Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

SYNTHESIS

WHAT ARE THE RECOMMENDED CLINICAL ASSESSMENT AND SCREENING TESTS DURING PREGNANCY?

KCE REPORT 248Cs
GOOD CLINICAL PRACTICE

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FOREWORD

Pregnancy usually is quite a joyful experience … of a very natural physiological happening. And it certainly is not a disease. At the same time it has become highly medicalized in our society. And this seems logic: now we, more than ever, know what can go wrong and are able to prevent adverse events, it is quite legitimate that one wants to take every opportunity to bring a healthy child onto this world. For future parents the stakes are particularly high, for involved doctors, midwives and other health professionals too. And - not surprisingly - in a medico-legal perspective we enter a thorny domain.

Formulate recommendations on preventive medicine is never easy and - a fortiori – this is the case in the field of prenatal care. It is not in vain that the World Health Organization has held it useful to review and emphasize principles of good care specifically for this domain.

Obviously it must be evidence-based care: use of appropriate technology, locally available, multi-disciplinary and holistic. And it must put the future mother in the centre of attention. So far, no earth-shattering matters. Yet – and here the WHO starts its recommendations' list – caring for women with normal pregnancies should be 'de-medicalized'. Cultural identity and associated aspirations of the future parents deserve special attention. They must get all necessary information to make their 'right decisions'. With the latter we enter a highly sensitive ethical domain, where, in addition to the 'right to know', the 'right not to know' equally can be invoked.

However, before recommending a prenatal test or intervention, every case must be carefully weighed, again and again: each abnormal result we absolutely seek not to overlook in women with a problem pregnancy, inevitably comes at the expense of a generally larger number of women with normal pregnancies, women that are rendered idly worried, eventually getting an amniocentesis even up to a medical abortion.

These basically are known technical limitations of such biological testing. Hence, choices seldom are easy and sometimes they provoke intense debate.

We sincerely thank all the members of the guideline group, all of whom spared neither time nor effort to bring this project to a successful conclusion. Thanks to their expert contribution these recommendations will, we hope at least, connect all the better with the clinical reality in our country.

Christian LÉONARD
Deputy general director

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General director

SYNTHESIS

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1. INTRODUCTION

1.1. Background

Each year, more than 125 000 births are registered in Belgium.[1] An early, adequate and continuous prenatal care with timely identification and management of risk factors is fundamental for a good pregnancy outcome. To avoid consequences of malpractice, inappropriate use of resources and inequality between patients, prenatal care should be based on the best scientific evidence. In 2004, the KCE had published a clinical guideline for antenatal care (KCE Report 6).[2] However, since 2004, the health professionals who are involved in the management of pregnant women face new scientific evidence and emerging issues (e.g. lower threshold for the diagnosis of gestational diabetes[3] or new screening tests for preeclampsia risk). Furthermore, it appears that some laboratory tests that were not recommended in 2004 continue to be broadly prescribed in Belgium.[4] This observation can indicate a possible overuse of the screening tests with a risk of misallocation of resources but also deleterious effects on pregnant women such as overdiagnosis, overtreatment, and related anxiety.

1.2. Remit of the guideline

The main objectives pursued by this guideline are to offer information on best practices for baseline clinical care of all pregnancies and comprehensive information for the follow-up of the low-risk pregnant women. The scope of this guideline was defined in collaboration with the guideline development group (GDG) members and stakeholders which decided to focus on low-risk pregnant women, i.e. women who do not have identified risk factors, known pre-existing conditions or complications requiring additional tests or adapted management (see Table 1). According to the Intermutualistic Agency (IMA), in 2010, 78.3% of Belgian pregnant women could be considered as low-risk (based on age; socioeconomic status (Bénéficiaires de l'Intervention Majorée-rechthebbenden van de verhoogde tegemoetkoming); and on the basis of medicines consumption that may suggest co-morbidity).[4] The principles of perinatal care proposed by the World Health Organization (WHO) in 1998 are used as a reference within this guideline, notably the first principle underlying that pregnancy and birth should be viewed as a natural process in life and that essential care should be provided to women with the minimum set of interventions necessary (Chalmers et al. 2001 and WHO 1998 in Australian guideline).[5]

This guideline focus on baseline clinical care for all pregnancies. It does not include information on the additional care that some women will require due to specific risk factors or pre-existing conditions. Although the guideline addresses screening for many of the complications of pregnancy, it does not include information on the investigation and appropriate management of these complications (for example, the management of pre-eclampsia, fetal anomalies and multiple pregnancies). In addition, this guideline does not provide advices about general lifestyle and nutrition of pregnant women (except for CMV and toxoplasmosis), nor about procedures or care that are not specifically related to pregnancy (e.g. breast examination for cancer screening). Furthermore, this guideline does not cover the follow-up of long term health status or severe maternal morbidity (e.g. diabetes, renal failure, heart failure occurring during the pregnancy and that have to be followed up after the delivery).

This guideline provides recommendations based on current scientific evidence. Healthcare providers are encouraged to interpret these recommendations in the context of the individual patient situation, values and preferences.

