

Stillbirth and Neonatal Death Alliance (PSANZ-SANDA)

# Clinical Practice Guideline for the Care of Women with Decreased Fetal Movements

October 5, 2016

in partnership with



Research and education to prevent stillbirth

and endorsed by



The Royal Australian and New Zealand College of Obstetricians and Gynaecologists









The Royal Australian College of General Practitioners

#### **Produced by:**

This clinical guideline was produced by a multidisciplinary working group led by the Mater Research Institute, University of Queensland, Brisbane, Australia, under the auspices of the Stillbirth and Neonatal Death Alliance (SANDA) of the Perinatal Society of Australia and New Zealand (PSANZ) in partnership with the Stillbirth Foundation Australia. Support for guideline development was received from the Mater Foundation, Mater Health Services.





#### Endorsed by:

The clinical guideline has been endorsed by: Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG); Australian College of Midwives (ACM); Royal Australian College of General Practitioners (RACGP); Stillbirth Foundation Australia; Australian National Council for Stillbirth and Neonatal Death Support (SANDS); National SIDS Council of Australia Ltd (SIDS and Kids); Still Aware.

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#### **Disclaimer:**

The main objective of this guideline is to provide advice to health care providers on the care of women with concerns of decreased fetal movements (DFM), and to enhance consistency in information and care provided to women. This guideline has been developed to help reduce the risk of adverse pregnancy outcomes, including perinatal death or disability and maternal anxiety.

This guideline is not intended to be prescriptive. It is designed to provide the best available information, enabling integration of the best evidence, clinicians' judgement and individual choice in arriving at decisions about care. Clinical practice guidelines are considered as generally-recommended practice. Due to the lack of high-quality evidence, recommendations in this guideline are mainly consensus-based, following consideration of the available evidence.

#### Further review and information:

This guideline will remain current until the next review on or before **June 2018**. Requests for further information, comments or suggestions are encouraged and can be forwarded to:

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# **Glossary of terms**

Acidaemia	Increased acidity of the blood caused by an increased concentration of hydrogen ions and measured by pH.
Amniotic fluid	The fluid that surrounds the fetus within the amniotic sac.
Antenatal	The period of the pregnancy before birth
Antepartum	Before the onset of labour.
Apgar score	A system to assess the status of the baby after birth. The Apgar score is recorded at 1 minute and 5 minutes after birth and is based on the following five variables: heart rate, respiratory effort, muscle tone, reflex irritability and colour, with a maximum score of 10.
Body mass index (BMI)	A person's weight in kilograms divided by the square of height in meters.
Cardiotocography (CTG)	The electronic monitoring of the fetal heart rate (cardio) and of uterine contractions (toco). The fetal heart rate is recorded by means of either an external ultrasonic abdominal transducer or a fetal scalp electrode. Uterine contractions are recorded by means of an abdominal pressure transducer. The recordings are graphically represented over time.
Congenital anomaly	A structural malformation, chromosomal abnormality, genetic syndrome or metabolic disorder which is present from birth.
Customised birthweight	Using a weight reference for the baby that is individualised (customised), and not based on population averages. Factors shown to be predictive of birthweight are maternal height and weight, ethnicity, fetal gender and gestational age. The customised birthweight standard is an adjusted standard for the individual baby.
Doppler ultrasound	A diagnostic tool that uses high frequency ultrasound to detect the presence or absence of blood flow and to measure blood flow velocity.
Fetal death	See "Stillbirth"
Fetomaternal haemorrhage (FMH)	The passage of blood across the placental interface from the fetus to mother. FMH may be diagnosed using flow cytometry or the Kleihauer test which detects fetal red blood cells separately to the mother's red blood cells. FMH may be acute or chronic and may be asymptomatic. Although the volume of significant FMH is not defined and is gestational age dependent, it is associated with fetal mortality and morbidity.
Fetal growth restriction (FGR)	Also known as 'intrauterine growth restriction' (IUGR). This term is often used interchangeably with the term 'small for gestational age' (SGA). SGA is defined as a baby with an antenatal ultrasound biometry assessment less than the 10 <sup>th</sup> percentile for gestational age.
	FGR refers to babies that have failed to reach their growth potential during pregnancy, which can be assessed by serial ultrasound scans. They are frequently <i>but not always</i> SGA.
Flow cytometry	A test used to detect FMH by differentiating fetal and maternal blood cells.
Gestation	The time from conception to birth. The duration of gestation is measured from the first day of the last normal menstrual period.

Human placental lactogen	hPL is a hormone produced by the placenta that modifies the metabolic		
(hPL)	state of the mother during pregnancy to facilitate the energy supply of the fetus.		
Hypertension	Elevated blood pressure exceeding 140/90 mmHg.		
Hypoglycaemia	Low level of blood glucose (<4.0 mmol/L).		
Hyperglycaemia	High level of blood glucose (>7.0 mmol/L when fasting or >11.0 mmol/L at any time).		
Kick-chart	A method of counting fetal movements and recording them within a defined time frame.		
Live birth	The complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which after such separation breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord or definite movement of the voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. The definition of a live birth is independent of gestational age.		
Neonatal	Pertaining to the newborn period, which is the first 28 days after birth.		
Neonatal mortality rate (NMR)	The number of neonatal deaths (those occurring within the first 28 days following birth) per 1000 births.		
Oligohydramnios	Reduced amniotic fluid volume		
Perinatal mortality rate (PMR) Preterm birth	The number of stillbirths and neonatal deaths per 1000 births. The birth of a baby at less than 37 weeks gestational age.		
Randomised controlled trial	A comparative study in which participants are randomly allocated to intervention and control groups and are followed up to examine differences in outcomes between the two groups.		
Small for gestational age (SGA)	A fetus or baby with an estimated birthweight or actual birthweight less than the 10 <sup>th</sup> percentile for gestational age, according to National birthweight percentiles.		
Singleton	A single baby.		
Stillbirth (Fetal Death)	Death prior to the complete expulsion or extraction from its mother of a product of conception of 20 or more completed weeks of gestation; or if the gestational age is not known, a birthweight of 400g or more. The death is indicated by the fact that after such separation, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.		
Stillbirth rate	The number of stillbirths per 1000 births.		

## 1. Purpose of this guideline

Stillbirth affects over 2,700 families in Australia and New Zealand<sup>1</sup>, and over 2.64 million families worldwide annually<sup>2</sup>. Stillbirths are often preceded by maternal perception of decreased fetal movement (DFM)<sup>3, 4</sup>. DFM is also strongly linked to adverse perinatal outcomes such as neurodevelopmental disability, infection, feto-maternal haemorrhage (FMH), emergency delivery, umbilical cord complications, small for gestational age (SGA) and fetal growth restriction (FGR)<sup>5, 6</sup>. Decreased fetal movements for some women may be associated with placental dysfunction, which could lead to fetal growth restriction and/or stillbirth<sup>7</sup>. While evidence is still emerging in this area, some studies indicate that a reduction in stillbirth rates may be achieved by increasing maternal, clinician and community awareness about the importance of DFM.

