Introduction

This briefing paper presents a structured evidence review to help determine the suitability of recommendations from the key development sources listed below, to be developed into a NICE quality standard. The draft quality statements and measures presented in this paper are based on published recommendations from these key development sources:


Structure of the briefing paper

The body of the paper presents supporting evidence for the draft quality standard reviewed against the three dimensions of quality: clinical effectiveness, patient experience and safety. Information is also provided on available cost-effectiveness evidence and current clinical practice for the proposed standard. Where possible, evidence from the clinical guidelines is presented. When this is not available, other evidence sources have been used.
## 1 Services – Access for vulnerable groups

### 1.1 NICE CG62 Recommendation 1.2.3.1 and NICE CG110 1.1.1 [KPI] and 1.1.2 [KPI]

#### 1.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<table>
<thead>
<tr>
<th>Guideline recommendations</th>
<th>CG62 1.2.3.1 Antenatal care should be readily and easily accessible to all pregnant women and should be sensitive to the needs of individual women and the local community.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CG110 1.1.1 [KPI] In order to inform mapping of their local population to guide service provision, commissioners should ensure that the following are recorded:</td>
</tr>
<tr>
<td></td>
<td>• The number of women presenting for antenatal care with any complex social factor.</td>
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<td></td>
<td>• The number of women within each complex social factor grouping identified locally.</td>
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<td></td>
<td>CG110 1.1.2 [KPI] Commissioners should ensure that the following are recorded separately for each complex social factor grouping:</td>
</tr>
<tr>
<td></td>
<td>• The number of women who:</td>
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<tr>
<td></td>
<td>o attend for booking by 10, 12+6 and 20 weeks.</td>
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<tr>
<td></td>
<td>o attend for the recommended number of antenatal appointments, in line with national guidance⁹.</td>
</tr>
<tr>
<td></td>
<td>o experience, or have babies who experience, mortality or significant morbidity.</td>
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<tr>
<td></td>
<td>• The number of appointments each woman attends.</td>
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<tr>
<td></td>
<td>• The number of scheduled appointments each woman does not attend.</td>
</tr>
</tbody>
</table>

| Proposed quality statement | Pregnant women in vulnerable groups are encouraged to access antenatal care¹. |

<table>
<thead>
<tr>
<th>Draft quality measure</th>
<th>Structure:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a) Evidence of local needs assessment to ensure that antenatal care is readily and easily accessible and sensitive to the needs of vulnerable groups.</td>
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<tr>
<td></td>
<td>b) Evidence of local arrangements for outreach to encourage pregnant women in vulnerable groups to access and maintain contact with antenatal care.</td>
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<tr>
<td></td>
<td><strong>Process:</strong> Proportion of pregnant women in vulnerable groups not attending one scheduled antenatal appointment who are followed up by the antenatal service before their next scheduled appointment.</td>
</tr>
<tr>
<td></td>
<td>Numerator – the number of pregnant women in the denominator followed up by the antenatal service before their next scheduled appointment.</td>
</tr>
</tbody>
</table>

¹ See appendix A for summary of all draft quality statements.
### Denominator

- the number of pregnant women in vulnerable groups not attending one scheduled antenatal appointment.

### Outcome:

a) The number of pregnant women in vulnerable groups attending for booking by 10 weeks.

b) The number of pregnant women in vulnerable groups attending for booking between 10+1 weeks and 12+6 weeks.

c) The number of pregnant women in vulnerable groups attending for booking between 13 and 20 weeks.

d) The number of pregnant women in vulnerable groups attending the recommended number of antenatal appointments.

### Discussion points for TEG

- Is it acceptable/preferable to refer to ‘vulnerable groups’ rather than ‘women with a complex social factor’ (terminology used in CG110)? Is this too broad as may encompass additional groups for whom the evidence has not been reviewed such as those with learning disabilities, mental health problems for example. Note that CG110 groups include women: with a history of drug/alcohol misuse; migrants to the UK; younger than 20 years; who experience domestic abuse. RCOG standards use the term ‘women with social needs’.

- Quality statement is very broad as written – is this appropriate? Can sufficient measures be defined or should the statement be more specific?

- Is it possible to specify a timeframe for follow-up after a DNA (process measure) or is it adequate to say ‘before next scheduled appointment’?

- How should ‘follow-up’ be defined (process measure) - phone call or letter for example?

- Are outcomes a)-c) all useful or would the aspiration be booking by 10 weeks? Is there a risk of unintended consequences for women not being followed up in such an assertive way if they present >10 weeks?

### 1.1.2 Clinical and cost-effectiveness evidence

Recommendation 1.2.31 from CG62 is based on consideration of a meta-analysis of three RCTs which showed a significantly lower number of average visits to a hospital outpatient clinic when a policy of home visits was implemented, and the 1993 Department of Health initiative ‘Changing childbirth’.

Recommendations 1.1.1 and 1.1.2 in CG110 are derived from the GDG’s interpretation of common themes across four chapters of evidence (see chapters 4-7 of full guideline for study details). The majority of the evidence
comprised studies of very poor methodological quality, with little of it being conducted in the UK.

Recommendations 1.1.1 and 1.1.2 were developed because the GDG felt that comparative outcome data for sub-groups of potentially vulnerable women are needed in order to identify which service models meet these different needs and improve outcomes for these different groups. Based on consensus, the GDG made a key priority recommendation that this information be collected in order to inform service planning.

The GDG felt that a recommendation to encourage collection of ongoing audit data for service change was a key output of this guideline. In order to monitor the effectiveness of service change in improving access to and contact with antenatal care, the GDG identified key process outcomes. These are gestation at booking and the proportion of scheduled antenatal appointments attended.

For gestation at booking the GDG agreed three gestations that should be used as audit targets: 10 weeks, 12+6 weeks and 20 weeks of pregnancy. 10 weeks was chosen as this is the target set out in CG62. The GDG acknowledged this to be a difficult target to attain, especially for women in vulnerable groups, and so added a second target for early booking; a target well recognised within maternity services, which is booking by the end of the first trimester of pregnancy (12+6 weeks). A gestation for late booking was chosen by GDG consensus based on what the GDG recognised as a widely accepted definition and which is associated with the upper limit for carrying out serum screening for Down’s syndrome and anomaly screening using ultrasound (20 weeks).

A new health economic model was developed for CG110 to assess the cost effectiveness of additional care versus normal antenatal care services. This demonstrated (for women who misuse substances and young women aged under 20) that an additional service could be considered cost effective if it was able to book more women in the first trimester and maintain contact than if only routine antenatal care was provided. The number of women needed to book early to make a service cost effective varies, depending on the cost of the service provided.

1.1.3 Patient experience

None identified.

1.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full
accompanying report from the NPSA) did not identify any incidents relating specifically to this area of care in the sample reviewed. Incidents relating broadly to the provision and organisation of antenatal services were identified, which included some relating to availability of care.

1.1.5 Current practice

In 2006, it was reported that around 16% of all pregnant women, including many of those under 18 years of age, delay seeking maternity care until they are five or more months pregnant².

A national review of maternity care published in 2008³ reported that 78% women attend a ‘booking’ appointment by 12 weeks. It is also noted that late initial contact with the service and late booking are more prevalent in London and other large towns and cities and among women from some ethnic minority groups, particularly women from Black African and Bangladeshi ethnic groups.

In 2010, 5% of women self-reported being more than 12 weeks pregnant when they first saw a health professional about their pregnancy care⁴. 11% reported having their booking appointment when they were 13 or more weeks pregnant – a significant decrease from 21% in 2007. 1% of women reported having no antenatal check-ups at all. Note: all three survey questions were answered by more than 23,000 participants, the characteristics of whom are unknown.

Access to antenatal assessment is a national priority in the NHS⁵. The current NHS performance standard for the percentage of women being assessed by 12 weeks and 6 days of pregnancy is 90%. Latest data (Q4 2010/11) shows performance is being maintained – 92% of women who gave birth in this period saw a midwife or a maternity healthcare professional for a health and social care needs, risks and choices assessment within 12 weeks and 6 days⁶. This is comparable with the previous quarter (Q3 2010/11) where 93% of women were seen and assessed within the time period. This is not broken

down by particular groups of pregnant women. This indicator is not included in the national performance measures for 2012/13\(^7\).

The latest triennial review of maternal deaths from the Centre for Maternal and Child Enquiries (CMACE) looks at access to antenatal care for women who have died in the UK directly or indirectly related to pregnancy. A considerable improvement in women accessing and staying in touch with maternity services compared with the last review is reported\(^8\). During the 3 years 2006–08, 31 women who died from any cause had features of domestic abuse (excludes 3 women who died in early pregnancy). Out of these 31 deaths, 11 (35%) women were late or non-attenders for antenatal care. Of 48 deaths of known substance misusers, 22 (46%) women were late or non-attenders for antenatal care. There seemed to be a higher percentage of women of Black Caribbean or Pakistani ethnic origin reported as poor or non-attenders for maternity care compared with women of White ethnic origin. It is noted that numbers relating to ethnicity are small and the coding of ethnicity may also be problematic.

