improved stress tolerance, decreased resting fetal heart rate, advanced neurobehavioural maturation, improved viability of the placenta and increased amniotic fluid levels. Physical exercise is also associated with shorter labour and a decreased rate of operative intervention.

Weight gain and obesity

In high-income countries, strategies that increase the proportion of women entering pregnancy within the optimum weight range is a priority due to the growing evidence of a causal relation between obesity and adverse pregnancy outcomes.[202] Further research is urgently needed to identify the most useful approaches to weight management before, during, and after pregnancy.[202]

A Dutch prospective cohort study of 1,149 low-risk pregnant women reported that 1.4% of the women were underweight, 53.8% had a normal weight, 29.6% were overweight, and 15.1% were obese at 12 weeks' gestation.[262] A study published in 2015, using data from 28 US states found that 20.9% women gained inadequate weight, 32.0% gained adequate weight, and 47.2% gained excessive gestational weight.[263] Maternal obesity is associated with an increased risk of complications such as:[262;264-267]

- fetal congenital anomalies

- gestational diabetes mellitus
- pregnancy induced hypertension
- pre-eclampsia
- poor fetal growth
- Macrosomia (excessive fetal growth)
- caesarean section
- poor neonatal outcomes including shoulder dystocia
- perinatal mortality
- lower breastfeeding rates
- longer hospital stay
- long-term retention of maternal weight.

Macrosomia is affected by maternal BMI, maternal weight gain during pregnancy, blood glucose levels, and genetic and placental factors. Macrosomia is associated with an increased risk of adverse obstetric and neonatal outcomes during labour and delivery, such as shoulder dystocia and brachial plexus injury. Macrosomia is also a risk factor for obesity in childhood, adolescence and early adulthood.[268;269]

Knowledge of personal BMI, gestational weight gain target limits and appropriate weight management strategies can improve outcomes for overweight and obese pregnant women. Overweight and obese pregnant women are more likely to misclassify their BMI than women with normal BMI[270] and they also tend to overestimate weight gain recommendations.[271] Height, weight and BMI should be recorded at the initial antenatal appointment. Overweight and obese women should be offered nutrition counselling and the benefits of physical activity should be explained. Other antenatal interventions include dietary programmes with energy intake restriction, educational materials, behavioural intervention and food diaries.[272;273]

Pregnancy and the months following pregnancy are recognised as critical junctures for weight management interventions. Pregnancy is 'a teachable moment' when women may be receptive to health advice.[274;275] Additional strategies include

educating the public about the value of a healthy pre-pregnancy weight.[276] Governments should also ensure that sufficient weight management support services are in place to deal with referrals from healthcare professionals.[277] A cross-sectional survey of 195 countries was conducted in 2012 and 2013 to determine the presence and content of national pre-pregnancy, pregnancy and postnatal maternal weight guidelines.[278] Completed surveys were received from 66 countries, including Ireland. Guideline content and rationale varied considerably between countries, and respondents perceived that within their country, policies were not widely known.

An online survey of obstetric, midwifery and allied health staff conducted in a tertiary maternity centre in the state of Queensland, Australia, found that despite the development of a state-wide clinical practice guideline on the management of pregnancy-related obesity there was a need for more staff education and training about BMI classification, gestational weight gain targets, communication and counselling.[279;280] Frontline staff have highlighted the usefulness of clinical guidelines in helping to make decisions based on clinical evidence, telling women they are overweight or obese, making appropriate referrals for example, to a dietician and preparing a pregnancy plan.[281]

Breastfeeding

Breastfeeding is important for the health of both mother and baby. Breastfed infants have a reduced risk of acute infections such as otitis media, neonatal enterocolitis respiratory illness and allergic disease. Breastfeeding reduces the risk of the child subsequently becoming obese. Exclusive breastfeeding is recommended by the World Health Organization (WHO) for infants up to six months of age.[282] After this time, complementary foods can be introduced. Baby-led breastfeeding is also considered best practice in determining the frequency and duration of a breastfeed.[283] Formula feeding is associated with acquired immunodeficiency in infants, a higher risk of respiratory tract infection, gastrointestinal illness, and sudden infant death syndrome. It is also associated with a long-term cognitive and developmental disadvantage in children. Women who breastfeed have a reduced risk of postnatal depression,

cardiovascular disease, breast cancer and ovarian cancer[282] compared to women who did not breastfeed. They also have a faster return to pre-pregnancy weight. Breastfeeding is associated with a reduced risk of type 2 diabetes later in life for the mother, even if she developed gestational diabetes.

