An Roinn Sláinte
Department of Health

Stratification of clinical risk in pregnancy

National Clinical Guideline No. 23

Annex B: A modified Delphi study

National Patient Safety Office
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NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

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Collaboration in Ireland for Clinical Effectiveness Reviews

Risk factors for inclusion as criteria within the clinical guideline on risk classification during pregnancy: A modified Delphi study

September 2018

Health Information and Quality Authority
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HRB Health Research Board

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

RCSI

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The members of the Guideline Development Group who provided support in the development of this report are:

Professor Michael Turner	Professor of Obstetrics and Gynaecology, UCD Centre for Human Reproduction, Coombe Women and Infants University Hospital
Dr Karen Power	National Project Manager, National Clinical Effectiveness Committee (NCEC) Childbirth Guideline Development Group, Health Service Executive (HSE)

About HRB-CICER

In 2016, the Department of Health requested that the Health Research Board (HRB) fund an evidence synthesis service called HRB-CICER (Collaboration in Ireland for Clinical Effectiveness Reviews) to support the activities of the Ministerial appointed National Clinical Effectiveness Committee (NCEC). Following a competitive process, the Health Information and Quality Authority (HIQA) was awarded the contract for the five-year period from 2017 to 2022. The HRB-CICER team comprises a dedicated multidisciplinary research team supported by staff from the Health Technology Assessment (HTA) team in HIQA and the HRB Centre for Primary Care Research at the Royal College of Surgeons in Ireland (RCSI), as well as national and international clinical and methodological experts.

With regard to clinical guidelines, the role of the HRB-CICER team is to independently review evidence and provide scientific support for the development, by guideline development groups, of National Clinical Guidelines for the NCEC. The HRB-CICER team undertakes systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines as well as estimating the budget impact of implementing the guidelines. The HRB-CICER team also works closely with the guideline development groups; provides tailored training sessions; assists in the development of clinical questions and search strategies; performs systematic reviews of international clinical guidelines and supports the assessment of their suitability for adaption to Ireland; and supports the development of evidence-based recommendations informed by the evidence produced by HRB-CICER within the National Clinical Guidelines.

Membership of the evaluation team

Members of the HRB-CICER Evaluation Team were Barrie Tyner, Dr Barbara Clyne, Michelle O'Neill, Karen Jordan, Mahdiye Phillips, Professor Susan M. Smith and Dr Máirín Ryan.

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Table of contents

ACKNOWLEDGEMENTS **3**

ABOUT HRB-CICER **4**

TABLE OF CONTENTS **5**

LIST OF FIGURES **6**

EXECUTIVE SUMMARY **8**

1 INTRODUCTION **10**

1.1 BACKGROUND 10
1.2 PROCESS OF GUIDELINE DEVELOPMENT 10
1.3 AIM 11

2 METHODS **12**

2.1 STUDY DESIGN 12
2.2 PANEL SELECTION 14
2.3 SYSTEMATIC REVIEW OF THE LITERATURE 14
2.4 STATEMENT EXTRACTION AND DEVELOPMENT 15
2.5 APPROACH TO SURVEY ADMINISTRATION: ROUND ONE AND ROUND TWO 15
2.5.1 Round one *16*
2.5.2 Round two *17*
2.6 ROUND THREE: FACE-TO-FACE MEETING 17

3 RESULTS **19**

3.1 PANEL PARTICIPANTS 19
3.2 ROUND ONE 19
3.3 ROUND TWO 19
3.4 ROUND THREE 20
3.5 INCLUDED RISK FACTORS AND LEVEL OF CARE 24

4 DISCUSSION **27**

4.1 SUMMARY OF FINDINGS 27
4.2 COMPARISON WITH OTHER STUDIES 27
4.3 STRENGTHS AND LIMITATIONS 28
4.4 CONCLUSION 28

REFERENCES **30**

APPENDIX 1 COMPLETE LIST OF EXTRACTED RISK FACTORS **32**

APPENDIX 2 EXAMPLE STATEMENTS INCLUDED IN DELPHI SURVEY **35**

APPENDIX 3 EXCLUDED RISK FACTORS **37**

APPENDIX 4 SUMMARY RESULTS FROM THREE DELPHI ROUNDS **38**

List of Tables

Table 2.1 Key stakeholders in the delivery of care to pregnant women in Ireland represented on the Childbirth GDG and invited as Delphi panel members 14
Table 3.1 Risk factor statements that were modified by the childbirth GDG .....23~~24~~
Table 3.2 Final risk factors included by Childbirth GDG with level of care.....25~~26~~

List of Figures

Figure 2.1 Flow chart of modified Delphi 13
Figure 3.1 Modified Delphi: overview of results 21

List of abbreviations

ADAPTE	A systematic approach to guideline adaptation
AGREE II	Appraisal of Guidelines for Research and Evaluation instrument version 2
AHMAC	Australian Health Ministers' Advisory Council
BMI	Body Mass Index
DoH	Department of Health, Ireland
GDG	Guideline development group
HBV	Hepatitis B virus
HRB-CICER	Health Research Board - Collaboration in Ireland for Clinical Effectiveness Reviews
HTA	Health Technology Assessment
KCE	Belgian Health Care Knowledge Centre
NCEC	National Clinical Effectiveness Committee, Ireland
NICE	The National Institute for Health and Care Excellence, England and Wales

Executive summary

Background and objectives

The *National Maternity Strategy – Creating a Better Future Together* (2016) advocates a risk-based approach to ensure that women are provided with the most appropriate model of care in line with their clinical risk. The Strategy highlights the need to stratify pregnant women according to their clinical risk into three risk groups, normal risk, medium risk and high risk. The aim of this study was to reach a formal consensus on the risk factors to use as criteria for stratifying pregnant women according to their clinical risk into these three risk groups.

Methods

A three-step modified Delphi method was used to establish consensus. Members of the Childbirth Guideline Development Group (experts representing key stakeholders in the delivery of care to pregnant women in Ireland and service users) were invited to participate as an expert panel. Risk factors were extracted from three high-quality guidelines identified and assessed according to the AGREE ll instrument in a previous systematic review conducted by HRB-CICER. These were then converted into statements for use in the Delphi survey. In round one, 59 risk factor statements were distributed to the panel. Panel members were asked to rate their agreement using a five-point Likert scale (a scale that offers a range of answer options from one extreme attitude to another) for level of agreement. If in agreement with the statement (that is to say, that the risk factor should be included), the panel members were asked to indicate the most appropriate level of care (for example, Specialised Care – high risk or Assisted Care – medium risk) for a pregnant woman with that risk factor and add any additional comments. The same method was again used for round two, but with the modification of a nine-point Likert scale. Anonymised, summarised group feedback (percentages and median scores) was provided to the group after rounds one and two. Round three consisted of a final face-to-face meeting of the panel with small and large group discussions and anonymous voting.

Results

In round one, 59 risk factor statements were presented. Of these, five risk factors reached consensus for both inclusion and the most appropriate level of care. In round two, a further 19 risk factors reached full consensus. The remaining 35 risk factors were retained for discussion during the face-to-face meeting in round three. After small and large group discussions and anonymised voting, a further 25 risk factors reached full consensus for inclusion and the most appropriate level of care (one risk factor was split into two separate risk factors). The Delphi panel agreed 49 statements — 28 categorised as Specialised Care (high risk) and seven categorised as Assisted Care (medium risk). Of the remaining 14

statements, 13 should be assessed by a consultant at the first antenatal visit to decide whether Specialised Care (high risk) or Assisted Care (medium risk) is needed. One risk factor was regarded as a trigger for referral to social work. Eleven risk factors were excluded.

Conclusions

Using a modified Delphi approach, the multidisciplinary Childbirth Guideline Development Group reached consensus on the inclusion of 49 of 59 identified risk factors — 28 categorised as Specialised Care (high risk) and 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 Specialised Care (high risk) or Assisted Care (medium risk) is required, and one recommends referral to social work. The main strengths of the modified Delphi approach include transparency and efficiency and the incorporation of a final face-to-face meeting, which allowed the multidisciplinary experts to discuss and clarify outstanding issues. Overall, this was a robust methodology for achieving a rigorous consensus within this multidisciplinary group of experts.

1 Introduction

The *National Maternity Strategy – Creating a Better Future Together,*[1] published in February 2016 advocates a risk-based approach to ensure that women are provided with the most appropriate model of care in line with their clinical risk. The Strategy highlighted the need to stratify pregnant women according to their clinical risk into three risk groups, normal risk, medium risk and high risk. Following publication of the National Maternity Strategy Report, the Minister for Health mandated the commissioning and quality assurance of national clinical guidelines through the National Clinical Effectiveness Committee (NCEC) to support its implementation.