2. RISK FACTORS

A list of risk factors was defined by the GDG, based on the KCE 2004, NICE 2008 and Australian 2014 guidelines.[2, 5, 6]

Table 1 – Risk factors that may require additional care (non-exhaustive list)

General information
Age < 18 years or > 40 years
Late antenatal care: 1st antenatal consultation after 20 weeks
Lack of social support, domestic violence, psycho-social vulnerability
Use of medicines
Immunization status (lack of vaccination against hepatitis B, rubella and/or lack of history of rubella, varicella, toxoplasmosis, cytomegalovirus)
Obesity (body mass index (BMI) 35 kg/m² or more at first contact) or underweight (BMI less than 18 kg/m² at first contact)
Lifestyle factors
Drug use
Alcohol consumption
Active and/or passive smoking
At-risk sexual behaviours (for STD)
Familial history
Familial diseases or genetic disorders
Personal history
All pre-existing pathologies or surgical interventions that can have an impact on the pregnancy, including: • obesity (BMI, 35 kg/m² or more at first contact) or underweight (BMI less than 18 kg/m² at first contact) • diabetes • endocrine disorders • auto-immune disorders • cardiovascular diseases • lung diseases • renal diseases • hepatic diseases • haematological disorders • malignancy • neurological disorders

• psychiatric disorders
Gynaecological history
Uterine pathology (congenital anomaly, abnormal cervix cytology)
Uterine surgery (e.g. caesarean section, myomectomy or cone biopsy)
Genital mutilation
Experiences in previous pregnancies
Three or more documented miscarriages
Pregnancy induced hypertension, pre-eclampsia and HELLP syndrome
Gestational diabetes
Postpartum psychosis/ Depression
Rhesus isoimmunisation or other significant blood group antibodies
Preterm birth
Multiple pregnancy
Grand multiparity (parity four or more)
Severe perinatal morbidity (congenital or acquired)

This definition of risk factors leads to formulate a general recommendation:

Recommendation
To identify the need for additional care, it is recommended to collect information relative to: the current pregnancy, the lifestyle factors that may impact pregnancy, the personal and the familial history, and finally, the gynecological and obstetrical antecedents. Risk factors and pre-conditions have to be listed to inform the pregnant women and their healthcare practitioners that additional care may be required. This history taking will be completed with a clinical exam to identify risk factors (measure of blood pressure, weight, detection of a pre-existing diabetes by a fasting glycaemia measurement…).

3. PATIENT CENTEREDNESS

Information to women is paramount during pregnancy. Several issues deserve explanations and should be addressed during consultations such as the description of the different steps of pregnancy or explanations of harm and benefit for each test and care in order to promote an informed decision-making process.

In order to take into account the women's perspective in the present guideline, two approaches were used. One consists on wording the recommendation with a verb which opens the discussion with women. This is why *strong recommendations* (see Chapter 4) are formulated with the verb "offer". Another approach aims to develop specific recommendations on patient centeredness during pregnancy. Since it was not the aim of this guideline to draw a literature review on this topic, the Australian 2014 guideline[5] was used as a source of recommendations. These general recommendations have no level of evidence and concern 4 issues: preparation for pregnancy, birth and parenthood; informed decision-making; documented decisions; sufficiently long first visit. For more information on patient centeredness during pregnancy, we refer to the Australian 2014 (Aus 2014) and NICE 2008 guidelines.[5, 6]

KCE 2015 based on Aus 2014	Recommendations
	● Consider that women and their partners should be assisted to prepare for pregnancy, birth and parenthood.
	● Offer to all women evidence-based information that can easily be understood and encourage them to participate in decisions about care. It is indeed important that women have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals.
	● Consider to document the discussions and decisions in a record easily available for different healthcare professionals.
	● Consider a longer first antenatal visit than the following visits because of the large volume of information which needs to be exchanged.

4. CLINICAL RECOMMENDATIONS

The methodology used to develop the clinical recommendations of this guideline is described in the chapter 5. Two methods were used: a systematic review of literature for ten topics (named 'full search') and the ADAPTE process based on the Australian guideline 2014 for 24 other clinical questions (named 'update').

Recommendations are marked as following:

- **[KCE 2004] indicates that the evidence presented in the Australian 2014 guideline did not argue to a change in the content of the KCE 2004 recommendation.**
- **[KCE 2004, amended] indicates that the recommendation has been amended depending on the evidence reported by the Australian 2014 guideline.**
- **[KCE 2004, slightly amended] indicates that a minor change was performed in the recommendation according to discussion with stakeholders and GDG**
- **[KCE 2015] indicates that the evidence has been reviewed but no major changes have been made to the previous recommendation.**
- **[new KCE 2015] indicates that the evidence has been reviewed and the recommendation has been updated or added.**
- **[KCE 2015, based on Aus 2014] indicates that a recommendation was imported from the Australian 2014 guideline. This mark was only used for patient centeredness and information of pregnant women.**

The strength of the full search recommendation was assigned using the GRADE system. The strength of recommendations depends on a balance between all desirable and all undesirable effects of an intervention (i.e., net clinical benefit), quality of available evidence, values and preferences, and estimated cost (resource utilization). For this guideline, no formal cost-effectiveness study or systematic search for economic literature was conducted (because of resource constraints), although studies identified through the medical literature searches were sometimes taken into account.

The strength of each recommendation was taken into account within the wording ("Offer" for a strong and "Consider" for a weak positive recommendation; "Do not offer" for a strong or "do not offer routinely" for a weak negative recommendation). Table 2 shows the signification of the strength of recommendation.