The WHO and United Nations Children's Fund (UNICEF) developed the 'Global Strategy for Infant and Young Child Feeding' in 2002.[284] This provides governments, international organisations and concerned parties with a framework for actions necessary to protect, promote and support infant and young child feeding. The 'Baby-friendly Health Initiative' is one of this strategy's nine operational targets. This involves developing and implementing a comprehensive policy on infant and child feeding, strengthening the capacity of health services to support appropriate feeding, improving the skills of healthcare professionals, and strengthening community-based support.

The 'Baby-friendly Health Initiative' was first introduced by the WHO and UNICEF in 1991 and updated in 2006. In 2010, more than 22,000 hospitals in 157 countries had been designated 'baby-friendly'. External certification is achieved through compliance with 'The Ten Steps to Successful Breastfeeding' best practice standards to increase breastfeeding.[285] Mother-to-mother support groups, lay or peer counsellors, and community-based workers have proven to be effective in helping mothers to initiate breastfeeding, continue exclusive breastfeeding for six months and sustain breastfeeding for up to two years or more. Strategies that rely mainly on face-to-face support are more likely to succeed than those that do not.[286] Women should be offered ongoing visits on a scheduled basis so they can predict that support will be available. Support that is only offered when women initiate the contact is unlikely to be effective. Support should be tailored to the needs of the setting and the population group.

In 2015, 180 UK healthcare organisations, including 114 maternity units were accredited as 'baby-friendly'. UK breastfeeding initiation rates increased from 62% in

1990, to 76% in 2005, to 81% in 2010.[287] The 2010 UK Infant Feeding Survey reported that while initiation rates were high, breastfeeding rates at six to eight weeks are less than 50%.[287] Exclusive breastfeeding is rare after three months and less than 2% of women breastfeed exclusively at six months.

Reasons for discontinuing breastfeeding included:

- painful breasts, cracked nipples and mastitis
- concerns about infant growth and whether infants receive sufficient milk
- negative attitudes of family, peers and the public towards breastfeeding.

Australian breastfeeding rates at initiation and six months have increased from 86% and 46.6% in 1995 to 96% and 64% in 2010, respectively.[288] The number of 'Baby-friendly' hospitals in Australia increased from one in 1995 to 76 (30% of births) by 2012. A study of 6,752 women four months following birth was conducted in Queensland, Australia in 2010. Breastfeeding initiation rates were high (96%) and similar in 'Baby-friendly Health Initiative'-accredited and non-accredited hospitals. When breastfeeding initiation rates were high and evidence-based-practices supporting breastfeeding were common, baby-friendly accreditation did not affect breastfeeding rates.[288] Women who had early skin-to-skin contact, attempted breastfeeding within the first hour, roomed-in, and received no in-hospital supplementation were more likely to continue to breastfeed at one month and four months than women who experienced fewer than four of these hospital practices.

Smoking

The prevalence of smoking among pregnant women in developed countries is estimated to be between 13-38%. Exposure in utero occurs through maternal smoking or passive smoke. Maternal smoking is associated with an increased risk of low birth weight, abruption, stillbirth, decreased head circumference, sudden infant death syndrome, respiratory infections, otitis media, asthma, childhood cancer, hearing loss, dental caries, and the metabolic syndrome. Adverse cognitive and

behavioural outcomes include conduct disorder, attention-deficit or hyperactivity disorder, poor academic achievement, and cognitive impairment.[289]

Studies have shown more than half of women who smoke fail to quit completely during pregnancy.[290] Factors affecting the ability to quit include, a lower socio-economic status, a partner who smokes, the degree of addiction and multiple former pregnancies. Smoking cessation counselling should be considered as a first-line intervention for pregnant smokers. A five step intervention program, known as the "5 A's[*****]" model, is recommended in clinical practice to help pregnant women stop smoking.[291] Obstetricians in the US state of Ohio reported that 98% of them asked their pregnant patients about smoking, 66% gave advice, 44% assessed, 29% assisted and 6% arranged follow-up visits or referrals.[292] They reported that barriers to the use of the 5 A's method of smoking cessation with pregnant women included time constraints and poor referral pathways. Interactive online training programmes including case simulations, lectures and interviews have been designed for health professionals to help pregnant women quit smoking.[293]