A report from the Confidential Enquiry into Maternal and Child Health CEMACH found that, in 2007, 49% of women who had a still birth and 52% who had a neonatal death had an antenatal booking by 12 weeks compared with 71% in the general maternity population in 2005\(^9\). The report suggests that booking for maternity care after 12 weeks may be more common in women who have a stillbirth and neonatal death and that this may be related to issues such as maternal social deprivation and poor access to health services.

1.1.6 Current indicators

Department of Health (2011) *The operating framework for the NHS in England 2011/12*. Integrated performance measures (IPMs) for national oversight:

SQU12: Maternity 12 weeks - Percentage of women in the relevant PCT population who have seen a midwife or a maternity healthcare professional, for health and social care assessment of needs, risks and choices by 12 weeks and 6 days of pregnancy.

IPMs available from [www.dh.gov.uk](http://www.dh.gov.uk)
2 Services - Documentation

2.1 NICE CG62 Recommendation 1.2.4.2 and CG110 1.1.10

2.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

| Guideline recommendations | CG62 1.2.4.2 Maternity services should have a system in place whereby women carry their own case notes.
|                          | CG110 1.1.10 Ensure that the hand-held maternity notes contain a full record of care received and the results of all antenatal tests.
| Proposed quality statement | Pregnant women have a full record of all antenatal test results in their hand-held maternity notes.
| Draft quality measure | **Structure:** Evidence of local arrangements to ensure that pregnant women have a full record of all antenatal test results in their hand-held maternity notes.
| | **Process:** Proportion of pregnant women receiving antenatal care who have a full record of all antenatal test results in their hand-held maternity notes appropriate to their stage of pregnancy.
| | Numerator – the number of pregnant women in the denominator with a full record of all antenatal test results in their hand-held maternity notes appropriate to their stage of pregnancy.
| | Denominator – the number of pregnant women receiving antenatal care.

Discussion points for TEG

- The importance of structured and standardised maternity records is recognised in the guideline. Should this be included in the statement?
- How should ‘full record of all antenatal test results’ be defined in order to achieve the process measure? Should a checklist of minimum essential tests/timings be constructed?

2.1.2 Clinical and cost-effectiveness evidence

Recommendation 1.2.4.2 from CG62 is based on three RCTs which examined the effect of giving women their own maternity case notes to carry during pregnancy. From these, the GDG concluded that women like to carry their own records and that this can lead to an increased feeling of control. Also that it may facilitate communication between the pregnant woman and the health professionals involved with her care.
Recommendation 1.1.10 in CG110 is derived from the GDG’s interpretation of common themes identified across four chapters of evidence (see chapters 4-7 of full guideline for study details), where it was recognised that the handheld version of the records should be kept complete and up to date, including all antenatal test results.

### 2.1.3 Patient experience

None identified.

### 2.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full accompanying report from the NPSA) identified a number of incidents relating to either missing records or incidents where antenatal tests had not been carried out.

### 2.1.5 Current practice

There is currently no national format for hand-held maternity records although anecdotaly it is estimated that the West Midlands antenatal notes are used for around 50% of pregnant women in England.

The Maternity Services Secondary Uses Dataset has been approved by the Information Standards Board and will include data capture on routine booking appointment activities and screening tests. The Information Standards Notice, which will mandate local implementation, is awaited. This information standard is not intended to define or specifically design clinical and patient care records.

### 2.1.6 Current indicators

None identified.
# Initial risk assessment – Body mass index

## 3.1 NICE CG62 Recommendation 1.2.2.2 and 1.5.1.1, PH11 6(2) and PH27 2(8) and 2(12)

### 3.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<table>
<thead>
<tr>
<th>Guideline recommendations</th>
<th>CG62 1.2.2.2 A system of clear referral paths should be established so that pregnant women who require additional care are managed and treated by the appropriate specialist teams when problems are identified.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CG62 1.5.1.1 Maternal weight and height should be measured at the booking appointment, and the woman’s body mass index should be calculated (weight [kg]/height[m]$^2$).</td>
</tr>
<tr>
<td></td>
<td>PH11 6(2) Health professionals should refer pregnant women with a BMI over 30 to a dietitian for assessment and advice on healthy eating and exercise. Do not recommend weight-loss during pregnancy.</td>
</tr>
<tr>
<td></td>
<td>PH27 2(8) Measure weight and height at the first contact with the pregnant woman, being sensitive to any concerns she may have about her weight. If these data are not available at their first booking appointment, then the midwife should do this. Do not rely on self-reported measures of weight and height. Clearly explain why this information is needed and how it will be used to plan her care. Weigh her in light clothing using appropriate, calibrated weighing scales that are regularly checked. Calculate BMI by dividing weight (kg) by the square of height (m$^2$), or use the BMI calculator after measuring and weighing. Use BMI percentile charts for pregnant women under 18 years, as a BMI measure alone does not take growth into account and is inappropriate for this age group.</td>
</tr>
<tr>
<td></td>
<td>PH27 2(12) Offer women with a BMI of 30 or more at the booking appointment a referral to a dietitian or appropriately trained health professional for assessment and personalised advice on healthy eating and how to be physically active. Encourage them to lose weight after pregnancy.</td>
</tr>
</tbody>
</table>

| Proposed quality statement | Pregnant women with a body mass index over 30 at the booking appointment are referred to a dietitian. |

<table>
<thead>
<tr>
<th>Draft quality measure</th>
<th><strong>Structure:</strong> Evidence of local arrangements to ensure that pregnant women with a body mass index over 30 at the booking appointment are referred to a dietitian.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Process:</strong> Proportion of pregnant women with a body mass index over 30 at the booking appointment who are referred to a dietitian.</td>
</tr>
<tr>
<td></td>
<td>Numerator – the number of pregnant women in the denominator referred to a dietitian.</td>
</tr>
<tr>
<td></td>
<td>Denominator – the number of pregnant women with a body mass index over 30 at the booking appointment.</td>
</tr>
</tbody>
</table>
mass index over 30 at the booking appointment.

| Discussion points for TEG | • Potential implementation issues of recommending referral to only a dietitian specifically. Can ‘or other appropriate health professional’ be satisfactorily defined?
|                           | • This does not address clinical risk in terms of (for example) obstetric-led care – is the focus right here? |

### 3.1.2 Clinical and cost-effectiveness evidence

Recommendation 1.2.2.2 in CG62 was extrapolated from two systematic reviews and four additional RCTs on the effects of continuous care during pregnancy and childbirth, and one RCT on satisfaction with continuity of care. In most cases, these demonstrated an association between continuity of care and lower intervention rates (compared with standard care), as well as beneficial effects on various psychosocial outcomes.

Recommendation 1.5.1.1 from CG62 is based on a number of studies relating maternal weight with infant birthweight and preterm delivery. These include a retrospective study of 1092 pregnant women that found weekly weight gain and maternal weight at booking were the only factors (taking into account maternal gestation, age and smoking habit) that had an association with infant birthweight. Also, a prospective observational study of 7589 women in their first pregnancy that reported that underweight status (BMI < 19.8 kg/m²) before pregnancy increased the likelihood of delivering preterm. A longitudinal study of 156 healthy pregnant women showed that net weight gain during pregnancy was independently influenced by BMI status and energy intake. Women at the highest level of BMI gained significantly less weight from first to third trimester compared with women at the medium or low levels of BMI and the mean birthweight in the three BMI groups did not differ.

Recommendation 6 in NICE public health guidance 11 is based on an evidence review of the effectiveness of public health interventions to improve the nutrition of postpartum women. This consisted of a number of RCTs on diet and physical activity to promote weight loss.

Recommendation 2 in NICE public health guidance 27 is inferred from UK-based qualitative research on various aspects of weight management during pregnancy. This included evidence that women may be unaware of potential effects of obesity during pregnancy, evidence suggesting communication difficulties between overweight pregnant women and health professionals, as well as health professionals reporting that women’s access to information and advice on weight management is often ad hoc.

It is noted that earlier guidance (PH11) recommends referral to a dietitian specifically and more recent guidance (PH27) recommends referral to a
dietitian or ‘appropriately trained health professional’. This was due to concerns (from co-opted experts and stakeholders) about the number of dietitians available for providing this kind of service.

3.1.3 Patient experience

None identified.

3.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full accompanying report from the NPSA) identified incidents relating to failure to follow up women with a BMI over 30 kg/m². ‘Follow up’ may have related either to obstetric or anaesthetic referral to ensure that the woman is seen antenatally and a plan of care made for her pregnancy and delivery and/or referral to dietetic services.

3.1.5 Current practice

The 2006-08 CMACE review found that BMI data was available for 227 (87%) of the mothers who died. A national organisational survey of maternity units found that 218 (99%) units reported recording both maternal height and weight in the handheld notes, while 63% reported entering both on to the electronic system. Almost all units (98%) recorded BMI in the notes and just over half (55%) entered BMI on the electronic system. The same national obesity project reports that postnatal referral to a dietitian or nutritionist was offered to only 4% of women with a booking BMI greater than or equal to 35 kg/m². No data on antenatal referral is available.

