An Roinn Sláinte
Department of Health

Stratification of clinical risk in pregnancy

National Clinical Guideline No. 23

2020

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

This National Clinical Guideline has been developed by the Childbirth Guideline Development Group (CGDG), established under the auspices of the HSE National Clinical Programme for Obstetrics and Gynaecology and the National Women and Infants Health Programme. The National Clinical Effectiveness Committee (NCEC) was requested by the Minister for Health to commission this guideline arising from the National Maternity Strategy Report 2016-2026.

Using this National Clinical Guideline

This National Clinical Guideline standardises and identifies antenatal risk factors associated with normal, medium and high risk pregnancies. This guideline is intended for use by all clinical staff caring for women during pregnancy alongside the hospital and hospital group Senior Management Teams (SMTs) and the National Women and Infants Health Programme (NWIHP), who have corporate responsibility for implementation of the recommendations. It should be applied during the woman's first hospital antenatal visit and at all subsequent visits because there may be a change to the woman's risk. Stratification of risk during labour or postpartum will not be considered within this clinical guideline.

Disclaimer

NCEC National Clinical Guidelines do not replace professional judgment in particular cases where the clinician or health professional decides that guideline recommendations are inappropriate in the circumstances presented by a patient, or whereby an individual patient declines a recommendation as a course of action in their care or treatment plan. In these circumstances the decision not to follow a recommendation, along with the rationale for the non-compliance, should be recorded in the woman's healthcare record.

Users of NCEC National Clinical Guidelines must ensure they have the current version (hardcopy or softcopy) by checking the relevant section in the National Patient Safety Office on the Department of Health website: https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines/

Whilst every care has been taken to ensure that all the information contained in this publication is correct, the Department of Health cannot accept responsibility for any errors or omissions which may have occurred.

Published by:

The Department of Health, Block 1, Miesian Plaza, 50-58 Lower Baggot Street, Dublin 2, D02 XW14, Ireland.
Tel: +353 (1) 6354000
www.health.gov.ie
ISSN 2009-6259.

Citation text

Department of Health (2020). Stratification of clinical risk in pregnancy (NCEC National Clinical Guideline No. 23). Available at: https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines/

Membership of the Guideline Development Group (GDG)

The GDG was chaired by Professor Michael Turner, Lead, Clinical Programme Obstetrics and Gynaecology. This National Clinical Guideline is supported by the Clinical Programme for Obstetrics and Gynaecology, the Institute of Obstetricians and Gynaecologists and the National Women and Infants Health Programme (NWIHP).

Membership nominations were sought from a variety of clinical and non-clinical backgrounds to represent stakeholders within the maternity services. GDG members included those involved in obstetrics, midwifery, anaesthesiology, neonatology, clinical risk, quality assurance, Clinical Indemnity Scheme, education, the National Women and Infants Programme and representatives of maternity service users (Table 1). Please see Appendix 1 for the terms of reference.

Table 1. Members of the Childbirth GDG

Name	Job title and affiliation
Prof Michael Turner, Chair	Lead, Clinical Programme Obstetrics & Gynaecology (until December 2019)
Dr Peter Boylan	Institute of Obstetricians and Gynaecologists
Ms Triona Cowman	Director, Centre for Midwifery Education
Ms Anna Deasy	Clinical Risk Manager, Coombe Women and Infants University Hospital
Ms Angela Dunne	Midwifery Director, NWIHP
Ms Mary Flynn	Assistant Director of Midwifery, Cork University Maternity Hospital
Dr Jennifer Hogan	Specialist Registrar Obstetrics and Gynaecology
Prof Joan Lalor	Professor of Midwifery, Trinity College Dublin
Ms Connie McDonagh	Director of Midwifery, St Luke's General Hospital, Kilkenny
Ms Niamh McGoldrick	Service User
Mr Kilian McGrane	Director, NWIHP
Ms Elaine McGrath	Service User (until June 2019)
Dr Peter McKenna	Clinical Director, NWIHP
Dr Léan McMahon	Quality Assurance, NWIHP
Dr Niamh Murphy	Specialist Registrar Obstetrics and Gynaecology
Dr John Murphy	Lead, Clinical Programme for Neonatology
Dr Cathal O'Keeffe	Head of Clinical Risk, State Claims Agency (June 2018 - March 2019)
Ms Margaret Philbin	Former Director of Midwifery, Rotunda Hospital
Ms Caroline Plascott	CGDG Coordinator (until January 2019)
Dr Karen Power	CGDG Project Manager (until December 2019)
Dr Michelle Quinlan	General Practitioner
Ms Karen Robinson	Clinical Risk Advisor, State Claims Agency (from March 2019)
Dr Jeremy Smith	Lead, Clinical Programme for Anaesthesiology
Dr Karen Smith	General Practitioner (until May 2018)
Ms Deirdre Walsh	Clinical Risk Advisor, State Claims Agency (until May 2018)

Credits

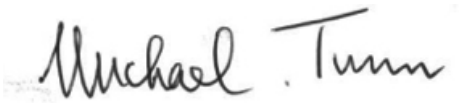
The role of the NCEC is to prioritise, quality assure and recommend clinical guidelines to the Chief Medical Officer for endorsement by the Minister for Health. It is intended through Ministerial endorsement that full implementation of the guideline will occur through the relevant service plans.

The NCEC and the Department of Health acknowledge and recognise the Chair and members of the Guideline Development Group (GDG) for the development of the guideline. The NCEC and Department of Health express thanks and gratitude to everyone contributing to this National Clinical Guideline, especially those who gave of their time on a voluntary basis.

Acknowledgments

The Chair, Professor Michael Turner, acknowledges the Childbirth Guideline Development Group as contributors to the development of this National Clinical Guideline. All members approved the final clinical guideline. Ms Shelley O'Neill, Mr Barrie Tyner and Mr Patrick Moran of HRB-CICER carried out the search for evidence, systematic review and budget impact analysis and were extremely supportive throughout the process. Ms Pauline Dempsey was integral to facilitating all links between the NCEC, Clinical Effectiveness Unit and the Childbirth GDG. Dr Karen Power and Prof Michael Turner wrote and prepared the final document and submitted the guideline for NCEC quality assurance.

The time and effort for the external review, carried out by Ms Shona Hamilton and Dr Patrick O'Brien, is gratefully acknowledged.



Signed by the Chair,
Professor Michael Turner
November 2019

National Clinical Guidelines

Providing standardised clinical care to patients in healthcare is challenging. This is due to a number of factors, among them variations in environments of care and complex patient presentations. It is self-evident that safe, effective care and treatment are important in ensuring that patients get the best outcomes from their care.

The Department of Health is of the view that supporting evidence-based practice, through the clinical effectiveness framework, is a critical element of the health service to deliver safe and high quality care. The National Clinical Effectiveness Committee (NCEC) is a Ministerial committee set up in 2010 as a key recommendation of the report of the Commission on Patient Safety and Quality Assurance (2008). The establishment of the Commission was prompted by an increasing awareness of patient safety issues in general and high profile health service system failures at home and abroad.

The NCEC on behalf of the Department of Health has embarked on a quality assured National Clinical Guideline development process linked to service delivery priorities. Furthermore, implementing National Clinical Guidelines sets a standard nationally, to enable healthcare professionals to deliver safe and effective care and treatment while monitoring their individual, team and organisation's performance.

The aim of National Clinical Guidelines is to reduce unnecessary variations in practice and provide an evidence base for the most appropriate healthcare in particular circumstances. As a consequence of Ministerial mandate, it is expected that NCEC National Clinical Guidelines are implemented across all relevant services in the Irish healthcare setting.

The NCEC is a partnership between key stakeholders in patient safety. NCEC's mission is to provide a framework for national endorsement of clinical guidelines and clinical audit to optimise patient and service user care. The NCEC has a remit to establish and implement processes for the prioritisation and quality assurance of clinical guidelines and 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. The aim of the suite of National Clinical Guidelines is to provide guidance and standards for improving the quality, safety and cost-effectiveness of healthcare in Ireland. The implementation of these National Clinical Guidelines will support the provision of evidence-based and consistent care across Irish healthcare services.

NCEC Terms of Reference

1. Provide strategic leadership for the national clinical effectiveness agenda.
2. Contribute to national patient safety and quality improvement agendas.
3. Publish standards for clinical practice guidance.
4. Publish guidance for National Clinical Guidelines and National Clinical Audit.
5. Prioritise and quality assure National Clinical Guidelines and National Clinical Audit.
6. Commission National Clinical Guidelines and National Clinical Audit.
7. Align National Clinical Guidelines and National Clinical Audit with implementation levers.
8. Report periodically on the implementation and impact of National Clinical Guidelines and the performance of National Clinical Audit.
9. Establish sub-committees for NCEC workstreams.
10. Publish an annual report.

Table of contents

List of tables

List of figures

Glossary of terms and abbreviations

ADAPTE - The ADAPTE process provides a systematic approach to adapting guidelines produced in one setting for use in a different cultural and organisational context (The ADAPTE Collaboration, 2009).

Appraisal of Guidelines for Research and Evaluation instrument version 2 (AGREE II) - international tool designed to help guideline developers assess the methodological quality and reporting of practice guidelines.

Assisted carestream - intended for mothers and babies considered to be at medium risk, and for normal risk women who choose an obstetric service (pg6, Department of Health, 2016).

Clinical Guideline - systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific circumstances.

National Clinical Guidelines - a suite of guidelines that meet specific prioritisation and quality assurance criteria and that have been recommended by the National Clinical Effectiveness Committee. Clinical guidelines endorsed by the Minister will be titled 'National Clinical Guidelines'.

Normal Risk - a woman who does not have identified risk factors, known pre-existing conditions, or complications requiring additional tests or adapted management (Gyselaers et al., 2015).

Risk - the probability that a hazard will give rise to harm (Edwards and Elwyn, 2001).

Senior Management Team – Master or Chief Executive Officer, Clinical Director and Director of Midwifery/Nursing.

Specialised carestream – intended for high risk mothers and babies, will be led by a named obstetrician, and will be delivered by obstetricians and midwives, as part of a multidisciplinary team (pg6, Department of Health, 2016).

Supported carestream - intended for normal risk mothers and babies, with midwives leading and delivering care within a multidisciplinary framework (pg 6, Department of Health, 2016).

Abbreviations

The following abbreviations are used in this document:

AGREE II	Appraisal of Guidelines for Research and Evaluation instrument version 2
AHMAC	Australian Health Ministers' Advisory Council
CEO	Chief Executive Officer
CGDG	Childbirth Guideline Development Group
CS	Caesarean Section
DoH	Department of Health
DOM/N	Director of Midwifery/Nursing
EPDS	Edinburgh Postnatal Depression Scale
FA	Folic Acid
GDM	Gestational Diabetes Mellitus
HIQA	Health Information Quality Authority
HPO	Healthcare Pricing Office
HRB	Health Research Board
HRB-CICER	Collaboration in Ireland for Clinical Effectiveness Review
HSE	Health Services Executive
IMIS	Irish Maternity Indicator System
IVF	In Vitro Fertilisation
KCE	Belgian Health Care Knowledge Centre
MN-MS	Maternal and Newborn - Clinical Management System
NALA	National Adult Literacy Agency
NCEC	National Clinical Effectiveness Committee
NHS	National Health Service (UK)
NICE	The National Institute for Health and Care Excellence, England and Wales
NICU	Neonatal Intensive Care Unit
NPEC	National Perinatal Epidemiology Centre
NTD	Neural Tube Defect
NWIHP	National Women and Infants Health Programme
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCPI	Royal College of Physicians Ireland
SCA	State Claims Agency
SMT	Senior Management Team
WHO	World Health Organization

1 National Clinical Guideline recommendations

1.1 Summary of recommendations

The recommendations were based on consensus at the CGDG to manage the implementation and governance of the risk assessment. Consensus was agreed following a review of the limited literature worldwide, feedback from interested parties nationally and discussion at the meetings. Therefore, there is no 'level of evidence' or grading assigned.

Recommendation 1
All women presenting to hospital for antenatal care should have their pregnancy risks assessed at the first visit. The level of risk should be kept under review before, during and after delivery.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital Senior Management Team (SMT) (e.g. Master or CEO, Director of Midwifery/Nursing (DOM/N), Clinical Director), Doctors and Midwives.**

Recommendation 2
All maternity hospitals/units should have carestreams in place depending on the stratification of clinical risk. Information on stratification should be provided locally to all disciplines providing clinical care.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMT.**

Recommendation 3
The hospital booking system should facilitate allocation to the different carestreams. The allocation for all hospital antenatal visits should be recorded in the healthcare record.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital SMTs.**

Recommendation 4
The carestreams should be women-centred and team-based irrespective of risk stratification.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMT, Doctors, Midwives, Anasthesiologists and Allied Healthcare professionals.**

Recommendation 5
Appropriate continuity of antenatal carer should be promoted and, if the level of risk evolves, women should be able to transition seamlessly between carestreams.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMT, Doctors and Midwives.**

Recommendation 6
Women should be informed about their individual risks related to pregnancy. They should be given an opportunity to input into any decisions about risk assessment.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMT, Doctors and Midwives.**

Recommendation 7
Up-to-date local hospital-level clinical data should be available and used in assessing and communicating risk to pregnant women (for example, data from the Irish Maternity Indicator System (IMIS)).