This guideline has been developed on behalf of the Perinatal Society of Australia and New Zealand (PSANZ) in recognition of the variation in clinical practice and information provided to women regarding decreased fetal movements (DFM)<sup>8, 9</sup>.

#### 1.1 Aims and objectives

The aim of this guideline is to improve the quality of care for women with DFM, and has been developed with the following objectives:

- Provide an evidence-based approach to the management of women with DFM;
- Improve consistency in the management of women with DFM;
- Assist health care providers to counsel women with DFM;
- Reduce maternal anxiety about fetal activity and self-monitoring;
- Aid in the identification of women with higher-risk pregnancy; and
- Improve outcomes for women and their babies.

The management of women with specific pregnancy conditions identified during the course of care, in accordance with this guideline (e.g. fetal growth restriction, hypertension, diabetes), is beyond the scope of this guideline, as is the management of DFM in multiple pregnancy.

#### 1.2 Target audience

This guideline targets health care professionals providing antenatal care in Australia and New Zealand and encourages them to provide consistent, best-practice management for women with singleton pregnancies who report or who are concerned about DFM in the third trimester of pregnancy. Pregnant women and their partners may also find this guideline helpful.

An information brochure has also been prepared in multiple languages to inform and assist women and their health care providers to facilitate shared management decisions. This brochure is based on the key recommendations set out in this guideline. More information is available at https://sanda.psanz.com.au/resources/pregnancy/.

## 1.3 Methods

These clinical guidelines have utilized the National Health and Medical Research Council (NHMRC) guidelines for the development of clinical practice guidelines<sup>10, 11</sup>. Refer to Appendix B for methods of guideline development, Appendix C for an overview of the literature review, and Appendix D for evaluation criteria of evidence levels and grading of recommendations.

## 2. Summary of clinical practice recommendations and care pathway

## 2.1 Recommendations for fetal movement monitoring

Recommendations	Evidence level and references*	Recommendation grade*
Recommendation 1	·	
a. All pregnant women should be routinely provided with verbal and written information regarding normal fetal movements during the antenatal period. This information should include a description of the changing patterns of movement as the fetus develops, normal wake/sleep cycles and factors which may modify the mother's perception of fetal movements, such as maternal high BMI and placental position.	III-3 8, 12	с
b. Clinicians should emphasise the importance of maternal awareness of fetal movements at every routine antenatal visit in the third trimester.	$\langle \langle \rangle$	v
Recommendation 2		
Women with a concern about decreased fetal movements should be advised to contact their health care provider immediately.	III-3 3, 5, 12	C
Recommendation 3		
a. Maternal concern of DFM overrides any definition of DFM based on numbers of fetal movements.	<b>III-3</b> 3, 5, 12, 13	V
<ul> <li>b. The use of kick-charts is not currently recommended as part of routine antenatal care.</li> </ul>	 14	В

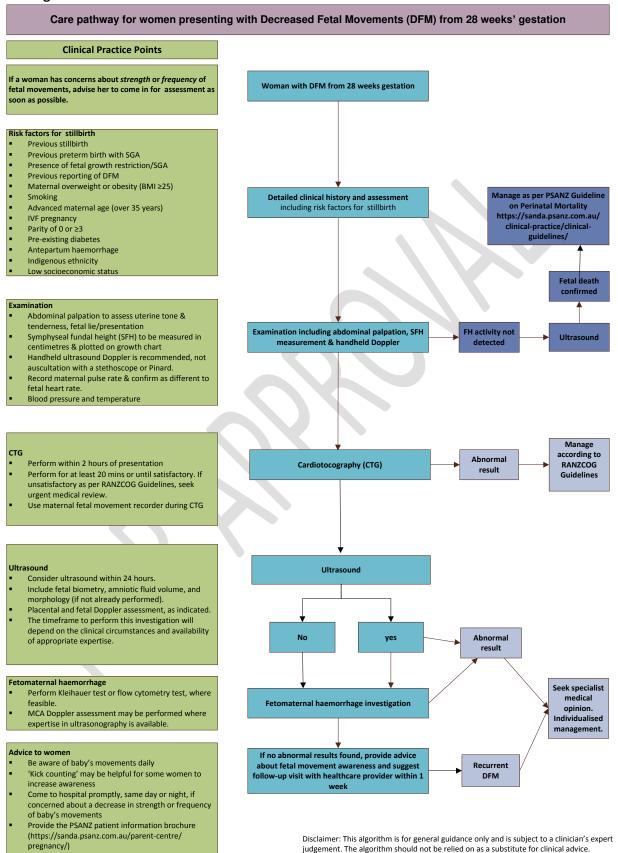
## 2.2 Recommendations for the investigation of decreased fetal movements

Recommendations	Evidence level and references	Recommendation grade*
Recommendation 4		
a. When a woman reports DFM, assessment of the woman and her fetus should be undertaken as soon as possible.	III-3 8, 12, 15, 16	В
<ul> <li>b. This assessment should preferably be undertaken within 2 hours.</li> </ul>	12	v
Recommendation 5		
a. Women who report DFM should be assessed for the presence of other risk factors associated with an increased risk of stillbirth (i.e. fetal growth restriction, hypertension, diabetes, advanced maternal age etc).	III-3 3	с
<ul> <li>Women with DFM in combination with other risk factors should be managed as a high-risk pregnancy.</li> </ul>		V

Recommendations	Evidence level and references	Recommendation grade*
Recommendation 6		
Clinical assessment of a woman with DFM should include review of fetal size as noted by symphysis-fundal height measurements.		v
Recommendation 7		
<ul> <li>a. A CTG should be performed to exclude immediate fetal compromise.</li> </ul>	<b>III-3</b> 12, 15, 17	с
<ul> <li>Further evaluation is recommended for women with any abnormal CTG pattern.</li> </ul>		v
Recommendation 8		
Ultrasound scan assessment for fetal biometry and amniotic fluid volume should be considered as part of the preliminary investigation of a woman reporting DFM.	<b>III-3</b> 3, 5, 12, 15, 17, 18	В
Recommendation 9		
Ultrasound scan assessment should include evaluation of fetal morphology if this has not already been performed.	<b>III-2</b> 12	С
Recommendation 10		
Where an ultrasound scan assessment for DFM is indicated, the timeframe to perform this investigation will be guided by the clinical circumstances and availability of appropriate expertise.		v
Recommendation 11		
Testing for feto-maternal haemorrhage should be considered in the preliminary investigation of women with DFM.	19	v
Recommendation 12		
In the presence of a normal clinical assessment (including a CTG and ultrasound), if maternal concern of DFM persists, specialist medical opinion should be sought and further management should be individualised.	20	V

\* Appendix D offers a description of evidence classification levels and grading of recommendations used in this guideline.