In a survey of 6252 women with a child under 5 years old, 37% said that their midwife discussed weight issues with them, leaving 63% who didn’t. For those who considered themselves to be overweight, midwives discussed their weight in 54% of cases. Half of those surveyed said that the midwife measured their BMI (so some had their BMI measured without the results being discussed). For women who were overweight, two thirds of them had their BMI measured. 12% of those identified as having a high BMI were referred to a dietitian or nutritionist.

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3.1.6 Current indicators

None identified.
Initial risk assessment – Venous thromboembolism

NICE CG62 Recommendation 1.2.2.2 and RCOG 37a (1) and (6)

Relevant clinical guideline recommendations and proposed quality statement

| Guideline recommendations | CG62 1.2.2.2 A system of clear referral paths should be established so that pregnant women who require additional care are managed and treated by the appropriate specialist teams when problems are identified.
| | RCOG 37a (1) All women should undergo a documented assessment of risk factors for venous thromboembolism (VTE) (listed in Table 1, Figure 1 and Appendix III) in early pregnancy or before pregnancy. This assessment should be repeated if the woman is admitted to hospital for any reason or develops other intercurrent problems.
| | RCOG 37a (6) Women at high risk of VTE in pregnancy, such as those with previous VTE, should be offered pre pregnancy counselling and a prospective management plan for thromboprophylaxis in pregnancy. Those who become pregnant before receiving such counselling should be referred to a consultant obstetrician or trust-nominated expert in thrombosis in pregnancy early in pregnancy.

| Proposed quality statement | Pregnant women at high risk of venous thromboembolism at the time of booking are referred to a specialist service.

| Draft quality measure | Structure: Evidence of local arrangements to ensure that pregnant women at high risk of venous thromboembolism at the time of booking are referred to a specialist service.
| | Process: Proportion of pregnant women at high risk of venous thromboembolism at the time of booking, who are referred to a specialist service.
| | Numerator – the number of pregnant women in the denominator referred to a specialist service.
| | Denominator – the number of pregnant women at high risk of venous thromboembolism at the time of booking.

Discussion points for TEG

- Definition of high risk can be taken from RCOG 37a (Single previous VTE with either thrombophilia/family history or unprovoked/estrogen-related; or previous recurrent VTE (> 1)). Note this is a small sub-group of women.
- Definition of specialist service can also be taken from RCOG 37a – “consultant obstetrician or trust-nominated expert in thrombosis in pregnancy”.

Discussion points for TEG

- Definition of high risk can be taken from RCOG 37a (Single previous VTE with either thrombophilia/family history or unprovoked/estrogen-related; or previous recurrent VTE (> 1)). Note this is a small sub-group of women.
- Definition of specialist service can also be taken from RCOG 37a – “consultant obstetrician or trust-nominated expert in thrombosis in pregnancy”.

Quality standard topic: Antenatal care
4.1.2 Clinical and cost-effectiveness evidence

Recommendation 1.2.2.2 in CG62 was extrapolated from two systematic reviews and four additional RCTs on the effects of continuous care during pregnancy and childbirth, and one RCT on satisfaction with continuity of care. In most cases, these demonstrated an association between continuity of care and lower intervention rates (compared with standard care), as well as beneficial effects on various psychosocial outcomes.

Recommendations 1 and 6 in RCOG green-top guideline 37a originate from the need to offer prophylaxis to pregnant women at increased of VTE. Recommendation 1 states that the timing of the assessment should be as early as possible in view of evidence for increased thrombotic risks associated with complications in the first trimester (such as hyperemesis gravidarum) and the fact that many antenatal VTE events (including fatal events) occur in the first trimester. Recommendation 1 is graded ‘C’ (derived from good quality case-control or cohort studies) and recommendation 6 is a ‘good practice point’ (recommended best practice based on the clinical experience of the guideline development group).

4.1.3 Patient experience

None identified.

4.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). A comprehensive analysis of recent reported incidents (please see full accompanying report from the NPSA) did not identify any specific incidents relating to this area of care. An earlier report from the NPSA highlighted that, in light of previous NPSA work streams and analysis, the risk assessment and care of women having VTE prophylaxis is an important patient safety issue.

4.1.5 Current practice

The latest CMACE review of maternal deaths, reports that risk factors for thromboembolism were present in sixteen of the eighteen women who died
from thrombosis and/or thromboembolism during the period 2006–08\textsuperscript{13}. In seven women there was inadequate thromboprophylaxis according to the standards at the time. Five cases involved a failure of appropriate referral to a consultant obstetrician or psychiatrist. Compared with the previous report, however, there were few instances of unnecessary delay in treatment and few cases in which known risks were ignored.

4.1.6 Current indicators

None identified.

5 Initial risk assessment – Gestational diabetes

5.1 NICE CG62 Recommendation 1.2.2.2 and 1.9.1.1 [KPI]

5.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

| Guideline recommendations | CG62 1.2.2.2 A system of clear referral paths should be established so that pregnant women who require additional care are managed and treated by the appropriate specialist teams when problems are identified.

CG62 1.9.1.1 [KPI] Screening for gestational diabetes using risk factors is recommended in a healthy population. At the booking appointment, the following risk factors for gestational diabetes should be determined:
  - body mass index above 30 kg/m²
  - previous macrosomic baby weighing 4.5 kg or above
  - previous gestational diabetes (refer to ‘Diabetes in pregnancy’ [NICE clinical guideline 63], available from www.nice.org.uk/CG063)
  - family history of diabetes (first-degree relative with diabetes)
  - family origin with a high prevalence of diabetes:
    - South Asian (specifically women whose country of family origin is India, Pakistan or Bangladesh)
    - black Caribbean
    - Middle Eastern (specifically women whose country of family origin is Saudi Arabia, United Arab Emirates, Iraq, Jordan, Syria, Oman, Qatar, Kuwait, Lebanon or Egypt).

Women with any one of these risk factors should be offered testing for gestational diabetes (refer to ‘Diabetes in pregnancy’ [NICE clinical guideline 63], available from www.nice.org.uk/CG063).

| Proposed quality statement | Pregnant women with one or more risk factors for diabetes at the time of booking are offered testing for gestational diabetes.

| Draft quality measure | Structure: Evidence of local arrangements to ensure that pregnant women with one or more risk factors for diabetes at the time of booking are offered testing for gestational diabetes.

  Process: Proportion of pregnant women with at least one risk factor for diabetes at the time of booking who undergo testing for gestational diabetes.

  Numerator – the number of pregnant women in the denominator undergoing testing for diabetes.

  Denominator – the number of pregnant women with at least one risk factor for diabetes at the time of booking.

| Discussion points for TEG | • Is this now standard practice?  

Quality standard topic: Antenatal care
5.1.2 Clinical and cost-effectiveness evidence

Recommendation 1.2.2.2 in CG62 was extrapolated from two systematic reviews and four additional RCTs on the effects of continuous care during pregnancy and childbirth, and one RCT on satisfaction with continuity of care. In most cases, these demonstrated an association between continuity of care and lower intervention rates (compared with standard care), as well as beneficial effects on various psychosocial outcomes.

The principle of screening for gestational diabetes in recommendation 1.9.1.1 is based largely on a well-conducted RCT which seems to suggest that treating women who have mild gestational diabetes in pregnancy is likely to be effective in reducing the risk of complications. There is low-grade evidence from effectiveness studies that impaired glucose tolerance in pregnancy or frank gestational diabetes is associated with macrosomia, and possible increases in the incidence of pre-eclampsia and preterm delivery.

Various studies on risk factors for gestational diabetes were considered in CG62 consisting of two systematic reviews, one observational study, one case-control study, one RCT, one retrospective study, one cross-sectional study and one prospective population-based study. Further evidence on the effectiveness of screening tests was considered, which included the same RCT, retrospective study and cross-sectional study, as well as three additional prospective cohort studies and a prospective randomised study. The GDG concluded that, owing to the heterogeneity among studies for different screening tests, there is no obvious best test available to screen for gestational diabetes. The evidence for the accuracy of these tests is further undermined by the fact that the thresholds for sensitivity and specificity are determined by the individual researchers rather than with reference to an agreed standard.

The GDG concluded that while screening using risk factors is less sensitive than performing a glucose challenge or glucose tolerance test, it is more practical and less disruptive for women.

The last group of women listed in recommendation 1.9.1.1 (family origin with high prevalence of diabetes) was identified from the Diabetes Atlas (third edition) 2006 using prevalence of type 2 diabetes as a surrogate for gestational diabetes.

A health economic model was develop to consider screening based on risk factors (age, ethnicity, BMI and family history of gestational diabetes) and/or blood tests followed by a diagnostic test. The possibility of universal diagnostic testing was also considered. Evidence from this shows that screening and treating gestational diabetes is cost-effective using
identification of risk factors as the screening method followed by a diagnostic oral glucose tolerance test.