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital SMT, Doctors and Midwives.**

Recommendation 8
Risk stratification in the maternity services should be consistent and aligned with national clinical guidelines.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMT.**

Recommendation 9
Implementation of carestreams in individual maternity units should take cognisance of local resources and, where appropriate, may need to be provided on a maternity network or national basis.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMT.**

Recommendation 10
The implementation of risk stratification should be reviewed annually by the senior management team in each maternity hospital/unit.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **NWIHP.**

Recommendation 11
National guidance on risk stratification should be reviewed annually by the National Women and Infants Health Programme (NWIHP) based on recent clinical developments and national audits.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **NWIHP.**

Recommendation 12
All maternity hospitals/units will provide education on this guideline.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital SMT.**

2 Development of the National Clinical Guideline

2.1 Background

In February 2016 the Department of Health published Ireland's first National Maternity Strategy Report. The Strategy highlighted the need to customise maternity care according to a woman's clinical risk.

"The National Women and Infants Health Programme will ensure that pregnant women are offered choice in the selection of an appropriate pathway of care, based on safety, risk profile and needs; individual risk/need profiles will be reviewed at each interaction with the maternity service" (National Maternity Strategy 5.7 p97)

Subsequently, the Minister for Health commissioned the Health Services Executive (HSE) to develop a suite of NCEC quality assured clinical guidelines for national implementation. As a result, a national guideline on pregnancy and clinical risk was developed.

The Childbirth Guideline Development Group (CGDG) was established and had their first meeting in June 2017. It was agreed that in order to support the implementation of the National Maternity Strategy and the three carestreams, it was necessary to develop a guideline on clinical risk in the antenatal period. This includes stratification of women's clinical risk at the first hospital antenatal appointment and during all subsequent antenatal appointments into normal, medium and high risk pregnancies.

2.2 Clinical and financial impact of antenatal risk stratification

Risk may be defined as the probability that a hazard will give rise to harm (Edwards and Elwyn, 2001). A hazard is a situation with the potential to cause harm. There are two dimensions of risk. Firstly, *"How is probability interpreted?"*, as individuals evaluate risks and benefits differently and secondly, *"What is the nature and severity of the harm?".*

Risk is multifaceted. There may be clinical risk related to the individual woman and there may also be individual or team-based factors that contribute (Table 2). There may be organisational risk, including financial, to the health services. There may be risk for fund-holders, insurers, policy-makers and politicians. These risks may be interdependent, for example, clinical risk may increase if an organisation is poorly managed or financial resources are inadequate.

There is no national or international consensus about the risk factors for adverse clinical outcomes for pregnancy. However, various lists have been published (Domiciliary Births Group, 2004; Eunice Kennedy Shriver National Institute of Child and Human Development, 2018; "Fetal Health Surveillance: Antepartum and Intrapartum Consensus Guideline," 2007; Meaney, S et al., 2016; NICE National Institute for Health and Care Excellence, 2014; South Australia Maternal, Neonatal & Gynaecology Community of Practice, 2014).

Developing risk factors is complicated because of confounding variables. Advancing maternal age may, for example, be associated with an increased risk of obesity and Type 2 diabetes mellitus, preterm birth, low birth weight, labour complications and chromosomal defects (McDonnell et al., 2015). A woman may have more than one risk factor and there is a paucity of scientific data on how different risk factors interact. Furthermore, clinical practice is evolving. There has been an increase in multiple births in Ireland, for example, which may be explained in part by assisted reproduction (Healthcare Pricing Office (HPO), 2018).

Table 2. Framework of contributory factors influencing clinical practice (Vincent et al., 1998)

Factor types	Contributory influencing factors
Patient factors	Condition e.g. Complexity and seriousness Language and communication Personality and social factors
Task factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results Decision-making aids
Individual (Staff) factors	Knowledge and skills Competence Physical and mental health
Team factors	Verbal communication Written communication Supervision and seeking help Team structure (congruence, consistency, leadership etc.)
Work environmental factors	Staffing levels and skills mix Workload and shift patterns Design, availability and maintenance or equipment Administrative and managerial support Environment Time delays
Organisational and management factors	Financial resources and constraints Organisational structure Policy, standards and goals Safety culture and priorities
Institutional factors	Economic and regulatory context National Health Service Executive Links with external organisations

Pregnancy risk is particularly complex because of the risk for both the woman and her baby which may or may not be aligned. Also, the cut-off point for risk may differ for the woman and her baby. Maternal obesity, for example, is associated with an increase in both maternal and foetal risks but the Body Mass Index (BMI) level that is associated with an increase in gestational diabetes mellitus (GDM) may be different to the level that is associated with an increased risk of congenital malformation (Gilmartin et al., 2008).

Pregnancy risk also depends on the setting in which care is provided. The risk of maternal and perinatal mortality and morbidity is higher in developing countries compared with developed countries. Therefore, in assessing the risk of pregnancy for women attending the maternity services in Ireland, it is important that risk is based on accurate and up-to-date metrics for care delivered in this country rather than care delivered in other settings (Healthcare Pricing Office (HPO), 2018; Irish Maternity Indicator System, 2018; Manning et al., 2018).

It is important to draw a distinction between obstetric interventions (rate) and complications (risk). The rate of Caesarean section (CS), for example, is not the same as the risk of CS. There is also no national or international consensus as to what constitutes the optimum CS rate and almost certainly this is likely to vary from country to country.

It is also important to identify the complications of obstetric interventions. This information is central to the dialogue between a woman and clinical staff in making decisions about models of care and about individual interventions. There are well-established variations in the risk of complications and interventions within a country, between hospitals and probably between individual clinicians, for example, the risk of operative abdominal or vaginal delivery (Irish Maternity Indicator System, 2018). It is desirable that any decisions by the woman and clinical staff are informed by data on evidence-based information which may include local risks and benefits.

Pregnancy risk may be influenced by a woman's social and demographic characteristics that are not modifiable, for example, age, parity, ethnicity, family history, previous obstetric history, and comorbidities. Pregnancy risk may also be influenced by modifiable factors such as smoking, alcohol abuse, illicit drugs, poor diet, vaccinations or inadequate dietary intake or supplements. These factors may influence decisions about the most appropriate model of care.

Advances in medical care may reduce pregnancy risks and have made birth safer than ever before in terms of decreased maternal mortality. However, advances in medicine have also added to the high risk population (e.g. IVF) and the demand on resources, further increasing both clinical and operational risk.

Stratification of pregnant women into normal, medium and high-risk categories is arbitrary and made difficult when there is a dearth of information, inappropriate analysis or incomparable processes and procedures. It may be unclear whether the presence of a single risk factor is enough to necessitate a high-risk pregnancy carestream or if a multifactorial/combined risk factor algorithm is more appropriate. This is complicated by the fact that pregnancy covers up to 42 weeks of changes and a lifetime of predisposing factors, potentially contributing to risk.

Despite the complexity of stratifying a pregnant woman based on risk, healthcare professionals need to give guidance, based on evidence and/or professional consensus opinion for grading a woman's risk profile. This is arguably the best way to manage a diverse group of women and to optimise the skill sets of midwives, obstetricians, anaesthesiologists and other allied healthcare professionals.

2.3 Rationale for this National Clinical Guideline

The National Maternity Strategy "Creating a Better Future Together 2016-2026" advocates a risk-based approach to ensure that women are provided with the most appropriate model of care in line with their clinical risk (Department of Health, 2016). The Strategy highlighted the need to stratify pregnant women according to their clinical risk into three risk groups, normal risk (Supported Care), medium risk (Assisted Care - requiring a higher level of oversight) and high risk (Specialised Care - requiring a more intensive level of care, either throughout or at a particular stage of care). Following the publication of the National Maternity Strategy Report, the Minister for Health mandated as a matter of priority the commissioning and quality assurance of prioritised national guidelines through the National Clinical Effectiveness Committee (NCEC) to support its implementation. This is the first in a suite of guidelines intended to carry out this objective.

This NCG 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 and is in line with current best practice. Clinical decisions and therapeutic options should be discussed with a senior clinician on a case-by-case basis as necessary and documented, along with the rationale for deviation from the guideline, in the clinical notes.

2.4 Aim and objectives

This guideline stratifies a woman's clinical risk at the first hospital antenatal visit and during all subsequent antenatal appointments into normal, medium and high risk pregnancies.

2.5 Guideline scope

This guideline is relevant for all clinical staff caring for pregnant women in the antenatal period. It should be used during the woman's first hospital antenatal visit and thereafter at all antenatal visits where there is a change to the woman's risk factors. Stratification of risk during labour or post birth will not be considered within this clinical guideline.

2.6 Conflict of interest statement

The guideline development process followed the conflict of interest policy set out by the NCEC. All members of the Childbirth Guideline Development Group (CGDG) and quality assurance reviewers were required to complete a Conflict of Interest declaration which was managed by the Project Manager. There were no conflicts of interest stated.

2.7 Sources of funding

No external funding was received for this project. The systematic review of relevant clinical guidelines, the Delphi report, the economic review and the budget impact analysis was funded by the Department of Health.

2.8 Guideline methodology

Summary

Reproduced below is an extract of the "Systematic review of clinical guidelines on risk stratification in pregnancy". The systematic review was conducted to inform the CGDG discussions as to whether quality clinical guidelines exist, which are similar to the agreed scope and could thus be adopted without modification, adapted with modification suitable for the Irish setting (using the ADAPTE process), or if a de novo clinical guideline would need to be developed.

The systematic review identified three high quality international clinical guidelines (two modules from Australia considered one guideline, one from the UK and one from Belgium). However, none of the three guidelines included a medium risk factor category as is set out by the National Maternity Strategy (Appendix 8), therefore rendering them ineligible for a straightforward adoption.

A three-round modified Delphi process was conducted to provide a systematic and methodologically robust consensus approach to produce a list of risk factors to be used as criteria within this guideline. Unlike a classical Delphi approach, where there is an open first round to facilitate the generation of possible criteria or statements, this modified Delphi began with statements based on the risk factors included in all three high quality international clinical guidelines identified in the systematic review of clinical guidelines (Dalkey and Helmer, 1962). The aim was to identify risk factors to stratify pregnant women at a normal, medium and high risk, during the period from the first hospital antenatal appointment to before the intrapartum period. The details of the Delphi study are available in Annex B *"Risk factors for inclusion as criteria within the clinical guideline on risk stratification during pregnancy: A modified Delphi study".*

The full systematic review and Delphi study were conducted by the Health Research Board Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER). A sample search strategy and summary are in Appendix 2.

Step 1: Formulate the key questions

The key question was "What clinical guidelines include stratification of risk during pregnancy within their scope?" with the key objectives being to identify and appraise eligible clinical guidelines which stratify a woman's risk during pregnancy.

Table 3. PICOS developed for the systematic review

P-Population	Pregnant women during the antenatal period
I-Intervention	Stratification or identification (through screening, and/or diagnostic tests) of the following risks: • Risk based on maternal characteristics which are not modifiable (for example age, parity, ethnicity) • Risk based on medical history (for example diabetes, congenital anomaly, HIV, epilepsy, obesity) • Risk based on previous obstetric history (for example previous caesarean section, previous perineal tear, previous shoulder dystocia) • Risk based on family history • Risk based on modifiable risk factors (for example smoking, alcohol, illicit drugs) • Risk based on clinical exams during pregnancy – relating to the health of the foetus (for example chromosomal anomalies, foetal growth) – other risk factors (for example anaemia <9g/dl, multiple pregnancy, development of rhesus antibodies).
C-Comparison	Not relevant
O-Outcome	Not relevant
S-Study design	National or Regional Clinical Guidelines

Step 2: Search methodology

A search strategy was developed (see Appendix 2) to identify relevant clinical guidelines of risk in pregnancy at the first hospital antenatal visit and during the antenatal period. A conservative approach was adopted to capture as many relevant clinical guidelines as possible. The search strategy was based on a recent systematic review that aimed at mapping current clinical guidelines in antenatal care. A combination of appropriate MeSH terms and free text words were used based on the PICOS (Population, Intervention, Comparison, Outcome, and Study design) framework outlined in Table 3.

Database searches within PubMed and Embase were performed on the 6 June 2017. Grey literature sources (including guideline repositories, guideline developer websites and websites of national ministries of health) were searched from 6 June 2017 to 20 June 2017 and periodically again until 1 September 2017. The full list of grey literature sources is provided in Appendix 2. In addition, GDG members identified clinical guidelines from their national and international links. Eligibility criteria included clinical guidelines published from 2007 onwards and available in the English language.

Step 3: Screen and appraise the evidence

Citations returned from searches were screened by one reviewer, first by title, then by abstract to eliminate clearly irrelevant documents. Selected full text articles were reviewed against the full inclusion and exclusion criteria.

Data extracted included the criteria used by the clinical guidelines to stratify women according to clinical risk, details on the evidence base used to inform the recommendations and clinical questions addressed. Where an update to a clinical guideline was available, the update was considered as the primary document. When supplementary or legacy documents were referenced all effort was made to locate and include them.

From 1,608 unique identified citations (see Figure A1. PRISMA Flow chart of included and excluded studies for literature review) seven clinical guidelines met the inclusion and exclusion criteria (Table A1) and were included within the review (Table 4). Four of the clinical guidelines were from European settings: Northern Ireland (Guidelines and Audit Implementation Network (GAIN), 2016), England and Wales (NICE National Institute for Health and Care Excellence, 2008), Spain (Working Group of the Clinical Practice Guidelines for Care in Pregnancy and Puerperium, 2014) and Belgium (Gyselaers et al., 2015), two from Australia (Australian Government Department of Health and Ageing, 2014, 2012; Queensland Health, 2016) and one from an international public health agency (WHO Steering Group, 2016).