Table 2 – Strength of recommendations according to the GRADE system

Grade	Definition
Strong	The desirable effects of an intervention clearly outweigh the undesirable effects *(the intervention is to be put into practice)*, or the undesirable effects of an intervention clearly outweigh the desirable effects *(the intervention is not to be put into practice)*
Weak	The desirable effects of an intervention probably outweigh the undesirable effects *(the intervention probably is to be put into practice)*, or the undesirable effects of an intervention probably outweigh the desirable effects *(the intervention probably is not to be put into practice)*

Source: Andrews JC, Schunemann HJ, Oxman AD, Pottie K, Meerpohl JJ, Coello PA, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. J Clin Epidemiol. 2013;66(7):726-35.

4.1. Schedule of antenatal visits

4.1.1. Number of appointments - update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004	• At the beginning of pregnancy, offer to pregnant women without risk factors a program with either 10 appointments if this is their first pregnancy or 7 appointments if they have already given birth.	Strong	A**

** These appointments concern not exclusively gynaecologists but also midwives and general practitioners involved in the follow-up of pregnancies.*
*** Level of evidence from Australian 2014 guideline: A=One or more level I studies with a low risk of bias or several level II studies with low risk of bias (see Table 3 in chapter 5.3.).*

4.2. Clinical examination

4.2.1. Body mass index (BMI) – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004	• Offer to weigh each pregnant woman and calculate her BMI starting from the 1st consultation (and/or at a preconception consultation).	Strong	B*
	• Offer to regularly monitor each pregnant woman's weight change.	Strong	NA (PP)**
KCE 2015 based on Aus 2014	• Advise each pregnant woman on the appropriate weight gain in relation to her BMI.	Strong	A***

** Level of evidence from Australian 2014 guideline: B=One or two level II studies with a low risk of bias or systematic review/several level III studies with a low risk of bias; ** PP=practice point; *** A=One or more level I studies with a low risk of bias or several level II studies with low risk of bias (see Table 3 in chapter 5.3.)*

4.2.2. Blood pressure - update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004	• Offer to measure each pregnant woman's blood pressure at every visit during pregnancy, and during the preconception consultation. A diastolic blood pressure ≥ 90 mmHg is considered as a risk factor for complications such as pre-eclampsia.	Strong	NA*

** Level of evidence from Australian 2014 guideline: B only for blood pressure measurement at the first antenatal visit and consensus-based for the measurement afterwards; B=One or two level II studies with a low risk of bias or systematic review/several level III studies with a low risk of bias (see Table 3 in chapter 5.3.)*

4.2.3. Proteinuria – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004 amended	• Consider to assess proteinuria in pregnant women during the first consultation so as to identify kidney disease and urinary tract problems. After 20 weeks of pregnancy, consider to search for the presence of proteinuria at each visit in combination with taking blood pressure measurements in order to screen for pre-eclampsia. In Belgium, test strips (dipsticks) are often able to measure several elements in addition to proteins, such as nitrites.	Weak	NA*

** Level of evidence from Australian 2014 guideline: Consensus-based recommendation in absence of evidence for the first part and C for the second one but slightly different from the KCE recommendation; C=One or two level III studies with a low risk of bias or level I or II studies with a moderate risk of bias (see Table 3 in chapter 5.3.)*

4.2.4. Fundal height – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004	• From the 24th week of pregnancy onwards, offer to determine the height of the uterine fundus in each pregnant woman during each visit in order to detect abnormal uterine growth.	Strong	NA (CBR)*

** Level of evidence from Australian 2014 guideline: CBR=Consensus based recommendation because insufficient evidence to support recommendation (see Table 3 in chapter 5.3.)*

4.2.5. Fetal position – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004	• Starting from the 36th week or later, offer to each pregnant woman to determine the fetal position (using Leopold's maneuvers). Starting from the 36th week, malposition of the fetus can influence the management at the end of pregnancy and during childbirth. When a positional anomaly is suspected, consider confirming this by ultrasound examination.	Strong	C*

** Level of evidence from Australian 2014 guideline: C=One or two level III studies with a low risk of bias or level I or II studies with a moderate risk of bias (see Table 3 in chapter 5.3.)*

4.2.6. Fetal movements – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004	• Advise each pregnant woman to be aware of the usual pattern of movement for her baby and to contact a health care professional if she has any concerns about decreased or absent movements.	Strong	NA (CBR)*

** Level of evidence from Australian 2014 guideline: CBR=Consensus based recommendation because insufficient evidence to support recommendation*

4.3. Technical examination

4.3.1. Fetal heart auscultation – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004 amended	• Starting from 12 weeks of pregnancy, consider to detect the fetal cardiac rhythm via Doppler auscultation at each visit. This exam is used to confirm that the fetus is alive.	Weak	NA (CBR)*

** Level of evidence from Australian 2014 guideline: CBR=Consensus based recommendation because insufficient evidence to support recommendation*

4.3.2. Ultrasound scan during the first trimester – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004 slightly amended	• Offer to each pregnant woman to perform an ultrasound, between 11 and 13 weeks 6 days*, notably to be able to determine the gestational age and to detect multiple pregnancies. Accurate knowledge of the gestational age improves, for example, the efficiency of screening tests for Down syndrome and could decrease the number of inductions due to an incorrect term assessment.	Strong	B**