Alcohol

A population-based study in four countries, published in 2014, reported rates of alcohol consumption during pregnancy that ranged from 20-80% in Ireland, and from 40-80% in the UK, Australia and New Zealand.[294] The authors recommended that healthcare professionals should continue to advise all pregnant women to abstain from alcohol during pregnancy, irrespective of professionally perceived risk of exposure.[294] The results of studies on the effects of alcohol consumption on health outcomes of babies are conflicting which has led to a lack of consistency in clinical and government guidelines.[294] Alcohol consumption during pregnancy can cause fetal alcohol spectrum disorder. This is one of the leading causes of impaired intellectual development, neurological and learning disorders, and birth defects in the US, affecting 1% of births.[295] Fetal alcohol syndrome is a more severe form that

[*****] The 5 A's are Ask, Advise, Assess, Assist and Arrange.

results in malformations of the face, intrauterine growth retardation and neurodevelopmental abnormalities of the central nervous system.

Transition to parenthood

Maternity services should support the transition to parenthood by addressing the postnatal health and social needs of the mother.[296] In the community, home visits, women's support groups, community health workers and the continuity of specialized midwifery care in the postnatal period, can lead to improvements in maternal and newborn health.[297] Specialised clinical and counselling strategies have been developed to assist healthcare professionals provide additional support to certain groups, such as teenagers, so that they can make a confident and effective transition to parenthood.[96]

3.6 Leadership, Governance and Management

3.6.1 Overview

Maternity services should have effective leadership, governance and management arrangements in place, with clear lines of accountability. This is discussed in more detail in the following sections:

- leadership
- governance arrangements.

The literature review did not return results relating specifically to management and information to inform the development of this section of the standards was instead sought from additional national and international evidence and through stakeholder engagement.

3.6.2 Leadership

Strong professional organisations provide leadership.[298] This includes national professional associations of midwifery and nursing, medical practitioners and health and social care professions and from civil society, including women's groups. These

professional organisations can help to set standards for education, maternity care and patient safety, improve health regulation and practice, and build leadership skills. They can also work with governments and other key stakeholders to develop health policies to improve maternity services.[299] Leadership, in relation to maternity services, involves advocacy on behalf of women and their babies.[300]

Change is implemented at a local level by local leaders or champions. These leaders assume responsibility, follow evidence-based practice, deliver quality maternity care, study new technology, document and plan processes, transition women and their babies seamlessly between maternity care settings, lead multidisciplinary teams with respect and professionalism, educate women and their families, and know their own limitations.[301;302] Change and redesign of maternity services requires consideration of four levels of care[303]:

- the experience of women, their families and support networks
- the clinical microsystems that provide direct maternity care
- the hospitals and healthcare organisation that house and support clinical microsystems
- the environment of policy, payment, regulation, accreditation and litigation and other macro-level factors that influence the delivery of maternity care.

Barriers to the implementation of clinical guidelines include organisational issues (lack of facilities or equipment), structural factors such as financial disincentives and existing local standards and individual factors (knowledge, attitude and skills). Strategies that help change behaviour and implement guidelines should be multi-faceted, based on audit and feedback, and facilitated by local opinion leaders.[304] The implementation of guidelines is becoming increasingly important with regard to reimbursement and medicolegal challenges.

Implementing change within organisations is a complex and dynamic process.[305] Changing long-standing clinical practice is difficult. A qualitative study conducted in 10 public hospitals in Argentina and Uruguay found the barriers to change in clinical

practice included limited access to information, negative attitudes toward changes in practice, lack of skills in performing new practices, lack of medical resources and explicit guidelines and a perceived need to practice defensive medicine.[306] Interventions to change long-standing clinical practice need to be adapted to translate evidence-based approaches to different cultures and contexts. Improving access to information, use of role models, skill development and improved resources and support may be effective ways to overcome barriers to change in obstetric care.[306]

3.6.3 Governance arrangements

The Health Service Executive (HSE) defines clinical governance as 'the system through which healthcare teams are accountable for the quality, safety and experience of patients in the care they have delivered'.[307] Clinical governance combines managerial, organisational and clinical approaches to develop systems and processes to protect and promote evidence-based practice. Multi-faceted strategies, based on audit and feedback help to implement obstetric and neonatal clinical guidelines and achieve a high standard of care.[304] Types of audit include:[302]

- criterion-based or standards-based audit
- peer review
- 'near-miss' reviews of severe acute maternal morbidity
- maternal and perinatal death reviews
- confidential enquiries into perinatal deaths and maternal deaths.