5.1.3 Patient experience

A prospective survey in Australia reviewed in CG62 found no differences in the levels of anxiety, depression or women’s concerns about the health of their babies between those who screened negatively compared to those who screened positively. There was some evidence that receiving a positive screen result reduces women’s health perceptions and makes them more likely to rate their health as ‘fair’ rather than ‘very good’ or ‘excellent’. A prospective cohort study in Canada showed no significant association between false positive test results and anxiety levels, depression or woman’s concern for health of their baby.

5.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full accompanying report from the NPSA) identified incident data suggesting that some women are not receiving testing for gestational diabetes. The data also highlighted the importance of following up the results of any tests that are performed.

5.1.5 Current practice

CG62 reports that a UK survey of obstetric units in 1999 indicated that 67% of units were using a risk factor assessment for gestational diabetes at that time, using a combination of the factors listed in recommendation 1.9.1.1.

5.1.6 Current indicators

None identified.
6 Initial risk assessment – Pre-eclampsia

6.1 *NICE CG62 Recommendation 1.9.2.2 and CG107 1.1.2.1 [KPI]*

6.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

| Guideline recommendations | CG62 1.9.2.2 At the booking appointment, the following risk factors for pre-eclampsia should be determined:  

- age 40 years or older  
- nulliparity  
- pregnancy interval of more than 10 years  
- family history of pre-eclampsia  
- previous history of pre-eclampsia  
- body mass index 30 kg/m² or above  
- pre-existing vascular disease such as hypertension  
- pre-existing renal disease  
- multiple pregnancy.  

More frequent blood pressure measurements should be considered for pregnant women who have any of the above risk factors.  

CG107 1.1.2.1 [KPI] Advise women at high risk of pre-eclampsia to take 75 mg of aspirin¹⁴ daily from 12 weeks until the birth of the baby. Women at high risk are those with any of the following:  

- hypertensive disease during a previous pregnancy  
- chronic kidney disease  
- autoimmune disease such as systemic lupus erythematosis or antiphospholipid syndrome  
- type 1 or type 2 diabetes  
- chronic hypertension.|
| Proposed quality statement | Pregnant women at high risk of pre-eclampsia at the time of booking are advised to take 75 mg of aspirin daily from 12 weeks until the birth of the baby.|
| Draft quality measure | Structure: Evidence of local arrangements to ensure that pregnant women at high risk of pre-eclampsia at the time of booking are advised to take 75 mg of aspirin daily from 12 weeks until the birth of the baby.  

Process: Proportion of pregnant women at high risk of pre-eclampsia at the time of booking who are advised to take 75 mg of aspirin daily from 12 weeks until the birth of the baby.  

Numerator – the number of pregnant women in the denominator advised to take 75 mg of aspirin daily from 12 weeks until the birth of the baby. |

¹⁴ In this guideline, drug names are marked with an asterisk if they do not have UK marketing authorisation for the indication in question at the time of publication (August 2010). Informed consent should be obtained and documented.
weeks until the birth of the baby.

Denominator – the number of pregnant women at high risk of pre-eclampsia at the time of booking.

<table>
<thead>
<tr>
<th>Discussion points for TEG</th>
</tr>
</thead>
</table>

- There will be some circumstances in which aspirin is contraindicated (e.g. allergy, medical condition precluding use of aspirin). Can contraindications be defined so that the statement might read “Pregnant women at high risk of pre-eclampsia at the time of booking are advised (unless contraindicated) to take 75 mg of aspirin daily from 12 weeks until the birth of the baby”?

- Use of aspirin in women with moderate risk factors is not included (CG107 1.1.2.2). Note lack of clear evidence for this group.

### 6.1.2 Clinical and cost-effectiveness evidence

The CG62 GDG found that no current screening test offered a high enough diagnostic value, to be used in routine care. The quality of the studies reviewed under ‘accuracy of screening tests’ was variable, with deficiencies in many areas of methodology. In particular, studies suffered from a lack of blinding and relatively small sample sizes. There was heterogeneity regarding the reference standard used in each study. Lack of information and definitions were also noted. The GDG felt it was important to highlight accepted risk factors for developing pre-eclampsia as stated in recommendation 1.9.2.2.

Recommendation 1.1.2.1 in CG107 is based on evidence that aspirin prophylaxis reduces the occurrence of pre-eclampsia, preterm birth and fetal and neonatal mortality in women at high risk of developing the condition. The body of evidence reviewed consisted of a Cochrane systematic review and a meta-analysis using individual-patient data assessing the effectiveness of antiplatelet agents (mainly aspirin) in reducing the risk of pre-eclampsia, and a further RCT on a specific population of women with the converting enzyme DD and history of pre-eclampsia. Evidence for the use of low-dose aspirin (75 mg/day) is consistent with a small risk reduction for pre-eclampsia and there are sufficient data on the safety of aspirin in the doses used in pre-eclampsia prophylaxis trials to make recommendations for clinical practice. The ratio of benefits to risks was clearly in favour of advising aspirin prophylaxis for women at high risk of pre-eclampsia and not to those at low risk. The GDG defined the factors for ‘high risk’ as stated in the recommendation. The GDG believed it was important to start using aspirin from 12 weeks (earliest gestational age for which evidence concerning the use of aspirin in the prevention of pre-eclampsia was identified) given that the pathological events that lead to clinical syndrome of pre-eclampsia begin in the first half of the second trimester and there is a suggestion of a greater effect if aspirin is given before 20 weeks. There was no conclusive evidence to identify the optimal gestational age at which to discontinue treatment.
The GDG’s economic analysis showed aspirin prophylaxis to be cost saving compared with no aspirin. The guideline notes that the dosage relationship was difficult to disentangle. While there was some suggestion from the evidence that higher doses (>75 mg/day) might be more effective, the GDG’s health economic analyses suggested that 75 mg/day is optimal and the GDG felt the evidence was insufficient to justify use of another dose.

6.1.3 Patient experience

None identified.

6.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full accompanying report from the NPSA) did not identify any incidents relating to this area of care in the sample reviewed.

6.1.5 Current practice

The 2006-08 CMACE review of maternal deaths found that, of the 22 deaths resulting from eclampsia, pre-eclampsia or acute fatty liver of pregnancy (AFLP), 20 demonstrated substandard care\(^{15}\). Nine deaths from intracranial haemorrhage, the single largest cause of death, indicate a failure of effective antihypertensive therapy. There were four women in whom GPs made errors. These were mainly around failure to refer appropriately to specialist services, often because of a failure to appreciate the significance of symptoms or signs of preeclampsia.

No current practice data specifically on identification of risk factors or administration of prophylactic aspirin was identified.

6.1.6 Current indicators

None identified.

7 Informed decision-making - General

7.1 NICE CG62 Recommendations 1.1.1.4 [KPI], 1.1.1.5, 1.1.1.8 and 1.1.1.10

7.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

| Guideline recommendations | CG62 1.1.1.4 [KPI] Pregnant women should be offered information based on the current available evidence together with support to enable them to make informed decisions about their care. This information should include where they will be seen and who will undertake their care.  
CG62 1.1.1.5 At each antenatal appointment, healthcare professionals should offer consistent information and clear explanations, and should provide pregnant women with an opportunity to discuss issues and ask questions.  
CG62 1.1.1.8 Pregnant women should be informed about the purpose of any test before it is performed. The healthcare professional should ensure the woman has understood this information and has sufficient time to make an informed decision. The right of a woman to accept or decline a test should be made clear.  
CG62 1.1.1.10 Information about antenatal screening should include balanced and accurate information about the condition being screened for. |
| Proposed quality statement | Pregnant women are offered balanced and consistent information which they understand and enables them to make informed decisions about their care. |
| Draft quality measure | Structure: Evidence of local arrangements to ensure that pregnant women are offered balanced and consistent information which they understand and enables them to make informed decisions about their care.  
Process:  
a) Proportion of pregnant women presenting to antenatal services who receive information about where they will be seen and who will provide their antenatal care.  
Numerator – the number of pregnant women in the denominator receiving information about where they will be seen and who will provide their antenatal care.  
Denominator – the number of pregnant women presenting to antenatal services.  
b) Proportion of tests offered to pregnant women for which information about the purpose is provided to the woman before the test is accepted or declined.  
Numerator – the number of tests in the denominator for which information about the purpose is provided to the woman before... |
the test is accepted or declined.

Denominator – the number of tests offered to pregnant women.

c) Proportion of antenatal screening tests offered to pregnant women for which information about the condition(s) being screened for is provided to the woman before the test is accepted or declined.

Numerator – the number of antenatal screening tests in the denominator for which information about the condition(s) being screened for is provided to the woman before the test is accepted or declined.

Denominator – the number of antenatal screening tests offered to pregnant women.