** It is recommended to provide to the pregnant woman and her partner during a previous consultation clear information on possible screening tests for Down syndrome and to allow enough time for informed consent.*
*** Level of evidence from Australian 2014 guideline: B=One or two level II studies with a low risk of bias or systematic review/several level III studies with a low risk of bias (see Table 3 in chapter 5.3.)*

For the screening for fetal chromosomal abnormalities such as Down syndrome, we refer to the KCE report 222 on non invasive prenatal test for trisomy 21.[7]

4.3.3. Ultrasound scan during the second trimester – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004	• Offer to perform an ultrasound, between the 18th and the 22nd week, on each pregnant woman to detect structural abnormalities.	Strong	B*

** Level of evidence from Australian 2014 guideline: B=One or two level II studies with a low risk of bias or systematic review/several level III studies with a low risk of bias (see Table 3 in chapter 5.3.)*

4.3.4. Ultrasound scan during the third trimester – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004 amended	• During the 3rd trimester, consider performing an ultrasound so as to determine the fetal position, to assess fetal growth and to re-assess placental position if indicated by the second trimester ultrasound.	Weak	NA

4.4. Haematological assessment

4.4.1. Anaemia – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004	• Offer to test each pregnant woman for anaemia in early pregnancy. In addition to the haemoglobin level, it is also useful to measure the MCV, MCH and MCHC** levels. A second examination at the beginning of the 3rd trimester may be indicated ahead of childbirth.	Strong	NA (CBR)*
KCE 2004 amended	• There is no evidence that platelet and leukocyte counts are useful during pregnancy. However, in Belgium, this test is often routinely performed in the laboratory at the time of anaemia detection.	NA	NA

** Level of evidence from Australian 2014 guideline: CBR= Consensus based recommendation because insufficient evidence to support recommendation (see Table 3 in chapter 5.3.). **MCV= Mean corpuscular volume; MCH= Mean corpuscular haemoglobin; MCHC= Mean corpuscular haemoglobin concentration*

4.4.2. Blood group, rhesus and atypical red cell antibodies – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004	• Offer to determine in early pregnancy each pregnant woman's blood group and rhesus (Rh) factor if they are unknown and to screen for atypical red cell antibodies.	Strong	B*

** Level of evidence from NICE 2008 guideline: B= recommendation directly based on level II evidence or extrapolated recommendation from level I evidence (see Table 3 in chapter 5.3.)*

4.4.3. Haemoglobin disorders – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004	• Do not routinely offer to each pregnant woman screening for haemoglobin disorders based on haemoglobin electrophoresis. Offer selective screening based on risk factors*.	Weak	NA (CBR)**

** Risk factors= family history of anaemia, thalassaemia or other abnormal haemoglobin variant; women originate from areas other than North Europe; clinical symptoms suggesting a haemoglobin disorder (such as recurrent acute pain syndromes or increased susceptibility to infections); abnormal low results of MCV or MCH.*
*** Level of evidence from Australian 2014 guideline: CBR=Consensus based recommendation because insufficient evidence to support recommendation*

4.5. Screening tests for infections

4.5.1. Cytomegalovirus – full search

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2015	• There is insufficient evidence to support routine screening in all pregnant women for cytomegalovirus infection. A single serological test preferably prior to pregnancy can be useful as it may encourage (non-immune) women, to take preventive measures or as it may reassure (at least partially) those who are immune. • In case serological tests for cytomegalovirus infections are offered, pregnant women and their partners should be informed in detail about all the possible consequences and asked for their consent.	Weak	Very low
New KCE 2015	**Recommendation**	**Strength of Recommendation**	**Level of Evidence**
	• Despite a lack of clearly proven benefits, discuss primary prevention measures with pregnant women to reduce the risk of cytomegalovirus infection, such as: • Regularly wash your hands, especially after contact with saliva or urine of small children (e.g. changing diapers) or wear protective gloves when changing diapers or handling children's dirty laundry. • Clean toys, countertops, and other surfaces that come into contact with young children's bodily fluid.	Strong	Very low
New KCE 2015	**Policy recommendation**	**Strength of Recommendation**	**Level of Evidence**
	• More data on the diagnostic accuracy of serological tests, value of amniocentesis and imaging, clinical evolution of infected infants and harmful effects for healthy pregnancies need to be collected in the Belgian context, in order to evaluate the benefits and harms, both on the short term and on the long term, of cytomegalovirus screening appropriately.	NA	NA

4.5.2. Toxoplasmosis – full search

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2015	• There is insufficient evidence to support a routine screening in all pregnant women for toxoplasmosis infection, repeated at different periods of pregnancy. A single serological test prior to or at the beginning of pregnancy can be useful as it may encourage (non-immune) women to take preventive measures or as it may reassure those who are immune.	Weak	Very low
	Recommendation	**Strength of Recommendation**	**Level of Evidence**
New KCE 2015	• Despite a lack of clearly proven benefits, discuss with the non-immune pregnant women prevention measures to reduce the risk of toxoplasmosis infection, such as: • washing hands before handling food • thoroughly washing all fruit and vegetables, including ready-prepared salads, before eating • thoroughly cooking raw meats and ready-prepared chilled meals • wearing gloves and thoroughly washing hands after handling soil and gardening • avoiding cat faeces.	Strong	Very low