Criterion-based or standards-based audit seeks to improve patient care and outcomes by systematically reviewing care against explicit standards. Identification and implementation of change is used to achieve the desired standard. A peer review is a process whereby a group of healthcare professionals evaluate each other's clinical performance. A 'near-miss' review deals with severe obstetric complications, which occur more frequently than maternal deaths. These reviews include individual cases and can include the perspective of the surviving mother. Confidential enquiries

into perinatal deaths and maternal deaths review and investigate the cause of death and contributing factors. The UK Confidential Enquiry into Maternal Deaths, which was established in 1952, is recognised as the 'gold standard' for maternal death reviews.(121) It is an anonymous investigation of maternal deaths at a regional or national level to identify the causes and factors associated with these deaths. Its methodology is now used in many developed countries around the world. Deaths are reviewed anonymously by clinical experts. Results of these reviews are used to identify system issues and missed opportunities, which form the basis for national guidelines, local protocols and recommendations. Recommendations are disseminated at all levels including government agencies, indemnity schemes for malpractice insurance, health service providers, risk managers, professional organisations and individual healthcare professionals.

Under law, healthcare professionals need to be accountable for acts and omissions they cause to the people they provide care to.(197;308) Accountability to a higher authority is fundamental to the protection and trust of women and their babies receiving care. Clinical governance and accountability also extends to medical service contractors. These providers should be regulated or licensed. Changes to services requiring consent, should be reflected in patient consent forms.(309)

Maternal mortality and morbidity case reviews and tools for assessment of maternity services are also used. Tools target areas shown to have the greatest impact on maternity services including infrastructure, supplies, the organisation of services and case management. Benchmarking†††††† is also seen as key to improving maternity services.(310)

The 2009 'Transforming Maternity Care' symposium in the US identified 11 critical focus areas for change.(299) These include: performance measurement, disparities in access and outcomes of maternity care, the liability system, scope of services, coordination of maternity care (across time, settings, and professions), clinical

†††††† Benchmarking means measuring processes and outcomes against the 'best in class'.

controversies (homebirth, vaginal birth after caesarean [VBAC], vaginal breech and twin birth, elective induction, and caesarean section without medical indication), decision-making, healthcare professionals' education, workforce composition and distribution and health information technology.

3.7 Workforce

3.7.1 Overview

Safe, high-quality maternity services are supported by qualified and competent healthcare professionals. This means that regular training is provided to ensure the best possible care is delivered to women and their babies. Aspects affecting care provided by maternity service providers include:

- training and maintenance of professional competence
- inter-professional communication
- multidisciplinary teams.

3.7.2 Training and maintenance of professional competence

The passive didactic approach to training and maintenance of professional competence is shown to have limited effectiveness.[311;312] Studies supporting the use of active, multi-faceted strategies and simulation-based training are discussed in the following paragraphs.

Active multifaceted strategies

Nineteen hospitals in Argentina and Uruguay were randomly assigned to either receive a multi-faceted behavioural intervention to develop and implement guidelines for the management of the third stage of labour or no intervention.[313] The behavioural intervention included the selection of opinion leaders, interactive workshops, academic detailing,‡‡‡‡‡ training in manual skills, reminders, and feedback over 18 months. In this study, opinion leaders were identified by their peers using a

‡‡‡‡‡Academic detailing involves education in the workplace combining interactive, one-on-one communication by trained health professionals.[314]

questionnaire. These leaders were asked to participate in workshops to develop and disseminate evidence-based guidelines within their own hospital. Workshops were followed up with monthly progress reports. Ten hospitals were assigned to the intervention and in these hospitals the use of prophylactic oxytocin in the third stage of labour had increased and the episiotomy rate had decreased at the end of the intervention. These results were sustained 12 months after the end of the intervention.