**Outcome:** Pregnant women feel sufficiently informed and supported to make decisions about their care.

<table>
<thead>
<tr>
<th>Discussion points for TEG</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Consider this overarching statement alongside 8 to compare the different approaches (i.e. general vs specific).</td>
</tr>
<tr>
<td>• Can this general statement be measured adequately?</td>
</tr>
<tr>
<td>• Does process a) capture patient choice?</td>
</tr>
</tbody>
</table>

### 7.1.2 Clinical and cost-effectiveness evidence

Common areas were chosen to search for evidence regarding the effectiveness of information giving, which could be drawn on to illustrate general principles. These were: breastfeeding information, dietary information, smoking cessation and travel safety. A range of trials and studies were considered (see section 3 of full clinical guideline), the interpretation of which is summarised as follows: there is some evidence that breastfeeding initiation rates and breastfeeding duration can be improved by interactive antenatal breastfeeding education. One-to-one counselling and peer support antenatally are also effective. There is some evidence that intensive antenatal dietary counselling and support is effective in increasing women’s knowledge about healthy eating and can affect eating behaviours. There is no evidence linking this with improved pregnancy outcomes. There is good-quality evidence to show that smoking cessation interventions help women reduce smoking and decrease adverse neonatal outcomes. Evidence about car travel safety is of poor quality but findings suggest focused antenatal information provision may increase appropriate use of car restraints for babies.

There is a small amount of good-quality evidence on providing information about alcohol consumption in pregnancy that suggests that using a variety of methods does not alter reported behaviour, although it can improve knowledge about recommended safe levels.

There is high-quality evidence that informational leaflets are effective in increasing the knowledge of pregnant women about screening tests (in
general and for Down’s syndrome), and that the use of a touch screen method does not improve uptake rate of screening tests compared with the leaflets but may reduce anxiety and be particularly useful for women with abnormal results. Videos can increase knowledge of prenatal diagnosis without increasing anxiety. Decision analysis techniques can also be useful.

There is evidence from a well-conducted qualitative study showing that the process of informed decision making for prenatal screening tests is hampered by inadequate information provided to pregnant women during consultations, and the divergent approaches taken by clinicians and patients.

Evidence shows that the decision whether or not to undergo a prenatal screening test is usually made by the woman herself. However, those choosing to undergo testing report that healthcare professionals also have a strong influence on their decision. Women prefer getting information from face-to-face discussion or counselling rather than other methods.

There is evidence that both written and verbal information leads to a higher uptake of HIV screening tests in pregnant women without increasing their anxiety.

### 7.1.3 Patient experience

An Australian retrospective cohort study reviewed in NICE clinical guideline 62 shows that the decision on whether or not to undergo a prenatal screening test is usually made by the woman herself. However, those choosing to undergo testing report that healthcare professionals also have a strong influence on their decision. The study also reported that women prefer getting information from face-to-face discussion or counselling rather than other methods. A further six descriptive studies also suggest that women prefer information to be provided on a face-to-face basis. The extent to which there was an understanding of what was said was dependent upon their working background.

NICE clinical guideline 62 also reports high-quality evidence to indicate that pregnant women do not have sufficient knowledge to make the informed decisions that need to be made regarding Down’s syndrome screening and they find the concept of risk calculation particularly difficult to understand. Providing them with more information does not lead to an increase in their anxiety level. Good evidence from a cohort study shows that women taking part in prenatal screening programme are inadequately informed regarding aspects of testing and the further pathway of management when an increased risk is identified.

An interview with 51 people about their experiences of pregnancy found that especially in a first pregnancy, women wanted to know about various aspects
of pregnancy including detailed information about the changes happening inside their body; how to take care of their health and the health of the unborn baby; understanding results of tests and what symptoms and emotions to expect\textsuperscript{16}. Several people had felt less need for information in later pregnancies, but still valued reassurance that everything was progressing well and reminders of what they needed to do. Timing of information was important. Most women wanted information very early, when they were feeling most unsure and anxious. Several people commented on the need for clear and understandable information. This might mean explaining technical jargon or long medical words, or having more available in another language. Women also wanted advice that was sensitive to different religious and cultural needs. One young mother found some midwives did not give her much information. She preferred one midwife who took time to explain things in a way she could understand.

A synthesis of three pieces of qualitative research undertaken by the Department of Health about the experience of expectant and new parents found that many women are too tired or too unwell to take in or remember important information, particularly if it is delivered only verbally\textsuperscript{17}. Some women, especially first-time mothers, are worried about being seen to be a good parent and therefore afraid to ask questions. This is particularly the case with younger women. Women whose first language isn’t English may not be able to take in large quantities of information, especially in medical and specialist language. They may also rely on other people to translate and interpret, and information may be lost or distorted. Also, women with low literacy may find printed information difficult to understand, but not want to admit it. The report also found that it’s important that advice is given at the right stage of pregnancy. Face-to-face appointments with healthcare professionals are valued by both parties. Some women feel their appointments are rushed and describe leaving appointments frustrated, and with unanswered questions.

7.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full accompanying report from the NPSA) identified incidents where women had not been given sufficient or relevant information to enable them to make an informed decision about their care.


\textsuperscript{17} Department of Health (2011) Parents’ views on the maternity journey and early parenthood. Available from www.dh.gov.uk
7.1.5 Current practice

In 2010, 83% of 25,198 survey respondents reported that, thinking about their antenatal care, they were always spoken to in a way they could understand. A further 15% felt this happened sometimes and the remaining 2% reported that they were not spoken to in a way they could understand. 74% of 24,859 respondents reported that, thinking about their antenatal care, they were always involved enough in decisions about their care. This is an increase from 67% in 2007. 22% felt they were sometimes involved enough, and the remaining 4% felt that they were not involved enough in decisions about their care.

An interview with 51 people about their experiences of pregnancy found that most information about normal pregnancy came through regular maternity appointments with GPs, midwives and obstetricians. Mostly people were very satisfied with this support, although a few felt they got conflicting or misleading information. Antenatal classes were another generally popular source of information for those people who went to them.

NICE clinical guideline 62 reports evidence from three qualitative studies on the perspectives of clinicians and women regarding information giving. These showed that the process of informed decision making for prenatal screening tests is hampered by inadequate information provided to pregnant women during consultations, and the divergent approaches taken by the information provider (clinicians) and information taker (patients). Although the healthcare providers intend to provide complete information about Down’s syndrome screening and its subsequent pathway to prospective parents, their ability to do so is limited by time constraints, their limited experience of the condition after birth and a lack of factual information given in the sources they used to acquire knowledge about Down’s syndrome. With regards to use of leaflets specifically for information giving, it was found that time constraints, fear of litigation, power hierarchies, and imperativeness of current technological interventions act as barriers in promoting leaflets for informed decision making in maternity care. Women were found to merely comply with the information provided by health professionals and were unable to make an ‘informed choice’.

7.1.6 Current indicators

None identified.

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8 Informed decision-making – Asymptomatic bacteriuria

8.1 NICE CG62 Recommendations 1.1.1.4 [KPI], 1.1.1.5, 1.1.1.8, 1.1.1.10 and 1.8.1.1

8.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

| Guideline recommendations | CG62 1.1.1.4 [KPI] Pregnant women should be offered information based on the current available evidence together with support to enable them to make informed decisions about their care. This information should include where they will be seen and who will undertake their care. |
| CG62 1.1.1.5 At each antenatal appointment, healthcare professionals should offer consistent information and clear explanations, and should provide pregnant women with an opportunity to discuss issues and ask questions. |
| CG62 1.1.1.8 Pregnant women should be informed about the purpose of any test before it is performed. The healthcare professional should ensure the woman has understood this information and has sufficient time to make an informed decision. The right of a woman to accept or decline a test should be made clear. |
| CG62 1.1.1.10 Information about antenatal screening should include balanced and accurate information about the condition being screened for. |
| CG62 1.8.1.1 Women should be offered routine screening for asymptomatic bacteriuria by midstream urine culture early in pregnancy. Identification and treatment of asymptomatic bacteriuria reduces the risk of pyelonephritis. |

| Proposed quality statement | Pregnant women are offered information which they understand about the risks associated with asymptomatic bacteriuria in order to make informed decisions about their care. |

| Draft quality measure | Structure: Evidence of local arrangements to ensure that pregnant women are offered information which they understand about the risks associated with asymptomatic bacteriuria in order to make informed decisions about their care. |
| Process: Proportion of pregnant women receiving antenatal care who receive information about the risks associated with asymptomatic bacteriuria. |
| Numerator – the number of pregnant women in the denominator receiving information about the risks associated with asymptomatic bacteriuria. |
| Denominator – the number of pregnant women receiving antenatal care. |
**Outcome:** Pregnant women feel informed about the risks associated with asymptomatic bacteriuria, which helps them to make decisions about their care.

<table>
<thead>
<tr>
<th>TEG discussion points</th>
</tr>
</thead>
<tbody>
<tr>
<td>- See notes for draft statement 7, (general vs specific).</td>
</tr>
<tr>
<td>- Is timing important for measurement?</td>
</tr>
</tbody>
</table>

### 8.1.2 Clinical and cost-effectiveness evidence

See sections 7.1.2 and 9.1.2.

### 8.1.3 Patient experience

None identified.

### 8.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full accompanying report from the NPSA) did not identify any incidents relating specifically to this area of care in the sample reviewed.

### 8.1.5 Current practice

None identified.