# 2.3 Care pathway for women presenting with decreased fetal movements from 28 weeks' gestation



## 3. Background

## 3.1 Maternal perception of fetal movement and adverse events

Maternal perception of fetal movement has long been used as an indicator of fetal wellbeing and vitality<sup>21</sup>. The quality and timing of fetal movements reflects neurobehavioural development and maturation of the fetus, and follows a general pattern with advancing gestation<sup>22, 23</sup>. Maternal perception of fetal movement tends to commence from 16 to 20 weeks gestation<sup>24</sup>, with these first movements described as a "flutter", "butterflies" or "bubbles"<sup>23</sup>. As pregnancy progresses, description of movements changes to reflect increasing strength, more complex limb and trunk movements and greater frequency<sup>23</sup>. In a qualitative study of 40 women within 2 weeks of delivery of uncomplicated pregnancies, 39 of the women described the fetal movements at this stage as "strong and powerful", and half described the fetal movements as "large"<sup>25, 26</sup>.

Studies conducted on the correlation between maternal perception of fetal movements and fetal movements seen on ultrasound scans demonstrated large variations, with correlation rates between maternal perception and actual fetal movement ranging from 16-90%<sup>27-30</sup>. This variation may be related to a number of factors, including fetal size, specific movement patterns of the baby<sup>24</sup>, gestational age, amniotic fluid volume, medications, fetal sleep state, obesity, anterior placentation, smoking and parity<sup>31-34</sup>. Whilst the type of fetal movements may change as pregnancy advances in the third trimester, evidence does not support that the number of fetal movements decreases as pregnancy advances or prior to the onset of labour<sup>12</sup>.

Other considerations that complicate the interpretation of fetal health based on the number of fetal movements are the limited understanding of patterns of fetal activity during "sleep" and active cycles, and the changes in the type of movements as pregnancy advances. Fetal movements are usually absent during fetal "sleep" cycles. Fetal "sleep" cycles occur regularly throughout the day and night and usually last 20 to 40 minutes<sup>32, 33</sup>, rarely exceeding 90 minutes in a healthy fetus<sup>16, 32, 33</sup>.

Maternal perception of a gradual diminishment of fetal activity can indicate pregnancies at increased risk of adverse outcomes. Studies have reported associations between DFM and low birth weight<sup>15, 35-42</sup>, oligohydramnios, preterm birth<sup>35, 43</sup>, threatened preterm labour<sup>35</sup>, congenital malformations and chromosomal abnormalities<sup>44</sup>, feto-maternal haemorrhage<sup>45</sup>, perinatal brain injuries and disturbed neurodevelopment<sup>46, 47</sup>, intrauterine infections<sup>48</sup>, low Apgar scores and acidaemia<sup>36, 38</sup>, hypoglycaemia<sup>35</sup>, umbilical cord complications and placental insufficiency<sup>7, 15, 41</sup>, emergency delivery, induction of labour and Caesarean section, stillbirths and neonatal deaths<sup>49-53</sup>.

Fetal growth restriction appears to be a major factor contributing to the increased risk of adverse outcomes in these pregnancies<sup>15, 50, 54-58</sup>. A case-control study from the UK reported that FGR was present in 11% of women with DFM compared with 0% in the control group<sup>18</sup>, suggesting that persistent DFM may alert clinicians to the presence of FGR. A case-control study of 18,000 births across 6 maternity hospitals in Queensland, Australia found that of pregnant women in the third trimester who reported decreased fetal movement, 16% of these had a baby with FGR<sup>27</sup>.

DFM is a common cause for maternal concern, with 40 percent of pregnant women overall expressing concern about DFM one or more times during pregnancy<sup>59</sup>, and 4-16% of women contacting their health care provider because of concern during the third trimester<sup>12, 60, 61</sup>. Even in pregnancies that are initially deemed as low risk, DFM is associated with the risk of adverse perinatal outcome, including fetal growth restriction (FGR), preterm birth and stillbirth<sup>15, 34, 35, 52, 56, 60, 62</sup>. A prospective, population-based study in Norway reported a fetal death rate in women who had a live fetus at time of presentation with DFM was 8.2 per 1000, compared to 2.9 per 1000 in the general population<sup>49</sup>.

#### 3.2 Perinatal mortality in Australia and New Zealand

Stillbirth affects 2,700 families per year across Australia and New Zealand, and one baby is stillborn for every 138 births across Australia<sup>63, 64</sup>. Fetal death rates have failed to show any significant reduction for more than a decade<sup>65</sup>, while the decline in perinatal and neonatal mortality rates in high income countries is largely attributed to advances in neonatal care<sup>66</sup>.

Both Australia and New Zealand report fetal deaths from 20 weeks (or weight of  $\geq$  400 grams if gestation unknown), and neonatal deaths up to 28 days after birth. In Australia, this is reported as a *perinatal mortality rate* and in New Zealand it is reported as a *perinatal related mortality rate*.

Based on data from the National Perinatal Statistics Unit in Australia, there were 309,489 births and 2,998 perinatal deaths in Australia in 2013, giving a perinatal mortality rate (PMR) of 9.7 per 1000 births<sup>1</sup>. Perinatal mortality comprised 2,191 stillbirths and 807 neonatal deaths, giving a stillbirth rate of 7.1 per 1000 births and a neonatal death rate of 3 per 1000 births. The PMR of babies born to Aboriginal or Torres Strait Islander mothers was higher than that of babies born to non-Indigenous mothers (18.0 versus 9.7 per 1000 births)<sup>1</sup>.

In New Zealand in 2013, there were 60,039 births and 589 perinatal deaths, giving a perinatal mortality rate of 10.0 per 1000 births. Fetal death rates in New Zealand in 2013 were 7.4 per 1000 births, and neonatal death rates were 2.6 per 1000 births<sup>67</sup>. The overall perinatal related death rate per 1000 births for Māori (11.49), Pacific (13.47) and Indian (13.68) mothers is statistically significantly higher than among Other Asian (7.66), Other (8.62) and New Zealand European (8.77) mothers<sup>67</sup>. The largest numbers of stillbirths occur in the 'unexplained death' category (30 percent in 2013), accounting for between 71 and 103 deaths per year in New Zealand from 2007 to 2013.

Across various studies, the wide variation in the reported contribution of *unexplained* stillbirths from 15%<sup>68</sup> to 71%<sup>69</sup> has been attributed to varying classification systems used, thoroughness of the investigation of deaths and the various definitions of stillbirth<sup>70</sup>. The large proportion of unexplained antepartum stillbirths<sup>71</sup> is a major barrier to further reduction of stillbirth and perinatal mortality rates. The majority of these unexplained deaths occur in late gestation in apparently healthy pregnancies. Many of these babies are, however, found to be growth-restricted after birth<sup>72, 73</sup>, indicating potential for the prevention of some of these deaths if antenatal detection and appropriate intervention had been achieved.

Other factors which are associated with an increased risk of stillbirth in a high income country setting include: maternal age older than 35 years; maternal overweight and obesity; maternal smoking; primiparity; previous stillbirth; and pre-existing maternal diabetes or hypertension<sup>74</sup> (See Appendix A).