The QUARITE§§§§§ study asked two leading healthcare professionals from participating maternity units to join an initial workshop and intervention programme to foster local leadership and empower obstetric teams.(315). This was followed up with quarterly auditing and on-site educational outreach training. An overall reduction in maternal mortality was seen in the intervention hospitals.

A 2012 US perinatal safety initiative involved the implementation and standardisation of evidence-based protocols, formalised team training which emphasised communication, standardisation of electronic fetal monitoring using a course and exam, and an obstetrical emergency simulation programme for high-risk care scenarios including maternal seizure, maternal haemorrhage and shoulder dystocia.(218) Over a two year period, the incidence of adverse outcomes was reduced and staff and patient experiences were improved.

Practical obstetric multi-professional training (PROMPT) is multi-professional training programmes developed to reduce adverse neonatal and perinatal outcomes and improve teamwork and communication.(316) Training typically involves a full day of hospital-based short lectures and scenario based simulation training in obstetric emergencies, led by trainers from the hospital's own staff. Training empowers key staff to introduce local improvements and run PROMPT training courses in their own unit.(317) Maternity units in eight public hospitals in metropolitan and regional Victoria,

Australia introduced PROMPT training over three and a half years and retrospectively evaluated its effects on organisational culture and perinatal outcomes. Organisational culture was measured before and after PROMPT using the Safety Attitude Questionnaire. Significant increases were found in Safety Attitude Questionnaire scores in the domains of teamwork, safety and perception of management. There was a significant improvement in clinical outcomes, such as Apgar scores at one minute, cord lactates and average length of baby's stay in hospital during or after training, but there was no change in Apgar scores at five minutes or the proportion of women with high blood loss.

Practical obstetric multi-professional training (PROMPT) is one of a number of training programmes developed to reduce adverse neonatal and perinatal outcomes through multi-professional training aimed at improving communication and teamwork. Implementation of the programme in the UK has resulted in significant improvements across a range of outcomes.[316]

Simulation-based training

Simulation training can help midwives, nurses, obstetricians, anaesthetists, neonatologists and paediatricians to improve communication, decision-making, teamwork, and clinical practice in response to obstetric and neonatal emergencies.[312] Approaches to simulation-based training include basic models or mannequins, computer-based programmes, full scale simulation and computerised full body mannequins programmed to respond to the actions of healthcare professionals.

Simulation-based multidisciplinary team training can be used to identify gaps in the knowledge of healthcare professionals caring for women and their babies, to rehearse complicated surgical procedures, and to detect latent system errors.[311] It can also help to identify unsupportive policies and practices, to inform system-wide quality improvement and increase patient safety.[318]

3.7.3 Inter-professional communication

Inter-professional communication takes place on two levels: between healthcare professionals and women and their partners and or families, and between healthcare professionals themselves.

Communicating with women and their partners or families

Patients should be communicated with in an informative and sensitive way. General practitioners (GPs), midwives, obstetricians, maternal-fetal medicine specialists, paediatricians and neonatologists often have to tell women and their partners emotionally devastating information. This is particularly true following the ultrasound conducted between 20 and 22 weeks' gestation.[319] Training on breaking bad news should be available to healthcare professionals. Special consideration should be given to non-native women with little or no English, adolescents and women with an intellectual disability.

An educational programme in advanced communication skills and common psychological issues was offered to midwives and doctors in a tertiary referral centre in Melbourne with the aim of improving identification and support of women with psychosocial issues in pregnancy.[320] A before and after survey design was used to evaluate the effects of the six month educational programme. Participants were more likely to ask directly about domestic violence, past sexual abuse and concerns about caring for the baby following the educational programme. They were less likely to report that psychosocial issues made them feel overwhelmed. They reported significant gains in knowledge of psychosocial issues and competence in dealing with them. Participants were highly positive about the experience of participating in the programme.

A prospective cross-sectional study was conducted to determine which communication methods are used most frequently by midwifery group practice midwives and clients.[321] A sample of midwifery group practice midwives from an Australian tertiary maternity hospital was taken and data about modes of midwife-

client contact were collected 24 hours per day, for two consecutive weeks. Visits, phone-calls, texts and emails were included. Details about 1,442 midwife-client contacts were obtained. The majority of contact was via text, between the hours of 07:00 and 14:59 with primiparous women when the primary midwife was on call. The use of text as the preferred communication method raises issues regarding data security and retrieval, accountability, confidentiality and text management during off-duty periods.