1.1 Background

The *Clinical Guideline on Risk Classification during Pregnancy* is the first of a suite of clinical guidelines to be developed to support the implementation of the National Maternity strategy. At the first meeting of the Childbirth Guideline Development Group (GDG) in June 2017, the scope of the *Clinical Guideline on Risk Classification during Pregnancy* was agreed. The guideline focuses on how to stratify women according to risk during the antenatal period. This includes stratification at the initial ~~booking~~ antenatalappointment and during all subsequent antenatal appointments. Stratification of risk during labour or postpartum (after birth) is not considered within this clinical guideline.

1.2 Process of guideline development

Guidance from the NCEC[2] offers four approaches to developing clinical guidelines, depending on the availability of resources, existing high-quality guidelines and potential barriers to guideline implementation:

1. *De novo* development.
2. Using the evidence base from an existing guideline.
3. Adapting a single or a number of existing clinical guidelines using the ADAPTE[3] process.
4. Straightforward adoption of an existing clinical guideline without modification.

Before agreeing an approach, a clinical question was agreed upon and a systematic review of existing clinical guidelines on risk in pregnancy was performed by HRB-CICER. This review identified a number of clinical guidelines that included criteria or risk factors that identify pregnant women who might require additional care. However, no high-quality guideline with a three-level risk stratification, as described in the National Maternity Strategy, was

identified, largely due to the fact that the medium risk category is not defined within the context of the clinical literature.

Consequently, since no risk-stratification system was identified which could be easily adopted for use, the Childbirth GDG decided that adapting a single or a number of existing high-quality clinical guidelines (as per the AGREE ll appraisal instrument[4]) using the ADAPTE process[3] was the preferred approach. When selecting between guidelines and recommendations to create an adapted guideline, the steps followed in coming to group consensus must be agreed and recorded.[2, 3] Several methods of formal consensus (for example Delphi, nominal group technique) were considered for use in this ADAPTE process.[5-7] Given the number and range of disciplines represented on the Childbirth GDG (Table 2.1), the Delphi method was chosen as it facilitates and documents the consensus process, allows anonymous cross-disciplinary communication and provides an opportunity for the panel members to adjust their responses in light of the perspectives of others.

1.3 Aim

The aim of this study was to facilitate reaching a formal consensus on risk factors to use as criteria when stratifying pregnant women according to their clinical risk into the three risk groups, identified in the National Maternity Strategy as normal risk, medium risk or high risk. These risk factors were identified in a systematic review of clinical guidelines for risk assessment in pregnancy, conducted to support this guideline (section 2.3).

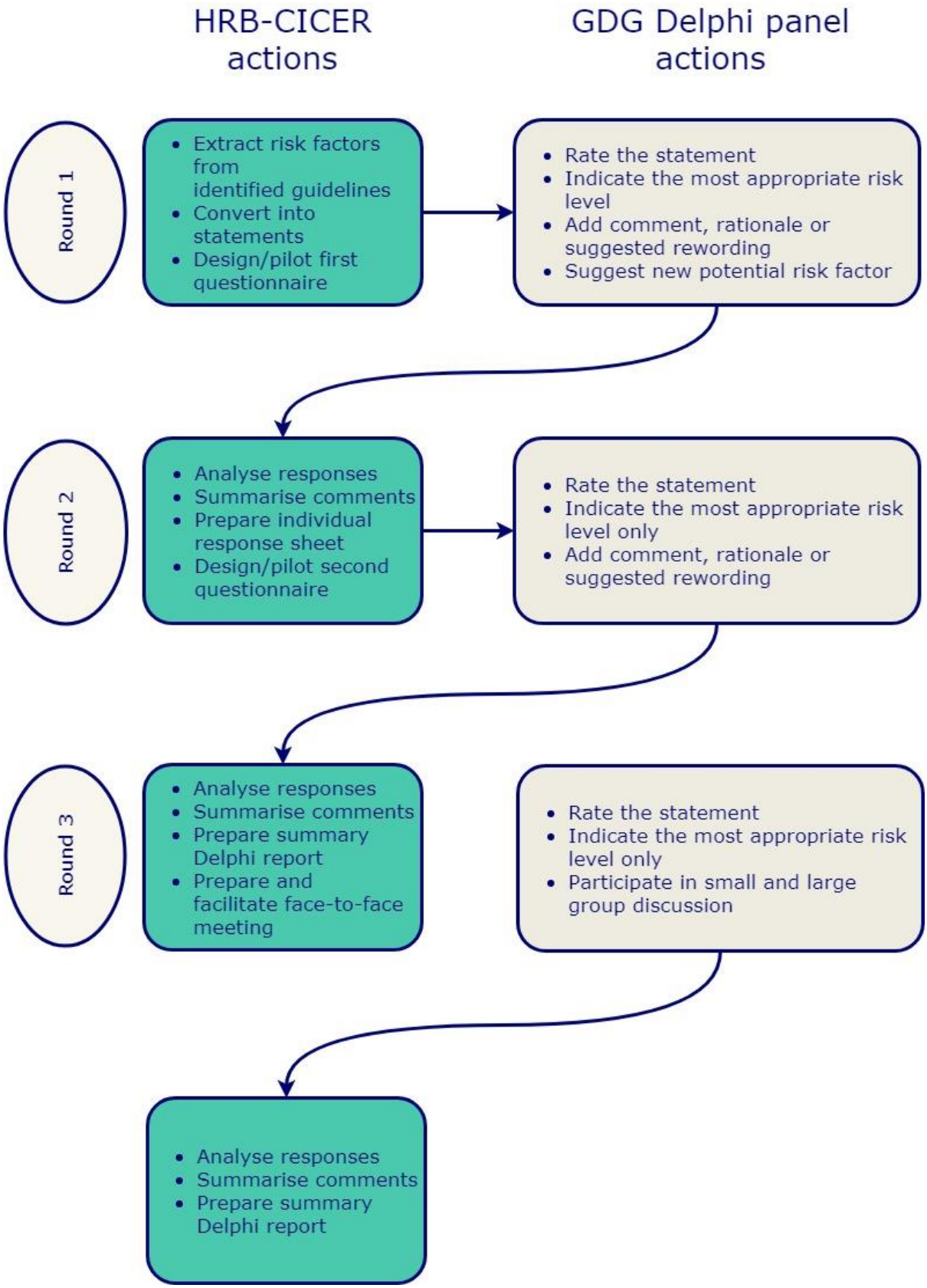
2 Methods

A protocol was agreed with the Childbirth GDG prior to commencing this study. This protocol, available on request, outlined the explicit methods to be employed. The key elements are summarised in sections 2.1 to 2.6.

2.1 Study design

The consensus process incorporated a three-step modified Delphi method which took place between November 2017 and June 2018. The Delphi technique is a method which aims to develop a consensus opinion on a specific subject within an expert group in a structured way. The Delphi method is an iterative process involving a series of intensive questionnaires, punctuated by anonymised group feedback.[8, 9] It is a widely used in healthcare research,[10-13] and is considered to be a robust methodology for achieving a rigorous consensus between a multidisciplinary group of experts on a specific topic. It is appropriate to use when there is incomplete knowledge, uncertainty or lack of evidence,[14] and has the potential to recognise and acknowledge the contributions of each participant, thus avoiding undue influence from individual group members.[15] The modified Delphi method employed here consisted of two rounds of online questionnaires and a final face-to-face meeting. The modified Delphi method facilitates expert interaction in the final round, allowing members of the panel to provide further clarification on outstanding issues and present arguments in order to justify their viewpoints. An overview of the modified Delphi approach and the roles of HRB-CICER and the Childbirth GDG in this process is presented in Figure 2.1.

Figure 2.1 Flow chart of modified Delphi



2.2 Panel selection

The panel members were recruited entirely from the Childbirth GDG. The Childbirth GDG is a multidisciplinary group consisting of 22 key stakeholders in the delivery of care to pregnant women in Ireland (Table 2.1).

