An Roinn Sláinte
Department of Health

# Stratification of clinical risk in pregnancy

National Clinical Guideline No. 23

## Annex D: Budget impact analysis

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

HRB Health Research Board

CICER Collaboration in Ireland for Clinical Effectiveness Reviews

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CICER
Collaboration in Ireland for Clinical Effectiveness Reviews

# Budget impact analysis –

## Stratification of Clinical Risk in Pregnancy

July 2019

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

HRB Health Research Board

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

RCSI

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## About HRB-CICER

In 2016, the Department of Health requested the Health Research Board (HRB) to fund a dedicated multidisciplinary research group to support the activities of the Ministerial appointed National Clinical Effectiveness Committee (NCEC). Called HRB-CICER (Collaboration in Ireland for Clinical Effectiveness Reviews), a five-year contract (2017 to 2022) was awarded following a competitive process to the Health Information and Quality Authority (HIQA). The HRB-CICER team comprises a dedicated multidisciplinary research team (including expertise in health economics, qualitative and quantitative research methods and epidemiology) 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.

Guideline development groups submit clinical guidelines for appraisal and endorsement by the NCEC as National Clinical Guidelines. HRB-CICER provides independent scientific support to guideline development groups tailored according to their specific needs. The main role of the HRB-CICER team is to undertake systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines and to estimate the budget impact of implementing the guidelines. Additional support can be provided by HRB-CICER to guideline development groups including; providing tailored training sessions and working closely with the guideline development groups to develop clinical questions and search strategies; performing systematic reviews of international clinical guidelines; supporting the assessment of their suitability for adaption to Ireland and assisting in the development of evidence-based recommendations.

## Membership of the Evaluation Team

The members of the HRB-CICER and HIQA Evaluation Team were: Dr Patrick Moran, Michelle O'Neill, Professor Susan Smith and Dr Máirín Ryan.

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## Declaration of agreement

This declaration is to be completed by the Chair and Programme Manager of the Childbirth Guideline Development Group for *Stratification of Clinical Risk in Pregnancy* guideline. To estimate the budget impact of the clinical guideline recommendations, assumptions must be made about what constitutes standard practice in antenatal care in Ireland. The assumptions are underpinned by the best available evidence based on consultation with healthcare stakeholders, synthesis of relevant data and expert clinical opinion. By signing this declaration, the Chair and Programme Manager confirm that they agree with the statement below.

The guideline makes a series of recommendations about the clinical care of pregnant women, some of which will necessitate changes to customary clinical practice. Assumptions around these changes form the basis of the budget impact analysis (BIA). To the best of our knowledge, the changes presented in this report accurately reflect all of the required changes to customary clinical practice that will result from the implementation of the guideline.

Michael Turner

25th July 2019

Professor Michael Turner

Chair, Childbirth Guideline Development Group

Date

Karen Power

25th July 2019

Dr Karen Power

Programme Manager

Date

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# List of abbreviations that appear in this report

| | |
|---|---|
| **BIA** | Budget impact analysis |
| **CGDG** | Childbirth Guideline Development Group |
| **CNM3** | Clinical Nurse Manager 3 |
| **CSO** | Central Statistics Office |
| **HIQA** | Health Information and Quality Authority |
| **HIV** | Human Immunodeficiency Virus |
| **HRB-CICER** | Health Research Board Collaboration in Ireland for Clinical Effectiveness Reviews |
| **HSE** | Health Service Executive |
| **HTA** | Health technology assessment |
| **IT** | Information Technology |
| **MN-CMS** | Maternal and Newborn Clinical Management System |
| **NWIHP** | National Women and Infants' Health Programme |
| **QA** | Quality assurance |
| **WTE** | Whole Time Equivalent (Staff) |

# 1. Introduction

## 1.1 Scope of work

A budget impact analysis (BIA), addresses the expected changes in the expenditure of a healthcare system after the adoption of a new intervention.[1] The completion of a BIA is a required step in the development of national clinical guidelines in Ireland.[2] In the context of guideline development, the purpose of the BIA is to quantify the resource implications of implementing the recommendations. That is, to synthesise the best available knowledge in order to estimate the additional resources and costs to the healthcare system.[3] This BIA was developed to support the childbirth guideline development group (CGDG), who prepared the clinical guideline, *Stratification of Clinical Risk in Pregnancy*, for the Irish healthcare system.