Communication between maternity services staff

Good clinical handover is an important part of patient safety. Failure in handovers happen when there is a loss of situational awareness based on information received.[322] Establishing situational awareness relies on clear communication using SBAR (situation, background, assessment and recommendations). A structured direct observational study of 70 perinatal shift-to-shift handover communication was conducted in an academic perinatal setting to identify potential improvements.[322] Forty-four per cent of handovers took two minutes or more per patient. Distractions occurred in over half of handovers. There was no active inquiry in 43%, no eye contact in 32% and information was not read back in 97%. Perinatal handovers are at risk for inadequate situation assessment because of variability and limitations in handover communication and process. The receivers' opinions of handover communication were very positive, indicating a lack of awareness of patient safety threats during handover.

Communication is important between staff providing maternity services. Education programmes emphasise teamwork and communication, and empower all staff to raise concerns.[218;323] Care pathways standardise processes and improve communication between healthcare professionals.[119] They also make it easier to know what to expect from colleagues, making deviation from the norm more apparent.

Good clinical handover is an important part of patient safety. Failure in handovers happen when there is a loss of situational awareness, or knowing what is going on based on information received.[322] Establishing situational awareness relies on clear communication using SBAR (situation, background, assessment and recommendations). It also relies on the process used to communicate, including duration, interruptions and or distractions, eye contact, active inquiry and reading information back. Shift-to-shift handover in maternity services could be improved using video reflection or simulation training.[322]

3.7.4 Multidisciplinary teams

In obstetrics, multidisciplinary teams are recommended for the management of women with complex medical conditions.[324] Multidisciplinary teams integrate separate discipline approaches into a single consultation and directly involve the woman in these discussions. Good communication strategies and an effective simulation-based training mechanism are required to develop multidisciplinary teams.

US hospitals that have adopted collaborative models of care between obstetricians midwives, nurses, and other healthcare professionals provide high-quality specialised care.[323] Weekly interdisciplinary departmental grand rounds dealing with specific topics, cases, best practice and lectures have also helped to improve clinical outcomes.

Interventions to maintain workforce motivation and enhance performance include support to manage and deal with job stressors, policies for dual practice among healthcare workers, exit interviews and modifications of the organisational infrastructure and work environment.[325] A review of the effectiveness of facility level inputs for improving maternal and newborn health outcomes found that facility-based stress training and management interventions to maintain a well-performing and motivated workforce significantly reduced job stress and improved job satisfaction.[325] Evidence of the impact of physical environment, exit interviews and organisational culture modifications was limited and inconclusive.

3.8 Use of Resources

3.8.1 Overview

An effective maternity service that meets the needs of women and their babies makes the best use of available resources in the community and in maternity units. New techniques and technologies should be continuously assessed for their potential to improve maternity care. Few articles were identified in relation to the use of resources and this standard was developed predominantly through advice and expert opinion sought through extensive stakeholder engagement.

3.8.2 Facility Resources and Integrated Care

The quality of emergency obstetric and neonatal intervention is dependent on hospital facility resources.[325] Hospital facilities should be sufficiently equipped, staffed by skilled personnel, and have strong links with primary care. Managerial and administrative support, staff training, the referral process, and post-discharge care are all controlled by facility resources. Co-ordination is required between care facilities to ensure maternity care is integrated across settings, providers and levels of care.[213]

3.8.3 Health Technology Assessment

New procedures should be assessed by responsible government bodies prior to their introduction into clinical practice. Health technology assessments are based on clinical effectiveness and economic evaluation. NICE conducted a retrospective analysis of all procedures notified to the interventional procedures programme between 2002 and 2012, identifying 1,094 notified procedures. Notifications came from all specialties, with the largest numbers in general surgery (125), followed by urology (104), orthopaedics (99), interventional radiology (93), cardiology (82), and obstetrics and gynecology (82).[326]

3.9 Use of Information

3.9.1 Overview

The collection of information about the care of women and their babies is an essential part of the communication process between healthcare professionals, women, policy makers and regulators. Information can be used to plan, manage, deliver and monitor safe, high-quality maternity services. This section addresses how information is collected, recorded, used and shared. The following issues are discussed:

- data collection
- health records
- registries and data sharing
- surveys
- confidentiality
- standardisation of definitions
- dissemination of information.