Eligible clinical guidelines were independently appraised by two reviewers using the Appraisal of Guidelines for Research and Evaluation (AGREE ll) quality appraisal tool, with any disagreement resolved by discussion. The AGREE ll Instrument assesses the methodological rigour and transparency with which a clinical guideline is developed. This quality appraisal aids in identifying which clinical guidelines may be suitable for consideration in the ADAPTE process. Full definitions and explanations for the domains under which each eligible guideline was scored are outlined in the full literature review available in Annex A. Three guidelines had a high overall guideline assessment score (>90%, Table 4). The risk factors presented within these three guidelines were used in the three-step Delphi process to develop robust and transparent consensus on risk factors and their risk category for this guideline.

Table 4. AGREE II scaled domain and overall assessment scores

Clinical Guideline	Domain 1 Scope & Purpose	Domain 2 Stakeholder Involvement	Domain 3 Rigour of Development	Domain 4 Clarity of Presentation	Domain 5 Applicability	Domain 6 Editorial Independence	Overall Guideline Assessment
AHMAC 2012/2014	89%	100%	93%	92%	94%	100%	100%
KCE 2015	100%	86%	98%	97%	81%	92%	100%
NICE 2008	89%	89%	95%	100%	90%	63%	92%
GAIN 2016	75%	86%	53%	86%	33%	79%	67%
QCG 2016	83%	83%	48%	100%	52%	67%	75%
AETSA 2014	97%	89%	74%	86%	54%	67%	75%
WHO 2016	100%	100%	96%	100%	83%	100%	100%

AETSA: Andalusian Agency for Health Technology Assessment, AHMAC: Australian Health Ministers' Advisory Council, GAIN: Guidelines and Audit Implementation Network, Northern Ireland, KCE: Belgian Health Care Knowledge Centre, NICE: National Institute for Health and Care Excellence, England, QCG: Queensland Clinical Guidelines, WHO: World Health Organization

Please see Appendix 9 for distinctions between which risk factors were drawn from which guidelines.

Step 4: Three-step modified Delphi

A three-step modified Delphi method was used to establish consensus on the final list of risk factors. The first two steps were conducted through an online survey with a final face-to-face round consisting of small and large group discussions and anonymised voting. Members of the CGDG were invited to participate as an expert panel. A total of 59 risk factors were extracted from three high-quality guidelines, and through the Delphi process the CGDG panel reached consensus on the inclusion of 49 of 59 identified risk factors — 28 categorised as high risk and seven categorised as medium risk. Of the remaining 14 risk factors, 13 should be assessed by a consultant at the first antenatal visit to decide whether the risk is normal, medium or high, and one recommends referral to social work. Full details of the Delphi study are available in Annex B *"Risk factors for inclusion as criteria within the clinical guideline on risk stratification during pregnancy: A modified Delphi study".*

Step 5: Develop and grade the recommendations

The risk factor stratification list (Appendix 9) is largely evidence-based with consensus agreement as described in the above steps. All recommendations are consensus based. They were developed to manage the governance and implementation of the risk factor stratification list, therefore, there is no 'level of evidence' or grading assigned.

The strength of the recommendation was decided following a process of considered judgement by the CGDG that takes into account the problem priority, potential benefits and harms of the options, resource use, equity, acceptability, feasibility and the available evidence as described overleaf (Table 5).

Table 5. Factors that strengthen a recommendation

Factors that can strengthen a recommendation	Questions to consider
Benefits & harms of the options	Certainty of this evidence? Is there important uncertainty about how much people value the main outcomes? Are the desirable anticipated effects large? Are the undesirable anticipated effects small? Are the desirable effects large relative to the undesirable effects?
Costs (resource allocation)	Are the resources required small? Is the incremental cost small relative to the net benefit?
Equity	What would be the impact on health inequities?
Acceptability	Is the option acceptable to key stakeholders?
Feasibility	Is the option feasible to implement?

A **strong** recommendation reflects the CGDG's consensus that the potential positive outcome is highly valued, benefits will outweigh the harms and the cost implications are justified.

A **conditional** recommendation reflects the CGDG's consensus that the balance between benefit and harm is uncertain or the feasibility of implementation is uncertain or likely to be difficult.

All twelve recommendations were deemed 'strong'.

2.9 Consultation summary

The CGDG endeavoured to ensure that all interested parties had an opportunity to contribute to the development of this NCG. The CGDG would like to acknowledge the significant contribution made by the various stakeholders from professional, academic and patient groups (Appendix 3).

2.10 International external review

International external review was completed by the following two experts in their respective fields of midwifery and obstetrics;

1. Ms Shona Hamilton, Consultant Midwife, Northern Health and Social Care Trust
2. Dr Patrick O'Brien, Consultant Obstetrician, University College London Hospitals

The CGDG is very grateful to these reviewers and appreciates the time commitment and expertise that was involved in their review. Reviewers were requested to consider the guideline in accordance with the questions recommended by the National Quality Assurance Criteria for Clinical Guidelines Version 2 (HIQA/NCEC, 2015). The external reviewers were also asked to provide any additional feedback they had. All feedback received was reviewed and incorporated where appropriate.

2.11 Implementation

A plan for implementation of this guideline is outlined in Appendix 5.
Funding for guideline implementation is subject to service planning and estimates process.

Table 6. Summary of enablers and barriers to successful implementation

Enablers	Barriers
Good local leadership	Lack of local leadership
Effective multidisciplinary team work	Lack of clear, standardised communication
Effective communication	Lack of audit and evaluation supports, e.g. information and communication technology (ICT)
Local training	Lack of governance
IT-resources	Understaffing
Regular review and evaluation	Poor staff confidence
Available carestreams	Fear of litigation
	Increased time for first hospital antenatal appointment
	Staff overwhelmed with volume of guidelines

2.12 Monitoring and audit

Monitoring of this NCG will require a collaborative approach within the hospital groups if carestreams are shared within the network. Until the structure of the carestreams are completely developed alongside the implementation of the risk stratification (Recommendation 2), audit cannot be prescriptive. Sample audit questions are available in Appendix 7. While some questions require a chart review, others focus on the governance, training and policy documentation. However, it is noted that audit should evolve over time once the standardised healthcare form is developed, as set out by the BIA, and the guideline has reached full implementation.

2.13 Plan to update this National Clinical Guideline

It was agreed by the Guideline Development Group that this guideline should be reviewed on a three-yearly basis and updated as appropriate. Therefore, unless evidence is published in the interim that requires immediate update (as per recommendation 11), this guideline will be reviewed again in 2022 by the National Women and Infants Health Programme (NWIHP).

3 National Clinical Guideline Recommendations

3.1 Key question and evidence statements

The key question was “What clinical guidelines include stratification of risk during pregnancy within their scope?” with the key objective to identify and appraise eligible clinical guidelines which stratify a woman’s risk during pregnancy. The PICOS is outlined in Section 2.8. This key question sets the groundwork for stratifying a woman’s clinical risk at the first hospital antenatal appointment and during all subsequent antenatal appointments into normal, medium and high risk pregnancies.

Seven international clinical guidelines were identified that cover the period from the first hospital antenatal appointment and throughout the antenatal period and include a consideration of risk in pregnancy. The quality of the clinical guidelines were assessed using a validated appraisal tool (AGREE II). Three clinical guidelines (AHMAC 2012 and 2014 (two modules considered here as one guideline), KCE 2015, NICE 2008) emerged as being of very high quality. In particular, these three offered the availability of precise clinical questions, comprehensive search strategies and graded evidence tables. These are the required components when considering using an existing clinical guideline for the adaption process. Moreover, these guidelines provided criteria to indicate when a woman is considered to have a higher than normal risk of adverse events and would need additional care. Important to note is that no international clinical guideline included a level equivalent to medium risk.

Risk factors are broken down into five groups; maternal characteristics which are not modifiable, medical history, previous obstetric history, family history and modifiable risk factors. A normal risk pregnancy is defined as follows “a woman with a normal risk pregnancy is defined as one who does not have identified risk factors, known pre-existing conditions or complications requiring additional tests or adapted management”(Gyselaers et al., 2015).

Using a modified Delphi approach, the multidisciplinary CGDG reached consensus on the inclusion of 49 of 59 identified risk factors and exclusion of 10. Twenty-eight were categorised as Specialised Care (high risk), seven categorised as Assisted Care (medium risk). Of the remaining 14 risk factors, 13 should be assessed by a consultant at the first antenatal visit to decide whether Supported Care (normal risk), Assisted Care (medium risk) or Specialised Care (high risk) is required, and one recommends referral to the social work service (Appendix 9).

Recommendation 1
All women presenting to hospital for antenatal care should have their pregnancy risks assessed at the first visit. The level of risk should be kept under review before, during and after delivery.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital Senior Management Team (SMT) (e.g. Master or CEO, Director of Midwifery/Nursing, Clinical Director), Doctors and Midwives.**

Good practice points

- A list of risk factors to be included in the first antenatal visit assessment is included in Appendix 9.
- Risk factors should be reviewed at every antenatal visit.
- Non-modifiable risk factors, obstetric, medical and familial history are unlikely to change during the antenatal period and will not require revision unless information unknown previously is presented to the healthcare professional.
- All risk may be modified after clinical assessment.

Recommendation 2
All maternity hospitals/units should have carestreams in place depending on the stratification of clinical risk. Information on stratification should be provided locally to all disciplines providing clinical care.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMTs.**

Good practice points

- Carestreams are set out in the National Maternity Strategy Report (Appendix 8) as Supported (normal risk), Assisted (medium risk) and Specialised (high risk).
- It is expected that the delivery of each of the three carestreams may need to be provided across hospital networks instead of within all 19 maternity hospitals/units (Recommendation 8). If an individual maternity hospital/unit does not provide a particular carestream (e.g. specialised), clear guidance on the referral pathway for these women should be in place.

Recommendation 3
The hospital booking system should facilitate allocation to the different carestreams. The allocation for all hospital antenatal visits should be recorded in the healthcare record.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital SMTs.**

Practical guidance for implementation

- It is outlined in the BIA that there should be a standardised national healthcare record form developed by a CMM3 (Appendix 4). The CMM3 will also be tasked with supporting the integration of the risk assessment form in to the current hospital systems within the first year of appointment.
- The MN-CMS will need to be reviewed to ensure adherence to the guideline and updated if necessary.

Recommendation 4
The carestreams should be women-centred and team-based irrespective of risk stratification.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMTs, Doctors, Midwives, Anaesthesiologists and Allied Healthcare Professionals caring for pregnant women.**

Good practice points

- Risk can vary throughout pregnancy. As such, each woman should always have the support of multidisciplinary teams to provide the best possible outcome for her and her baby.
- Healthcare professionals caring for pregnant or postpartum women should be familiar with NCEC NCG No 5. Communication (Clinical Handover) in Maternity Services.

Recommendation 5
Appropriate continuity of antenatal carer should be promoted and, if the level of risk changes, women should be able to transition seamlessly between carestreams.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMTs, Doctors and Midwives.**

Good practice point

- Seamless transitions should occur for women moving from lower risk to higher risk categories and vice versa.

Recommendation 6
Women should be informed about their individual risks related to pregnancy. They should be given an opportunity to input into any decisions about risk assessment.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMTs, Doctors and Midwives.**

Good practice point

- Women should have informed choice and access to the appropriate level of care. A choice of birth setting should be facilitated where it is safe to do so.

Recommendation 7
Up-to-date local hospital-level clinical data should be available and used in assessing and communicating risk to pregnant women (for example, data from the Irish Maternity Indicator System).

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital SMT, Doctors and Midwives.**

Good practice point

- The Irish Maternity Indicator System (IMIS) is produced monthly within every maternity hospital/unit. The National Perinatal Epidemiology Centre (NPEC) produce annual reports and some of the larger maternity units produce annual clinical reports. All healthcare staff communicating risks to pregnant women should remain knowledgeable about data relating to their hospital outcomes.

Recommendation 8
Risk stratification in the maternity services should be consistent and aligned with national clinical guidelines.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMTs.**

Good practice points

- A communication system within hospitals/units/groups should be set up to keep healthcare staff up-to-date with new national clinical guidelines or information involving the same.
- A list of maternity clinical practice guidelines is provided in Appendix 10.
- The current NCEC National Clinical Guidelines that have a maternity component include No. 5. Communication (Clinical Handover) in Maternity Services and No. 6. Sepsis Management.

Recommendation 9
Implementation of carestreams in individual maternity units should take cognisance of local resources and, where appropriate, may need to be provided on a maternity network or national basis.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **Hospital and Hospital Group SMTs.**

Good practice points

- Medium risk is a new category in both national and international guidelines. When combined with the expected difficulty for smaller units and those with restricted resources to offer all three carestreams, it may be safer and more efficient to combine medium and high-risk categories. However, this may restrict women's choice of place of birth.
- The delivery of the carestreams will be individual for each hospital/unit and their group.

Recommendation 10
The implementation of risk stratification should be reviewed annually by the senior management team in each maternity hospital/unit.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **NWIHP**

Recommendation 11
National guidance on risk stratification should be reviewed annually by the NWIHP based on recent clinical developments and national audits.

Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **NWIHP**

Recommendation 12
All maternity hospitals/units will provide education on this guideline.