The scope of the guidelines themselves dictates what will be 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.

## 1.2 Risk assessment in pregnancy

The first hospital visit should ideally take place in the first trimester so that risk assessment and appropriate investigations can be completed when they are most likely to of benefit. At this appointment a detailed medical history is obtained from the woman and a health care record created for that pregnancy.

The first hospital antenatal appointment is used to gather information about risk factors such as acute or chronic medical or surgical history. Information is also obtained about any relevant lifestyle risk factors and the management of previous pregnancies, including any postnatal or neonatal complications.

Several measurements and tests are also carried out during the first antenatal appointment. These include blood pressure, weight and height. Urine and blood samples are also obtained to gather data on blood group, full blood count, and Rhesus factor, and to test for a range of risk factors that affect the management of the pregnancy, including bacteriuria, rubella immune status, and diseases such as HIV, hepatitis C and syphilis.

The purpose of the *Stratification of Clinical Risk in Pregnancy* guideline is to standardise antenatal risk assessment across Ireland by introducing a common set of clinical markers that will be used to stratify women in early pregnancy according to their level of risk.

# 2. Methods

A budget impact analysis (BIA) addresses the expected changes in the expenditure of a health care system when introducing a new intervention. In the case of clinical guideline development, the intervention is any recommendation that will lead to a change in the treatment pathway. In this context, the BIA aims to quantify the resource implication of any recommendation identified as representing a change to standard clinical practice. The purpose of this analysis is 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 analysis was conducted in accordance with the HIQA guidelines for budget impact analysis and economic evaluation in Ireland.[4, 5]

## 2.1 Study perspective

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).[4, 5] 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.

## 2.2 Time horizon

The time horizon represents the timeframe over which resource use is planned. In accordance with national guidelines, the annual budget impact was estimated over a five year time horizon.[4, 5] No discounting was applied to account for temporal differences in when costs were incurred over the five year time horizon.

## 2.3 Measurement and valuation of resources

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 childbirth guideline development group 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.

## 2.4 Rationale for included interventions

A BIA of a clinical guideline considers the changes to the treatment pathway arising from implementing the clinical recommendations. The focus of the *Stratification of Clinical Risk in Pregnancy* guideline is on standardising the risk assessment that is carried out across all maternity hospitals and units in Ireland and implementing a consistent system for stratifying women into three risk groups (normal, medium and high as outlined in the National Maternity Strategy 2016-2026). This stratification will then inform the type of antenatal care women receive, with the National Maternity Strategy 2016-2026 recommending that three distinct carestreams be implemented that are tailored to the needs of women in each category.[6]

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 relevant staff to be aware of and understand the new risk assessment procedure. They should be informed about 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 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 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 the 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.

## 2.5 Rationale for excluded interventions

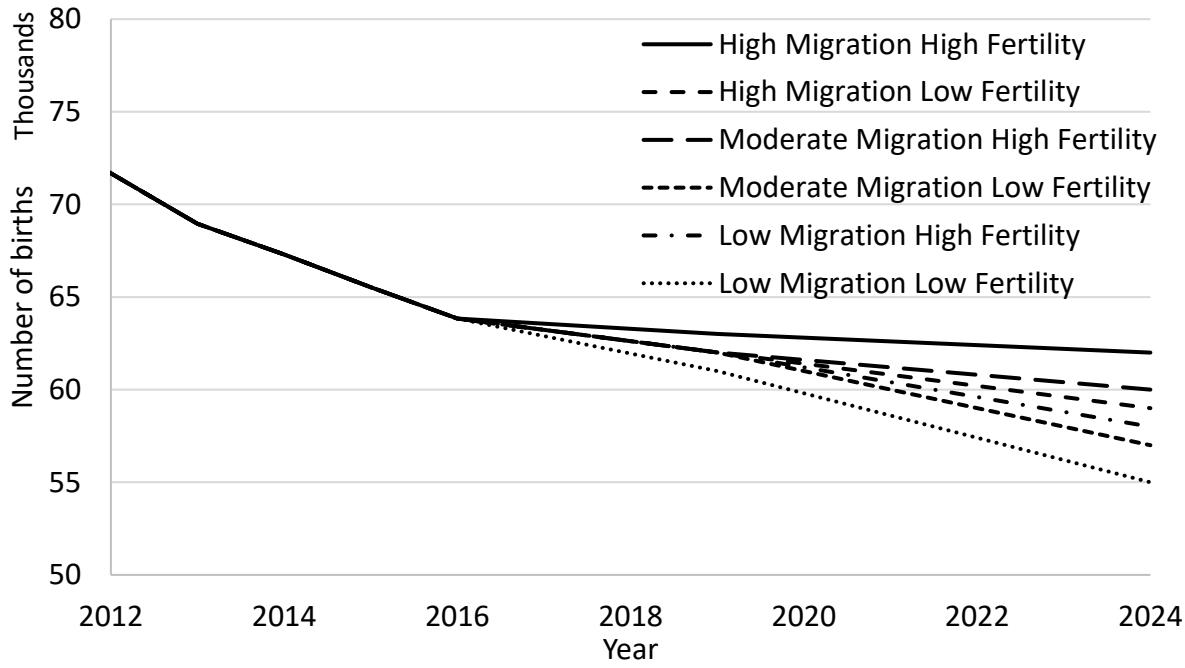
*Stratification of Clinical Risk in Pregnancy* focuses specifically on the introduction of standardised risk assessment, based on a list of clinical markers developed by the CGDG. The specification of the different carestreams that should be available to women based on their risk status is not within the scope of this clinical guideline.