3.9.2 Data collection

Three types of healthcare data are collected: primary, secondary and linked.[327;328] Primary healthcare data is collected for a specific purpose, for example, demographic, medical, prescription and lifestyle related information. It can be costly and time consuming to collect primary healthcare data.[329] Secondary data is data collected for other purposes, such as hospitals admissions, discharge, and transfer systems, pharmacy databases, laboratory information system, or medical claims database. Linked healthcare data is data linked between databases using personal patient identifiers, such as individual health identifier, social security number, or death index. Secondary data captured electronically for administrative, audit and research purposes can often address the same questions.

3.9.3 Health records

Health records store healthcare information and are key to providing timely and effective maternity care. Medical record documentation can be improved through ongoing education of healthcare professionals, academic detailing, guidelines, chart audit and feedback, and incentive programmes.[330]

Health information technology can be used to reduce disparities in antenatal care in under-resourced settings by:[331]

- increasing women's awareness of the importance of pre-conception and early antenatal care
- facilitating spatial mapping of access gaps
- improving continuity of health records
- supporting collaborative quality improvement
- facilitating performance measurement
- enhancing health promotion
- assisting with the co-ordination of care
- reducing clinical errors
- improving the delivery of preventive health services
- providing decision support
- encouraging completeness of documentation
- supporting data integration
- facilitating spatial mapping of access gaps.

These principles or points are also relevant to high-income countries.

3.9.4 Registries and data sharing

Registries collect data to monitor safety, identify variations in clinical practice patterns, assess the safety of medical therapies and medical devices, measure patient reported outcomes, examine real-world effectiveness, and perform

comparative effectiveness research.[332] They are sponsored by medical societies, governmental organisations, academic collaboratives, and the life sciences industry.

Projects such as EUROCAT,****** network European registries to enable tracking of important epidemiological data to identify trends and risk-factors.[333] The pooling of information between maternity units concerning uncommon and severe complications of pregnancy and birth can lead to larger, combined, more valid, datasets for analysis. Results can be used to inform policy and clinical practice.[240;334]

A standardised neonatal information collection system was established in Northern Ireland neonatal intensive care units in 1994.[335] Sharing specialist neonatology information helped to facilitate regular auditing, feedback and the development of evidence-based clinical standards, leading to an overall reduction in neonatal mortality.

3.9.5 Surveys

Surveys measure what is actually happening in a maternity care service, as opposed to what should be happening. The design, conduct and reporting of surveys affects the validity and reliability of results. The Obstetric Anaesthetists' Association has facilitated national surveys in obstetric anaesthesia since 1998. These surveys gather information to gauge knowledge, beliefs, education opportunities and attitudes and behaviours of respondents.[336;337;337]

Satisfaction is one of the most frequently reported outcome measures for quality of care. A literature review published in 2013, compared available measures of satisfaction with care during labour and birth.[338] Nine questionnaires of satisfaction with care during labour and birth were identified. Instruments varied in psychometric properties and dimensions. Most described questionnaire construction and tested some form of reliability and validity. The authors concluded that despite the interest

******EUROCAT is a European network of population-based registries for the epidemiologic surveillance of congenital anomalies. EUROCAT began in 1979 and now surveys more than 1.7 million births per year, gathering data from 43 registries in 23 countries.

in measures of satisfaction, only a small number of validated measures of satisfaction with care during labour and birth are available. The Newcastle satisfaction with nursing scales were administered by interviewers to 189 women in the postnatal period prior to hospital discharge.(339) They were found to be a valid measure of maternal satisfaction with inpatient postnatal nursing care.

Questionnaires are also used to compile national data on maternity care. In England, the National Maternity Survey is conducted every four years and published by the National Perinatal Epidemiology Unit, Oxford. The ongoing nature of the survey allows comparisons to be made over time. In 2010, a random sample of 10,000 women who had recently given birth in England over a two week period was selected by the Office for National Statistics from birth registration records.(340) Over half, (5,333 women) responded to a purpose-designed questionnaire about their experience of care during pregnancy, childbirth and the early months at home.