### 8.1.6 Current indicators

None identified.
9 Screening and testing – Asymptomatic bacteriuria

9.1 NICE CG62 Recommendation 1.8.1.1

9.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<table>
<thead>
<tr>
<th>Guideline recommendations</th>
<th>CG62 1.8.1.1 Women should be offered routine screening for asymptomatic bacteriuria by midstream urine culture early in pregnancy. Identification and treatment of asymptomatic bacteriuria reduces the risk of pyelonephritis.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed quality statement</td>
<td>Pregnant women are offered screening at the booking appointment for asymptomatic bacteriuria by midstream urine culture.</td>
</tr>
<tr>
<td>Draft quality measure</td>
<td>Structure: Evidence of local arrangements to ensure that pregnant women are offered screening at the booking appointment for asymptomatic bacteriuria by midstream urine culture.</td>
</tr>
<tr>
<td></td>
<td>Process: Proportion of pregnant women receiving antenatal care who undergo screening at the booking appointment for asymptomatic bacteriuria by midstream urine culture.</td>
</tr>
<tr>
<td></td>
<td>Numerator – the number of pregnant women in the denominator undergoing screening at the booking appointment for asymptomatic bacteriuria by midstream urine culture.</td>
</tr>
<tr>
<td></td>
<td>Denominator – the number of pregnant women receiving antenatal care.</td>
</tr>
</tbody>
</table>

9.1.2 Clinical and cost-effectiveness evidence

Evidence from RCTs indicate an increased risk between asymptomatic bacteriuria (ASB) and maternal and fetal outcomes, such as preterm birth and pyelonephritis, among untreated women compared with women without bacteriuria. Urine culture (midstream) is accepted as the reference standard for diagnosis of ASB, with a higher sensitivity and specificity compared to less expensive options such as reagent strips.

A health economics analysis of culture compared to dipstick screening was carried out (either were considered more cost-effective than a policy of no screening at all, given the reduction of maternal and infant morbidity). The analysis supports the conclusion that the culture method is favourable, being more cost-effective than the dipstick method. It should be noted that the analysis includes assumptions about averting preterm birth and a Cochrane review considered in the updated guideline did not show an association between treating asymptomatic bacteriuria and reducing the incidence of preterm birth.
9.1.3  Patient experience

None identified.

9.1.4  Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full accompanying report from the NPSA) identified data relating to failure to follow up the results of a midstream urine specimen. This highlighted that, as well as providing screening, it is also important that the results are acted upon and treatment given when necessary.

9.1.5  Current practice

None identified.

9.1.6  Current indicators

None identified.
## 10 Services – Telephone advice

### 10.1 NICE CG110 Recommendation 1.1.13

#### 10.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<table>
<thead>
<tr>
<th>Guideline recommendations</th>
<th>CG110 1.1.13 At the booking appointment, give the woman a telephone number to enable her to contact a healthcare professional outside of normal working hours, for example the telephone number of the hospital triage contact, the labour ward or the birth centre.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed quality statement</td>
<td>Pregnant women, who contact maternity services by telephone for advice about their pregnancy, have the details of their call logged by the service and then recorded in their hand-held maternity notes.</td>
</tr>
</tbody>
</table>
| Draft quality measure     | **Structure:** Evidence of local arrangements to ensure that pregnant women, who contact maternity services by telephone for advice about their pregnancy, have the details of their call logged by the service and then recorded in their hand-held maternity notes.  
**Process:**  
a) Proportion of telephone calls to maternity services from pregnant women for which details of the call are documented by the service.  
Numerator – the number of telephone calls in the denominator for which details of the call are documented by the service.  
Denominator – the number of telephone calls to maternity services from pregnant women.  
b) Proportion of telephone calls to maternity services from pregnant women for which details of the call are documented in the woman’s hand-held maternity notes.  
Numerator – the number of telephone calls in the denominator for which details of the call are documented in the woman’s hand-held maternity notes.  
Denominator – the number of telephone calls to maternity services from pregnant women. |
| Discussion points for TEG | • This statement is not based directly on the guideline recommendation, would need to be based on TEG consensus – clear rationale needed.  
• Is logging of calls the best way to improve call handling?  
• Is it reasonable to expect call details to be recorded in women’s hand-held notes (and is this two concepts)? Is it enough for the service to keep a record of the content given the woman may not come in for review? |
10.1.2 Clinical and cost-effectiveness evidence

Recommendation 1.1.13 in CG110 is derived from the GDG’s interpretation of common themes across four chapters of evidence (see chapters 4-7 of full guideline for study details). The provision of a contact number was described in the evidence and endorsed as common practice by the GDG. While it will not always be possible for women to contact directly their individual healthcare professional (who may be a lone specialist in a particular area, such as substance-misuse), providing a 24-hour telephone number ensures that these women will always be able to contact a healthcare professional who should be able to provide immediate support and recognise whether a woman needs to be seen urgently by a healthcare professional. A message can be left for the specialist healthcare professional to let them know what has occurred and to enable them to plan any follow-up that may be necessary.

10.1.3 Patient experience

None identified.

10.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full accompanying report from the NPSA) did not identify any incidents relating specifically to this area of care. An earlier report from the NPSA highlighted that, in light of previous NPSA work streams and analysis, safe systems for providing telephone advice in the antenatal period is an important patient safety issue.

10.1.5 Current practice

In the 2010 national survey of women’s experiences of maternity services, 92% of 25,190 respondents had the name and telephone number of a midwife they could contact if they were worried\(^{20}\). For those who contacted a midwife (18,346), 72% reported always being given the help they needed and 23% sometimes, with the remaining 6% reporting not being given the help they needed.

Within CG110, the provision of a contact number was described in the evidence and endorsed as common practice by the GDG.

10.1.6 Current indicators

None identified.

11 Screening and testing – National fetal screening programmes

11.1 NICE CG62 Recommendation 1.7.1.1, 1.7.2.1 and 1.7.2.3 [KPI] and UK NSC Policy recommendations 2011-14

11.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

| Guideline recommendations | CG62 1.7.1.1 Ultrasound screening for fetal anomalies should be routinely offered, normally between 18 weeks 0 days and 20 weeks 6 days. |
| CG62 1.7.2.1 All pregnant women should be offered screening for Down’s syndrome. Women should understand that it is their choice to embark on screening for Down’s syndrome. |
| CG62 1.7.2.3 [KPI] The ‘combined test’ (nuchal translucency, beta-human chorionic gonadotrophin, pregnancy-associated plasma protein-A) should be offered to screen for Down’s syndrome between 11 weeks 0 days and 13 weeks 6 days. For women who book later in pregnancy the most clinically and cost-effective serum screening test (triple or quadruple test) should be offered between 15 weeks 0 days and 20 weeks 0 days. |

UK NSC Policy recommendations 2011-14 The gestational age window for combined test starts from 10 weeks + 0 days to 14 weeks + 1 day in pregnancy. The quadruple test window starts from 14 weeks + 2 days to 20 weeks + 0 days.

| Proposed quality statement | Pregnant women are offered fetal screening in accordance with current national screening programmes. |

| Draft quality measure | Structure: Evidence of local arrangements to ensure that pregnant women are offered fetal screening in accordance with current national screening programmes. |
| Process: | a) Proportion of pregnant women booking before 14 weeks who are offered the combined screening test for Down’s syndrome to take place between 10 weeks 0 days and 14 weeks 1 day. |
| | Numerator – the number of pregnant women in the denominator offered the combined screening test for Down’s syndrome to take place between 10 weeks 0 days and 14 weeks 1 day. |
| | Denominator – the number of pregnant women booking before 14 weeks. |
| | b) Proportion of pregnant women booking after 14 weeks who are offered the quadruple screening test for Down’s syndrome |

Draft quality measure: Structure: Evidence of local arrangements to ensure that pregnant women are offered fetal screening in accordance with current national screening programmes. Process: a) Proportion of pregnant women booking before 14 weeks who are offered the combined screening test for Down’s syndrome to take place between 10 weeks 0 days and 14 weeks 1 day. Numerator – the number of pregnant women in the denominator offered the combined screening test for Down’s syndrome to take place between 10 weeks 0 days and 14 weeks 1 day. Denominator – the number of pregnant women booking before 14 weeks. b) Proportion of pregnant women booking after 14 weeks who are offered the quadruple screening test for Down’s syndrome.
to take place between 14 weeks 2 days and 20 weeks 0 days.

Numerator – the number of pregnant women in the
denominator offered the quadruple screening test for Down’s
syndrome to take place between 14 weeks 2 days and 20
weeks 0 days.

Denominator – the number of pregnant women booking after
14 weeks.

c) Proportion of pregnant women receiving antenatal care who
are offered ultrasound screening for fetal anomalies to take
place between 18 weeks 0 days and 20 weeks 6 days.

Numerator – the number of pregnant women in the
denominator offered ultrasound screening for fetal anomalies to take
place between 18 weeks 0 days and 20 weeks 6 days.

Denominator – the number of pregnant women receiving
antenatal care.

Discussion points for TEG

- Is ‘fetal screening’ an acceptable term to capture the
  anomalies scan as well as screening for Down’s
  syndrome?