As a result, a limitation of this budget impact analysis is that it does not estimate the incremental costs associated with the implementation of these 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.

## 2.6 Target population

The unit of analysis is the entire maternity service in Ireland, comprising 19 separate maternity hospitals and units. 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, with CSO projections for 2024 ranging from 55,000 to 62,000 depending on what assumptions are made about future trends in fertility and migration (Figure 2.1). 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 antenatal appointments in each year.[7]

**Figure 2.1 Number of births per year, projected to 2024 (source CSO)**



## 2.7 Evidence of clinical- and cost-effectiveness of antenatal risk assessment

A systematic review of available evidence identified no previous studies examining the cost-effectiveness of using a formal risk stratification system during the antenatal period.[8] Given there has been little evaluation of the clinical effectiveness of comprehensive risk classification systems on patient and health system outcomes, the lack of economic evidence is unsurprising. A number of economic evaluations related to costs of screening for individual specific risk factors (e.g. individual medical factors such as hypertension, risk relating specifically to previous obstetric complications or psychosocial problems), but no studies focused on a comprehensive system of classification of a woman's risk during the antenatal period.

Therefore, this review focuses solely on the costs of implementing the guideline. Any potential benefits from improved identification and more appropriate management of women at high risk are not included.

## 2.8 Summary of assumptions and data requirements for BIA

The assumptions used when conducting the analysis were as follows:

- The length of time needed for the first 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 for more details).
- No formal training of staff is 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 tool 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.

# 3. Analysis and 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:

- Information day incorporating a formal launch of the national guideline for *Stratification of Clinical Risk in Pregnancy*
- 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.

## 3.1 Information day incorporating a launch of the National Clinical Guideline for Stratification of Clinical Risk in Pregnancy

Costs associated with hosting an information day incorporating a formal launch of the guideline are shown in Table 3.1. These were estimated based on similar events that were hosted by the NWIHP in the past. The purpose of this event is to promote information dissemination and knowledge sharing among key HSE staff responsible for managing services to which this guideline relates. These costs are indicative and may change depending on the venue, suppliers, etc. The items of expenditure included in the cost were:

- Venue hire for one day
- Catering
- Participant registration
- Invited speaker travel and accommodation

The cost of the considerable staff time required to plan and organise the information day was not included, on the basis that it would be carried out by staff within the CGDG as part of their current roles. The opportunity cost of the time required for health professionals to attend the information day was also not included. It is anticipated that attendance will comprise less than 100 HSE staff with responsibility for the management and delivery of maternity services throughout Ireland.

**Table 3.1 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 |

## 3.2 Implementation of standardised risk assessment

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.[9] The MN-CMS is currently live in four maternity hospitals (Cork University Maternity Hospital, National Maternity Hospital, Rotunda Hospital and University Hospital Kerry) 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.[10] These costs will be determined by the complexity of the work required 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 antenatal appointment.