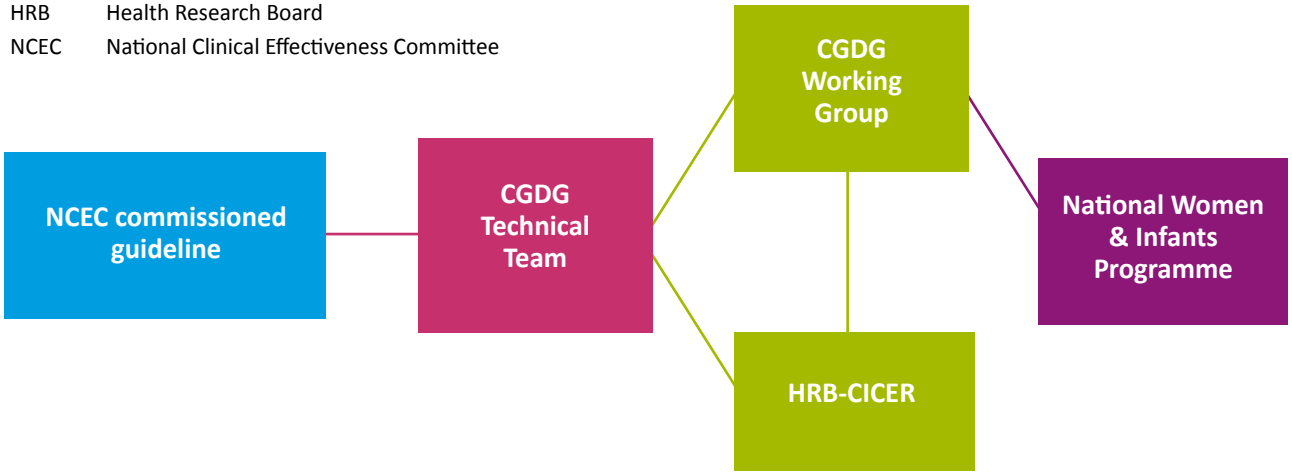
Level of evidence: **No included studies**
Strength of recommendation: **Strong**
Responsible for implementation: **NWIHP**

4 Appendices

Appendix 1: Childbirth GDG terms of reference

Governance Overview & Terms of Reference
Childbirth Guideline Development Group (CGDG)

CICER	Collaboration in Ireland for Clinical Effectiveness Reviews
CGDG	Childbirth Guideline Development Group
HRB	Health Research Board
NCEC	National Clinical Effectiveness Committee



CGDG Technical Team Membership

Chair	**Professor Michael Turner**
Project Manager	**Dr Karen Power**
Guideline co-ordinator	**Ms Caroline Plascott**
HRB-CICER representatives	**Ms Shelley O'Neill, Dr Barbara Clyne**
Quality Assurance	**Dr Léan McMahon**

CGDG Technical Team Terms of Reference

1. Appoint membership to the CGDG Working Group.
2. Approve Terms of Reference and Governance structures for the project.
3. Work consistently to facilitate collaboration and communications between NCEC, HRB-CICER and CGDG.
4. Review and approve the final output document prepared by the working group.
5. Get endorsement from HSE Corporate as per NCEC guidelines.
6. Keep the CGDG working group within agreed timeframe to the best ability.

CGDG Working Group Terms of Reference

1. Develop a National Clinical Guideline on “Clinical Risk in Pregnancy” using evidence-based approach where possible.
2. Review and revise other NCEC commissioned childbirth related guidelines where appropriate.
3. Use the findings from the literature search and economic assessment provided by HRB-CICER to develop and agree recommendations appropriately.
4. Provide feedback on relevant areas of expertise when required.
5. Work within required time frame of two years.

Quorum

The CGDG Working Group must have at least one third of its membership present in person or via teleconference (exclusive of the Project Team members).

Meetings

Meetings will take place bimonthly in Dublin. Teleconferencing facilities will be provided and notification of attendance by teleconference and apologies should be sent prior to the meeting.

Conflict of Interest

Each participant on the group will be asked to sign a form declaring any conflict of interest. Any conflict of interest that arises during the term of membership must be disclosed as soon as possible.

Meeting documentation

Meeting minutes will be taken by the project manager or nominated person and will be sent alongside the agenda and any other supporting documentation via email in advance of the next meeting.

Appendix 2: Search strategy and results

Report completed by HRB-CICER. For full details please see Annex 1 *"Systematic review of clinical guidelines on risk stratification during pregnancy"* (https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines/).

The following outlines the search strategy that was used to identify clinical guidelines that include within their scope stratifying a woman's risk during pregnancy, including the first hospital antenatal appointment and all subsequent antenatal appointments. A conservative approach was adopted to capture as many relevant clinical guidelines as possible. The processes outlined in the National Clinical Effectiveness Committee guideline developer's manual were followed and are described below (Department of Health, 2019).

Eligibility criteria included clinical guidelines published from 2007 onwards, available in the English language and that were National or regional clinical guidelines, covering the period from first hospital antenatal appointment up to intrapartum. Citations returned from searches were screened by one reviewer, first by title, then by abstract to eliminate clearly irrelevant documents. Selected full text articles were reviewed against the full inclusion and exclusion criteria (see Table A1).

Table A1. Inclusion and exclusion criteria

Inclusion	Exclusion
Clinical or Regional guidelines (based on a systematic review of evidence)	Consensus statements, consensus development, decision making or decision aid, systematic reviews, clinical trials, editorials and letters, and documents that are available in abstract only
First hospital antenatal appointment and antenatal period	Intrapartum and postpartum period
Published between 2007 and June 2017	Focuses on low resource settings
Available in English	Management and Treatment options

The search strategy was adapted from that used by WHO 2016 (WHO Steering Group, 2016). Searches were performed within PubMed and Embase databases on the 6 June 2017. Search strings included free text, MeSH terms and filters specific for clinical guidelines (Table A2, overleaf).

Table A2. Search strings

Database	Search string	Citations	Date of last search
PubMed	Search ("Pregnancy"[MeSH] OR "Hospitals, Maternity"[MeSH] OR "Maternal Health Services"[MeSH] OR "Gynecology"[MeSH] OR "Obstetrics"[MeSH] OR "prenatal care"[MeSH Terms] OR "antenatal care"[Text Word]) Filters: Guideline; published in the last 10 years; Humans; English Sort by: [pubsolr12]	857	09/08/2017
Embase	('prenatal care'/exp OR 'ante natal care':ti,ab OR 'antenatal care':ti,ab OR 'antenatal control':ti,ab OR 'prenatal care':ti,ab OR 'maternal care'/exp OR 'maternal care' OR 'pregnancy'/exp) AND 'practice guideline'/de AND (2007:py OR 2008:py OR 2009:py OR 2010:py OR 2011:py OR 2012:py OR 2013:py OR 2014:py OR 2015:py OR 2016:py OR 2017:py) AND [female]/lim AND [embase]/lim NOT [medline]/lim	811	09/08/2017

Grey literature sources were searched from 6 June 2017 to 20 June 2017 and periodically again until 1 September 2017. Grey literature sources included guideline repositories, guideline developer websites and websites of national ministries of health. The full list of grey literature sources is provided below. In addition, GDG members identified clinical guidelines from their national and international links.

The following sources were included within the search.

Guideline repositories:

- NHS Evidence database (UK)
- US National Clearing House
- eGuidelines (UK)
- United States National Guideline Clearinghouse
- Guidelines International Network
- NLH (National Library of Guidelines UK)

National health ministry websites and other publishers of guidelines:

- Australian National Health and Medical Research Council Clinical Practice Guidelines
- Canadian Medical Association InfoBase of Clinical Practice Guidelines
- New Zealand Guidelines Group
- NICE (The National Institute for Health and Care Excellence, UK)
- NCEC (National Clinical Effectiveness Committee, Ireland)
- Institute for Healthcare Improvement (USA)
- Scottish Intercollegiate Guidelines Network
- Japan Council for Quality Health
- CMA Infobase (Canadian Medical Association)
- ANHMRC (Australian National Health and Medical Research Council)
- Danish Secretariat for Clinical Guidelines
- ACOG (The American Congress of Obstetricians and Gynecologists)
- JOGC (Journal of Obstetrics and Gynaecology Canada)
- Singapore Ministry of Health
- Socialstyrelsen (Health and Medical Care and Social Services, Sweden)
- Finnish Medical Society Duodecim
- Danish Health Authority
- Geneva Foundation for Medical Education and Research
- Belgian Health Care Knowledge Centre
- AETSA (Andalusian Agency for Health Technology Assessment)
- Haute Autorité de santé
- German Institute of Medical Documentation and Information

Data collection and analysis

Citations were screened by one reviewer to eliminate clearly irrelevant studies. The remaining citations were reviewed per the inclusion criteria.

Results

From 1,608 unique identified citations, seven clinical guidelines (Australian Government Department of Health and Ageing, 2012, 2014; Guidelines and Audit Implementation Network (GAIN), 2016; Gyselaers et al., 2015; NICE National Institute for Health and Care Excellence, 2008; Queensland Health, 2016; WHO Steering Group, 2016; Working Group of the Clinical Practice Guidelines for Care in Pregnancy and Puerperium, 2014) met the inclusion and exclusion criteria (Table A1) and are included within the review (Table 3). Four of the clinical guidelines were from European settings: Northern Ireland (Guidelines and Audit Implementation Network (GAIN), 2016), England and Wales (NICE National Institute for Health and Care Excellence, 2008), Spain (AETSA and QCG) (Working Group of the Clinical Practice Guidelines for Care in Pregnancy and Puerperium, 2014) and Belgium (KCE) (Gyselaers et al., 2015); two from Australia (AHMAC) (Australian Government Department of Health and Ageing, 2014, 2012; Queensland Health, 2016) and one from an international public health agency (WHO Steering Group, 2016).

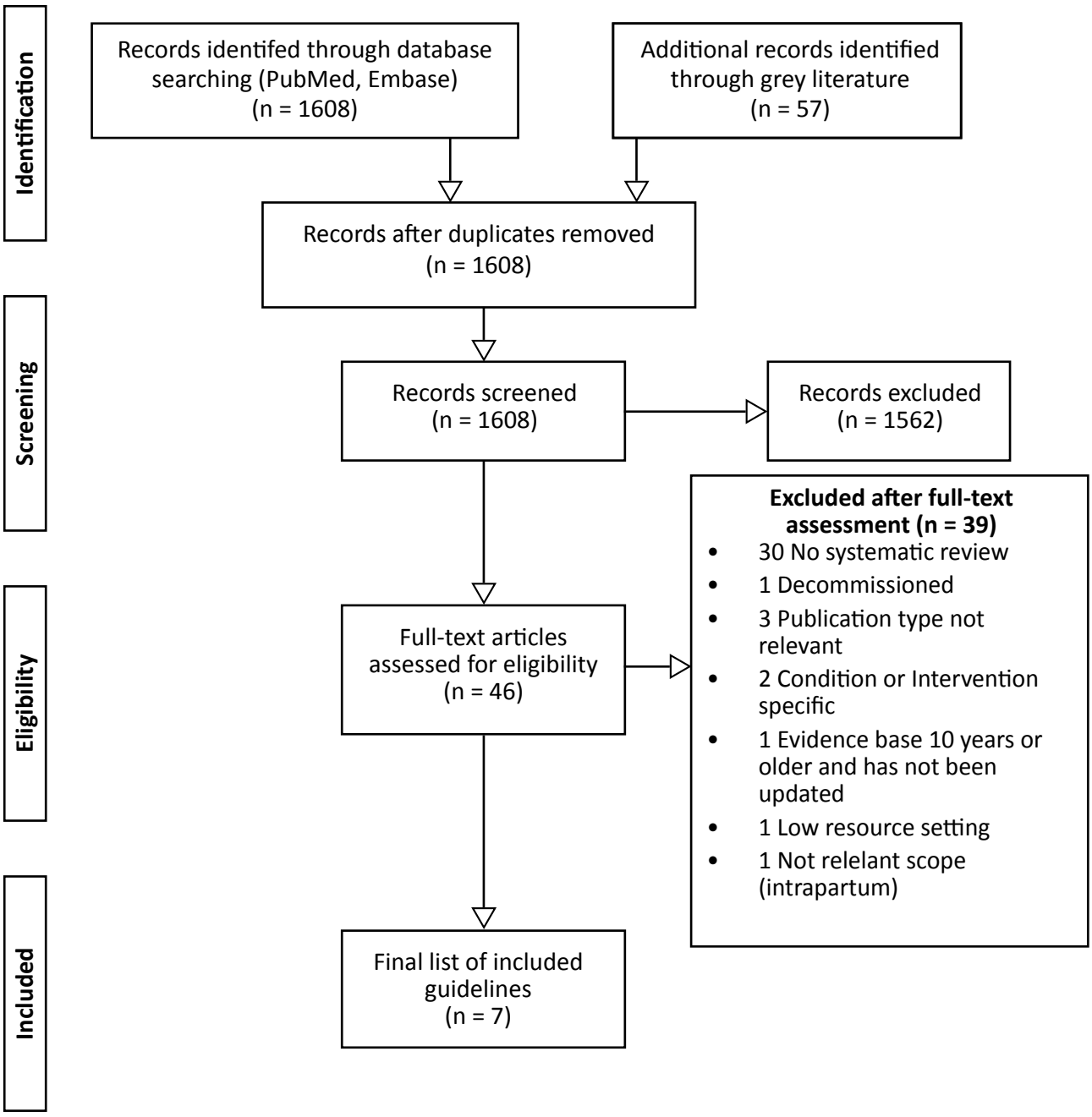
The included clinical guidelines were examined in the context of rigour, comprehensiveness and transparency of development using AGREE II. A full summary of AGREE ll scores for each of the included clinical guidelines is presented in Table A3.