#### 3.3 Clinical assessment of fetal movement concerns

Despite the apparent increased risk associated with maternal perception of DFM, a Norwegian study reported that one in four women could not recall having received any information about fetal movements during routine antenatal care<sup>8</sup>. Furthermore, existing guidelines on antenatal care<sup>75, 76</sup>, whilst acknowledging the importance of DFM, provide little guidance on what constitutes a clinically significant decrease in fetal movements, nor what is the best practice for management of DFM.

Wide variation in clinical practice regarding the management of DFM was shown in a recent survey of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)<sup>9</sup>, as well as in a similar survey for midwives in Australia and New Zealand<sup>77</sup>. These surveys revealed that, although monitoring fetal activity through asking women about fetal movements was considered an important part of routine antenatal care, the definition of alarm limits, the level of clinical assessment and the follow-up of women presenting with DFM varied widely.

These findings are consistent with other similar surveys from the UK<sup>78</sup> and Norway<sup>49</sup>. Variation in clinical practice was also confirmed in another Australian study<sup>27</sup>. In this clinical audit of practice

across six public hospitals in Queensland, 6-8% of pregnant women reported concern about DFM. Whilst the majority of these women were investigated by CTG, the use of ultrasound scan in the initial assessment of these women varied widely amongst clinicians.

Contributing factors relating to suboptimal care account for 30-50% of stillbirths and neonatal deaths<sup>69, 79, 80</sup>. A number of studies in Norway identified that an inappropriate response to maternal perception of DFM was a common factor contributing to stillbirths<sup>79-81</sup>. Prolonged DFM (>24 hours) as well as sudden loss of fetal movements was shown in 47%-64% of all stillbirths<sup>81, 82</sup>. Stillbirths which are preceded by a decrease in fetal activity form an important group on which to focus future research and prevention strategies towards reducing stillbirth rates.

## 3.4 Investigations of DFM prior to 28 weeks' gestation

There is currently insufficient evidence to inform the management of women who report DFM prior to 28 weeks gestation. Between 20 and 28 weeks gestation, conditions predisposing to DFM, e.g. fetal neuromuscular abnormalities, fetal anaemia, fetal hydrops and fetal growth restriction, may be unrecognised clinically. Fetal ultrasound to assess fetal biometry and amniotic fluid should be considered. CTG prior to 28 weeks can be difficult to interpret due to fetal immaturity and is not routinely recommended. Testing for FMH can also be undertaken by a Kleihauer test or flow cytometry. Where facilities and expertise are available, assessment for fetal anaemia can be undertaken by Doppler ultrasound of the fetal middle cerebral artery blood flow velocity.

Re	commendations	Evidence level and references*	Recommendation grade*
Re	commendation 1		
	All pregnant women should be routinely provided with verbal and written information regarding normal fetal movements during the antenatal period. This information should include a description of the changing patterns of movement as the fetus develops, normal wake/sleep cycles and factors which may modify the mother's perception of fetal movements, such as maternal high BMI and placental position. Clinicians should emphasise the importance of maternal awareness of fetal movements at every routine antenatal visit in the third trimester.	III-3 8, 12	С Х
Re	commendation 2	I	
sh	omen with a concern about decreased fetal movements ould be advised to contact their health care provider mediately.	III-3 3, 5, 12	C

## 4. Defining DFM and maternal perception of fetal activity

Attempts have been made to define normal patterns of fetal movements, but there is no universallyagreed definition of DFM. The most vigorously tested definition of DFM comes from Moore et al who recommend "less than 10 movements within 2 hours when the fetus is active"<sup>13</sup>. This is also the currently recommended alarm limit adopted by the American Academy of Paediatrics and the American College of Obstetricians and Gynaecologists<sup>76</sup>. In a study of women with normal, uncomplicated pregnancies, 99% of women were able to feel 10 movements within 60 minutes<sup>49</sup>. Another study of 705 women with low-risk pregnancy aimed to establish a reference value for perceived fetal movements in the second half of pregnancy. Using a modified "count to 10" method to perceive fetal movement, it found that 98% of women gave satisfactory recordings, with 90% of women perceiving 10 movements within 25 minutes at 22-36 weeks gestation, and within 35 minutes at 37-40 weeks<sup>83</sup>.

Antenatal education about fetal movement has been shown to reduce the time from maternal perception of DFM to health care-seeking behaviour<sup>12</sup>. A reduction in stillbirth rates has been associated with increased awareness of DFM in a recent quality improvement study in Norway<sup>8, 12</sup>. The study used a prospective "before-and-after" study design to evaluate the combined impact of providing women with information on DFM, and clinicians with clinical practice guidelines on DFM. This combined intervention was associated with a reduction in stillbirth rates, giving an adjusted odds ratio (OR) of 0.67 (95% CI: 0.49-0.94) in the overall study population and an adjusted OR of 0.51 (95% CI: 0.32-0.81) in women with DFM.

However, despite this link between maternal awareness of fetal movement, clinical education and stillbirth prevention, many women do not receive adequate information from their care providers<sup>84, 85</sup>. A recent prospective, descriptive study of 526 pregnant women at a large, metropolitan maternity facility found that more than one-third of women at 34 weeks gestation or later did not recall receiving information from their health care provider about fetal movement<sup>86</sup>. Pregnant women preferred to be given as much information as possible, and cited health professionals as a trustworthy source.

Women with DFM who ask for advice are often told that their baby may respond with movements within 20 minutes after having something sweet to eat, or after having an icy, cold drink. However, there is no evidence available to support this advice. Fetal movements have been shown not to be altered by intravenous glucose administration, or by a recent meal<sup>87-90</sup>.

## 5. The role of formal fetal movement counting

Recommendation 3	Evidence level and references*	Recommendation grade*
a. Maternal concern of DFM overrides any definition of DFM based on numbers of fetal movements.	III-3 3, 5, 12, 13	V
b. The use of kick-charts is not currently recommended as part of routine antenatal care.	l 14	В

A recent Cochrane review assessed the effect of formal fetal movement counting on perinatal death, major morbidity, maternal anxiety and satisfaction, pregnancy intervention and other adverse pregnancy outcomes, using five randomised trials, involving a total of 71,458 women<sup>14</sup>. Two of the included studies assessed a once-a-day fetal movement counting method with standard care as a control<sup>91, 92</sup>. Two studies compared two different fetal movement counting methods<sup>93, 94</sup>.

The largest study included in this review was the cluster-randomised trial by Grant *et al*<sup>91</sup> comparing formal fetal movement counting (using the Cardiff method) versus no instruction to monitor fetal movements. The control group in this study included selective use of counting based on clinician preference. The review authors concluded that there was not enough evidence to recommend or not recommend formal fetal movement counting for all women or for women at increased risk of adverse pregnancy outcomes, and recommended robust research in this area.

The large trial by Grant et al<sup>91</sup> contributing largely to the Cochrane Review findings, however, deserves closer review. This multicentre cluster randomised controlled trial was conducted to investigate the role of fetal movement counting in 68,654 women of at least 28 weeks gestation. When compared to women receiving standard antenatal care (including an informal query about fetal movements during antenatal clinic visits), this study found no significant reduction in the stillbirth rates in women undertaking daily fetal movement counting using a "kick-chart". There was, however, a trend towards more antenatal admissions in the fetal movement counting group than in the control group. Further, there was an increased use of other fetal testing methods, with more women having cardiotocography in the fetal movement counting group than in the group where movement counting was selective.