In this regard it is important to make a distinction between the use of software as a means of documenting the results of the standardised risk assessment, and the use of software as a clinical decision aid that informs decisions for diagnostic or therapeutic purposes. It is not envisioned that the MN-CMS implementation of the standardised risk tool will generate new information through any internal calculation of risk scores, or require the use of a classification algorithm that combines clinical markers using weights or other analytical techniques. Rather the aim is to enable risk assessment to be documented using the system, and for the overall risk category and assignment to the appropriate carestream to be noted.

While this approach is relatively more straightforward, it will require planning in order to

anticipate the types of data that need to be recorded, how these will be handled, and any other alerts or notifications that will be needed to ensure that women benefit from high quality, safe and timely maternity care, even if they switch between carestreams over the course of the pregnancy.

The current contract with the supplier includes a specified amount of maintenance and support. If the agreed specification for the update to the MN-CMS primarily involves the creation of new fields to hold data on the presence or absence of individual risk factors, the overall risk classification and the carestream chosen by the woman, then the existing contract with the supplier may cover this at no additional cost to the HSE. However, if substantial changes are needed then these will have to be communicated to the supplier and quotes obtained.

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 midwife (1 WTE CNM3 scale) over the first year of implementation of the guideline (Table 3.2).

**Table 3.2 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 |

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 centralization of high risk pregnancies.

## 3.3 Total incremental costs

The total direct costs to the HSE overall 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 (Table 3.3). 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 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 cost items (additional staff costs and information day). No significant costs are anticipated in years two to five.

### Table 1.3 Total Costs

| Item | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | total |
|---|---|---|---|---|---|---|
| Information day | €6,000 | 0 | 0 | 0 | 0 | €6,000 |
| Patient record update | N/A* | N/A* | N/A* | N/A* | N/A* | N/A* |
| Staff costs | €85,291 | 0 | 0 | 0 | 0 | €85,291 |
| **Total costs** | €91,291* | 0* | 0* | 0* | 0* | €91,291* |

* IT costs associated with creating a digital version of the risk assessment tool that is fully integrated with the existing electronic patient record are unavailable pending a detailed specification of the required changes – work that is currently in progress by the MN-CMS national project team.[10]

## 3.4 Sensitivity analysis

A sensitivity analysis was carried out to estimate the impact of the standardised risk assessment resulting in longer or shorter antenatal appointments. This analysis was based on estimates of the number of first antenatal appointments that would need to be conducted in each maternity hospital over the five-year time horizon from 2019 to 2023 and reflects the incremental cost of the staff time required, compared to the current standard of care.

The rationale for this sensitivity analysis is based on the possibility that implementing a standardised risk assessment tool may affect the average duration of the first antenatal appointment. Any such changes may not necessarily apply equally across all appointments. For instance, in cases where there are no significant risks to the mother or baby, standardised risk assessment is likely to have little impact on appointment times, or may even reduce the amount of time needed. However, where significant risks are identified and

the patient is being assigned to a carestream for those at medium or high risk, additional time may be needed to fully inform the woman about the alternative carestreams that are available, why this is being recommended and what that entails. The increase in mean consultation times will therefore be a weighted average of the effect in each relevant subgroup.

As no information is available on any such differences in the time needed to complete the new risk assessment procedure for different types of patients, or the proportion of women likely to be assigned to different risk groups, a range of values were modelled, from what were considered to be the extremes of an average decrease of five minutes, to an average increase of ten minutes per first antenatal appointment. Anecdotal evidence indicates that the average time for a first antenatal appointment at present is about 40 minutes, so these changes encompass first antenatal appointment times ranging from 35 minutes to 50 minutes on average. This range is based on the combined effect of a worst case in which those deemed to be at medium or high risk require up to 20 minutes extra, and a best case in which standardised risk assessment reduces the time required for women at normal risk by up to 5 minutes. Varying the percentage of women found to be at medium or high risk from 10% to 50%, the possible changes to average appointment times from any combination of these ranges from 4.5 minutes shorter to 10 minutes longer (Table 3.4).