4.5.3. Chlamydia – full search

	Recommendation	Strength of Recommendation	Level of Evidence
New KCE 2015	• Do not routinely offer to each pregnant women a Chlamydia trachomatis test.	Weak	Very low

4.5.4. Group B streptococcus – full search

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2015	• Offer a vaginal and rectal sampling for all women between the 35th and 37th weeks of pregnancy in view of a culture for the detection of Group B Streptococcus, except: • if a previous child has contracted invasive disease due to GBS; • if the GBS bacteriuria has been detected during pregnancy in progress; • if childbirth occurs before 37 weeks. In these three situations, the treatment can be established without sampling	Strong	Very low

4.5.5. Hepatitis B – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004 slightly amended	• For pregnant women with an unknown immune status, offer a detection of HBsAg (surface antigen of the hepatitis B virus) as effective postnatal intervention reduce the risk of mother-to-child transmission.	Strong	A*

** Level of evidence from Australian 2014 guideline: A=One or more level I studies with a low risk of bias or several level II studies with low risk of bias (see Table 3 in chapter 5.3.)*

4.5.6. Hepatitis C – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004 amended	• Do not routinely offer to each pregnant woman hepatitis C testing.	Weak	C*

** Level of evidence from Australian 2014 guideline: C=One or two level III studies with a low risk of bias or level I or II studies with a moderate risk of bias (see Table 3 in chapter 5.3.)*

4.5.7. Human immunodeficiency virus (HIV) – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004 slightly amended	• Offer to each pregnant woman HIV testing at the beginning of the pregnancy after having explained to her why it is useful.	Strong	B*

** Level of evidence from Australian 2014 guideline: B=One or two level II studies with a low risk of bias or systematic review/several level III studies with a low risk of bias (see Table 3 in chapter 5.3.)*

4.5.8. Rubella – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004 slightly amended	• For pregnant women with an unknown immune status, offer prior or at the beginning of pregnancy to test for IgG against rubella, in order to identify women who are not immune to rubella, advise them to avoid sick people with skin rash and to vaccinate them during the postpartum period.	Strong	B*

** Level of evidence from Australian 2014 guideline: B=One or two level II studies with a low risk of bias or systematic review/several level III studies with a low risk of bias (see Table 3 in chapter 5.3.)*

4.5.9. Syphilis – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004	• As treatment is favourable for the prognosis of both the mother and child, offer each pregnant woman to test for syphilis, in the beginning or before pregnancy.	Strong	B*

** Level of evidence from Australian 2014 guideline: B=One or two level II studies with a low risk of bias or systematic review/several level III studies with a low risk of bias (see Table 3 in chapter 5.3.)*

4.5.10. Herpes Simplex – update

KCE 2004 amended	Recommendation	Strength of Recommendation	Level of Evidence
	• Do not routinely offer each pregnant woman a serological test for herpes simplex.	Weak	IV*

** Level of evidence from RCOG 2007: IV= evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality.*

4.5.11. Varicella – update

KCE 2004 amended	Recommendation	Strength of Recommendation	Level of Evidence
	• For pregnant women who have not had varicella according to their medical history, consider to perform a detection of IgG against chicken pox. Non-immune pregnant women should stay away from anyone who has varicella or a skin rash.	Weak	NA

4.5.12. Asymptomatic bacterial vaginosis – update

KCE 2004 amended	Recommendation	Strength of Recommendation	Level of Evidence
	• Do not routinely offer pregnant women to test for asymptomatic bacterial vaginosis. In fact, evidence suggests that the detection and treatment of asymptomatic bacterial vaginosis for pregnant women at low risk does not have any effect on the risk of premature birth.	Weak	B*

** Level of evidence from Australian 2014 guideline: B=One or two level II studies with a low risk of bias or systematic review/several level III studies with a low risk of bias (see Table 3 in chapter 5.3.)*

4.5.13. Asymptomatic bacteriuria – update

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2004 amended	• Offer each pregnant woman testing for asymptomatic bacteriuria (on a mid-stream urine sample for a white blood cell count and culture) as treatment is effective and reduces the risk of pyelonephritis. Consensus among experts recommends performing this culture at the start of the second trimester.	Strong	A*

** Level of evidence from Australian 2014 guideline: A=One or more level I studies with a low risk of bias or several level II studies with low risk of bias (see Table 3 in chapter 5.3.)*

4.6. Screening for maternal clinical problems

4.6.1. Gestational diabetes - full search

	Recommendation	Strength of Recommendation	Level of Evidence
KCE 2015	• Offer a screening test for gestational diabetes mellitus in at-risk women between 24 and 28 weeks.	Strong	NA*
	• Consider to perform a screening test for gestational diabetes mellitus in pregnant women otherwise not at risk for gestational diabetes.	Weak	Very low
KCE 2015	**Recommendation**	**Strength of Recommendation**	**Level of Evidence**
	• There is currently insufficient evidence to recommend the replacement of the two-step screening strategy for gestational diabetes by another kind of screening or by other thresholds. The IADPSG** criteria should preferably be used within the framework of research and clinical data.	NA	NA

** The aim of the full search of literature was not to assess the efficacy of diabetes screening but to determine which screening strategies are more accurate. In the 2004 KCE guideline, screening of gestational diabetes between 24 and 28 weeks was supported by evidence of high level (level A= Recommendation directly based on level 1 evidence i.e. systematic review and meta-analysis of randomised controlled trials (RCTs) or at least one RCT)*
*** IAPDSG= International Association of Diabetes and Pregnancy Study Groups*