Table 2.1 Key stakeholders in the delivery of care to pregnant women in Ireland represented on the Childbirth GDG and invited as Delphi panel members

Multidisciplinary key stakeholders represented on the Childbirth GDG
▪ Institute of Obstetricians and Gynaecologists ▪ Centre for Midwifery Education ▪ The National Women and Infants Health Programme ▪ National Clinical Programme for Obstetrics and Gynaecology ▪ State Claims Agency ▪ The National Clinical Programme for Anaesthesia ▪ The National Clinical Programme for Paediatrics and Neonatology ▪ The Irish College of General Practitioners ▪ Patient representatives ▪ General practitioners ▪ Directors of midwifery ▪ Specialist registrars in obstetrics ▪ Clinical risk managers

Key: GDG – guideline development group

2.3 Systematic review of the literature

The modified Delphi was informed by a systematic review of clinical guidelines, performed by HRB-CICER as part of the early phase of the ADAPTE process and completed in September 2017. The systematic review identified clinical guidelines that stratified a woman's risk during pregnancy. Three clinical guidelines were identified as being of high quality according to the AGREE ll appraisal instrument,[4] and suitable for the ADAPTE process:[16]

1. KCE (Federaal Kenniscentrum voor de Gezondheidszorg - Belgian Health Care Knowledge Centre) 2015[17]
2. NICE (National Institute for Health and Care Excellence, England and Wales) 2008[18]
3. AHMAC (Australian Health Ministers' Advisory Council) 2012[19] and 2014[20] (published in two modules).

Full details of this review are available in the report *Systematic review of clinical guidelines for risk assessment in pregnancy* (2017).[21]

2.4 Statement extraction and development

Risk factors were extracted from each of the three guidelines identified in the systematic review and converted into statements for use in the Delphi survey. The risk factors were categorised by type of clinical and non-clinical risks associated with pregnancy, as identified by the Childbirth GDG:

1. Risk based on medical history (excluding obstetric history).
2. Risk based on previous obstetric history.
3. Risk based on maternal characteristics which are not modifiable.
4. Risk based on modifiable risk factors.
5. Risk based on family history.

For each risk factor, the original wording and the name of the reference guideline(s) was provided within the survey. The original wording was preserved where possible. Where there was a difference in wording used between the three reference guidelines, the wording used within the reference guideline that had performed the most up-to-date systematic review was presented. Where the risk factor was broad it was decided to keep it as in the original guideline; however, this did result in some overlap of risk factors (see Appendix 1 for a complete list of extracted risk factors). Further detail on the exact process used is described in the protocol (available on request).

2.5 Approach to survey administration: round one and round two

The approach involved two rounds of a self-administered secure web-based survey. Polldaddy® (Sligo, Ireland) was used to design and administer the survey. In preparation for each round, piloting of the survey was performed by the Childbirth GDG chair, Childbirth GDG project manager, HRB-CICER team and HTA directorate. Piloting was used to identify ambiguities, errors and improve the efficiency of administration.[14] The time needed to complete the survey was estimated to be approximately 20 to 60 minutes.

Each round of the survey began with the Childbirth GDG members receiving an email invitation from HRB-CICER and a link to register their preferred email address ensuring only those invited were eligible to participate.

2.5.1 Round one

Invitations to the round one survey were sent out on 22 November 2017. The survey remained open for two weeks and was followed-up with two reminders prior to closing on 6 December 2017.

Each statement was grouped by the five clinical and non-clinical risk categories (as listed in section 2.4). For each statement, panel members had the opportunity to:

1. Rate the statement presented in terms of a five-point Likert scale for level of agreement or disagreement (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree).
2. If in agreement with the statement, indicate the most appropriate level of care (for example Specialised Care – high-risk or Assisted Care – medium-risk).
3. Add a comment, rationale or suggestion for rewording if needed. Panellists could also add free text suggestions regarding the introduction of a new risk factor, with additional risk factors considered for round two if proposed independently by two or more Childbirth GDG members.[22]

An example of how statements appeared in round one and round two is shown in Appendix 2.

Although there is no set definition of consensus in a Delphi study,[23] reviews have highlighted that the most common definition for consensus is a percent agreement[24] with cut-off levels ranging from 51% - 80%.[25] For round one, a threshold of 80% was used to define consensus. For agreement to include a risk factor, if 80% or more responded with agree or strongly agree and no panel member disagreed (that is to say, disagree or strongly disagree), then consensus was considered achieved. Conversely, if 80% or more responded with either disagree or strongly disagree and no panel member agreed on including (agree or strongly agree), then consensus for excluding this risk factor was achieved. If 80% of panel members agreed on a level of care (medium or high risk) then consensus was considered to have been achieved.

The high threshold, with the additional caveat that no panel member indicated disagreement, was considered appropriate for the first round. This was to ensure any concern a Childbirth GDG member gave via the comment box, could be shared with the Delphi panel in round two. This provided panel members the opportunity to revise their scores in light of any concerns raised from round one.

2.5.2 Round two

Invitations to participate in round two were sent out on 15 January 2018. The survey remained open for two weeks and two reminders were sent prior to the survey closing on 29 January 2018. Round two included only those statements that did not achieve consensus in round one. In round two, the panel used the same voting method as described for round one, with some modifications. For each statement, panel members rated their agreement using a nine-point Likert scale (1-3: disagree, 5-6: neither agree nor disagree, 7-9 agree) instead of a five-point Likert scale. This change was included to provide additional reliability from the responses, as reliability has previously been demonstrated to increase with the number of response categories.[21] The panel also had knowledge of the level of group agreement (percentage of those that agreed or strongly agreed), the dispersion of panel member ratings (median and interquartile range) and a summary of the submitted comments from round one. This allowed participants to reflect on the group results and change their mind, while preserving the anonymity of their responses.

If 70% or more panel members rated a risk factor as seven, eight or nine on the nine-point Likert scale and fewer than 15% rated it as one, two or three, then that risk factor was considered to have achieved consensus. In all other situations it was assumed that there was a lack of agreement between the panel members. Consensus on the appropriate level of care was achieved when 70% or more of the panellists agreed on either medium or high risk. Where a panellist indicated they did not agree with the inclusion of the risk factor (responded six or less on the 9-point Likert scale), but did respond by error on the appropriate level of care, this response was excluded from the calculation of the percentage agreement.

2.6 Round three: face-to-face meeting

Round three comprised of a face-to-face meeting, mediated by facilitators from the HRB-CICER team. Prior to the face-to-face meeting, results from round two were summarised and circulated to the panel members, providing a summary of the level of group agreement (percentage of those that agreed or strongly agreed) and a summary of the submitted comments and suggested rewording of risk factors from round two. Only the survey statements that did not achieve consensus from round two were presented in round three.

Round three voting occurred using an interactive electronic voting system Mentimeter® (Stockholm, Sweden), retaining anonymity. For risk factors which had not achieved consensus, participants were asked if they wished to include or exclude the factor or if they were unsure. For each included statement, participants were asked to indicate the most appropriate level of care, for example Specialised Care (high risk) or Assisted Care (medium risk) or unsure. Agreement of 70% or over was used to determine acceptance or rejection of

a statement, as per round two. Where consensus was not reached, panel members were encouraged to discuss the statements in small groups of four to five members, followed by a full group discussion until agreement was reached via electronic voting to retain, modify, or eliminate the statement.

3 Results

3.1 Panel participants

Twenty-one of 22 members of the Childbirth GDG participated in the Delphi survey and completed round one. Before round two commenced one Childbirth GDG member retired and the remaining 20 panellists completed round two. Sixteen Childbirth GDG members participated in the face-to-face meeting.

3.2 Round one

In round one, 59 risk factors were presented. Of these, 26 statements were categorised as medical history, 18 as previous obstetric history, nine as maternal characteristics (non-modifiable), four as modifiable risk factors and two as family history. Overall, five risk factors achieved consensus that Specialised Care (high risk) was the most appropriate level of care (four medical history and one previous obstetric history). Twenty-six risk factors achieved consensus agreement as risk factors for additional care but did not achieve consensus on the most appropriate level of care. Twenty-eight risk factors did not achieve consensus on inclusion or exclusion. A total of 214 comments were received from the panel. Table 2.1 illustrates the flow of the results of the modified Delphi method.

3.3 Round two

In round two, 54 the risk factors were presented again. Of these, 22 statements were categorised as medical history, 17 as previous obstetric history, nine as maternal characteristics (non-modifiable), four as modifiable risk factors and two as family history. Twenty-eight were presented in full, requiring input on agreement to include or exclude the risk factor and also on the appropriate level of care for those included. Twenty-six risk factors required agreement on the level of care only. No additional risk factors were included in round two. After round two voting, 19 additional risk factors with level of care achieved consensus for inclusion into the guideline (12 medical history, five previous obstetric history, one maternal characteristics [non-modifiable], and one modifiable). Twelve statements achieved consensus agreement as risk factors for additional care but did not achieve consensus on the most appropriate level of care. Twenty-three risk factors did not reach consensus on inclusion or exclusion. A total of 208 comments were received from the panel.

3.4 Round three

The remaining 35 risk factors were retained for discussion during the face-to-face meeting in round three.