**Table 3.4 Range of changes in average appointment times**

| % at medium or high risk | **Additional time per women at medium or high risk (minutes)** | | | | | % at low risk | **Reduction in time per woman with normal risk (minutes)** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **0** | **5** | **10** | **15** | **20** | | **0** | **-1.5** | **-2.5** | **-3.5** | **-5** |
| 10 | 0 | 0.5 | 1 | 1.5 | 2 | 90 | 0 | -1.35 | -2.25 | -3.15 | -4.5 |
| 20 | 0 | 1 | 2 | 3 | 4 | 80 | 0 | -1.2 | -2 | -2.8 | -4 |
| 30 | 0 | 1.5 | 3 | 4.5 | 6 | 70 | 0 | -1.05 | -1.75 | -2.45 | -3.5 |
| 40 | 0 | 2 | 4 | 6 | 8 | 60 | 0 | -0.9 | -1.5 | -2.1 | -3 |
| 50 | 0 | 2.5 | 5 | 7.5 | 10 | 50 | 0 | -0.75 | -1.25 | -1.75 | -2.5 |

The number of appointments needed was calculated by combining the expected number of births from the CSO population projections with data from a systematic review that reported rates of miscarriage by gestational week to estimate the number of pregnancies of at least 13 weeks duration.[7] The population projection used in the primary analysis was the variant that assumes that fertility levels will remain constant and there will be high net migration over the next five years. The analysis was also carried out using the most pessimistic variant, which assumed declining fertility and reduced inward migration.
Cost of staff time was estimated based on the midpoint of the Staff Nurse/Midwife payscale as of 1 January 2019, and includes pay as well as PRSI and pensions costs. The proportion of births in each maternity hospital is based on 2014 CSO data, with births in the now closed Mount Carmel maternity hospital redistributed evenly across the three remaining Dublin

centres. It is assumed that these proportions remain constant over the time horizon.

Table 3.5 shows the cumulative 5-year costs (or savings) of staff time associated with changes to average first antenatal appointment times ranging from 5 minutes shorter to 10 minutes longer, using different assumptions about future migration and fertility rates. The results range from a reduction in staff time costs of €695,000, to an increase of €1.4million nationally over five years. These are the extreme values however. If, say, it is assumed that there will be no change in appointment times for low risk women, but that approximately 20% of women will be at medium or high risk and require an additional 10 minutes to discuss the implications of their risk status and the available carestreams, then average appointment times will be extended by 2 minutes (Table 3.4), and the estimated cumulative cost of the additional staff time required will be between €258,000 and €278,000 over five years, depending on the assumptions made in regard to fertility and migration (Table 3.5).

**Table 3.5 Sensitivity analysis of the 5-year cumulative impact of changing the average duration of the first antenatal visit, expressed as costs of staff time (€) for M1F1 and M3F2 population projections***