Although the trial was subject to some methodological bias due to the use of "within hospital" clusters, the overall stillbirth rate of the intervention and the control group combined fell during the study period from 4 per 1000 to 2.8 per 1000 births. It is postulated that this may be attributed to increased maternal awareness and vigilance toward DFM<sup>60, 91</sup>. There was some evidence of an indirect benefit of fetal movement counting as some of the deaths in the fetal movement counting group occurred as a result of suboptimal clinical management following presentation with a live fetus<sup>91</sup>.

A meta-analysis of three trials, including 1893 women with at-risk pregnancies provided with "kickcharts", illustrated a strong association between fetal growth restriction and DFM (OR 6.34, 95% CI 4.19-9.58)<sup>60</sup>. A recent literature review<sup>95</sup> of interventions to reduce stillbirth recommended routine fetal movement counting for high risk pregnancies only, especially where there is evidence of FGR. However, this recommendation is limited due to the studies upon which it is based. Limitations of two studies<sup>96, 97</sup> include the methodology used (non-randomised studies), the small numbers enrolled and changes in the population and in practice which may have occurred since these studies were undertaken; both of which were conducted in the late 1980s.

However, a more recent study in Norway demonstrated that a modified count-to-10 method of fetal movement counting may have contributed to a significant increase in antenatal detection of fetal growth restriction<sup>92</sup>. A multi-centre, randomized controlled trial of 1,076 pregnant women, assigned to either perform fetal movement counting from gestational week 28, or to receive standard antenatal care (controls), found that 87% of growth-restricted fetuses were identified antenatally in the intervention group, compared to 60% identified antenatally in the control group, with no increase in consultations or obstetric interventions. This trial also corroborates previous findings that fetal movement counting has not proven to increase maternal concern, anxiety, or risk of being examined in hospital<sup>8</sup>.

This finding dispels the concern about the introduction of formal fetal movement counting as a part of routine antenatal care, related to its potential to result in an increased number of antenatal hospital visits, interventions and costs without additional benefit. In line with the trend of increased interventions shown in the Grant trial<sup>91</sup>, another review of three case-controlled studies reported that the proportion of women requesting an antenatal visit based on complaints about DFM increased minimally, from 6.7 to 8.8%<sup>60</sup>. Monitoring of fetal movements in that population increased the number of antenatal visits in pregnancy by 2-3 visits per 100 pregnancies.

#### 6. Which investigations should be undertaken for DFM?

#### 6.1 Fetal heart rate monitoring

Recommendations	Evidence level and references	Recommendation grade
Recommendation 4		
a. When a woman reports DFM, assessment of the woman and her fetus should be undertaken as soon as possible.	<b>III-3</b> 8, 12, 15, 16	В
b. This assessment should preferably be undertaken within 2 hours.	12	v
Recommendation 5		
a. Women who report DFM should be assessed for the presence of other risk factors associated with an increased risk of stillbirth (i.e. fetal growth restriction, hypertension, diabetes, advanced maternal age, etc.).	III-3 3	C
b. Women with DFM in combination with other risk factors should be managed as a high-risk pregnancy.		v
Recommendation 6		
Clinical assessment of a woman with DFM should include review of fetal size as noted by symphysis-fundal height measurements.		v
Recommendation 7		
a. A CTG should be performed to exclude immediate fetal compromise.	<b>III-3</b> 12, 15, 17	с
b. Further evaluation is recommended for women with any abnormal CTG pattern.		v

The first step in the management of DFM is to ensure the fetus is alive and not in imminent danger of death. Once death is excluded, any coincidental associated pathology should also be excluded as a possible cause for DFM.

A handheld Doppler can immediately confirm the presence of a fetal heartbeat. In doubtful cases, cardiotocography (CTG) may be required to detect a fetal heart beat and to establish the fetal heart rate (FHR) pattern. In both situations, a fetal heartbeat needs to be differentiated from the maternal heartbeat. This is done, in most cases, by noting the difference between the FHR and the maternal pulse rate. If the presence of a fetal heart beat is not confirmed, or if still in doubt, then an immediate ultrasound scan assessment of fetal cardiac activity should be undertaken. Once fetal death is excluded, a CTG can assess for any signs of immediate fetal compromise.

Interpretation of the CTG fetal heart rate pattern is assisted by the RANZCOG classification of fetal heart rate patterns<sup>98</sup>. The presence of a normal FHR pattern (i.e. showing accelerations in fetal heart rate coinciding with fetal movements and the absence of decelerations) is a positive indicator of fetal wellbeing and suggests a normally functioning autonomic nervous system<sup>99</sup>. The fetal heart rate

(FHR) accelerates with 92-97% of all gross body movements felt by the mother<sup>100, 101</sup>. Other FHR patterns may or may not be associated with fetal compromise. For example, a "flat" FHR pattern showing reduced variability (<5bpm) may be present during the sleep cycle of a healthy fetus but is more likely to be associated with fetal compromise if it lasts for >90 minutes<sup>102-104</sup>.

Although CTG has become part of clinical practice, a Cochrane review<sup>105</sup> comprising 4 trials and 1588 women did not confirm or refute any benefits for routine antepartum CTG monitoring of "at risk" pregnancies. However, the authors acknowledge several limitations of this review, including the small numbers of women studied, methodological concerns, and also the fact that these trials were conducted in the early 1980s when these tests were first introduced into clinical practice. However, a 2011 retrospective, population-based cohort study of women presenting with maternal perception of DFM during the third trimester found that the CTG was a reliable screening indicator of fetal wellbeing, and that abnormal pregnancy outcomes were more common when the initial CTG was abnormal or persistently non-reassuring<sup>106</sup>.

Recent non-randomised studies have reported benefits of screening low- and at-risk pregnancies using CTG monitoring for the indication of DFM. For example, in a Norwegian study of 3014 women reporting DFM, a CTG was performed in 97.5% of cases and an abnormal result was detected in 3.2%<sup>107</sup>. In an observational study of women presenting with DFM who underwent CTG and an ultrasound scan, 21% had an abnormal result that required action and 4.4% required immediate delivery<sup>15</sup>. Another study showed that stillbirth rates (corrected for lethal congenital anomalies), after a normal and abnormal CTG, were 1.9 and 26 per 1000 births, respectively<sup>108</sup>. Although the evidence on the effectiveness of CTG monitoring in the identification of "at-risk" babies remains inconclusive, the use of CTG as a screening tool can be justified, as an abnormal FHR pattern may be associated with poor outcomes<sup>109</sup>.