4.6.2. Hypothyroidism – full search

	Recommendation	Strength of Recommendation	Level of Evidence
New KCE 2015	• Do not routinely offer screening for hypothyroidism to pregnant women at low risk for thyroid disease.	Weak	Very low

4.6.3. Vitamin D deficiency – full search

	Recommendation	Strength of Recommendation	Level of Evidence
New KCE 2015	• Do not offer screening for vitamin D deficiency to pregnant women.	Strong	No evidence
	• Do not routinely offer vitamin D supplementation to all pregnant women.	Weak	Very low

4.7. Screening of specific pregnancy related risks

4.7.1. Risk of preterm birth – full search

	Recommendation	Strength of Recommendation	Level of Evidence
New KCE 2015	• Do not screen for the risk of preterm birth with repeat digital exam.	Strong	Moderate
New KCE 2015	**Recommendation**	**Strength of Recommendation**	**Level of Evidence**
	• Primary screening for risk of preterm birth by cervical length measurements in low-risk women should only be performed within the framework of research.	Weak	Very low

For prevention of preterm birth in women at risk, we refer to the KCE report 228 published in 2014.[8]

4.7.2. Risk of preeclampsia – full search

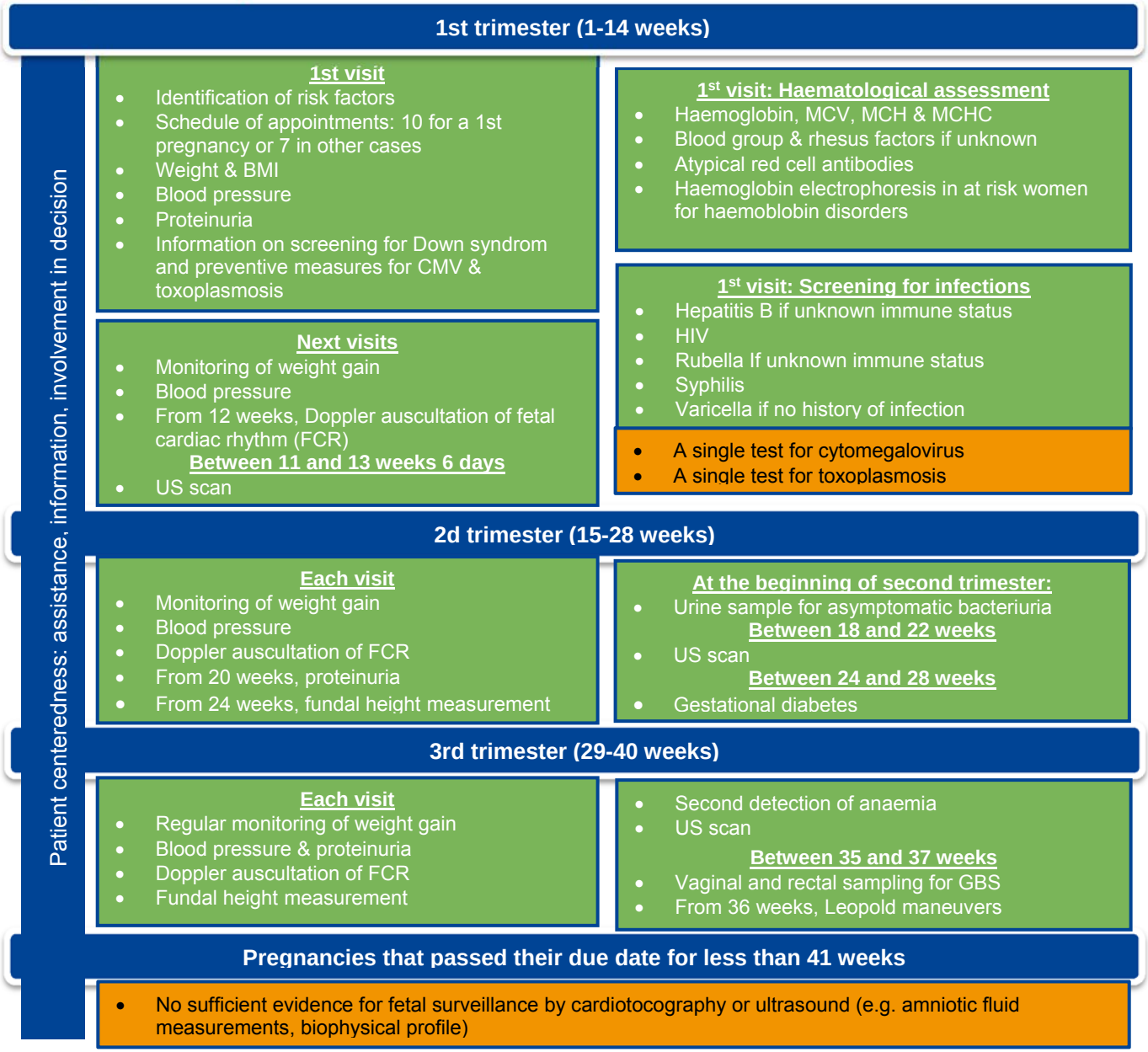
	Recommendation	Strength of Recommendation	Level of Evidence
New KCE 2015	• There is insufficient evidence to recommend additional screening (compared with usual routine assessment based on history and physical exam) for increased risk of pre-eclampsia in low risk women. Primary screening for risk of pre-eclampsia in low-risk women should only be performed within the framework of research.	NA	NA