3.9.6 Confidentiality

Confidentiality of information on behalf of women, their partners, babies and staff is important. A reason for the success of Confidential Enquiries into Maternal Deaths is due to the confidential and anonymous nature of the enquiry.(121)

3.9.7 Standardisation of definitions

Precision in language has become critically important with the evolution of the electronic health record and the proliferation of measurement in vital statistics and healthcare.(341) Clinical definitions must be standardised in order to build a robust national data infrastructure. The 'reVITALize' initiative is a US initiative which aims to standardise clinical definitions for written and verbal clinical communication, electronic health record data capture, vital statistics and public health surveillance, measurement, quality improvement, reporting, and research.(341) This includes the standardisation of obstetric data definitions. International projects such as the 'International Fetal and Newborn Growth Consortium for the 21st Century', have

developed consensus definitions, management protocols, and guidelines to standardise fetal, newborn and preterm growth assessment.[342]

An update on episiotomy rates internationally reported that statistics on episiotomy are often collected and reported in a haphazard way, if at all.[343] Statistics on episiotomy by parity are not collected systematically in many countries. Inaccurate estimation of blood loss may lead to misdiagnosis and inappropriate management of women postpartum haemorrhage.[199] There has been a call for a single definition of postpartum haemorrhage, training of staff in the assessment of blood loss and improvement in the way data is collected.[163] The incidence of amniotic fluid embolism in Australia, Canada, USA, UK and the Netherlands ranges from 1.9 per 100,000 maternities in the UK to 6.1 per 100,000 maternities in Australia.[164] This range is thought to be due to methodological differences between countries. There has been a call for the development of an agreed case definition and an agreed set of criteria so that the incidence of amniotic fluid embolism can be compared between and within countries.

3.9.8 Dissemination of information

Information should be disseminated to bring about improvement in maternity services. The provision of information to women and their families, feedback to healthcare professionals and integrated educational programmes are strategies to disseminate information and improve the safety of women and their babies.[218;344] Guidelines, protocols and recommendations arising from confidential maternal death enquiries in the UK and Ireland are disseminated to healthcare professionals, professional organisations, risk managers, central indemnity schemes for malpractice insurance and government bodies.[121] Research findings should also be communicated and disseminated in order to implement evidence-based practice.[345]

3.10 Summary of Literature Review

A systematic literature review was undertaken between April and September 2015 to retrieve and document recently published evidence in relation to standards in maternity services as they relate to the eight themes used for the standards framework. Additional articles of relevance were identified and included after the initial review as identified by HIQA or as recommended by members of the Maternity Standards Advisory Group. The results were documented by theme as outlined in the previous sections, with sub-themes within each section being determined in part by the categories of standards in use in Australia and New Zealand and in the United Kingdom.[28;346]

Evidence from the literature review focused more on the safety and quality dimensions, specifically effective care and support, with significantly less evidence returned in relation to capacity and capability factors. Where evidence was not available, for example to support the development of the leadership, governance and management theme, additional advice and input was sought from members of the Maternity Standards Advisory Group either individually or through discussion at meetings. Deficiencies in the evidence also informed questions and issues to be raised at focus groups undertaken with service users and frontline staff in November and December 2015. Individual meetings also took place with a number of senior administrative staff while onsite in a number of maternity units to inform the content of these themes. Furthermore, significant contributions were made to these sections through submissions to the public consultation on the draft standards that took place over eight weeks between March and May 2016.

4. Conclusion

This report documents the desktop research that was undertaken to inform the development of the *National Standards for Safer Better Maternity Services* as follows:

- a review of frameworks/strategies, standards and guidelines in place internationally
- an overview of the Irish context, including the National Maternity Strategy, existing standards and guidelines, and reviews and investigations of Irish maternity services
- the findings of a systematic literature review undertaken to identify and document recently published evidence about standards in maternity services.

This desktop research informed an initial draft of the standards that was refined at different stages throughout the standards development process including:

- detailed discussions at meetings of the Maternity Standards Advisory Group
- individual meetings with relevant stakeholders
- focus groups with women and their partners and with front-line staff working in maternity services
- an eight-week national public consultation, resulting in 127 submissions that were analyzed and reviewed.

Each of these steps, in conjunction with the desktop research documented in this report, formed the evidence base for the development of the *National Standards for Safer Better Maternity Services.*

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