Twenty-three were presented in full, requiring input on agreement on whether to include or exclude the risk factor and also on the appropriate level of care. Following small and large group discussions and anonymised voting, three risk factors were accepted without modification, nine risk factors were modified and accepted, and 11 were excluded. The majority of excluded risk factors were considered to be too broad to apply (see Appendix 3 for excluded risk factors).

Twelve risk factors required input on the level of care only. Of these 12, nine were accepted without modification and one accepted with modification. The consensus was that these 10 should all be assessed by a consultant at the first antenatal visit to decide whether that patient would be in the medium or high-risk category. Of the remaining two risk factors, one was accepted and modified and the consensus was that the patient be referred to a medical social worker, rather than consultant review. The remaining risk factor was accepted and modified by being broken into two separate risk factors, one medium risk and one high risk.

This resulted in 25 additional risk factors with level of care being agreed upon for incorporation into the guideline after round three (seven medical history, nine previous obstetric history, six maternal characteristics [non-modifiable], two modifiable and one family history).

Figure 3.1 Modified Delphi: overview of results

Round 1: 59 risk factor statements		
End of round 1		
28 risk factors did not achieve consensus	26 risk factors accepted for inclusion but had no consensus on the most appropriate level of care	5 risk factors with level of care accepted for inclusion: • 5 Specialised Care (high risk)

Round 2: 54 risk factor statements		
28 risk factor statements for inclusion or exclusion (plus level of care statements for any risk factor identified for inclusion)	26 level of care statements for risk factor identified for inclusion from round 1	
End of round 2		
23 risk factors did not achieve consensus	12 risk factors accepted for inclusion but had no consensus on the most appropriate level of care	19 risk factors with level of care accepted for inclusion: • 14 Specialised Care (high risk) • 5 Assisted Care (medium risk)

Round 3: 35 risk factor statements			
23 risk factor statements for inclusion or exclusion plus level of care statements for any risk factor identified for inclusion		12 level of care statements for risk factor identified for inclusion following round 2	
End of round 3			
12 were accepted without modification: • 1 Specialised Care (high risk) • 11 to be assessed by a consultant at 1st antenatal visit to decide medium or high-risk category	11 were accepted and modified: • 6 Specialised Care (high risk) • 1 Assisted Care (medium risk) • 3 to be assessed by a consultant at 1st antenatal visit to decide medium or high-risk category • 1 referral to social work	1 accepted and modified by being split into 2 separate risk factors	11 excluded

Final agreed risk statement
49 risk factors with level of care to be incorporated into guideline • 28 Specialised Care (high risk) • 7 Assisted Care (medium risk) • 13 were agreed should be assessed by a consultant at the first antenatal visit to decide Specialised Care (high risk) or Assisted Care (medium risk) • 1 referral to social work

In total, 12 risk factors were accepted with modifications in round three as summarised in Table 3.1. The majority of risk factors were modified as the original text was not specific enough and the Childbirth GDG felt more clarity was necessary. The risk factor 'BMI ≥ 35.0 kg/m² at first contact' was modified by being broken into two separate risk factors in order to be able to assign a risk level. The Childbirth GDG felt it was important to differentiate between a BMI ≥35.0 and < 39.9 kg, which they felt was medium risk, and a BMI ≥ 39.9, which they felt was high risk.

Table 3.1 Risk factor statements that were modified by the childbirth GDG

Original risk factor	Source guideline(s)	Modification	Rationale
Medical history			
Uterine surgery including caesarean section, myomectomy or cone biopsy	AHMAC KCE NICE	Previous classical caesarean section or myomectomy involving the uterine cavity opening	Important to capture opening of uterine cavity in the risk factor
Previous obstetric history			
Gestational diabetes	AHMAC KCE	Gestational diabetes mellitus requiring insulin	
Multiple pregnancy	KCE	Multiple pregnancy (this pregnancy)	Previous multiple pregnancy not considered a risk factor, only if in current pregnancy
Large-for-gestational-age infant (above 95th centile) or a baby weighing above 4.5 kg	AHMAC NICE	Baby weighing above 4.5kg with associated complications	Important to separate centile from weight as risks for ≥95th centile and ≥4.5kg not the same, with ≥95th centile mainly leading to normal pregnancy.
Pregnancy induced hypertension	KCE	History of pre-eclampsia, that is pregnancy hypertension with proteinuria	Pregnancy induced hypertension not sufficient detail, need to specifically state pre-eclampsia with proteinuria
Maternal characteristics (non-modifiable)			
≥ 40 years	KCE NICE	Age > 45 years	≥ 40 years too low, > 45 years more appropriate
≤ 18 years	KCE NICE	Age < 16 years at first visit	≤ 18 years too high, < 16 more appropriate
BMI ≥ 35.0 kg/m² at first contact	AHMAC NICE KCE	Became two separate risk factors 1. BMI ≥35.0 and < 39.9 at first contact 2. BMI ≥ 39.9	BMI ≥ 35.0 kg/m^2 needed to be separated as risk is different for ≥35.0 and ≥39.9 kg
Developmental delays or other disabilities	AHMAC	Women with disabilities	Dislike of wording 'Developmental delays', too broad and the risk depends on level of disability
Domestic violence	AHMAC KCE	Women with a history of 'ongoing' domestic violence	Previous history of domestic violence not relevant to current pregnancy – need to include 'ongoing'
Maternal characteristics (modifiable)			
Who smoke	NICE	Women who report continuing to smoke at first antenatal visit	Who smoke is not specific to pregnancy period. Need to emphasis importance of the risk posed by continuing to smoke in pregnancy
History of alcohol consumption	AHMAC KCE	History of binge drinking during pregnancy	Needs to be specific to pregnancy

Key: AHMAC - Australian Health Ministers' Advisory Council; BMI – body mass index; KCE - Belgian Healthcare Knowledge Centre; NICE - National Institute for Health and Care Excellence

3.5 Included risk factors and level of care

Following three Delphi rounds, 49 risk factors were agreed as suitable criteria to stratify pregnant women according to clinical risk. Of these, 28 were categorised as Specialised Care (high risk), seven as Assisted Care (medium risk), 13 should be assessed by a consultant at the first antenatal visit to decide between Specialised Care (high risk) or Assisted Care (medium risk) and one required referral to a medical social worker, as summarised in Table 3.2~~Table 3.2~~. For a full overview of results from each round see Appendix 4.

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Table 3.2 Final risk factors included by Childbirth GDG with level of care

Consensus statement	Level of care
Medical history 1. Autoimmune disorders such as antiphospholipid syndrome 2. Cystic fibrosis 3. Malignant disease 4. Hepatitis C infection 5. Diabetes mellitus requiring insulin 6. Cardiac disease, including hypertension 7. Renal disease 8. Hepatitis B virus (HBV) infection 9. Epilepsy requiring anticonvulsant drugs 10. HIV infection 11. Haematological disorders, including sickle cell or thalassaemia, thromboembolic disease 12. Previous classical caesarean section or myomectomy involving the uterine cavity opening 13. Bariatric surgery (gastric bypass, lap-banding) 14. Severe asthma 15. Hepatic disease 16. Previous cardiac surgery (including correction of congenital anomalies) *Previous obstetric history* 17. Severe pre-eclampsia 18. Puerperal psychosis 19. HELLP syndrome 20. Rhesus isoimmunisation or other significant blood group antibodies 21. Gestational diabetes mellitus requiring insulin 22. Multiple pregnancy (this pregnancy) *Maternal characteristics (non-modifiable)* 23. Age > 45 years 24. BMI ≥39.9 kg/m^2 *Maternal characteristics (modifiable)* 25. Use of illicit drugs such as heroin, cocaine (including crack cocaine) and ecstasy 26. History of binge drinking during pregnancy 27. Women who report continuing to smoke at first antenatal visit *Family history* 28. Family history of genetic disorder	Specialised Care (high risk)

Medical history 29. Gynaecological surgery (e.g. myomectomy, cone biopsy, large loop excision of the transformation zone [LLETZ]) 30. Genital mutilation *Previous obstetric history* 31. Preterm birth 32. Caesarean section *Maternal characteristics (non-modifiable)* 33. BMI<18 kg/m^2 at first contact 34. BMI ≥35.0 and < 39.9 kg at first contact 35. Age < 16 years at first visit	Assisted Care (medium risk)
Medical history 36. Psychiatric disorders (on medication) 37. Neurological disorders 38. Uterine pathology (congenital anomaly, abnormal cervix cytology) 39. Lung diseases 40. Endocrine disorders *Previous obstetric history* 41. Recurrent miscarriage (three or more consecutive pregnancy losses) or a mid-trimester loss 42. Antenatal or postpartum haemorrhage on two occasions 43. Stillbirth or neonatal death 44. Baby with a congenital anomaly (structural or chromosomal) 45. Small-for-gestational-age infant (below 5th centile) or a baby weighing below 2.5 kg 46. Baby weighing above 4.5kg with associated complications 47. History of pre-eclampsia that is pregnancy hypertension with proteinuria *Maternal characteristics (non-modifiable)* 48. Women with disabilities	Should be assessed by consultant at first antenatal visit to decide medium or high-risk category
Maternal characteristics (non-modifiable) 49. Women with a history of 'ongoing' domestic violence	Referral to medical social worker

Key: HIV - human immunodeficiency virus;

4 Discussion

4.1 Summary of findings

This study was conducted to facilitate a formal consensus being reached on risk factors to use as criteria when stratifying pregnant women according to their clinical risk into the three risk groups (normal risk, medium risk and high risk) as outlined in The *National Maternity Strategy – Creating a Better Future Together*.[1] Using a modified Delphi approach, the multidisciplinary Childbirth GDG reached consensus on the inclusion of 49 of 59 identified risk factors - 28 categorised as Specialised Care (high risk) and 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 Specialised Care (high risk) or Assisted Care (medium risk) is required and one required referral to medical social work.