- Note difference in timings for combined test between
  NICE and UK NSC recommendations. Which one
  should the QS recommend?

- Should this statement include all of FASP or focus only
  on combined screening test for Down’s syndrome?

11.1.2 Clinical and cost-effectiveness evidence

Structural anomalies screening

Recommendation 1.7.1.1 is based on a comprehensive evidence review of
the diagnostic value and effectiveness of different screening methods in
identifying serious structural abnormalities (see section 9.1 of full guideline for
study details).

Findings from a Health Technology Assessment review suggest a second-
trimester scan is the most cost-effective strategy for screening for fetal
anomalies. However, there is also evidence that each different method of
screening has its advantages and disadvantages, and these often seem to
balance out. No one screening method stands out as being much more cost-
effective than any other.

No evidence was found to support the use of selective rather than routine
ultrasound scanning for fetal anomalies.

The guideline notes that prenatal ultrasound scanning for fetal anomalies is
currently undertaken at around 20 weeks. Screening later than 20 weeks 6
days may delay the diagnosis of an abnormality to a point where termination
of an affected pregnancy becomes problematic, and so the screening window
is stated as 18 weeks 0 days and 20 weeks 6 days. The word ‘normally’ is used in recognition of potential difficulties in completing all anomaly scans within this time, such as where women are very overweight (when performing the scan can be difficult and time-consuming) and the risk of repetitive strain injury related problems for sonographers.

**Down’s screening**

NICE recommendations on screening for Down’s syndrome are based on a comprehensive evidence review of the diagnostic value and effectiveness of different screening methods in identifying babies with Down’s syndrome (see section 9.2 of full guideline for study details). The integrated test was found to be cost-effective and resulted in the fewest losses of normal fetuses. However, there were concerns regarding the practicality of screening by this two-stage method. There is also evidence that women prefer a one-stage test to the integrated test.

Evidence shows that the combined test in the first trimester is also cost-effective and has good diagnostic value for detection of Down’s syndrome and other chromosomal anomalies. UK NSC conclude that costs incurred from all strategies have been assessed which provides evidence that the combined screening test is more cost effective (than integrated or serum integrated tests) whilst still delivering to the set standard.

Among the currently used second-trimester tests, the quadruple test seems to have the best screening performance.

UK NSC recommendations appear to draw largely on the evidence considered in the NICE guidance including the 2003 Health Technology Assessment on first and second trimester antenatal screening for Down’s syndrome.

It is noted that the previous 2008 NSC publication states a time window of 11 weeks 0 days to 13 weeks +6 days for the combined test, which aligns to the NICE recommendation. It appears that 10 weeks to 13 weeks +6 days is stated as the window for biochemical testing, with the narrower window for ultrasound nuchal translucency (NT) measurement. The time window stated for the quadruple test in the 2007-10 guidance is 15 weeks to 20 weeks. It is assumed that the current 2011 guidance has been updated to provide a continuous screening period.

Supporting information in the current NSC Model of best practice (for 2011-2014) suggests that Trusts should consider screening women around 11

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weeks + 2 days of pregnancy in order to strike a balance between the benefits of all the markers.

11.1.3 Patient experience

CG62 concludes that ultrasound screening appears to be acceptable to women. Results from a well-conducted structured review show that visual confirmation of fetal wellbeing is the primary reason why women seek ultrasound during pregnancy. Evidence from a qualitative study indicates that detection of an isolated choroid plexus cyst on antenatal ultrasound leads to negative emotions and anxiety in the majority of women, who then seek additional information from other sources. In spite of reassurance in the form of a negative serum screening test for Down’s syndrome, a few women also opt for an invasive test for confirmation. In another study, detection of surgically treatable congenital anomalies on antenatal ultrasound led to increased anxiety levels in the parents but counselling by specialist staff helped to alleviate it significantly. The guideline concludes that ultrasound screening provides reassurance if no anomaly is detected but heightens anxiety if a possible problem is identified and that serum screening can have a detrimental effect on women’s attachment to pregnancy even with a low-risk result, owing to the uncertainty created by the probabilistic nature of the way the result is presented.

11.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full accompanying report from the NPSA) identified incidents where women had not been offered fetal screening, or were outside the timescales for screening.

11.1.5 Current practice

A national review of maternity care published in 2008 found that 99% of women received a fetal anomalies scan at 18 and 20 weeks and that all trusts offer screening for Down’s syndrome, although only 18% offered the most effective tests recommended in NICE guidance\textsuperscript{22}. The report notes that the NICE guidance had only just become operative and therefore that this rate would be expected to increase.

Achievement of QOF indicator MAT1 (Antenatal care and screening are offered according to current local guidelines) in 2010-11 was 49,056 points

\textsuperscript{22} Healthcare Commission (2008) \textit{Towards better births: a review of maternity services in England}
over 8,245 practices. 69 of these participating practices (0.8%) failed to achieve the available points.

The 2010 survey of women’s experiences of maternity services found that of expectant mothers offered scans for Down’s syndrome in their baby: 52% had a blood test only, 6% had a nuchal test only and 38% had a nuchal and blood test\(^\text{23}\). 3% of expectant mothers were offered no screening tests at all.

CG62 states that (at the time of publication - 2008) the measurement of inhibin A (the fourth analyte in the quadruple test) was not generally available in the UK.

UK NSC Models of best practice 2011-14 states that, presently, 89% of Trusts are on target to meet the previous Model of Best Practice policy and extensive work is being undertaken to support 100% implementation. All Trusts presently provide dating scans and the ability to measure NT is increasing. The development of capacity to undertake NT measurement and provide education, training and support for professionals is a key priority for the period 2010 to 2013.

CG62 found that fewer South Asian women than white women are offered screening and fewer of those who are offered it choose to go ahead with it. Some healthcare professionals appear to have misconceptions regarding the likely attitudes of South Asian women to screening and termination of pregnancy.

11.1.6 Current indicators

QOF MAT1 – Antenatal care and screening are offered according to current local guidelines (Additional services domain). QOF indicators are available from [www.nhsemployers.org](http://www.nhsemployers.org)

12  Fetal growth and well-being – Assessment of fetal presentation

12.1  *NICE CG62 Recommendation 1.10.4*

12.1.1  Relevant NICE clinical guideline recommendations and proposed quality statement

<table>
<thead>
<tr>
<th>Guideline recommendations</th>
<th>CG62 1.10.4 Fetal presentation should be assessed by abdominal palpation at 36 weeks or later, when presentation is likely to influence the plans for the birth. Routine assessment of presentation by abdominal palpation should not be offered before 36 weeks because it is not always accurate and may be uncomfortable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed quality statement</td>
<td>Pregnant women are offered an assessment of fetal presentation by abdominal palpation at 36 weeks or later.</td>
</tr>
</tbody>
</table>

| Draft quality measure | Structure: Evidence of local arrangements to ensure that pregnant women are offered an assessment of fetal presentation by abdominal palpation at 36 weeks or later.  
Process: Proportion of pregnant women of at least 36 weeks gestation receiving antenatal care who receive an assessment of fetal presentation by abdominal palpation at 36 weeks or later.  
Numerator – the number of pregnant women in the denominator receiving an assessment of fetal presentation by abdominal palpation at 36 weeks or later.  
Denominator – the number of pregnant women of at least 36 weeks gestation receiving antenatal care. |

| Discussion points for TEG | ● Would assessments at 36 or 41 weeks be equally acceptable or should the measure specify at 36 or 37 weeks to maximise opportunity for ECV? |

12.1.2  Clinical and cost-effectiveness evidence

A study in 1985 of clinicians using Leopold manoeuvres to assess presentation and engagement of the presenting part found that 53% of all malpresentations were detected. This finding was supported by a more recent study which looked specifically detection of breech presentation. The sensitivity and specificity of Leopold manoeuvres has been reported by one prospective study to be about 28% and 94% respectively.

12.1.3  Patient experience

One descriptive study reviewed in CG62 reported that women do not enjoy being palpated, finding it uncomfortable and not reassuring or informative.
12.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full accompanying report from the NPSA) did not identify any incidents relating specifically to this area of care in the sample reviewed.

12.1.5 Current practice

None identified.