| Maternity Hospital | Change in staff time costs (€1,000)** – M1F1 projections | | | | | | | Change in staff time costs (€1,000)** – M3F2 projections | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Change in average duration of a first antenatal appointment in minutes | | | | | | | | | | | | | |
| | -5 | -2 | 2 | 4 | 6 | 8 | 10 | -5 | -2 | 2 | 4 | 6 | 8 | 10 |
| Cavan General Hospital | -18.2 | -7.3 | 7.3 | 14.6 | 21.9 | 29.2 | 36.5 | -16.9 | -6.8 | 6.8 | 13.5 | 20.3 | 27.1 | 33.9 |
| Coombe Women & Infants University Hospital | -91.2 | -36.5 | 36.5 | 72.9 | 109.4 | 145.9 | 182.3 | -84.6 | -33.8 | 33.8 | 67.7 | 101.5 | 135.4 | 169.2 |
| Cork University Maternity Hospital | -83.2 | -33.3 | 33.3 | 66.5 | 99.8 | 133.1 | 166.4 | -77.2 | -30.9 | 30.9 | 61.8 | 92.6 | 123.5 | 154.4 |
| University Hospital Galway | -30.8 | -12.3 | 12.3 | 24.6 | 36.9 | 49.2 | 61.5 | -28.5 | -11.4 | 11.4 | 22.8 | 34.2 | 45.7 | 57.1 |
| University Hospital Kerry | -15 | -6 | 6 | 12 | 18 | 24 | 30 | -13.9 | -5.6 | 5.6 | 11.2 | 16.7 | 22.3 | 27.9 |
| Letterkenny University Hospital | -17.4 | -7 | 7 | 13.9 | 20.9 | 27.8 | 34.8 | -16.1 | -6.5 | 6.5 | 12.9 | 19.4 | 25.8 | 32.3 |
| Mayo University Hospital | -17.9 | -7.1 | 7.1 | 14.3 | 21.4 | 28.6 | 35.7 | -16.6 | -6.6 | 6.6 | 13.3 | 19.9 | 26.5 | 33.2 |
| Midlands Regional Hospital Mullingar | -24.8 | -9.9 | 9.9 | 19.8 | 29.8 | 39.7 | 49.6 | -23 | -9.2 | 9.2 | 18.4 | 27.6 | 36.8 | 46 |
| Midlands Regional Hospital Portlaoise | -18.8 | -7.5 | 7.5 | 15 | 22.6 | 30.1 | 37.6 | -17.4 | -7 | 7 | 14 | 20.9 | 27.9 | 34.9 |
| National Maternity Hospital | -96 | -38.4 | 38.4 | 76.8 | 115.2 | 153.5 | 191.9 | -89.1 | -35.6 | 35.6 | 71.2 | 106.9 | 142.5 | 178.1 |
| Our Lady of Lourdes Hospital | -34.9 | -14 | 14 | 27.9 | 41.9 | 55.8 | 69.8 | -32.4 | -13 | 13 | 25.9 | 38.9 | 51.8 | 64.8 |
| Portiuncula University Hospital | -20.5 | -8.2 | 8.2 | 16.4 | 24.6 | 32.7 | 40.9 | -19 | -7.6 | 7.6 | 15.2 | 22.8 | 30.4 | 38 |
| Rotunda Hospital | -92.7 | -37.1 | 37.1 | 74.1 | 111.2 | 148.3 | 185.3 | -86 | -34.4 | 34.4 | 68.8 | 103.2 | 137.6 | 172 |
| Sligo University Hospital | -14.5 | -5.8 | 5.8 | 11.6 | 17.4 | 23.2 | 29 | -13.5 | -5.4 | 5.4 | 10.8 | 16.1 | 21.5 | 26.9 |
| South Tipperary General Hospital | -11.4 | -4.5 | 4.5 | 9.1 | 13.6 | 18.2 | 22.7 | -10.5 | -4.2 | 4.2 | 8.4 | 12.7 | 16.9 | 21.1 |
| St. Luke's General Hospital | -18.6 | -7.4 | 7.4 | 14.9 | 22.3 | 29.8 | 37.2 | -17.3 | -6.9 | 6.9 | 13.8 | 20.7 | 27.6 | 34.5 |
| University Maternity Hospital Limerick | -46.9 | -18.7 | 18.7 | 37.5 | 56.2 | 75 | 93.7 | -43.5 | -17.4 | 17.4 | 34.8 | 52.2 | 69.6 | 87 |
| University Hospital Waterford | -21.8 | -8.7 | 8.7 | 17.4 | 26.1 | 34.8 | 43.5 | -20.2 | -8.1 | 8.1 | 16.2 | 24.2 | 32.3 | 40.4 |
| Wexford General Hospital | -20.3 | -8.1 | 8.1 | 16.2 | 24.4 | 32.5 | 40.6 | -18.8 | -7.5 | 7.5 | 15.1 | 22.6 | 30.1 | 37.7 |
| All | -694.6 | -277.8 | 277.8 | 555.7 | 833.5 | 1111.4 | 1389.2 | -644.6 | -257.8 | 257.8 | 515.7 | 773.5 | 1031.3 | 1289.2 |

* [F1: Total Fertility Rate to remain at its 2016 level of 1.8 for the lifetime of the projections, F2: Total Fertility Rate to decrease to 1.6 by 2031, M1: High net inward migration (+30,000 per annum in 2017/2051), M3: Low net inward migration (+10,000 per annum in 2017/2051)], ** Negative values indicate cost savings

# 4. Discussion

The most significant change associated with introducing standardised risk assessment relates to changing the electronic patient record system to gather and process the information on risk status and carestream. The additional functionality required includes being able to record a woman's risk classification and any changes to this over the course of the pregnancy, as well as the carestream that the woman has chosen in consultation with her care team, and the integration of this information into any other relevant aspects of the system.