Recommendations	Evidence level and references	Recommendation grade
Recommendation 8		
Ultrasound scan assessment for fetal biometry and amniotic fluid volume should be considered as part of the preliminary investigation of a woman reporting DFM.	<b>III-3</b> 3, 5, 12, 15, 17, 18	В
Recommendation 9		
Ultrasound scan assessment should include evaluation of fetal morphology if this has not already been performed.	III-2 12	С
Recommendation 10		
Where an ultrasound scan assessment for DFM is indicated, the timeframe to perform this investigation will be guided by the clinical circumstances and availability of appropriate expertise.		v

## 6.2 Ultrasound scans for DFM

Although evidence is currently lacking to recommend ultrasound assessment for all cases of women presenting with DFM, ultrasonography may be used for the detection of conditions that contribute to DFM. A prospective cohort study of 305 women reporting DFM found that of the 67 pregnancies

with poor perinatal outcomes, 4 were identified by CTG, 20 by ultrasound assessment of fetal growth, amniotic fluid volume and umbilical artery Doppler, and a further 24 were identified by low hPL level in the absence of any other abnormality<sup>42</sup>.

In a prospective cohort study of 3014 women with DFM<sup>107</sup>, detection of an abnormality using ultrasound (FGR, reduced amniotic fluid volume or fetal abnormality) was reported in 11.6%. The CTG in this study was abnormal in only 3.2% of cases and an abnormal umbilical artery Doppler was noted in 1.9%.

A recent Cochrane Review comprising 18 studies and over 10,000 women concluded that the use of Doppler ultrasound of the fetal umbilical artery in high-risk pregnancies reduced the risk of perinatal deaths and resulted in fewer obstetric interventions<sup>110</sup>. However, the review cautioned that current evidence was not of high quality and further studies were required.

In a Norwegian study<sup>12</sup>, an investigation protocol of CTG and ultrasound scan was used in the management of women reporting DFM. The study recommended that both investigations should be performed within 2 hours if women reported *no fetal movements* and within 12 hours if they reported *decreased fetal movements*. In this study, the ultrasound scan was conducted to assess fetal biometry, amniotic fluid volume, and fetal anatomy. The addition of umbilical artery Doppler studies in the investigation protocol did not show any further benefit.

Although the number of ultrasound scans more than doubled (OR 2.64, 95% CI 2.02-3.45), this appeared to be offset by a reduction in additional follow-up consultations and admissions for induction of labour<sup>12</sup>. The study reported no increase in the number of preterm births, infants requiring transfer to neonatal care, or infants with severe neonatal depression or fetal growth restriction. Importantly, a significant reduction in perinatal mortality was shown (OR 0.51, 95%CI 0.32-0.81).

Another study of 489 women reporting DFM<sup>17</sup> demonstrated that women reporting DFM, but no other pregnancy risk factor, did not require further follow-up once the CTG and the amniotic fluid volume were confirmed as normal. An ultrasound scan was performed to assess amniotic fluid. Women reporting DFM were 3.7 times more likely to have reduced amniotic fluid volume compared to women without DFM.

Recommendation 11	Evidence level and references	Recommendation grade
Testing for feto-maternal haemorrhage should be considered in the preliminary investigation of women with DFM.	19	v

## 6.3 Feto-maternal haemorrhage and DFM

Insignificant haemorrhage of fetal blood into the maternal circulation is common and usually unrecognised<sup>19</sup>; but when significant (i.e. acute large volume FMH, recurrent small/moderate FMH or chronic small volume loss over time) it can lead to fetal compromise and/or perinatal death. Massive feto-maternal haemorrhage (FMH) (varying from >50mls to >150mls) has been demonstrated in approximately 4% of stillbirths and in 0.04% of neonatal deaths<sup>111, 112</sup>. Moderate to severe FMH occurs in around 0.3% of all live births<sup>19</sup>. However, there is ambiguity over the definition of a clinically relevant volume of haemorrhage, as the rate of blood loss, chronicity of the bleed and gestational age of the fetus may also influence the risk of adverse perinatal outcome<sup>113</sup>.

Clinical risk factors do not reliably predict the likelihood of massive fetal to maternal haemorrhage <sup>112</sup> and DFM may be the only history suggesting this possibility<sup>19, 111, 114-116</sup>. A retrospective analysis of clinical data from a multihospital health care system in the U.S. found that decreased or absent fetal movement was reported by pregnant women in 54% of FMH cases and was the most common presenting sign<sup>117</sup>. An earlier review had found decreased or absent fetal movement reported as the presenting symptom of 27% of all FMH cases published in the medical literature to 1997<sup>45</sup>.

A sinusoidal FHR pattern is the classically described CTG sign indicating severe fetal anaemia<sup>111</sup>, however, this is not present in all cases. A recent study demonstrated that among a population associated with severe fetal anaemia, only 12.5% of cases demonstrated a sinusoidal pattern<sup>117</sup>. A normal CTG therefore cannot exclude significant fetal anaemia and the only "suspicious" CTG signs may be reduced or absent variability<sup>118</sup>.

It is suspected that a higher number of FMH cases are unreported, as in miscarriages or undiagnosed intrauterine fetal death. A recent study also found that FMH diagnosis is highly dependent on physician awareness of the condition. The incidence of diagnosed FMH in a large urban hospital, prior to an educational intervention for neonatologists, was 22 per 1000 anaemic neonates, compared to 182 per 1000 afterwards<sup>119</sup>.

Testing for FMH from a sample of the mother's blood is widely available by flow cytometry or the Kleihauer test. Where ultrasound facilities and appropriate expertise are available, assessment for fetal anaemia is undertaken by Doppler measurement of the fetal middle cerebral artery (MCA) velocity. If FMH is suspected or proven on flow cytometry or Kleihauer test, specialist medical opinion should be sought.

Recommendation 12	Evidence level and references	Recommendation grade
In the presence of a normal clinical assessment (including a CTG and ultrasound), if maternal concern of DFM persists, specialist medical opinion should be sought and further management should be individualised.	20	V

## 7. Ongoing maternal concern about DFM

Following exclusion of fetal compromise at an initial episode of DFM, maternal concern of DFM may persist or may result in subsequent consultations for DFM. To date, few studies guide the management of women who have ongoing concern about DFM. A small retrospective study, involving 203 women, showed that women with more than one presentation of DFM were at increased risk of poor pregnancy outcomes<sup>20</sup>. A larger retrospective cohort study in the UK, involving 1234 women reporting DFM beyond 36 weeks' gestation, found that 16.6% of these had more than one presentation for DFM. Of women with repeated DFM episodes, 44% birthed a SGA baby, and they were also more likely to have had high second-trimester uterine artery Doppler resistance indices<sup>120</sup>. This study concluded that women presenting with repeated DFM episodes should be considered at high risk for placental dysfunction irrespective of antenatal ultrasound or Doppler assessment results.

While research is limited, with the potential for increased risk, closer surveillance should be considered for women with ongoing concerns of DFM. Any management strategy for DFM needs to take into account the presence of other risk factors and the gestational age. A decision to deliver needs to be weighed against the risks to the mother and baby at that particular gestation<sup>65</sup>.