Table A3. AGREE ll scaled domain and overall assessment scores

Clinical Guideline	Domain 1 Scope & Purpose	Domain 2 Stakeholder Involvement	Domain 3 Rigour of Development	Domain 4 Clarity of Presentation	Domain 5 Applicability	Domain 6 Editorial Independence	Overall Guideline Assessment
AHMAC 2012[9] and 2014[11]	89%	100%	93%	92%	94%	100%	100%
KCE 2015[7]	100%	86%	98%	97%	81%	92%	100%
NICE 2008[10]	89%	89%	95%	100%	90%	63%	92%
GAIN 2016[6]	75%	86%	53%	86%	33%	79%	67%
QCG 2016[5]	83%	83%	48%	100%	52%	67%	75%
AETSA 2014[7]	97%	89%	74%	86%	54%	67%	75%
WHO 2016[4]	100%	100%	96%	100%	83%	100%	100%

Four clinical guidelines (AHMAC 2012 and 2014, KCE 2015, NICE 2008 and WHO 2016) emerged as being of very high quality. In particular, these four offered the availability of precise clinical questions, comprehensive search strategies and graded evidence tables. These are the required components when considering using an existing clinical guideline for the adaption process. Two of these four clinical guidelines (KCE 2015, WHO 2016) were informed by evidence bases gathered in the last three years. The other guidelines were in the process of being either reviewed or updated.

Figure A1. PRISMA Flow chart of included and excluded studies for literature review



Appendix 3: Consultation report

As part of the consultation process, the draft guideline was circulated for review to this list of groups, committees and organisations. The review request was circulated on the 1st March 2019 with a deadline of 29th March 2019.

Clinical leaders and healthcare managers	Masters/Clinical Directors for all 19 maternity hospitals/units Directors of Midwifery for all 19 maternity hospital/units Clinical Directors of the six hospital groups Chief DON/M's of the six hospital groups
Patient advocates and advocacy groups	Ms Brigid Doherty Dr Krysia Lynch SAGE Advocacy Vasa Praevia Ireland
International Review	1. Dr Patrick O'Brien, Consultant Obstetrician, University College London Hospital, UK 2. Ms Shona Hamilton, Consultant Midwife, Northern Health and Social Care Trust

Respondents included:

Rotunda Hospital, Our Lady of Lourdes Hospital Drogheda, University Maternity Hospital Limerick, National Maternity Hospital, University Hospital Galway, Cork University Maternity Hospital alongside University College Cork, Ms Judith Fleming Centre for Midwifery Education Dublin, Ms Brigid Doherty, SAGE Advocacy, Vasa Praevia Ireland and the two international reviewers.

Most of the feedback included text/language corrections and was amended as appropriate by the project manager. Some of the feedback included suggestions outside the scope of the guideline. All other feedback was reviewed, discussed by the CGDG and amended as appropriate. Amendments included appropriate cross referencing, clarification on wording of the risk factors and recommendations.

Appendix 4: Economic assessment

Part A: Economic evidence summary

Report completed by HRB-CICER. For full details please see Annex C "Risk in pregnancy - systematic review of economic literature" (https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines/).

Introduction

A systematic review of existing clinical guidelines that included stratification of risk in pregnancy was performed by HRB-CICER. As no high-quality guideline with a three-level risk stratification (as described in the National Maternity Strategy) was identified, the GDG decided that adapting a single or a number of existing high-quality clinical guidelines using the ADAPTE process (The ADAPTE Collaboration, 2009) was the preferred approach. Risk factors were extracted from three high-quality guidelines, identified through the systematic review and assessed according to the AGREE ll instrument. A three-round modified Delphi method was used to establish consensus on which of these risk factors should be included in the current guideline. Using this approach, the multidisciplinary GDG reached consensus on the risk factors to be used to stratify women according to risk within the Irish maternity services.

A systematic review of the cost-effectiveness of using a formal risk stratification system during the antenatal period was performed by HRB-CICER to inform the development of this NCG.

Methods

Data sources: A comprehensive search of PubMed, EMBASE, and the Cochrane Library (which includes the Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, the Health Technology Assessment Database and the National Health Service Economic Evaluation Database) was conducted in October 2018 using combinations of keywords and medical subject headings (MeSH) terms. The economic search was conducted by combining a generic clinical search to each database and applying the relevant economic filter. The search terms for both are presented below (Table A4 and A5). Studies that were published before 2008 were excluded (a 10-year time limit was applied to the search to ensure identified economic literature was applicable to current practice).

Selection criteria: Citations were screened by two reviewers to eliminate clearly irrelevant studies. Two people independently reviewed the remaining citations per the inclusion criteria, with any disagreements being resolved by discussion.

Health economic studies considered included economic evaluations (cost-effectiveness analysis, cost-utility analysis, cost-minimisation analysis and cost-benefit analysis) and comparative resource use studies evaluating any comprehensive system of stratification or identification of a woman's risk during the antenatal period (first hospital antenatal visit and during all subsequent antenatal appointments).

Economic literature review results

The search strategy identified 4,015 potentially relevant references through searching the listed databases and grey literature. After the exclusion of duplicates, 3,619 records were screened. All 3,619 records were excluded based on a review of the titles and abstracts (see Figure A1). A number of economic evaluations related to clinical outcomes and costs of screening for specific risk factors (for example, individual medical factors such as hypertension, risk relating specifically to previous obstetric complications or psychosocial problems) were identified; however, no studies focused on a comprehensive system of stratification of a woman's risk during the antenatal period.

Conclusion

There is a lack of economic evaluations to establish the cost-effectiveness and resource implications related to the implementation of stratification of a woman's risk during the antenatal period. There is a need for further research evaluating both the clinical effectiveness and cost-effectiveness of implementing such a system to underpin development of the guideline recommendations.

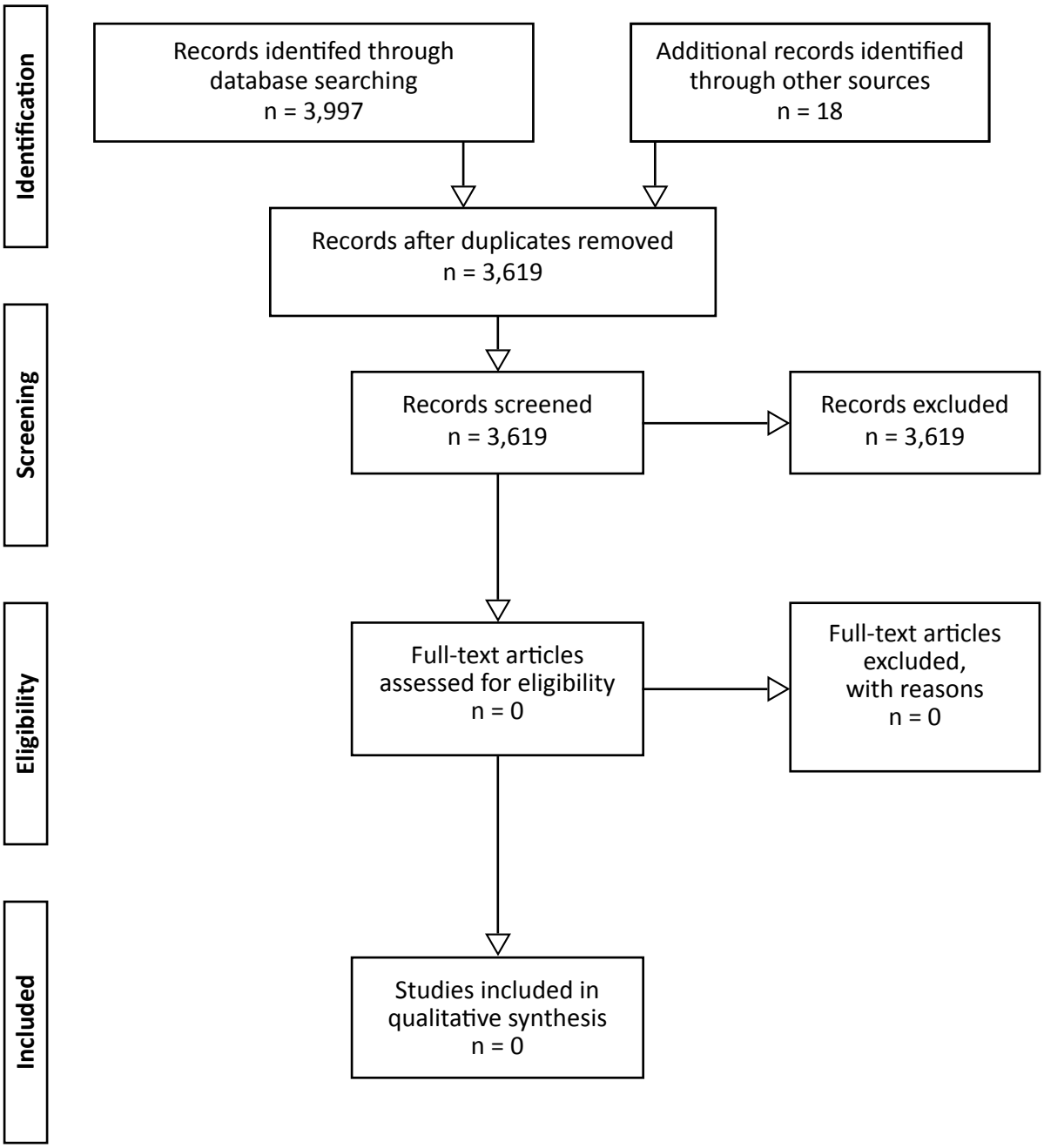
Table A4. Generic clinical search terms

PubMed	
1.	Pregnancy
2.	Hospitals, Maternity"[MeSH]
3.	"Maternal Health Services"[MeSH]
4.	"Gynecology"[MeSH]
5.	"Obstetrics"[MeSH]
6.	"prenatal care"[MeSH Terms]
7.	"antenatal care"
8.	OR /1-7
9.	risk stratification
10.	risk assessment
11.	risk management
12.	OR /10-11
13.	8 AND 12
14.	13 AND economic filter (described below)
15.	Limits published in the last 10 years, humans

Table A5. Economic filter

PubMed	
1.	Economics/
2.	“costs and cost analysis”/
3.	Cost allocation/
4.	Cost-benefit analysis/
5.	Cost control/
6.	Cost savings/
7.	Cost of illness/
8.	Cost sharing/
9.	“deductibles and coinsurance”/
10.	Medical savings accounts/
11.	Health care costs/
12.	Direct service costs/
13.	Drug costs/
14.	Employer health costs/
15.	Hospital costs/
16.	Health expenditures/
17.	Capital expenditures/
18.	Value of life/
19.	Exp economics, hospital/
20.	Exp economics, medical/
21.	Economics, nursing/
22.	Economics, pharmaceutical/
23.	Exp “fees and charges”/
24.	Exp budgets/
25.	(low N1 cost).mp.
26.	(high N1 cost).mp.
27.	(healthcare N1 cost*).mp.
28.	(fiscal or funding or financial or finance).tw.
29.	(cost N1 estimate*)
30.	(cost N1 variable)
31.	(unit N1 cost*)
32.	(economic* or pharmacoeconomic* or price* or pricing).tw.
33.	Or/1-32

Figure A2. Flow chart of included and excluded studies for economic literature review



Part B: Budget impact analysis summary

Report completed by HRB-CICER. For full details please see Annex D "Budget impact analysis – Clinical Risk in Pregnancy" (https://www.gov.ie/en/collection/c9fa9a-national-clinical-guidelines/).

Introduction

The purpose of this analysis was to estimate the likely ongoing resource and financial consequences for the Irish healthcare system of the clinical recommendations outlined in the Stratification of Clinical Risk in Pregnancy guideline.

The scope of the guideline dictates what was included in this analysis. The focus of the Stratification of Clinical Risk in Pregnancy guideline is solely on the implementation of a standardised risk assessment that will be used in all maternity hospitals and units in Ireland to identify women who are at increased risk of experiencing complications during pregnancy or postpartum that may affect them or their baby. The specification of the different carestreams that should be available to women based on their risk status is not within the scope of this clinical guideline.

Methods

In line with national guidelines, costs and benefits were assessed from the perspective of the publicly-funded health and social care system, the Health Service Executive (HSE). As such, only direct medical costs were included. Indirect costs such as decreased productivity associated with morbidity, treatment or death, or out-of-pocket expenses incurred by patients, for example travel costs, were excluded from the analysis.

In accordance with national guidelines, the annual budget impact was estimated over a five year time horizon. No discounting was applied to account for temporal differences in when costs were incurred over the five year time horizon.

Estimation of costs was carried out using a range of methods as appropriate to each item. Where possible, these estimates were informed by the experience of the CGDG in implementing previous guidelines in maternity care. Where there was no clear precedent, resource use was estimated by combining available empirical data with expert opinion from within the CGDG and relevant external groups. Specific data used to inform resource use and valuation estimates are described separately for each cost item below. All prices included VAT, where applicable.

The unit of analysis is the entire maternity service comprising 19 separate maternity hospitals and units in Ireland. The target population for this guideline is all pregnant women. The annual number of births per year has been falling in Ireland since reaching a peak of over 75,000 in 2009, to a current level of around 63,000 per annum. This trend is expected to continue in the coming years. The projected number of births was adjusted using data on pregnancies that do not survive to full term to estimate the total number of first hospital antenatal appointments in each year.