Estimates for the costs associated with adding this functionality to the current Maternal & Newborn Clinical Management System (MN-CMS) are currently unavailable, pending the completion of work by the MN-CMS National Project Team to develop a full specification of the required changes. If these are relatively simple updates that are limited to documenting items in additional data fields, then the costs may be covered under the existing support contract. However, if more substantial changes are required to integrate this information into the patient record, such as the automated generation of notifications or cross functionality with other systems, then additional costs may be incurred. Therefore, a complete estimate of the budget impact of the introduction of the *Stratification of Clinical Risk in Pregnancy* guideline is unavailable until a full specification of the changes is drawn up.

In addition to any IT costs, ongoing work to support and manage the implementation of the standardised risk assessment over the first year will require significant staff time. Per the advice of the CGDG, this was estimated as requiring one full time midwife for 12 months, at CNM3 grade, with an estimated cost of €85,291 (using midpoint of scale and including PRSI, pension costs and overheads).

The only other direct implementation cost is for the hosting of a one-day information event incorporating a formal launch of the guideline. This event will be used as a platform to raise awareness of the guideline within relevant clinical and academic circles, and to address any questions that may arise within the wider healthcare community about how standardised risk assessment will be implemented across Ireland. The anticipated cost of approximately €6,000 is based on similar events hosted by the HSE in the past, and the total cost is incurred in year 1.

Several assumptions were made in order to facilitate estimation of the incremental costs associated with implementation of this guideline, all of which were endorsed by the CGDG prior to running the analysis. The two most important ones related to training costs, and the impact of the standardised risk assessment on the time required to complete a first antenatal appointment.

It was assumed that all training on the use of the new risk assessment could be accommodated within the existing staff training and development schedule within each of

the 19 maternity units. The rationale for this was that standardised risk assessment is expected to be largely similar to existing risk practices, so the minimal training required can be conducted within the time that is already provided for routine staff training. It was also assumed that no formal training would be needed for General Practitioners. As the guideline and supporting documentation will be freely available on the website of the National Patient Safety Office, no printing or dissemination costs were included.

The potential for this guideline to have a major impact on appointment times was not considered to be a significant risk given that it involves harmonising the way risk assessment is carried out across all 19 maternity units rather than representing a major departure from current practice. However, while standardised collection of information on clinical markers may take the same (or possibly less) time for normal-risk cases, midwives may have to spend additional time explaining to those at medium or high risk what the different risk categories mean, what the recommended carestreams for women with a given risk status are, and allow them some time to make an informed decision.

Our analysis of the incremental costs of staff time if appointment times are affected as a result of these issues ranged from a saving of almost €700K over 5 years (if the guideline decreased average appointment times by five minutes), to incremental costs of almost €1.4M over 5 years (if average appointment times increased by ten minutes). These are extremes representing what were considered upper and lower bounds, since no data is currently available on the impact of the new risk assessment tool on appointment durations. It is also important to note that these figures represent the opportunity costs of the additional time needed to conduct the first antenatal appointment, rather than additional resources that will need to be allocated by the HSE in order to introduce this guideline. However, if no new resources are allocated then any additional time needed for the first antenatal appointment will displace staff activity in other areas.

The scope of the *Stratification of Clinical Risk in Pregnancy* guideline does not extend to specifying the type of carestream that should be made available to women depending on their risk status, or estimating the likely effect that improved management of those at medium or high risk will have on maternal and child health outcomes. These issues are likely to have substantial implications for the cost of maternity service provision, both in terms of additional resources required in the short term to set up and run these carestreams, as well as the cost savings that may accrue in the medium to long term from a combination of reduced maternal and infant morbidity, and being able to provide maternity services at the lowest appropriate level of complexity. At a broader level, increased emphasis on risk management in maternity care may also be associated with unintended consequences that affect costs, such as influencing women's preferences for choice of maternity carestream and mode of delivery in a way that may contribute to changes in intervention rates during labour

and birth.[11] However, although these issues may affect costs, they are outside the scope of the budget impact analysis for this guideline.

# 5. References[‡]

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[‡] All online references were accessed during preparation of this report. Please note that web addresses can change over time.