### 8. Discussion: Implementation and future research

Leading international authorities have recommended that women experiencing DFM should notify their health care providers as soon as reasonably possible. However, beyond this recommendation, there is limited guidance for clinicians on how to manage this presentation, resulting in much variation amongst clinicians with regards to appropriate clinical management. Cochrane reviews related to fetal movement counting and management of reported decreased fetal movements recommend further research in this area<sup>14, 121</sup>. This guideline was developed to promote clinical practice which is based on the best available international evidence, thereby improving information and counselling offered to women during the antenatal period and reducing variation in clinical practice in Australia and New Zealand.

The recommendations of this guideline cover two key areas: 1) information for pregnant women about what constitutes normal fetal movements and advice about reporting concerns of a reduction in fetal movements to a health care provider; and 2) information for clinicians with regards to the management and investigation of women reporting DFM. In the absence of robust research in this area, the thirteen key recommendations are largely based on consensus after careful consideration of the available evidence.

Improving the consistency and standard of information provided to pregnant women on fetal movements and on the significance of reporting decreased fetal movements is likely to reduce anxiety associated with DFM and, more importantly, may lead to timely intervention and a reduction in stillbirths. The findings of a Norwegian study<sup>12</sup> are encouraging in their demonstration of a reduction in the stillbirth rate by one-third following the implementation of a guideline and the provision of information about fetal movements to pregnant women.

The working party emphasises the importance of well-designed studies in order to develop and test appropriate screening tools which identify "at-risk" pregnancies on the basis of fetal movement. Further high-quality randomised controlled trials are needed to determine appropriate intervention strategies for women with DFM. Other outcomes which should be examined in future trials include maternal anxiety and morbidity, health care utilisation and costs. Trials should be adequately powered to examine the effect on perinatal mortality and major neonatal morbidity. Support for such research has been indicated by a recent survey of Obstetricians and Gynaecologists in Australia and New Zealand<sup>9</sup>.

Two large stepped-wedge, cluster-randomized trials currently underway will likely impact guidelines to support women experiencing a decrease in fetal movement. These trials in Scotland (AFFIRM study)<sup>122</sup> and Australia/New Zealand (My Baby's Movements)<sup>123</sup> hypothesise to reduce stillbirth rates through a package of interventions to a) increase pregnant women's awareness of fetal movement and prompt timely reporting of a decrease in fetal movement; and b) strengthen clinical management plans for women presenting to hospital with decreased fetal movements.

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Factor	aOR (95% CI)	PAR* (%)
Demographic and fertility		
Maternal age <sup>¥</sup>		
35-39 years	1.5 (1.2-1.7)	-
40-44 years	1.8 (1.4-2.3)	-
≥45 years	2.9 (1.9-4.4)	-
>35 years	1.7 (1.6-1.7)	12
Low education	1.7 (1.4-2.0)	4.9
Low socioeconomic status	1.2 (1.0-1.4)	9.0
No antenatal care	3.3 (3.1-3.6)	0.7
Assisted reproductive technology (ART), singleton pregnancy	2.7 (1.6-4.7)	3.1
Primiparity	1.4 (1.3-1.5)	15
Previous stillbirth	3.4 (2.6-4.4) <sup>π</sup>	1 <sup>π</sup>
Non-communicable disease and obesity		
BMI (kg/m²) €		
25-30	1.2 (1.1-1.4)	-
>30	1.6 (1.4-2.0)	
>25		8-18
Pre-existing diabetes	2.9 (2.1-4.1)	2-3
Pre-existing hypertension	2.6 (2.1-3.1)	5-10
Pre-eclampsia	1.6 (1.1-2.2)	3.1
Eclampsia	2.2 (1.5-3.2)	0.1
Fetal factors		
Small for gestational age (<10 centile)	3.9 (3.0-5.1)	23.3
Post-term pregnancy (≥42 weeks)	1.3 (1.1-1.7)	0.3
Rhesus disease	2.6 (2.0-3.2) <sup>±</sup>	0.6 <sup>±</sup>
Lifestyle factors		
Smoking	1.4 (1.3-1.5)	4-7
Illicit drug use	1.9 (1.2-3.0)	2.1

#### Appendix A. Risk factors for stillbirth in high-income country settings

**Notes**: High-income countries for aOR and PAR calculations include Australia, Canada, USA, UK and the Netherlands.  $\Sigma$  aOR=adjusted odds ratio (95% confidence interval). \*PAR=population attributable risk (the proportion of cases that would not occur *in a population* if the factor were eliminated). Calculated using a prevalence of 0.05%. \*Reference < 35 years of age. <sup>€</sup> Reference BMI < 25. Source: Unless otherwise stated: Flenady V, Koopmans L, Middleton P, et al. Major risk factors for stillbirth in high-income countries: a systematic review and meta-analysis. Lancet 2011; 377(9774): 1331-40. ±Lawn JE, Blencowe H, Waiswa P et al. Stillbirths: Stillbirths: rates, risk factors and potential for progress towards 2030. Lancet 2016; 387: 587–603. <sup>π</sup> Lamont K, Scott NW, Jones GT, Bhattacharya S. Risk of recurrent stillbirth: systematic review and meta-analysis. BMJ 2015; 350: h3080.

## Appendix B. Methods for guideline development

In 2010, the Australian and New Zealand arm of the international Fetal Movement Intervention and Assessment (FEMINA) collaboration developed this clinical practice guideline with a working party of clinicians and health service researchers. The process was coordinated by the Mater Mothers' Research Centre (MMRC), Mater Health Services, South Brisbane.

A literature review was undertaken based on questions identified by members of the working party (see Appendix CE). Relevant papers were identified and classified according to level of evidence (see Appendix D). Recommendations were prepared with strength of recommendation grading and were presented to the working party for consensus. Following comment and necessary amendments, a final consultation draft of the guideline was shared with stakeholders and a consumer advisory panel for endorsement and circulation (see Appendix G).

The working party adopted the procedures recommended by the NHMRC for developing this guideline. These procedures comprised:

- Review the scope of the guideline for clinical relevance, to identify questions, target groups and health outcomes relevant to the guideline;
- Assess existing guidelines;
- Conduct a systematic graded review of the literature, to identify and evaluate the evidence relating to the effectiveness and appropriateness of the recommended interventions;
- Subject the draft guideline to wider stakeholder consultation, including a consumer advisory panel;
- Refine the guideline and related materials to make them accessible to the target users.

The following steps have also been undertaken in collaboration with PSANZ:

- Disseminate and implement the guideline;
- Monitor, evaluate and maintain the guideline
- Identify gaps in current information for the ongoing refinement of the guideline.

In 2015-16, an update was undertaken to review the literature, evidence and recommendations. Additional clinical resources were highlighted, including 1) patient information brochures, 2) clinician eLearning opportunities, and 3) an updated care pathway to reflect updated evidence for investigation of decreased fetal movement and to add clinical practice points.

## Appendix C. Literature search

#### **Guiding research questions**

The following questions were raised by the working party and formed the basis of the search strategy:

- What is the definition of DFM?
- Within what time frame should a women report concerns of DFM?
- What is the role of formal fetal movement monitoring in reducing adverse pregnancy outcome?
- Which investigations should be conducted when a woman presents with DFM?
- What follow-up care should be provided to women who report DFM?