12.1.6 Current indicators

None identified.
### 13 Fetal growth and well-being – Referral for external cephalic version

#### 13.1 NICE CG62 Recommendation 1.11.2.1

#### 13.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

<table>
<thead>
<tr>
<th>Guideline recommendations</th>
<th>CG62 1.11.2.1 All women who have an uncomplicated singleton breech pregnancy at 36 weeks should be offered external cephalic version. Exceptions include women in labour and women with a uterine scar or abnormality, fetal compromise, ruptured membranes, vaginal bleeding and medical conditions.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed quality statement</td>
<td>Pregnant women with an uncomplicated singleton breech pregnancy at 36 weeks or later are offered referral for external cephalic version.</td>
</tr>
</tbody>
</table>
| Draft quality measure      | **Structure:** Evidence of local arrangements to ensure that pregnant women with an uncomplicated singleton breech pregnancy at 36 weeks or later are offered referral for external cephalic version.  
**Process:**  
a) Proportion of pregnant women with an uncomplicated singleton breech pregnancy at 36 weeks or later who are offered referral for external cephalic version.  
Numerator – the number of pregnant women in the denominator offered referral for external cephalic version.  
Denominator – the number of pregnant women with an uncomplicated singleton breech pregnancy at 36 weeks or later.  
b) Proportion of pregnant women with an uncomplicated singleton breech pregnancy at 36 weeks offered referral for external cephalic version, who are referred for external cephalic version.  
Numerator – the number of pregnant women in the denominator referred for external cephalic version.  
Denominator – the number of pregnant women with an uncomplicated singleton breech pregnancy at 36 weeks or later offered referral for external cephalic version. |
| Discussion points for TEG  | • As with draft statement 12, is referral at 36 or 41 weeks for ECV equally desirable from a measurement perspective? |

#### 13.1.2 Clinical and cost-effectiveness evidence
Two systematic reviews identified nine RCTs that examined the effect of ECV for breech at term and before term. ECV before 37 weeks of gestation did not make a significant difference to the incidence of noncephalic births at term, nor to the rate of caesarean section. Performing ECV at term (defined differently across the RCTs, from 33-40 weeks to 37 weeks or more) reduced the number of noncephalic births by 60% when compared with no ECV. A significant reduction in caesarean section was also observed in the ECV group when compared with no ECV. The guideline notes that ECV is associated with adverse maternal and fetal outcomes, which can be minimised by fetal monitoring during the procedure.

13.1.3 Patient experience

None identified.

13.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). An analysis of recent reported incidents (please see full accompanying report from the NPSA) did not identify any incidents relating specifically to this area of care in the sample reviewed.

13.1.5 Current practice

Trusts vary widely in the extent to which they offer ECV to women, from all women to practically none\(^\text{24}\). Staff did not show a great deal of enthusiasm in the staff survey for increasing the ECV rate; 19% of midwives and 16% of medical staff thought ECV could be offered to more women (n=4950).

13.1.6 Current indicators

None identified.

14 Informed decision-making – Prolonged pregnancy

14.1 NICE CG70 Recommendations 1.1.1 [KPI] and 1.3.1.2

14.1.1 Relevant NICE clinical guideline recommendations and proposed quality statement

| Guideline recommendations | CG70 1.1.1 [KPI] Women should be informed that most women will go into labour spontaneously by 42 weeks. At the 38 week antenatal visit, all women should be offered information about the risks associated with pregnancies that last longer than 42 weeks, and their options. The information should cover:
| | • membrane sweeping:
| | o that membrane sweeping makes spontaneous labour more likely, and so reduces the need for formal induction of labour to prevent prolonged pregnancy
| | o what a membrane sweep is
| | o that discomfort and vaginal bleeding are possible from the procedure
| | • induction of labour between 41+0 and 42+0 weeks
| | • expectant management.
| | CG70 1.3.1.2 At the 40 and 41 week antenatal visits, nulliparous women should be offered a vaginal examination for membrane sweeping.
| Proposed quality statement | Pregnant women are offered information at their 38 week antenatal appointment about management options beyond 40 weeks including membrane sweeping, induction of labour and expectant management to enable them to make informed decisions about their care.
| Draft quality measure | Structure: Evidence of local arrangements to ensure that pregnant women are offered information at their 38 week antenatal appointment about management options beyond 40 weeks including membrane sweeping, induction of labour and expectant management to enable them to make informed decisions about their care.
| | Process:
| | a) Proportion of pregnant women attending their 38 week antenatal appointment who receive information about management options beyond 40 weeks including membrane sweeping, induction of labour and expectant management.
| | Numerator – the number of pregnant women in the denominator receiving information about management options beyond 40 weeks including membrane sweeping, induction of labour and expectant management.
| | Denominator – the number of pregnant women attending their 38 week antenatal appointment.
b) Proportion of pregnant women receiving information about management options beyond 40 weeks whose preferences for this are documented.

Numerator – the number of pregnant women in the denominator whose preferences for management beyond 40 weeks are documented.

Denominator – the number of pregnant women receiving information about management options beyond 40 weeks.

Outcome: Pregnant women who have attended their 38 week appointment (or later) feel sufficiently informed about management options beyond 40 weeks to make decisions about their care.

14.1.2 Clinical and cost-effectiveness evidence

There is a dearth of good up-to-date evidence relating to information giving and emotional support to women and their families/partners during the induction of labour process. Evidence from four UK surveys (three published before 1990) suggested that up to 40% of women felt they were not given adequate information relating to issues about induction of labour. In light of the limited evidence base, the GDG placed a high value on the need for information provision for women and considered that women should receive information concerning induction of labour that includes the reasons, methods and options. No evidence was identified which assessed the best methods of information giving.

14.1.3 Patient experience

None identified.

14.1.4 Patient safety

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (see Appendix B). A comprehensive analysis of recent reported incidents (please see full accompanying report from the NPSA) did not identify any incidents relating specifically to this area of care in the sample reviewed.

14.1.5 Current practice

The 2011 review decision for NICE clinical guideline 70 includes an analysis by the NICE implementation team. This indicates that the recommendations about providing information were thought to be very important but some voiced concerns about how much time would be allocated to this locally. There were some uncertainties about the current baseline practice of membrane sweeping, and that membrane sweeps were likely to add to the workload of services. Further advice has suggested that over the last few years since publication, membrane sweeping has become more widely used.
14.1.6 Current indicators

None identified.
### Appendix A: Summary of draft quality statements

<table>
<thead>
<tr>
<th></th>
<th>Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pregnant women in vulnerable groups are encouraged to access antenatal care.</td>
</tr>
<tr>
<td>2</td>
<td>Pregnant women have a full record of all antenatal test results in their hand-held maternity notes.</td>
</tr>
<tr>
<td>3</td>
<td>Pregnant women with a body mass index over 30 at the booking appointment are referred to a dietitian.</td>
</tr>
<tr>
<td>4</td>
<td>Pregnant women at high risk of venous thromboembolism at the time of booking are referred to a specialist service.</td>
</tr>
<tr>
<td>5</td>
<td>Pregnant women with one or more risk factors for diabetes at the time of booking are offered testing for gestational diabetes.</td>
</tr>
<tr>
<td>6</td>
<td>Pregnant women at high risk of pre-eclampsia at the time of booking are advised to take 75 mg of aspirin daily from 12 weeks until the birth of the baby.</td>
</tr>
<tr>
<td>7</td>
<td>Pregnant women are offered balanced and consistent information which they understand and enables them to make informed decisions about their care.</td>
</tr>
<tr>
<td>8</td>
<td>Pregnant women are offered information which they understand about the risks associated with asymptomatic bacteriuria in order to make informed decisions about their care.</td>
</tr>
<tr>
<td>9</td>
<td>Pregnant women are offered screening at the booking appointment for asymptomatic bacteriuria by midstream urine culture.</td>
</tr>
<tr>
<td>10</td>
<td>Pregnant women who contact maternity services by telephone for advice about their pregnancy, have the details of their call logged by the service and then recorded in their hand-held maternity notes.</td>
</tr>
<tr>
<td>11</td>
<td>Pregnant women are offered fetal screening in accordance with current national screening programmes.</td>
</tr>
<tr>
<td>12</td>
<td>Pregnant women are offered an assessment of fetal presentation by abdominal palpation at 36 weeks or later.</td>
</tr>
<tr>
<td>13</td>
<td>Pregnant women with an uncomplicated singleton breech pregnancy at 36 weeks or later are offered referral for external cephalic version.</td>
</tr>
<tr>
<td>14</td>
<td>Pregnant women are offered information at their 38 week antenatal appointment about management options beyond 40 weeks including membrane sweeping, induction of labour and expectant management to enable them to make informed decisions about their care.</td>
</tr>
</tbody>
</table>
Appendix B: Definition of patient safety

The National Patient Safety Agency (NPSA) defines patient safety in the following terms:

Every day more than a million people are treated safely and successfully in the NHS, but the evidence tells us that in complex healthcare systems things will and do go wrong, no matter how dedicated and professional the staff. When things go wrong, patients are at risk of harm, and the effects are widespread and often devastating for patients, their families and the staff involved. Safety incidents also incur costs through litigation and extra treatment, and in 2009/10 the NHSLA paid out approximately £827,000,000 in litigation costs and damages. These incidents are often caused by poor system design rather than the error of individuals i.e. ‘they are an accident waiting to happen’.

In short patient safety could be summarised as ‘The identification and reduction of risk and harm associated with the care provided to patients’ or ‘Preventing patients from being harmed by their treatment’. Examples of this might be ‘operating on or removing the wrong organ, ten times the dose of an opioid, giving a colonoscopy to the wrong patient with the same name as someone else in the waiting room etc.’ These risks are unlikely to be identified through clinical trials or traditional evidence bases and so other evidence sources, such as the National Reporting and Learning System, need to be analysed to highlight the risks and improve system development. This does not however give an accurate picture of prevalence in that way that methods such as casenote review may do.