4.7.3. Surveillance of pregnancies that passed their due date – full search

	Recommendation	Strength of Recommendation	Level of Evidence
New KCE 2015	• Routine use of antenatal electronic fetal heart rate monitoring (cardiotocography) or ultrasound (e.g. amniotic fluid measurements, biophysical profile) is not supported by evidence for fetal assessment in women with an uncomplicated pregnancy who have passed their due date for less than one week.*	NA	Very low

* *Induction is usually offered to women who have reached 41 weeks of pregnancy.*

4.8. Algorithm



Do not do routinely

Screening for infections
- Chlamydia trachomatis
- Hepatitis C
- Herpes simplex
- Bacterial vaginosis
- Repeated tests for cytomegalovirus
- Repeated tests for toxoplamosis

Screening for maternal clinical problems
- Hypothyroidism (screening/treatment)
- Vitamin D deficiency (screening/supplementation)

Screening for specific pregnancy related risks
- Repeated digital exam for risk of preterm birth

In clinical research only

- Use of IADPSG criteria for diabetes
- Screening for preterm birth risk by cervical length measurement
- Screening for pre-eclampsia risks by:
  - Doppler ultrasound measuring pulsatility index of the uterine arteries;
  - PAPP-A, PIGF in combination with soluble fms-like tyrosine kinase-1;
  - Fetal DNA and RNA in maternal plasma

5. METHODOLOGY

5.1. The Guideline Development Group

This guideline is the result of a collaboration between multidisciplinary groups of practising healthcare professionals and KCE researchers. At the start of the production of the guideline, the "College of physicians for the mother and the newborn, section maternity" submitted a list of obstetricians that were considered as potential members of the GDG. To add other healthcare providers, each organisation of midwives, general practitioners, neonatologists and organisation for birth and childhood (ONE, Kind & Gezin) was contacted.

Guideline development and literature review expertise, support, and facilitation were provided by the KCE Expert Team (P. Jonckheer, L. Verleye and S. Stordeur) and by two sub-contracting teams:

- the Ottawa Hospital Research Institute (N. Ahmadzai, M.T. Ansari, L.M. Gaudet and J.M. Tetzlaff), responsible for screening of hypothyroidism, vitamin D deficiency, risk of preterm birth, risk of preeclampsia and for surveillance of pregnancies that passed their due date;
- the National Clinical Guideline Centre (S. Carville, K. Dworzynski, J. Glenn, K. Jones and P. Miller), responsible for screening of cytomegalovirus, toxoplasmosis, chlamydia trachomatis, group B streptococcus infections and gestational diabetes.

5.2. Clinical research questions

5.2.1. Hierarchical approach

The KCE 2004 guideline focused on 34 main clinical questions. The discussion with the members of the GDG and representatives of professional organizations during a meeting of January 2014 and the comments received after this meeting allowed to select 10 questions for full literature search. These 10 topics were translated into research questions that are named "full search questions" in this report. Many of these research questions relate to the use of tests to screen for or establish the diagnosis of a certain condition or disease.

In this guideline, we used a multi-step approach for full search questions on diagnostic tests. First, we searched for 'direct' evidence: randomized or non-randomized studies that compared a management strategy including the use of a given test with a management strategy without the use of the test. If no direct evidence was available, we searched for evidence of possible therapeutic interventions for patients who would test positive if a test was applied. If applicable, this evidence was supplemented with diagnostic accuracy studies for the evaluated tests. It is why some research questions are subdivided into two sub-questions. For each question, the search for literature was conducted in MEDLINE (including PreMedline) (http://www.ncbi.nlm.nih.gov/pubmed), Embase (http://www.embase.com/) and The Cochrane Library (Cochrane Database of Systematic Reviews, DARE, Central, NHS EED and HTA database) (http://www.cochrane.org). The quality appraisal was performed using standardised checklists (such as AMSTAR for systematic review).

In addition to the 10 full search questions, 24 questions from the KCE 2004 guideline were considered to be updated according to the ADAPTE process. The KCE standard guideline development process starts with a search for existing guidelines produced by other institutions. For the present guideline, this search was performed in October 2013 in various databases including the National Guideline Clearinghouse, the GIN database and eight other guidelines websites. The search resulted in 95 guidelines, from which two potentially relevant guidelines were selected, covering similar inclusion criteria and topics, i.e. the NICE 2008 guideline and the Australian 2014 guideline.[5, 6] The 2 guidelines selected were both assessed to be of sufficient quality; however, the Australian 2014 guideline was preferred because it is an update of the NICE 2008 guideline.

5.3. Formulation of recommendations

5.3.1. Full search questions

Based on the retrieved evidence, a first draft of recommendations was prepared by a small working group (researchers from KCE). This first draft was, together with the evidence tables, circulated to the guideline development group prior to the face-to-face meetings (September 10, 2014; October 8, 2014; December 10, 2014; January 12, 2015; February 10, 2015). Based on the discussion meetings a second draft of

recommendations was prepared and once more circulated to the GDG for final approval. No formal consensus procedure was used. Each recommendation was formulated and graded according to the GRADE approach.