Introduction of a standard risk assessment is associated with a number of changes to standard practice that have resource implications. These include:

1. A requirement for all staff who need to be aware of and understand the new risk assessment procedure to be informed about what it is and how the results of the risk assessment should be interpreted and acted upon. This includes midwives, senior house offices, registrars, and consultant obstetricians.
2. Electronic patient records and software interfaces will need to be altered to enable recording of additional data pertaining to risk assessment and the overall risk stratification of individuals. This will also need the ability to be updated over the course of the pregnancy and capture information about changes in carestream due to changes in a woman's risk profile, or personal preferences. Reporting and auditing functions will also be required as an aid to demonstrating that this clinical guideline is being implemented fully and appropriately.
3. With or without the aid of IT support systems, there is a requirement for audit and quality assurance processes to be in place to ensure that good clinical governance of antenatal risk assessment is maintained.
4. It is assumed that the new risk assessment will not result in significant changes to first hospital antenatal appointment times, and so will not displace any current activity. The impact of this assumption was tested using sensitivity analysis to examine the likely costs associated with longer or shorter antenatal appointments following the introduction of this guideline.

In addition to the implications that the guideline will have for the provision of care, there are also once-off costs associated with initial introduction of the guideline at a knowledge sharing and information dissemination day that will be hosted by the National Women and Infants' Health Programme (NWIHP) to publicise the introduction of the guideline. An assessment of the costs of this event was also included in the analysis.

The assumptions used when conducting the analysis were as follows:

- The length of time needed for the first hospital antenatal appointment will not change significantly as a result of the introduction of a standardised risk assessment, so there will be no change in the number of appointments that are scheduled per day. A sensitivity analysis was carried out to assess the potential impact of changes in risk assessment resulting in longer or shorter appointments. This was modelled using a best-case scenario of standardised risk assessment resulting in average consultation times being five minutes shorter, and a worst-case scenario where it added ten minutes to each consultation (see Table 3.4 in the full BIA for more details).
- No formal training of staff will be required as the standardised risk assessment will replace similar non standardised assessment procedures that are already in place in each maternity hospital Communication of any changes associated with the new standardised assessment will be carried out within the usual staff notification and training procedures already in place within each maternity unit. It is assumed that since this will be conducted during time that is already reserved for routine staff training, there will be no additional cost. We also assume that any requirements for printing of paper copies of the risk assessment form will be covered through existing printing facilities in each maternity unit.
- Audit and monitoring of the new system will leverage existing processes in place in each hospital for existing risk assessment procedures, so no additional activity is required for this. Updates to IT systems to enable risk assessment and recording to be incorporated in the electronic patient record system are evaluated separately.

A limitation of this budget impact analysis is that it does not estimate the incremental costs associated with the implementation of the carestreams, or the cost savings that may accrue from improved management of women at medium or high risk, or from potentially treating a greater proportion of women in less resource intensive settings.

Results

Activities related to the introduction of the guideline that are associated with an incremental cost to the HSE, and which are included in this BIA, are as follows:

- Cost of an Information day incorporating a formal launch of the guideline Stratification of Clinical Risk in Pregnancy (see Table A6.)
- Modification of the electronic patient record to allow for the conduct and recording of the standardised risk assessment, and to manage the ongoing assignment of women to appropriate carestreams over the course of the pregnancy
- Cost of developing and integrating risk assessment into existing structures and processes (see Table A7.)

Table A6. Cost of Information day incorporating a formal guideline launch

Item	Description	Cost
Venue	Room hire	€1,000
Catering	Break and lunch for c.90 people	€4,000
Registration	Printed materials	€500
Invited speakers	Travel and subsistence for one international expert speaker	€500
	Total cost	€6,000
	Year(s) incurred	1

The cost of updating the Maternal & Newborn Clinical Management System (MN-CMS) to facilitate the recording of risk assessment information and the assignment of women to carestreams as appropriate over the course of the pregnancy was discussed with the HSE's MN-CMS National Project Team. The MN-CMS is currently live in four maternity hospitals (Rotunda Hospital, Cork University Maternity Hospital, University Hospital Kerry and the National Maternity Hospital), with deployment to the remaining 15 hospitals and units being carried out on a phased basis.

A precise specification of the required changes to the system is unavailable at present, so it is not possible to obtain detailed quotes on the costs of these updates from the supplier of the system. These costs will be determined by the complexity of the required work and the extent to which additional functionality is needed to ensure that this information is documented and recorded correctly, and can be updated continuously over the course of the pregnancy as required. Indeed, this is similar to any of the maternity units currently using an IT system for a woman's first hospital antenatal appointment.

The costs of implementation are likely to vary between maternity hospitals and units because there are presently wide variations in customary practices, variations in IT support and increasing centralisation of high-risk pregnancies.

It is anticipated that the ongoing process of developing the risk assessment form and integrating it into existing processes in a way that is safe, effective and efficient will require one full time member of staff (1 WTE midwife, CNM3 scale) over the first year of implementation of the guideline (Table A7).

Table A7. Cost of developing and integrating risk assessment into existing structures and processes

Item	Description	Cost
IT	Implementing standardised risk assessment in MN-CMS	No estimate available
Staff	1 WTE midwife (CNM3 scale) to support and manage the development and integration of standardised risk assessment in the first year	
	Midpoint of CNM3 scale	€60,944
	Employers PRSI @ 10.95%	€6,673
	Pension costs @ 4%	€2,438
	Overhead cost @ 25%	€15,236
	Total staff cost	€85,291
	Year(s) incurred	1

A sensitivity analysis was carried out to estimate the impact of the standardised risk assessment resulting in longer or shorter antenatal appointments.

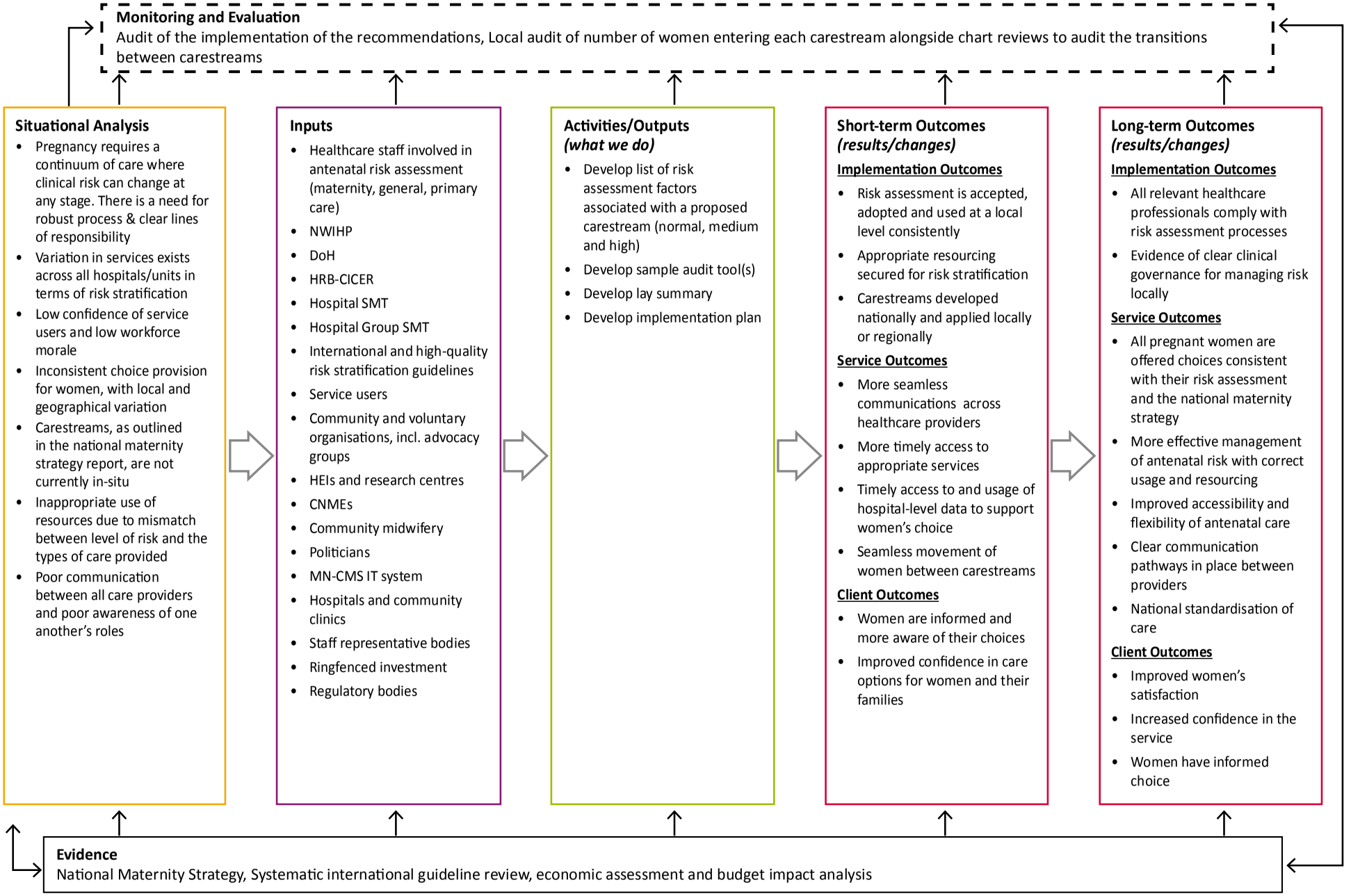
The rationale for this sensitivity analysis is based on the possibility that implementing a standardised risk assessment form may affect the average duration of the first hospital antenatal appointment. This is available in the full Budget Impact Analysis.

Conclusion

The total direct costs to the HSE of implementation of the Stratification of Clinical Risk in Pregnancy guideline is approximately €90,000, plus any additional costs associated with changing the electronic patient record to incorporate standardised risk assessment and information on carestreams. These costs are unknown at present, pending a full specification of the changes being drawn up by the MN-CMS National Project Team, and discussed with the third-party IT provider. It is hoped that these changes will be covered under the existing support and maintenance contract, at no additional costs to the HSE, but this cannot be confirmed until a detailed description of the required changes has been agreed.

If there is a cost associated with implementing these changes in the electronic patient record it is likely to be incurred in year one only, as are the other costs items (additional staff costs and information day). No significant costs are anticipated in years two to five.

Appendix 5: Logic model and implementation plan



Guideline recommendation or number(s)	Implementation enablers/ barriers/gaps	Action/intervention/task to implement recommendation	Lead responsibility for delivery of the action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
1. All women presenting to a maternity hospital/unit for antenatal care should have their pregnancy risks assessed at the first visit. The level of risk should be kept under review before, during and after delivery. 2. All maternity hospitals/units should have carestreams in place depending on the stratification of clinical risk. Information on stratification should be provided locally to all disciplines providing clinical care. 3. The hospital booking system should facilitate allocation to the different carestreams. The allocation for all hospital antenatal visits should be recorded in the healthcare record.	**Enablers** • Good local leadership • Effective multidisciplinary team work • Effective communication • Local training • IT-resources • Regular review and evaluation, with the results informing quality improvement plan • Available carestreams • Rotation of staff **Barriers** • Lack of local leadership • Lack of clear, standardised communication • Lack of audit and evaluation supports, e.g. Information and communications technology (ICT) and other resources • Lack of governance within the organisation • Understaffing • MN-CMS update • Staff confidence • Fear of litigation • Increased time for first hospital antetnatal appointment	Dissemination of the guideline and the risk stratification list through the senior management team (Master or CEO, Clinical Director and Director of Midwifery/Nursing) for all 19 maternity hospitals/units	Hospital Senior Management Team	✓			**Outcome** • All hospitals have adopted standardised antenatal risk assessment strategy • Appropriate local carestreams available in all Hospital Group regions related to risk category • Appropriate care plan including referral to specialist care if required **Verification** • Local and national monitoring (Appendix 7) • Local hospital policies and procedures on communication and referral between carestreams
		Local management team meetings to align the risk stratification and carestreams with local policies	Hospital Group, Senior management team (CEO, CD, DoN/M)		✓		
		Development of documentation describing how risk stratification works at the local level in line with this guideline	Hospital Group, Senior management team (CEO, CD, DoN/M)		✓		
		Delivery of an education workshop	NWIHP	✓			
		Training and education with staff on use of the risk assessment form and guideline	Hospital Senior Management Teams			✓	
		Redevelopment of the national healthcare record which includes the creation of a standardised risk assessment form.	New Midwife (CNM3) post		✓		

Guideline recommendation or number(s)	Implementation enablers/ barriers/gaps	Action/intervention/task to implement recommendation	Lead responsibility for delivery of the action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
4. The carestreams should be women-centred and team-based irrespective of risk stratification. 5. Appropriate continuity of antenatal carer should be promoted and, if the level of risk changes, women should be able to transition seamlessly between carestreams.	**Enablers** • Effective communication **Barriers** • Inadequate staffing levels	Development of local education and/ or internal policy	Hospital Senior Management Teams		✓		**Recommendation 4:** **Outcome** • Seamless transition between carestreams when appropriate • Improved women's satisfaction **Verification** • Improved results from the maternity patient survey (Appendix 6) • Local and national monitoring • Clear communication policies • Staff feedback and discussion **Recommendation 5:** **Outcome** • Evidence of appropriate transitions between carestreams **Verification** • Local and national monitoring • Improved results from the maternity patient survey (Appendix 6) • Staff feedback and discussion
		Deliver local education and training to staff involved in assessing and assigning clinical risk in pregnancy (midwives, nurses, obstetricians, anaesthesiologists) as appropriate	Hospital Senior Management Teams		✓		
		Allocation or change to a woman's carestream should be communicated to the woman's GP if on a combined care scheme	Woman's care team		✓		
		Development of local communication plan to women about risk stratification	Hospital Senior Management Teams		✓		