4.2 Comparison with other studies

There are a number of clinical guidelines which focus on assessing risk in pregnancy during the antenatal period. The previous systematic review of such clinical guidelines by HRB-CICER identified seven international guidelines [17-20, 26-29] that included criteria to identify women who might require additional care. However, no high-quality guideline with a three-level risk stratification, as described in the National Maternity Strategy, was identified. Consequently, the Childbirth GDG decided to review the risk factors included within the three high-quality clinical guidelines [17-20] identified in the systematic review, with a view to reaching consensus on which risk factors to use within this guideline.

The Delphi method is widely used in healthcare research,[10-13] and is considered to be a robust methodology for achieving consensus and developing clinical guidelines.[30] A number of the clinical guidelines identified in the above systematic review also applied consensus methods in their development. The NICE 2008 guideline,[18] the KCE guideline[17] and the AHMAC 2012[19] and 2014[20] guidelines utilised a Delphi approach in the development of their respective guidelines.

Given that source guidelines for the risk factors included in this Delphi process (the KCE 2015 guideline,[17] the NICE 2008 guidelines[18] and the AHMAC 2012[19] and 2014,[20]) were considered as high quality, it is unsurprising that 49 of 59 identified risk factors were included at the end of this current process. Fourteen of the included 49 could not easily be assigned to Specialised Care (high risk) or Assisted Care (medium risk), and instead these factors were identified as being best categorised after assessment by a consultant at the first antenatal visit or referral to social work. This may reflect the fact that the source guidelines were not developed within the context of a three-level risk stratification system,

as described in the National Maternity Strategy, and that the medium-risk category is not defined within the clinical literature.

4.3 Strengths and limitations

No high-quality guideline with a three-level risk stratification, as described in the National Maternity Strategy, could be identified and the medium-risk category is not defined within the clinical literature. Given this lack of evidence, the modified Delphi approach was utilised. The main strengths of this approach include transparency and efficiency, and the incorporation of a final face-to-face meeting which allowed the multidisciplinary experts to discuss and clarify reasons for disagreements, allowed participants to revaluate their opinions, and facilitated the generation of alternatives for issues that did not achieve consensus over the initial two rounds. The use of a web-based survey and interactive electronic voting system (round three) allowed for anonymity to be retained across all three rounds, reducing the potential for dominant panellists exerting undue influence in the group. The panel was comprised of multidisciplinary experts and stakeholders, importantly, including patient representatives. However, only 16 of the GDG attended the final face-to-face meeting meaning that not all stakeholders were represented in the final round.

The use of different consensus levels between rounds could be considered a weakness of this study, however, considering the variety of means of determining consensus outlined in the literature and lack of agreement on the best approach to adopt,[23-25] the variation was felt to be appropriate. For round one, the high threshold of 80%, with the additional caveat that no panel member indicated disagreement, was applied to ensure any concern raised as a comment, was shared with the Delphi Panel in round two. This provided panel members the opportunity to revise their final scores in light of any concerns raised from round one.

4.4 Conclusion

The purpose of this study was to facilitate a large multidisciplinary guideline development group to reach a formal consensus on risk factors to use as criteria when stratifying pregnant women according to their clinical risk into the three risk groups (normal risk, medium risk and high risk). Using a three round modified Delphi approach, the multidisciplinary Childbirth GDG reached consensus on the inclusion of 49 of 59 identified risk factors - 28 categorised as Specialised Care (high risk) and 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 Specialised Care (high risk) or Assisted Care (medium risk) is required and one recommends referral to social work. The main strengths of the modified Delphi approach include transparency and efficiency and the incorporation of a final face-to-face meeting, which allowed the multidisciplinary experts to discuss and

clarify outstanding issues. Overall, this was a robust methodology for achieving a rigorous consensus within this multidisciplinary group of experts.

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Appendix 1 Complete list of extracted risk factors

Risk factor	Source guideline(s)
Medical history	
1. Cystic fibrosis	NICE
2. Malignant disease	AHMAC KCE NICE
3. HIV infection	AHMAC NICE
4. Haematological disorders, including sickle cell or thalassaemia, thromboembolic disease	AHMAC KCE NICE
5. Autoimmune disorders such as antiphospholipid syndrome	AHMAC KCE NICE
6. Hepatitis C infection	AHMAC
7. Diabetes mellitus requiring insulin	AHMAC KCE NICE
8. Cardiac disease, including hypertension	AHMAC KCE NICE
9. Renal disease	AHMAC KCE NICE
10. Hepatitis B virus (HBV) infection	AHMAC NICE
11. Epilepsy requiring anticonvulsant drugs	AHMAC NICE
12. Severe asthma	AHMAC NICE
13. Hepatic disease	KCE NICE
14. Previous cardiac surgery (including correction of congenital anomalies)	AHMAC
15. Gynaecological surgery (for example, myomectomy, cone biopsy, large loop excision of the transformation zone [LLETZ])	AHMAC
16. Genital mutilation	AHMAC KCE
17. Uterine surgery including caesarean section, myomectomy or cone biopsy	AHMAC KCE NICE
18. Bariatric surgery (gastric bypass, lap-banding)	AHMAC
19. Psychiatric disorders (on medication)	AHMAC NICE KCE
20. Neurological disorders	KCE
21. Uterine pathology (congenital anomaly, abnormal cervix cytology)	KCE
22. Lung diseases	KCE

23. Endocrine disorders	AHMAC KCE NICE
24. Use of medicines	KCE
25. Immunization (Lack vaccination against hepatitis B, rubella and or lack of history of rubella, varicella, toxoplasmosis, CMV)	KCE
Previous obstetric history	
26. Puerperal psychosis	AHMAC KCE NICE
27. Severe pre-eclampsia	AHMAC KCE NICE
28. HELLP syndrome	KCE NICE
29. Rhesus isoimmunisation or other significant blood group antibodies	AHMAC KCE NICE
30. Preterm birth	AHMAC KCE
31. Gestational diabetes	AHMAC KCE
32. Multiple pregnancy	KCE
33. Caesarean section	AHMAC KCE NICE
34. Recurrent miscarriage (three or more consecutive pregnancy losses) or a mid-trimester loss	AHMAC NICE KCE
35. Stillbirth or neonatal death	AHMAC NICE
36. Baby with a congenital anomaly (structural or chromosomal)	AHMAC NICE KCE
37. Small-for-gestational-age infant (below 5th centile) or a baby weighing below 2.5	AHMAC NICE
38. Large-for-gestational-age infant (above 95th centile) or a baby weighing above 4.5 kg	AHMAC NICE
39. Antenatal or postpartum haemorrhage on two occasions	AHMAC NICE
40. Pregnancy induced hypertension	KCE
41. Grand multiparity (parity four or more)	AHMAC KCE NICE
42. Retained placenta on two occasions	NICE
43. Termination of pregnancy	KCE
Maternal characteristics (non-modifiable)	
44. BMI<18 kg/m^2 at first contact	AHMAC KCE NICE
45. ≥ 40 years	KCE NICE