# Appendix 1: Summary of Guideline recommendations and BIA implications

| No. | Recommendation | Current Practice | BIA Implications |
|---|---|---|---|
| 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. | At present a risk assessment is carried out at the first antenatal appointment, though the exact procedure for doing this may differ between hospitals/units. Level of risk is currently kept under review as the pregnancy progresses and after the birth of the baby. | Is not anticipated that the standardised risk assessment will involve collection of a large amount of additional data that is not already gathered at this appointment, rather the goal is to standardise the stratification of women into groups of normal, medium and high risk. Therefore, an assumption was made that the administration of the standardised risk assessment will not make a significant change to the duration of the first antenatal appointment. The potential impact resulting in longer or shorter appointments was tested in a sensitivity analysis.<br><br>Documentation describing how risk stratification works at the local level will need to be developed and provided in all sites. |
| 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. | Separate carestreams for normal, medium and high-risk women are not currently in operation. | Specification of the number and type of carestreams that will be created to care for those classified as being at normal, medium and high risk is outlined in the National Maternity Strategy 2016-2026. Therefore, outlining the costs associated with creating these carestreams is outside the scope of this BIA. |
| 3 | A midwife or clinician should allocate the woman to a carestream at the first antenatal visit using the risk factor stratification list (Guideline Appendix 10). The | Booking systems do not currently classify women into normal, medium and high-risk categories. | IT resources are required to adapt existing electronic patient record interfaces to include all the data fields required for risk assessment. For paper-based systems new risk assessment templates may need to be printed, but this will be done on-site from within existing resources. |

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| | booking system (paper or electronic healthcare record) should have the facility to record this allocation. The allocation for each subsequent antenatal visit should also be recorded in the healthcare record. | | |
| 4 | The carestreams should be women-centred and team-based irrespective of risk stratification. | Separate carestreams for those with normal, medium and high-risk classification are not currently in place. | No incremental budgetary costs anticipated. |
| 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. | Separate carestreams for those with normal, medium and high-risk classification are not currently in place. | Costs associated with recording risk status in individual patient records is examined under item no. 3 above. However, the implications of provision of parallel risk-based carestreams, including the transitioning between these, is outside the scope of the *Stratification of Clinical Risk in Pregnancy* guideline. |
| 6 | Women should be informed about their individual risks related to pregnancy. They should be given an opportunity to input into decisions about risk stratification and carestreams. | Standardised risk assessment and the provision of separate carestreams for those with normal, medium and high-risk classification are not currently in place. | The time needed to discuss this with women during the first antenatal appointment could potentially result in changes to the time needed to complete these consultations. The potential impact of this was tested in a sensitivity analysis. |

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| 7 | Up-to-date local hospital-level clinical data should be available and used in stratifying and communicating risk to pregnant women (for example, data from the Irish Maternity Indicator System (IMIS)) | These resources are currently available to hospital staff | No additional data will be provided as part of this guideline. |
| 8 | Risk stratification in the maternity services should be consistent and aligned with other national clinical guidelines. | No standardised risk stratification currently in place across all maternity hospitals/units. | No incremental budgetary costs anticipated. |
| 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. | Separate carestreams for normal, medium and high-risk women are not currently in operation. | Specification of the number and type of carestreams that will be created to care for those classified as being at normal, medium and high risk is not within the scope of this guideline. Therefore, this BIA does not examine the likely costs associated with implementation of these carestreams in maternity care. |
| 10 | The implementation of risk stratification should be reviewed annually by the senior management team in each maternity hospital/unit. | No standardised risk stratification currently in place across all maternity hospitals/units. | Audit and quality assurance (QA) systems may need to be adapted locally to facilitate the introduction of the standardised risk assessment, to verify that it is being implemented properly, and that subsequent decisions about women's carestream are being informed by their level of risk. This will leverage existing audit and QA systems already in place and any required alterations are assumed to be minor. Therefore, they are not included in this assessment. |
| 11 | National guidance on risk stratification should be reviewed annually by the | NCEC Guideline development process includes provision to | Costs of ongoing review of guidance on risk stratification was not included, as this is not a cost associated with national guideline development activity in general, rather than a cost associated with |

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| | NWIHP based on recent clinical developments and national audits. | update recommendations based on new evidence that may emerge following publication. | implementation of this particular guideline. |
| 12 | All maternity hospitals/units will provide education on this guideline | Training on individual guidelines is being managed as they are released. | Information about the new risk assessment and any implications it has for staff practices within each maternity hospital will be communicated to staff locally, during times that are already dedicated to staff updates and training. As such there are not additional costs associated with informing staff about the standardised risk assessment. |