5.3.2. Update of KCE 2004 recommendations

For the 24 clinical questions to be updated, no formal GRADE tables were produced. A card was elaborated gathering the KCE 2004 recommendation, a summary of the literature quoted by the Australian 2014 guideline, the Australian recommendation and a proposition of a recommendation for the KCE 2015 guideline. The level of evidence underlying each recommendation comes from the original source, i.e. either the Australian 2014 guideline or, when no evidence was provided by the Australian 2014 guideline, the NICE 2008 guideline or other sources referred by the Australian 2014 guideline. Because both guidelines did not use the GRADE evaluation, we systematically reported their classification of the levels of evidence (Table 3).

Table 3 – EAC categories of evidence level and grade of recommendation (2014)

Level of evidence	Intervention	Diagnostic accuracy	Prognosis	Aetiology	Screening intervention
I	Systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with an independent, blinded comparison with a valid reference standard, among consecutive persons with a defined clinical presentation	A prospective cohort study	A prospective cohort study	A prospective cohort study
III-1	Pseudorandomised trial	A study of test accuracy with an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation	All or none	All or none	Pseudorandomised trial (ie alternate allocation or some other method)

III-2	A comparative study with concurrent controls: • Non-randomised experimental trial • Cohort study • Case-control study • Interrupted time series with control group	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors among persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: • Non-randomised experimental trial • Cohort study • Case-control study
III-3	A comparative study without concurrent controls: • Historical control study • Two or more single arm study • Interrupted time series without parallel control	Diagnostic case-control study	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: • Historical control study • Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series, or cohort study of persons at different stage of disease	A cross-sectional study or case series	Case series

Grade	Definition
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in application
D	Body of evidence is weak and recommendation must be applied with caution
CBR	Recommendation formulated in the absence of quality evidence (where a systematic review of the evidence was conducted as part of the search strategy)
PP	Area is beyond the scope of the systematic literature review and advice was developed by the Experts Advisory Committee (EAC) and/or the Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care

Source: Adapted from NHMRC (2009) Levels of Evidence and Grades for Recommendations for Developers of Guidelines and NHMRC (2011) Procedures and Requirements for Meeting the 2011 NHMRC Standard for Clinical Practice Guidelines.

6. IMPLEMENTATION AND UPDATING OF THE GUIDELINE

6.1. Implementation

6.1.1. Dissemination towards target users

This guideline is intended to be used by care providers involved in the follow-up of pregnant women and their babies, especially obstetricians/gynaecologists, midwives, neonatologists and general practitioners. It is also of interest for parents-to-be, pregnant women and their partners.

This guideline should be disseminated through diverse channels such as websites or programmes for continous education. The dissemination of this guideline can further be supported by transforming this material into attractive and user-friendly tools tailored to specific caregiver groups and patient associations. The algorithm proposed in the synthesis can be used as a guide for the management and the follow-up of pregnant women.

6.1.2. Actors of the dissemination and implementation of this guideline

The dissemination and implementation of this guideline at a national level but also at regional levels is preferably performed in collaboration with partners whose mission is the improvement of the quality of care. The target organisations (high schools for midwives and nurses, universities, scientific associations – ISP/WIV, Superior Council of Health Promotion), professional organisations (VVOG, GGOLF, UPSFB, VLOV vzw, AFsF, UVV, Domus Medica, SSMG…), sickness funds, organisations of birth and childhood (e.g. ONE and its College of gynaecological advisors and midwives, Kind & Gezin, Dienst für kind und familie/kaleido-dg), prenatal centres, policy makers (Federal Public Service Public Health, Vlaamse Agentschap Zorg & Gezondheid[a], Direction Générale de la Santé en Fédération Wallonie-Bruxelles[b]) are invited to stimulate the dissemination of these updated recommendations towards the target users previously cited. In majority, their websites already proposed a link towards the KCE guideline 2004. The update will be easily transferred to these organisations.

6.2. Monitoring the quality of care

In the context of the development of indicators to provide an overview of the global care pathway of the (future) mother, both during the period of pregnancy, the delivery and the postnatal period, the InterMutualistic Agency (IMA) has already produced two reports, one relating to prenatal care (2010 data) and one relating to the period of delivery (inpatient only; data 2008-2012). A report on postnatal care (data 2012 or 2013) is currently in preparation.

For the report related to prenatal care, the IMA evaluated the implementation of the KCE guideline 2004[2] the year after its publication (IMA report based on data 2005) and 5 years later (data 2010).[4]

Three main aspects of antenatal care were examined in both reports: consultations with various care providers (general practitioners and specialists, midwives, physiotherapists), common laboratory tests and technical examinations. This updated clinical guideline will be transmitted to the working Group at IMA in order to monitor the implementation of the current recommendations.

6.3. Guideline update

KCE clinical guidelines are updated as needed so that recommendations take into account important new information. This guideline would ideally be reviewed 5 years after publication to determine whether all or part of it should be updated. If important new evidence is published earlier, we may decide to do a more rapid update of some recommendations.

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[a] Agency for Care and Health that develops and implements the health policy of the Flemish community. It is part of the Flemish Ministry for Welfare, Public Health and Family

[b] General Direction for Health in Wallonia-Brussels

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COLOPHON

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