46. ≤ 18 years	KCE NICE
47. BMI ≥ 35.0 kg/m² at first contact	AHMAC NICE KCE
48. Developmental delays or other disabilities	AHMAC
49. Domestic violence	AHMAC KCE
50. Previous experience of social dislocation	AHMAC
51. Late antenatal care: 1st antenatal consultation after 20 weeks	KCE
Maternal characteristics (modifiable)	
52. Use of illicit drugs such as heroin, cocaine (including crack cocaine) and ecstasy	AHMAC NICE KCE
53. History of alcohol consumption	AHMAC KCE
54. Who smoke	NICE KCE
55. Psychosocial issues	AHMAC
56. Particularly vulnerable or who lack social support	AHMAC KCE NICE
57. At-risk sexual behaviour (for STD)	KCE
Family history	
58. Family history of genetic disorder	KCE NICE
59. Familial diseases	KCE

Key: AHMAC - Australian Health Ministers' Advisory Council; BMI – body mass index; CMV - Cytomegalovirus vaccine; HELLP syndrome - Hemolysis, Elevated Liver Enzymes, Low Platelet Count; HIV - human immunodeficiency virus; KCE - Belgian Healthcare Knowledge Centre; NICE - National Institute for Health and Care Excellence; STD - sexually transmitted disease

Appendix 2 Example statements included in Delphi survey

Example of statements included in round one of the Delphi survey

Risk factors based on Medical History

Please indicate how strongly you agree or disagree with the following statement: *

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
Women with hepatitis B virus (HBV) infection should be considered for additional care	○	○	○	○	○

Source of risk factor (*evidence source*) and the wording used:

AMHAC 2012 & 2014 *(ADAPTE process NICE 2008)*: Hepatitis B infection

NICE 2008 *(SR 2012)*: hepatitis B virus (HBV) infected

If you agree or strongly agree with the statement above, then which level of care is appropriate?

- ○ Specialised care - (High risk)
- ○ Assisted care - (Medium risk)
- ○ Do not know

Any comments on this risk factor, suggestions for the wording or the rationale for your choices can be included below:

Back **Continue**

PAGE 6 OF 61

Example of statements included in round two of the Delphi survey

Please indicate how strongly you agree or disagree with the following statement: *

	Strongly Disagree	2	3	4	Neither Agree nor Disagree	6	7	8	Strongly Agree
Women who have undergone previous **cardiac surgery (including correction of congenital anomalies)** should be considered for additional care	○	○	○	○	○	○	○	○	○

If you agree or strongly agree with the statement above, then which level of care is appropriate?

- ○ Specialised Care - (high-risk)
- ○ Assisted Care - (medium-risk)
- ○ Do not know

Any comments on this risk factor, suggestions for the wording or the rationale for your choices can be included below:

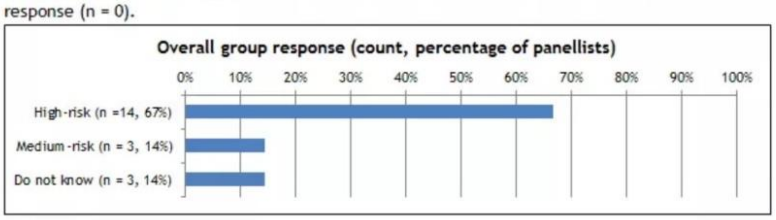
If this risk factor is too vague in your opinion or otherwise needs to be differentiated, please define what terms you would use to further classify this risk factor.

Panel members:	21
Group agreement:	95%
Median †	5
Interquartile range †	(4, 5)

Overall group response				
(0) Strongly disagree	(1) Disagree	(0) Neither agree not disagree	(8) Agree	(12) Strongly agree

† 5-point Likert scale (where 1 = Strongly disagree, 5 = Strongly agree)

Panel members (n = 21), Agreed should be considered for additional care (n =20), No response (n = 0).



Comments from first round

- Specialised Care (high-risk) for both the woman and her baby as her baby may have congenital anomalies (1 person commented)
- Too broad a category. Supported Care (normal-risk) unless there are confounding factors from the surgery then no need to escalate. Categories can always be escalated if complications arise (Person disagreed with the statement) (1 person commented)
- Maternal Medicine Clinic (1 person commented)
- Depends on condition (1 person commented)
- Depends on surgery and condition (1 person commented)
- May require more detailed scanning (1 person commented)

Appendix 3 Excluded risk factors

Risk factor	Source guideline(s)	Rationale
Medical history		
Use of medicines	KCE	Too broad
Immunization (Lack vaccination against hepatitis B, rubella and/or lack of history of rubella, varicella, toxoplasmosis, CMV)	KCE	Not antenatal risk
Previous obstetric history		
Grand multiparity (parity four or more)	AHMAC KCE NICE	Not antenatal risk on its own, depends on previous risks and modes of delivery
Retained placenta on two occasions	NICE	Not antenatal risk
Termination of pregnancy	AHMAC	Not antenatal risk
Maternal characteristics (non-modifiable)		
Previous experience of social dislocation	AHMAC	Not antenatal risk on its own – uncertain how previous history affects current pregnancy
Late antenatal care: 1st antenatal consultation after 20 weeks	KCE	Not antenatal risk on its own, for example could be related to migration
Maternal characteristics (modifiable)		
Psychosocial issues	AHMAC	Too broad
Particularly vulnerable or who lack social support	AHMAC KCE NICE	Too broad
At-risk sexual behaviour (for STD)	KCE	Too broad
Family history		
Familial diseases	KCE	Too broad

Key: AHMAC - Australian Health Ministers' Advisory Council; CMV - Cytomegalovirus vaccine; KCE - Belgian Healthcare Knowledge Centre; NICE - National Institute for Health and Care Excellence; STD - sexually transmitted disease

Appendix 4 Summary results from three Delphi rounds

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Medical history								
Cystic fibrosis	NICE	Agree: 100%	High: 95%					Cystic fibrosis <u>Level of care</u> Specialised Care (high risk)
Malignant disease	AHMAC KCE NICE	Agree: 100%	High: 90%					Malignant disease <u>Level of care</u> Specialised Care (high risk)
HIV infection	AHMAC NICE	Agree: 95% Neither agree nor disagree: 5%	High: 86% Medium: 5%					HIV infection <u>Level of care</u> Specialised Care (high risk)
Haematological disorders, including sickle cell or thalassaemia, thromboembolic disease	AHMAC KCE NICE	Agree: 95% Neither agree nor disagree: 5%	High: 86% Medium: 5%					Haematological disorders, including sickle cell or thalassaemia, thromboembolic disease <u>Level of care</u> Specialised Care (high risk)

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Autoimmune disorders such as antiphospholipid syndrome	AHMAC KCE NICE	Agree: 100%	High: 76% Medium: 14%	N/A	High: 100%			Autoimmune disorders such as antiphospholipid syndrome <u>Level of care</u> Specialised Care (high risk)
Hepatitis C infection	AHMAC	Agree: 100%	High: 71% Medium: 24%	N/A	High: 90% Medium: 10%			Hepatitis C infection <u>Level of care</u> Specialised Care (high risk)
Diabetes mellitus requiring insulin	AHMAC KCE NICE	Agree: 100%	High: 76% Medium: 19%	N/A	High: 90% Medium: 5%			Diabetes mellitus requiring insulin <u>Level of care</u> Specialised Care (high risk)
Cardiac disease, including hypertension	AHMAC KCE NICE	Agree: 100%	High: 67% Medium: 24%	N/A	High: 80% Medium: 15%			Cardiac disease, including hypertension <u>Level of care</u> Specialised Care (high risk)
Renal disease	AHMAC KCE NICE	Agree: 100%	High: 67% Medium: 19%	N/A	High: 80% Medium: 20%			Renal disease <u>Level of care</u> Specialised Care (high risk)

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Hepatitis B virus (HBV) infection	AHMAC NICE	Agree: 100%	High: 57% Medium: 29%	N/A	High: 70% Medium: 30%			Hepatitis B virus (HBV) infection <u>Level of care</u> Specialised Care (high risk)
Epilepsy requiring anticonvulsant drugs	AHMAC NICE	Agree: 95% Neither agree nor disagree: 5%	High: 71% Medium: 19%	N/A	High: 95% Medium: 5%			Epilepsy requiring anticonvulsant drugs <u>Level of care</u> Specialised Care (high risk)
Severe asthma	AHMAC NICE	Agree: 95% Neither agree nor disagree: 5%	High: 67% Medium: 29%	N/A	High: 85% Medium: 15%			Severe asthma <u>Level of care</u> Specialised Care (high risk)
Hepatic disease	KCE NICE	Agree: 91% Neither agree nor disagree: 9%	High: 57% Medium: 19%	N/A	High: 75% Medium: 20%			Hepatic disease <u>Level of care</u> Specialised Care (high risk)
Previous cardiac surgery (including correction of congenital anomalies)	AHMAC	Agree: 95% Disagree: 5%	High: 67% Medium: 14%	Agree: 80% Neither agree nor disagree: 15% Disagree: 5%	High: 75% Medium: 0%			Previous cardiac surgery (including correction of congenital anomalies) <u>Level of care</u> Specialised Care (high risk)