Guideline recommendation or number(s)	Implementation enablers/ barriers/gaps	Action/intervention/task to implement recommendation	Lead responsibility for delivery of the action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
6. Women should be informed about their individual risks related to pregnancy. They should be given an opportunity to input into decisions following risk assessment and assignment to a carestream.	**Enablers** • Educated workforce • Effective communication • Risk assessment form that supports decision making **Barriers** • Lack of education • Lack of awareness of the stratification system • Ineffective communication	Staff involved in assessing clinical risk in pregnancy (midwives, nurses, doctors, anaesthesiologists) provided with access to up-to-date information on local hospital maternity data relating to processes and outcomes. Development of a local decision form outlining the carestream and appropriate data about the individual unit to inform choice	Hospital Senior Management Team Hospital Senior Management Team		✓ ✓		**Outcome** • Improved woman/patient satisfaction **Verification** • Evidence of womans' choice being considered evident through chart review
7. Up-to-date hospital-level clinical and performance data should be available to and used in assessing and communicating risk to pregnant women (for example, the Irish Maternity Indicator System)	**Enablers** • Robust, timely and accurate data • SMT to review IMIS data monthly (or more frequently) **Barriers** • Lack of QA officers • Difficulties sourcing data • Infrequent data monitoring	Review of risk stratification carestreams locally in conjunction with the Hospitals IMIS report Work with QA officers to communicate IMIS data between SMT and the hospital staff	Hospital Senior Management Teams Hospital Senior Management Teams			✓ ✓	**Outcome** • Local hospital-level data available and communicated to all healthcare staff **Verification** • Local and national monitoring
8. Risk stratification in the maternity services should be consistent and aligned with national clinical guidelines.	**Enablers** • Access to up-to-date guidelines **Barriers** • Unavailable or inaccessible guidelines • Guidelines not up to date	Regular local management team meetings	Hospital Senior Management Teams			✓	**Outcome** • All national clinical guidelines implemented within the hospital **Verification** • KPI's associated with the national clinical guidelines are met

Guideline recommendation or number(s)	Implementation enablers/ barriers/gaps	Action/intervention/task to implement recommendation	Lead responsibility for delivery of the action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
9. Implementation of carestreams in individual maternity units should take cognisance of local resources and, where appropriate, may need to be provided on a maternity network or national basis.	**Enablers** • Effective communication • Effective team work **Barriers** • Lack of effective hospital or hospital group leadership	Ensure robust processes and procedures are in place for each unit Review of local resources by the hospital and group SMT	Hospital Senior Management Team Hospital Group Management Team, Hospital Senior Management Team		✓		**Outcome** • Coordinated availability of carestreams across the maternity network **Verification** • Review of local resources by the hospital and group SMT
10. The implementation of risk stratification should be reviewed annually by the senior management team in each maternity hospital/unit.	**Enablers** • Senior nominated staff with reviewing experience **Barriers** • Lack of accountability	Annual review of the risk stratification with relevant/ nominated leads	NWIHP			✓	**Outcome/Verification** • Annual hospital or hospital group review (as appropriate)
11. National guidance on risk stratification should be reviewed annually by the NWIHP based on recent clinical developments and national reviews.	**Enablers** • Effective leadership **Barriers** • Lack of resources	Annual review of risk stratification through the literature	NWIHP			✓	**Outcome/Verification** • Annual review on clinical risk in pregnancy for antenatal care
12. All maternity hospitals will provide education on this guideline	**Enablers** • National guidelines **Barriers** • Lack of dedicated staff or time for education	Education is delivered to all healthcare professionals involved in risk assessing a pregnant woman	Hospital Senior Management Team		✓		**Outcome/Verification** • All relevant staff members have received education on this guideline

Guideline recommendation or number(s)	Implementation enablers/ barriers/gaps	Action/intervention/task to implement recommendation	Lead responsibility for delivery of the action	Timeframe for completion			Expected outcome and verification
				Year 1	Year 2	Year 3	
All recommendations	**Enablers** • IT-resources **Barriers** • Lack of standardised records • MN-CMS update	Liaise with MN-CMS team to update IT system in line with guideline	NWIHP New midwife (CNM3) post	✓			**Outcome** • Accurate IT system in line with the national standard **Verification** • Updated MN-CMS
All recommendations	**Enablers** • IT-resources **Barriers** • Staff overwhelmed with volume of guidelines	Development and delivery of dissemination and communication plan	NWIHP	✓			**Outcome** • Improved knowledge and awareness of guideline recommendations • Women are more informed about their care choices **Verification** • Production of dissemination and communication plan

Dissemination and communication plan:

This guideline, including the risk stratification list will be disseminated to the;

- Six hospital group clinical directors and DOM/Ns,
- CEOs, DOMs and clinical directors or masters of the 19 maternity units,
- NWIHP, Department of Health, and other interested parties and professional bodies

Implementation tools:

- The risk stratification list is available in appendix 9
- A list of guidelines associated risk in pregnancy is available in appendix 10
- Audit guidance is available in appendix 7
- A lay summary is available in appendix 6 useful for communication to women
- An education day will be organised by NWIHP
- The NWIHP website and the NCEC will host links to the guideline and the associated supportive material

Implementation team:

The National Women and Infants Health Programme was part of the guideline development team and will ultimately oversee the implementation of the risk stratification and associated carestreams. Annual review of the service will be required as per Recommendations 8 and 9. The Master or Chief Executive Officer (CEO), Director of Midwifery/Nursing and Clinical Director are responsible for the local implementation. This local implementation may however, work best within a framework developed on a hospital group level. This will be dependent on the local resources. In this case the CEO, DON/M and Clinical director of the hospital group will be accountable for implementation.

Appendix 6: Supporting tools

This guideline can be accessed online within the clinical guideline section of the National Women and Infants Health Programme website (http://tiny.cc/NWIHP)

Lay summary

Background
In February 2016 the Department of Health published Ireland's first National Maternity Strategy Report. This report recommended customising maternity care according to a woman's clinical risk into three carestreams, normal, medium and high. A woman at normal risk is one who does not have identified risk factors, known pre-existing conditions, or complications requiring ongoing medical surveillance. Medium and high risk carestreams are assigned based on the level of specialisation required.

What does this mean for me?
Clinical risk will be assessed by asking you questions about your lifestyle and your medical and pregnancy history. A midwife or obstetrician will carry out this assessment at your first hospital antenatal appointment and will discuss the best carestream for you and your baby. The carestream you are assigned to may be changed throughout the antenatal period if your level of risk changes. Your healthcare team will provide you with the information you need tailored to your individual circumstances. The assignment of risk allows midwives and obstetricians to best manage your pregnancy care and to ensure a safe pregnancy and delivery of your baby.

What do I need to do?
It is important to attend your first hospital antenatal appointment as early as possible and tell your midwife or doctor about any conditions that may affect you or your baby. If you cannot attend for a scheduled appointment, please phone the hospital to reschedule it for soon afterwards. It is also important that all women, whatever their level of risk, aim to maintain a healthy lifestyle.

References:
Healthy Ireland, A framework for improved health and wellbeing 2013-2025 (available at https://health.gov.ie/wp-content/uploads/2014/03/HealthyIrelandBrochureWA2.pdf)

Irish Nutrition and Diabetic Institute (INDI), "Healthy eating during pregnancy" (https://www.indi.ie/images/Healthy_Eating_During_pregnancy_fact_sheet_Dec_2015_PDF.pdf)

The National Maternity Experience Survey

The National Maternity Experience Survey offers women the opportunity to share their experiences of Ireland's maternity services. The aim of the survey is to learn from the experiences of women to improve the safety and quality of the care that they and their baby receive.

The National Maternity Experience Survey is part of the National Care Experience Programme, which seeks to improve the quality of health and social care services in Ireland by asking people about their experiences of care and acting on their feedback. The National Care Experience Programme is a joint initiative by the Health Information and Quality Authority (HIQA), the Health Service Executive (HSE) and the Department of Health. The National Care Experience Programme also includes the National Inpatient Experience Survey — an annual survey providing patients with the opportunity to describe their experiences of public acute hospital care in Ireland.

The first National Maternity Experience Survey will be undertaken in February and March 2020. Women aged 16 or over who gave birth in October 2019 (and in some cases, November 2019) will be invited to participate.

The survey encompasses the full pathway of maternity care extending from the antenatal period through labour and birth to postnatal care in the community. It includes questions taken or adapted from a library of questions developed by the National University of Ireland Galway in collaboration with the National Care Experience Programme. The survey design is based on systematic reviews of comparable international maternity care survey programmes. Extensive engagement has taken place with stakeholders from across Ireland's maternity services including midwives, maternity service users, women's representatives, public health nurses, obstetricians, neonatal nurses and GPs, amongst others.

Responses to the survey will be reported at **www.yourexperience.ie** in Autumn 2020. The HSE will then act on the findings and introduce improvements to maternity services at local and national levels.

Further information is available on the National Maternity Experience Survey website **www.yourexperience.ie**. Should you wish to be kept up to date on the progress and results of the survey, please email your contact details to **info@yourexperience.ie** or follow us on social media;

- YourMaternityExperience
- CareExperience
- CareExperience

Appendix 7: Sample audit

Chart review

1. Are pregnant women stratified correctly at their first antenatal visit?
   a. Are all women who meet high risk criteria stratified into the high risk carestream?
   b. What % of women who were high risk were appropriately and inappropriately stratified?

2. Is there written evidence in the records that women participated in the decisions made about stratification?

Governance

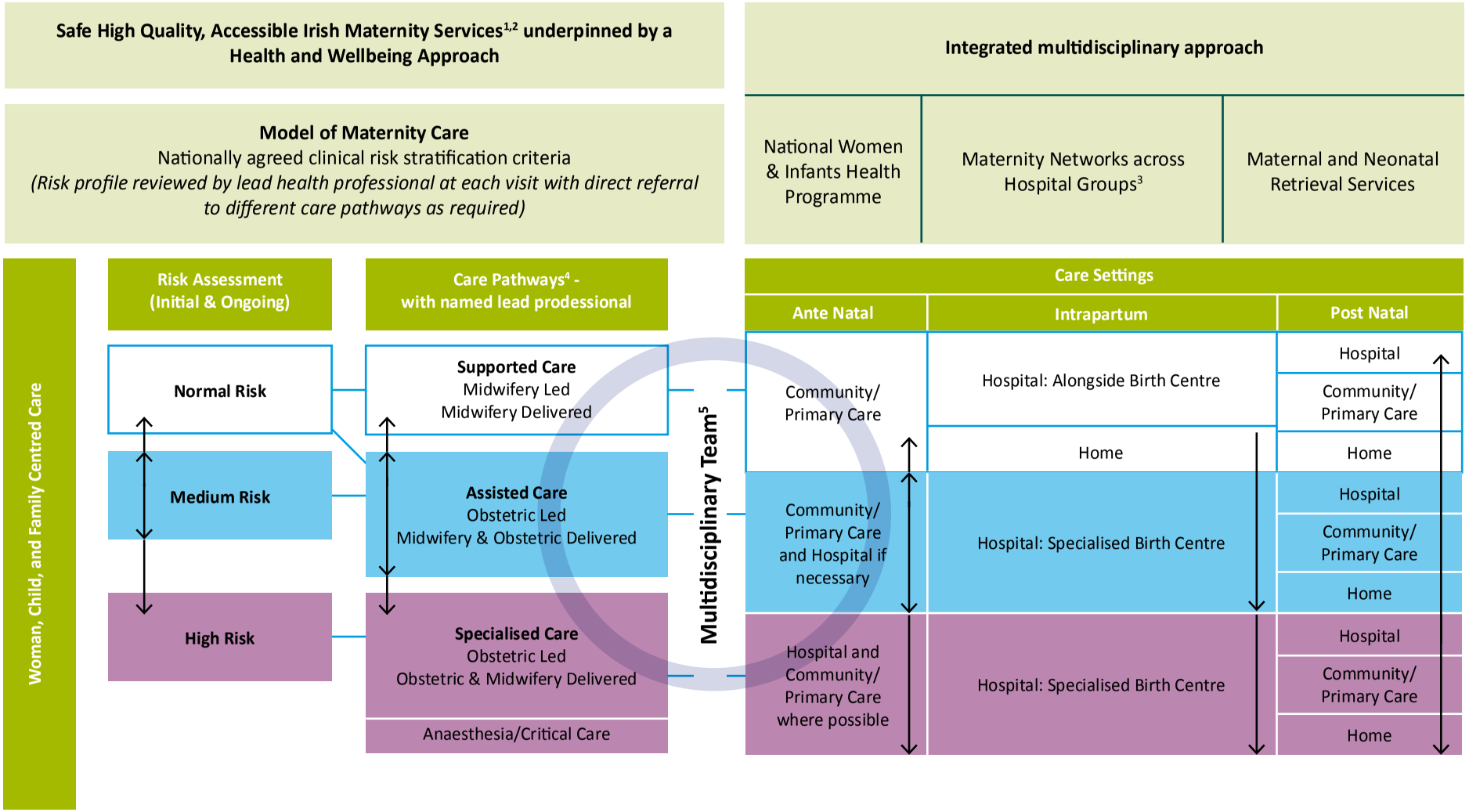
3. Is there a local policy to ensure effective communication to women of their choices?
4. Is the Irish Maternity Indicator System (IMIS) reviewed by Senior Management Team (SMT) monthly?
5. Does the SMT communicate the IMIS to all healthcare staff?
6. Have the appropriate clinical staff received training on clinical risk stratification in relation to the 'stratification of clinical risk' guideline?