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Gynaecological surgery (e.g. myomectomy, cone biopsy, large loop excision of the transformation zone [LLETZ])	AHMAC NICE	Agree: 90% Neither agree nor disagree: 10%	High: 19% Medium: 57%	N/A	High: 20% Medium: 75%			Gynaecological surgery (e.g. myomectomy, cone biopsy, large loop excision of the transformation zone [LLETZ]) <u>Level of care</u> Assisted Care (medium risk)
Genital mutilation	AHMAC KCE	Agree: 81% Neither agree nor disagree: 19%	High: 24% Medium: 52%	N/A	High: 15% Medium: 85%			Genital mutilation <u>Level of care</u> Assisted Care (medium risk)
Uterine surgery including caesarean section, myomectomy or cone biopsy	AHMAC KCE NICE	Agree: 95% Disagree: 5%	High: 19% Medium: 76%	Agree: 60% Neither agree nor disagree: 40%	High: 0% Medium: 60%	Reworded Agree: 86% Neither agree nor disagree: 7% Unsure: 7%	High: 100%	Previous classical caesarean section or myomectomy involving the uterine cavity opening <u>Level of care</u> Specialised Care (high risk)

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Bariatric surgery (gastric bypass, lap-banding)	AHMAC	Agree: 81% Neither agree nor disagree: 14% Disagree: 5%	High: 19% Medium: 57%	Agree: 55% Neither agree nor disagree: 45%	High: 10% Medium: 40%	Include: 93% Exclude: 7%	High: 100%	Bariatric surgery (gastric bypass, lap-banding) <u>Level of care</u> Specialised Care (high risk)
Psychiatric disorders (on medication)	AHMAC NICE KCE	Agree: 100%	High: 38% Medium: 62%	N/A	High: 50% Medium: 50%	N/A	Risk assessed by consultant Agree: 93% Disagree: 7%	Psychiatric disorders (on medication) <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk
Neurological disorders	KCE	Agree: 95% Neither agree nor disagree: 5%	High: 33% Medium: 43%	N/A	High: 30% Medium: 65%	N/A	Risk assessed by consultant Agree: 100%	Neurological disorders <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Uterine pathology (congenital anomaly, abnormal cervix cytology)	KCE	Agree: 90% Neither agree nor disagree: 10%	High: 38% Medium: 33%	N/A	High: 60% Medium: 35%	N/A	Risk assessed by consultant Agree: 100%	Uterine pathology (congenital anomaly, abnormal cervix cytology) <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk
Lung diseases	KCE	Agree: 81% Neither agree nor disagree: 19%	High: 48% Medium: 14%	N/A	High: 65% Medium: 30%	N/A	Risk assessed by consultant Agree: 93% Disagree: 7%	Lung diseases <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk
Endocrine disorders	AHMAC KCE NICE	Agree: 86% Neither agree nor disagree: 9% Disagree: 5%	High: 24% Medium: 48%	Agree: 50% Neither agree nor disagree: 50%	High: 15% Medium: 35%	Agree: 100%	Risk assessed by consultant Agree: 100%	Endocrine disorders <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Use of medicines	KCE	Agree: 76% Neither agree nor disagree: 10% Disagree: 14%	High: 0% Medium: 62%	Agree: 45% Neither agree nor disagree: 55%	High: 0% Medium: 40%	Include: 0% Exclude: 75% Unsure: 25%	N/A	Excluded
Immunization (Lack vaccination against hepatitis B, rubella and/or lack of history of rubella, varicella, toxoplasmosis, CMV)	KCE	Agree: 43% Neither agree nor disagree: 19% Disagree: 38%	High: 14% Medium: 29%	Agree: 15% Neither agree nor disagree: 65% Disagree: 20%	High: 0% Medium: 15%	Include: 0% Exclude: 100%	N/A	Excluded
Previous obstetric history								
Puerperal psychosis	AHMAC KCE NICE	Agree: 95% Neither agree nor disagree: 5%	High: 86% Medium: 5%					Puerperal psychosis <u>Level of care</u> Specialised Care (high risk)

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Severe pre-eclampsia	AHMAC KCE NICE	Agree: 100%	High: 57% Medium: 38%	N/A	High: 70% Medium: 30%			Severe pre-eclampsia <u>Level of care</u> Specialised Care (high risk)
HELLP syndrome	KCE NICE	Agree: 90% Neither agree nor disagree: 10%	High: 71% Medium: 19%	N/A	High: 75% Medium: 25%			HELLP syndrome <u>Level of care</u> Specialised Care (high risk)
Rhesus isoimmunisation or other significant blood group antibodies	AHMAC KCE NICE	Agree: 86% Neither agree nor disagree: 14%	High: 67% Medium: 19%	N/A	High: 90% Medium: 10%			Rhesus isoimmunisation or other significant blood group antibodies <u>Level of care</u> Specialised Care (high risk)
Preterm birth	AHMAC KCE	Agree: 95% Neither agree nor disagree: 5%	High: 24% Medium: 62%	N/A	High: 15% Medium: 85%			Preterm birth <u>Level of care</u> Assisted Care (medium risk)

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Caesarean section	AHMAC KCE NICE	Agree: 71% Neither agree nor disagree: 19% Disagree: 10%	High: 10% Medium: 62%	Agree: 70% Neither agree nor disagree: 30%	High: 0% Medium: 70%			Caesarean section <u>Level of care</u> Assisted Care (medium risk)
Gestational diabetes	KCE AHMAC	Agree: 86% Neither agree nor disagree: 0% Disagree: 14%	High: 33% Medium: 52%	Agree: 60% Neither agree nor disagree: 35% Disagree: 5%	High: 20% Medium: 40%	Reworded Agree: 88% Disagree: 12%	High: 100%	Gestational diabetes mellitus requiring insulin <u>Level of care</u> Specialised Care (high risk)
Multiple pregnancy	KCE	Agree: 29% Neither agree nor disagree: 33% Disagree: 38%	High: 10% Medium: 19%	Agree: 40% Neither agree nor disagree: 35% Disagree: 25%	High: 0% Medium: 40%	Reworded Agree: 100%	High:81% Unsure: 19%	Multiple pregnancy (this pregnancy) <u>Level of care</u> Specialised Care (high risk)

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Recurrent miscarriage (three or more consecutive pregnancy losses) or a mid-trimester loss	AHMAC NICE KCE	Agree: 100%	High: 38% Medium: 52%	N/A	High: 50% Medium: 50%	N/A	Risk assessed by consultant Agree: 100%	Recurrent miscarriage (three or more consecutive pregnancy losses) or a mid-trimester loss <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk
Stillbirth or neonatal death	AHMAC NICE	Agree: 95% Neither agree nor disagree: 5%	High: 48% Medium: 29%	N/A	High: 65% Medium: 35%	N/A	Risk assessed by consultant Agree: 100%	Stillbirth or neonatal death <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Baby with a congenital anomaly (structural or chromosomal)	AHMAC NICE KCE	Agree: 95% Neither agree nor disagree: 5%	High: 38% Medium: 43%	N/A	High: 45% Medium: 50%	N/A	Risk assessed by consultant Agree: 80% Disagree: 13% Unsure: 7%	Baby with a congenital anomaly (structural or chromosomal) <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk
Small-for-gestational-age infant (below 5th centile) or a baby weighing below 2.5 kg	AHMAC NICE	Agree: 90% Neither agree nor disagree: 10%	High: 24% Medium: 57%	N/A	High: 40% Medium: 55%	N/A	Risk assessed by consultant Agree: 87% Unsure: 13%	Small-for-gestational-age infant (below 5th centile) or a baby weighing below 2.5 kg <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Large-for-gestational-age infant (above 95th centile) or a baby weighing above 4.5 kg	AHMAC NICE	Agree: 81% Neither agree nor disagree: 9.5% Disagree: 9.5%	High: 19% Medium: 48%	Agree: 70% Neither agree nor disagree: 25% Disagree: 5%	High: 5% Medium: 65%	Reworded Agree: 100%	Risk assessed by consultant Agree: 100%	Baby weighing above 4.5kg with associated complications <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk
Antenatal or postpartum haemorrhage on two occasions	AHMAC NICE	Agree: 100% Neither agree nor disagree: 0% Disagree: 0%	High:24% Medium: 62%	N/A	High:35% Medium: 65%	N/A	Risk assessed by consultant Agree: 73% Neither agree nor disagree: 7% Unsure: 20%	Antenatal or postpartum haemorrhage on two occasions <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk
Pregnancy induced hypertension	KCE	Agree: 71% Neither agree nor disagree: 14% Disagree: 14%	High:10% Medium: 57%	Agree: 55% Neither agree nor disagree: 40% Disagree: 5%	High:15% Medium: 40%	Reworded Agree: 100%	Risk assessed by consultant Agree: 100%	History of pre-eclampsia that is pregnancy hypertension with proteinuria <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Grand multiparity (parity four or more)	AHMAC KCE NICE	Agree: 76% Neither agree nor disagree: 19% Disagree: 5%	High:10% Medium: 57%	Agree: 60% Neither agree nor disagree: 35% Disagree: 5%	High: 0% Medium: 60%	Include: 6% Exclude: 94%	N/A	Excluded
Retained placenta on two occasions	NICE	Agree: 86% Neither agree nor disagree: 9% Disagree: 5%	High:19% Medium: 52%	Agree: 60% Neither agree nor disagree: 40%	High:5% Medium: 55%	Exclude: 100%	N/A	Excluded
Termination of pregnancy	AHMAC	Agree: 24% Neither agree nor disagree: 52% Disagree: 24%	High:5% Medium: 14%	Agree: 20% Neither agree nor disagree: 70% Disagree: 10%	High:5% Medium: 15%	Exclude: 81% Unsure: 19%	N/A	Excluded

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Maternal characteristics (non-modifiable)								
BMI <18 kg/m^2 at first contact	AHMAC KCE NICE	Agree: 95% Neither agree nor disagree: 5%	High: 24% Medium: 62%	N/A	High: 10% Medium: 85%			BMI<18 kg/m^2 at first contact <u>Level of care</u> Assisted Care (medium risk)
≥ 40 years	KCE NICE	Agree: 86% Neither agree nor disagree: 9% Disagree: 5%	High: 5% Medium: 76%	Agree: 60% Neither agree nor disagree: 40%	High: 0% Medium: 60%	Reworded Include: 75% Exclude: 13% Unsure: 13%	High: 100%	Age > 45 years <u>Level of care</u> Specialised Care (high risk)

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
≤ 18 years	KCE NICE	Agree: 67% Neither agree nor disagree: 14% Disagree: 19%	High: 5% Medium: 57%	Agree: 50% Neither agree nor disagree: 50%	High: 5% Medium: 45%	Reworded Include: 100%	Medium: 100%	Age < 16 years at first visit <u>Level of care</u> Assisted Care (medium risk)
BMI ≥ 35.0 kg/m² at first contact	AHMAC NICE KCE	Agree: 86% Disagree: 14%	High: 29% Medium: 57%	Agree: 70% Neither agree nor disagree: 30%	High: 25% Medium: 45%	N/A	Reworded and split into 2 Agree: 100%	1. BMI ≥35.0 and < 39.9 kg at first contact <u>Level of care</u> Assisted Care (medium risk) 2. BMI ≥ 39.9 <u>Level of care</u> Specialised Care (high risk)
Developmental delays or other disabilities	AHMAC	Agree: 86% Neither agree nor disagree: 9% Disagree: 5%	High: 5% Medium: 67%	Agree: 65% Neither agree nor disagree: 35%	High: 0% Medium: 65%	Reworded Agree: 100%	Risk assessed by consultant Agree: 100%	Women with disabilities <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Domestic violence	AHMAC KCE	Agree: 81% Neither agree nor disagree: 9.5% Disagree: 9.5%	High: 19% Medium: 52%	Agree: 70% Neither agree nor disagree: 25% Disagree: 5%	High: 5% Medium: 55%	N/A	Reworded and risk assessed by consultant Agree: 100%	Women with a history of 'ongoing' domestic violence <u>Level of care</u> Referral to the medical social worker rather than consultant review at every antenatal visit
Previous experience of social dislocation	AHMAC	Agree: 52% Neither agree nor disagree: 33% Disagree: 14%	High: 5% Medium: 33%	Agree: 40% Neither agree nor disagree: 50% Disagree: 10%	High: 0% Medium: 35%	Include: 13% Exclude: 81% Unsure: 6%	N/A	Excluded

Risk factor	**Source guideline(s)**	**Round 1 results***		**Round 2 result^**		**Round 3 result^**		**Final risk factor wording and level of risk**
		Inclusion	**Level of care**	**Inclusion**	**Level of care**	**Inclusion**	**Level of care**	
Late antenatal care: 1st antenatal consultation after 20 weeks	KCE	Agree: 43% Neither agree nor disagree: 24% Disagree: 33%	High: 5% Medium: 33%	Agree: 45% Neither agree nor disagree: 45% Disagree: 10%	High: 0% Medium: 45%	Include: 13% Exclude: 81% Unsure: 6%	N/A	Excluded
Maternal characteristics (modifiable)								
Use of illicit drugs such as heroin, cocaine (including crack cocaine) and ecstasy	AHMAC NICE KCE	Agree: 100%	High: 67% Medium: 19%	N/A	High: 90% Medium: 10%			Use of illicit drugs such as heroin, cocaine (including crack cocaine) and ecstasy <u>Level of care</u> Specialised Care (high risk)

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
History of alcohol consumption	AHMAC KCE	Agree: 57% Neither agree nor disagree: 19% Disagree: 24%	High: 0% Medium: 43%	Agree: 40% Neither agree nor disagree: 55% Disagree: 5%	High: 5% Medium: 35%	Reworded: Agree: 88% Neither agree nor disagree: 6% Disagree: 6%	High: 75% Medium: 6% Unsure: 19%	History of binge drinking during pregnancy <u>Level of care</u> Specialised Care (high risk)
Who smoke	KCE 2015 NICE	Agree: 57% Neither agree nor disagree: 14% Disagree: 29%	High: 14% Medium: 33%	Agree: 35% Neither agree nor disagree: 60% Disagree: 5%	High: 5% Medium: 30%	Reworded: Agree: 87% Disagree: 13%	High: 75% Medium: 25%	Women who report continuing to smoke at first antenatal visit <u>Level of care</u> Specialised Care (high risk)

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Psychosocial issues	AHMAC	Agree: 76% Neither agree nor disagree: 10% Disagree: 14%	High: 5% Medium: 62%	Agree: 45% Neither agree nor disagree: 55%	High: 0% Medium: 40%	Include: 12% Exclude: 88%	N/A	Excluded
Particularly vulnerable or who lack social support	AHMAC KCE NICE	Agree: 90% Neither agree nor disagree: 5% Disagree: 5%	High:10% Medium: 67%	Agree: 50% Neither agree nor disagree: 45% Disagree: 5%	High: 0% Medium: 45%	Include: 6% Exclude: 94%	N/A	Excluded

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
At-risk sexual behaviour (for STD)	KCE	Agree: 67% Neither agree nor disagree: 19% Disagree: 14%	High:10% Medium: 43%	Agree: 45% Neither agree nor disagree: 50% Disagree: 5%	High:10% Medium: 30%	Exclude: 88% Include: 12%	N/A	Excluded
Family history								
Family history of genetic disorder	KCE NICE	Agree: 81% Neither agree nor disagree: 14% Disagree: 5%	High:10% Medium: 48%	Agree: 50% Neither agree nor disagree: 40% Disagree: 10%	High: 0% Medium: 55%	Agree: 100%	Risk assessed by consultant Agree: 100%	Family history of genetic disorder <u>Level of care</u> Should be assessed by a consultant at the first antenatal visit to decide medium or high risk

Risk factor	Source guideline(s)	Round 1 results*		Round 2 result^		Round 3 result^		Final risk factor wording and level of risk
		Inclusion	Level of care	Inclusion	Level of care	Inclusion	Level of care	
Familial diseases	KCE	Agree: 48% Neither agree nor disagree: 43% Disagree: 9%	High:5% Medium: 24%	Agree: 40% Neither agree nor disagree: 50% Disagree: 10%	High: 0% Medium: 40%	Exclude: 86% Include: 14%	N/A	Excluded

Key: AHMAC - Australian Health Ministers' Advisory Council; BMI – body mass index; CMV - Cytomegalovirus vaccine; KCE - Belgian Healthcare Knowledge Centre; N/A – not applicable; NICE - National Institute for Health and Care Excellence; STD - sexually transmitted disease

* Consensus level - 80%

^ Consensus level - 70%

Health Research Board-Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER),
Health Information and Quality Authority (HIQA),
George's Court
George's Lane
Smithfield
Dublin 7
Phone: +353 (0) 1 814 7400
Web: www.hiqa.ie
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