Recommendations

Both paper-based and electronic systems will need to provide;

- Space for documenting appropriate carestream at the first hospital antenatal visit.
- Space for documenting/changing the appropriate carestream throughout pregnancy including reason for change, date and by whom.
- Space for documenting the woman's preference.

Appendix 8: Recommended Model of Maternity Care



[1] In line with the overriding safety principle, a risk based approach will be utilised. Practice will be evidence-based using national clinical guidelines and audit, and quality improvement approaches will be adopted.

[2] Each birth centre should have access to an immediate emergency team response for clinical deterioration.

[3] For high risk and complex women or babies specialist services outside the network may be required.

[4] Within each of these care pathways, women can also avail of a shared model of care with the GP, as provided for by the Maternity and Infant Care Scheme.

[5] Spanning the acute, primary and community sectors, modern maternity services are multi-disciplinary in nature, and as such require the involvement of a range of health professionals. The input of the wider multidisciplinary team will be co-ordinated by the lead healthcare professional.

Reference: Figure 25. National Maternity Strategy Report 2016-2026

Appendix 9: Risk factor stratification list

Risk factor		Source guideline(s)	Level of care
MEDICAL HISTORY			
1.	Cystic fibrosis	NICE	Specialised Care (high risk)
2.	Malignant disease	AHMAC KCE NICE	Specialised Care (high risk)
3.	HIV infection	AHMAC NICE	Specialised Care (high risk)
4.	Haematological disorders, including sickle cell or thalassaemia, thromboembolic disease	AHMAC KCE NICE	Specialised Care (high risk)
5.	Autoimmune disorders such as antiphospholipid syndrome	AHMAC KCE NICE	Specialised Care (high risk)
6.	Hepatitis C infection	AHMAC	Specialised Care (high risk)
7.	Diabetes mellitus requiring insulin	AHMAC KCE NICE	Specialised Care (high risk)
8.	Cardiac disease, including hypertension	AHMAC KCE NICE	Specialised Care (high risk)
9.	Renal disease	AHMAC KCE NICE	Specialised Care (high risk)
10.	Hepatitis B virus (HBV) infection	AHMAC NICE	Specialised Care (high risk)
11.	Epilepsy requiring anticonvulsant drugs	AHMAC NICE	Specialised Care (high risk)
12.	Severe asthma	AHMAC NICE	Specialised Care (high risk)
13.	Hepatic disease	AHMAC NICE	Specialised Care (high risk)
14.	Previous cardiac surgery (including correction of congenital anomalies)	AHMAC	Specialised Care (high risk)
15.	Gynaecological surgery (e.g. myomectomy, cone biopsy, large loop excision of the transformation zone [LLETZ])	AHMAC NICE	Assisted Care (medium risk)
16.	Genital mutilation	AHMAC KCE	Assisted Care (medium risk)

Risk factor		Source guideline(s)	Level of care
17.	Previous classical caesarean section or myomectomy involving the uterine cavity opening	AHMAC KCE NICE	Specialised Care (high risk)
18.	Bariatric surgery (gastric bypass, lap-banding)	AHMAC	Specialised Care (high risk)
19.	Psychiatric disorders (on medication)	AHMAC NICE KCE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
20.	Neurological disorders	KCE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
21.	Uterine pathology (congenital anomaly, abnormal cervix cytology)	KCE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
22.	Lung diseases	KCE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
23.	Endocrine disorders	AHMAC KCE NICE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
PREVIOUS OBSTETRIC HISTORY			
24.	History of puerperal psychosis	AHMAC KCE NICE	Specialised Care (high risk)
25.	Severe pre-eclampsia	AHMAC KCE NICE	Specialised Care (high risk)
26.	HELLP syndrome	KCE NICE	Specialised Care (high risk)
27.	Rhesus isoimmunisation or other significant blood group antibodies	AHMAC KCE NICE	Specialised Care (high risk)
28.	Preterm birth	AHMAC KCE	Assisted Care (medium risk)
29.	Caesarean section	AHMAC KCE NICE	Assisted Care (medium risk)
30.	Gestational diabetes mellitus requiring insulin	KCE AHMAC	Specialised Care (high risk)

Risk factor		Source guideline(s)	Level of care
31.	Multiple pregnancy (this pregnancy)	KCE	Specialised Care (high risk)
32.	Recurrent miscarriage (three or more consecutive pregnancy losses) or a mid-trimester loss	AHMAC NICE KCE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
33.	Stillbirth or neonatal death	AHMAC NICE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
34.	Previous baby with a congenital anomaly (structural or chromosomal)	AHMAC NICE KCE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
35.	History of small-for-gestational-age infant (below 5th centile) or a baby weighing below 2.5 kg	AHMAC NICE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
36.	Baby weighing above 4.5kg with associated complications	AHMAC NICE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
37.	Antenatal or postpartum haemorrhage on two occasions	AHMAC NICE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
38.	History of pre-eclampsia that is pregnancy hypertension with proteinuria	KCE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk
MATERNAL CHARACTERISTICS (NON-MODIFIABLE)			
39.	BMI <18 kg/m^2 at first contact	AHMAC KCE NICE	Assisted Care (medium risk)
40.	Age > 45 years	KCE NICE	Specialised Care (high risk)
41.	Age < 16 years at first visit	KCE NICE	Assisted Care (medium risk)
42.	BMI ≥35.0 and < 39.9 kg at first contact	AHMAC NICE KCE	Assisted Care (medium risk)
43.	BMI ≥ 39.9		Specialised Care (high risk)
44.	Women with disabilities	AHMAC	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk

Risk factor		Source guideline(s)	Level of care
45.	Women with a history of 'ongoing' domestic violence	AHMAC KCE	Referral to the medical social worker rather than consultant review at every antenatal visit
MATERNAL CHARACTERISTICS (MODIFIABLE)			
46.	Current use of illicit drugs such as heroin, cocaine (including crack cocaine) and ecstasy	AHMAC NICE KCE	Specialised Care (high risk)
47.	History of binge drinking during pregnancy	AHMAC KCE	Specialised Care (high risk)
48.	Women who report continuing to smoke at first antenatal visit	KCE 2015 NICE	Specialised Care (high risk)
FAMILY HISTORY			
49.	Family history of genetic disorder	KCE NICE	Should be assessed by a consultant at the first antenatal visit to decide normal, medium or high risk

Appendix 10: List of other Clinical Practice Guidelines relevant to risk

Available from the Clinical Guidelines section of the NWIHP website http://tiny.cc/NWIHP

Listed in alphabetical order

PROGRAMME GUIDELINES

Antenatal Magnesium Sulphate for Fetal Neurprotection
Antenatal Routine Enquiry regarding Violence in the Home
Bacterial Infections Specific to Pregnancy
Chickenpox in pregnancy
Cord Prolapse
Delivery after Previous Caesarean Section
Ectopic Pregnancy
Fetal Growth Restriction - Recognition, Diagnosis and Management
Guidelines for the Critically Ill Woman in Obstetrics
Hypertension
Intrapartum Fetal Heart Rate Monitoring
Listeriosis
Management of Multiple Pregnancy
Management of Obstetric Anal Sphincter Injury
Management of Pelvic Girdle Pain in Pregnancy and Postpartum
Management of Second Trimester Miscarriage
Methadone Prescribing and Administration in Pregnancy
National Medication Programme in O&G: Antimicrobial Prescribing Guidelines - Vol 1
National Medication Programme in O&G: Antimicrobial safety in pregnancy and lactation - Vol 2
Nausea and vomiting
Nutrition for Pregnancy
Obesity and Pregnancy
Ovarian Cysts in Postmenopausal Women
Oxytocin to Accelerate or Induce Labour
Parvovirus B19 Exposure/Infection during Pregnancy
Preterm Prelabour Rupture of the Membranes (PPROM)
Resuscitation of the Pregnant Woman
The Diagnosis and Management of Pre-Eclampsia and Eclampsia
The Irish Maternity Early Warning System (IMEWS)
The Management of Breech Presentation
Tocolytic Treatment in Pregnancy
Urinary Retention
Urinary Tract Infection (UTI)
Venous Thromboprophylaxis in Pregnancy

NON PROGRAMME GUIDELINES

Adult Asthma in Pregnancy
Crisis Pregnancy National Strategy 2012 - 2016
Guidelines for Health Professionals working in Maternity Settings on the Care of Women with Concealed Pregnancy
Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus
Preventing Perinatal Transmission

Reference list

Australian Government Department of Health and Ageing, 2014. *Clinical practice guidelines antenatal care - Module II.*

Australian Government Department of Health and Ageing, 2012. *Clinical Practice Guidelines Antenatal care - Module I.*

Dalkey, N., Helmer, O., 1962. *An Experimental Application of the DELPHI Method to the Use of Experts. Mangement Sci. 9, 458–467.* http://dx.doi.org/10.1287/mnsc.9.3.458

Department of Health, 2019. *How to develop a National Clinical Guideline. A manual for guideline developers.*

Department of Health, 2016. *Creating a Better Future Together, National Maternity Strategy 2016-2026.*

Domiciliary Births Group, 2004. *Report to the Chief Executive Officers of the Health Boards.*

Edwards, A., Elwyn, G., 2001. *Understanding risk and lessons for clinical risk communication about treatment preferences. Qual. Health Care QHC 10 Suppl 1, i9-13.*

Eunice Kennedy Shriver National Institute of Child and Human Development, 2018. *What are the factors that put a pregnancy at risk?*

Fetal Health Surveillance: Antepartum and Intrapartum Consensus Guideline, 2007. . J. Obstet. Gynaecol. Can., 4 29.

Gilmartin, A. "Bird" H., Ural, S.H., Repke, J.T., 2008. *Gestational Diabetes Mellitus. Rev. Obstet. Gynecol. 1, 129–134.*

Guidelines and Audit Implementation Network (GAIN), 2016. *Guideline for admission to midwife-led units in Northern Ireland and the Northern Ireland normal labour and birth care pathway.*

Gyselaers, W., Jonckheer, P., Ahmadzai, N., Ansari, M., Carville, S., Dworzynski, L.G., Gaudet, L., Glen, J., Jones, K., Miller, P., Tetzlaff, J.M., Alexander, S., Allegaert, K., Beeckman, K., Ceysens, G., Christiane, Y., De Ronne, N., De Thysebaert, B., Dekker, N., Denys, A., Eeckeleers, P., Hernandez, A., Mathieu, E., Seuntjens, L., Verleye, L., Stordeur, S., 2015. *What are the recommended clinical assessment and screening tests during pregnancy? (KCE)*

Healthcare Pricing Office (HPO), H.S.E. (HSE), 2018. *Perinatal Statistics Report.*

HIQA/NCEC, 2015. *National Quality Assurance Criteria for Clinical Guidelines Version 2.*

Irish Maternity Indicator System, 2018. *Irish Maternity Indicator System (IMIS).*

Manning, E., Leitao, S., Corcoran, P., McKernan, J., de Foubert, P., Greene, R.A., on behalf of the Severe Maternal Morbidity Group, 2018. *Severe Maternal Morbidity in Ireland Annual Report 2016.*

McDonnell, R., Delany, V., O'Mahony, M.T., Mullaney, C., Lee, B., Turner, M.J., 2015. *Neural tube defects in the Republic of Ireland in 2009-11. J. Public Health Oxf. Engl. 37, 57–63.* https://doi.org/10.1093/pubmed/fdu016

Meaney, S, Waldron, M., Corcoran, P., Greene, R., Sugrue, S., 2016. *Planned Home Births in Ireland Annual Report 2014.*

NICE National Institute for Health and Care Excellence, 2014. *Intrapartum care for healthy women and babies.*

NICE National Institute for Health and Care Excellence, 2008. *Antenatal care for uncomplicated pregnancies.*

Queensland Health, 2016. *Non-urgent referral for antenatal care.*

South Australia Maternal, Neonatal & Gynaecology Community of Practice, 2014. *Standards for Maternal & Neonatal Services in South Australia 2015.*

The ADAPTE Collaboration, 2009. *The ADAPTE Process: Resource Toolkit for Guideline Adaptation. Version 2.0.*

Tyner, B., O'Neill, M., Carty, P., Smith, S.M., Ryan, M., 2017. *Systematic review of clinical guidelines on risk stratification during pregnancy.*

Vincent, C., Taylor-Adams, S., Stanhope, N., 1998. *Framework for analysing risk and safety in clinical medicine. BMJ 316, 1154–1157.*

WHO Steering Group, 2016. *WHO recommendations on antenatal care for a positive pregnancy experience. World Health Organ.*

Working Group of the Clinical Practice Guidelines for Care in Pregnancy and Puerperium, 2014. *Clinical Practice Guidelines for Care in Pregnancy and Puerperium, in: Ministry of Health SSaE. Spain: AETSA.*

An Roinn Sláinte
Department of Health

Department of Health, Block 1, Miesian Plaza, 50-58 Lower Baggot Street,
Dublin 2, D02 VW90, Ireland

Tel: +353 1 6354000 • Fax: +353 1 6354001 • www.health.gov.ie