#### Search strategy

A literature search was undertaken of major guideline websites (see below) and electronic databases: Medline OVID, CINAHL, Cochrane Library databases and Maternity and Infant Care.

The search of electronic databases was limited to the English language, and searches were undertaken using the following terms:

#### Medline OVID

(("fetal Movement" OR "foetal movement").sh,ab,ti. OR ("fetal motility" or "foetal motility").sh,ab,ti. OR ("fetal activity" or "foetal activity").sh,ab,ti. OR ("fetal hypomotility" or "foetal hypomotility").sh,ab,ti. OR ("fetal hypoactivity" or "foetal hypoactivity").ab,ti. OR (fetal adj2 movement).ab,ti. OR (foetal adj2 movement).ab,ti.))

#### **Cochrane Library**

(fetal OR foetal) near/3 (movement\* OR activity OR motility OR hypomotility OR hypoactivity).ti,ab.

MeSH descriptor Fetal Movement explode all trees

#### <u>CINAHL</u>

"Fetal Movement" (CINAHL heading) OR ("fetal movement\*" OR "foetal movement\*" OR "fetal activity" OR "foetal activity" OR "fetal hypoactivity" OR "foetal hypomotility" OR "fetal motility" OR "foetal motility").ab,ti

#### Maternity and infant care

"fetal movement".de OR ("fetal movement\$" OR "foetal movement\$" OR "fetal activity" OR "foetal activity" OR "fetal hypoactivity" OR "foetal hypoactivity" OR "fetal hypomotility" OR "foetal hypomotility" OR "fetal motility" OR "foetal motility").ab,ti

Relevant references provided in bibliographies from various articles were searched manually, as were any references recommended in personal communications with experts in the field.

The relevant existing guidelines were searched at the National Guideline Clearinghouse (http://www.guideline.gov/).

The literature review was updated in 2015-2016 to include evidence published between May 2010 and July 2016. As such, 42 articles have been added as key citations in this update.

## Appendix D. Level of evidence & grading of recommendations

The relevant papers were identified and classified according to level of evidence. Evidence based recommendations were prepared and graded on the strength of the evidence. This classification of the evidence and grading of the recommendations was based, as stated below, on criteria advocated by the National Health and Medical Research Committee<sup>10</sup>.

Level	Description
Level I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
Level II	Evidence obtained from at least one properly designed randomised controlled trial.
Level III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
Level III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case control studies, or interrupted time series with a control group.
Level III-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
Level IV	Evidence obtained from case series, either post-test or pre-test and post-test.

## Levels of Evidence

#### Grading of recommendations<sup>124</sup>

Grade of recommendation	Description
A	Body of evidence can be trusted to guide practice
В	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	The body of evidence is weak and the recommendation(s) must be applied with caution.
V	Body of evidence is inadequate and recommendation is based on consensus for good clinical practice

## Body of Evidence Matrix <sup>124</sup>

Component	А	В	С	D
	Excellent	Good	Satisfactory	Poor
Evidence base <sup>1</sup>	several level I or Il studies with low risk of bias	one or two level II studies with low risk of bias or a SR/ multiple level III studies with low risk of bias	level III studies with low risk of bias, or level I or II studies with moderate risk of bias	level IV studies, or level I to III studies with high risk of bias
Consistency <sup>2</sup>	all studies consistent	most studies consistent and inconsistency may be explained	some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical impact	very large	substantial	moderate	slight or restricted
Generalisability	population/s studied in body of evidence are the same as the target population for the guideline	population/s studied in the body of evidence are similar to the target population for the guideline	population/s studied in body of evidence differ to target population for guideline but it is clinically sensible to apply this evidence to target population <sup>3</sup>	population/s studied in body of evidence differ to target population and hard to judge whether it is sensible to generalise to target population
Applicability	directly applicable to Australian healthcare context	applicable to Australian healthcare context with few caveats	probably applicable to Australian healthcare context with some caveats	not applicable to Australian healthcare context

<sup>1</sup> Level of evidence determined from the NHMRC evidence hierarchy;

<sup>2</sup> If there is only one study, rank this component as 'not applicable';

<sup>3</sup> For example, results in adults that are clinically sensible to apply to children OR psychosocial outcomes for one cancer that may be applicable to patients with another cancer.

# Appendix E. Guideline working party

These updated clinical guidelines have been compiled by the following clinicians, health researchers and representatives from collaborating organizations:

Name	Role and/or affiliation
Dr Glenn Gardener	Director, Maternal-Fetal Medicine, Mater Health Services; Research Fellow, Stillbirth Research Program, Mater Research Institute – The University of Queensland; Brisbane, Australia
Ms Lisa Daly	PhD Candidate, Stillbirth Research Program, Mater Research Institute – The University of Queensland; Brisbane, Australia
A/Prof Vicki Flenady	Leader, Stillbirth Research Program, Mater Research Institute – The University of Queensland; Secretary PSANZ/SANDA; Brisbane, Australia
Dr Yogesh Chadha	Senior Staff Specialist, Royal Brisbane and Women's Hospital; Brisbane, Australia
Prof David Ellwood	Professor of Obstetrics & Gynaecology, Griffith University School of Medicine, and Director of Maternal-Fetal Medicine, Gold Coast University Hospital
Dr J Frederik Frøen	Head of Research and Perinatal Epidemiologist, Norwegian Institute of Public Health; Oslo, Norway
Prof Jeremy Oats	Chair, Victorian Consultative Council on Obstetric and Paediatric Mortality and Morbidity; Professorial Fellow, Melbourne School of Population and Global Health, University of Melbourne; Chair PSANZ/ SANDA
Dr Wendy Burton	Chair, Antenatal/Postnatal Specific Interest Group for the RACGP; Chair, Mater Mothers' Hospital Alignment; Maternity Lead, Brisbane South Primary Health Network; General Practitioner, Brisbane, Australia
Ms Victoria Bowring	General Manager, Stillbirth Foundation Australia
Dr Adrienne Gordon	Senior Staff Specialist - Neonatology at Royal Prince Alfred Hospital and NHMRC Early Career Fellow, University of Sydney, Australia
Dr Alexander Heazell	Senior Clinical Lecturer in Obstetrics, Maternal and Fetal Health Research group, University of Manchester; Board Chair, International Stillbirth Alliance. Manchester, United Kingdom
Prof Susan McDonald	Professor of Midwifery, La Trobe University and Mercy Hospital for Women; Melbourne, Australia
A/Prof Kassam Mahomed	Senior Staff Specialist, Ipswich Hospital, and The University of Queensland, Australia
Dr Jane E Norman	Professor of Maternal-Fetal Health, University of Edinburgh, Scotland

The original guideline development also included the following working party members:

Name	Role and/or affiliation
Dr Scott Preston	General practitioner, medical educator; Brisbane, Australia
Dr Ruth Fretts	Senior staff specialist, Brigham and Women's Hospital and Harvard University Medical School; Boston, USA
Ms Julie MacPhail	Mater Medical Research Institute, Mater Health Services; Brisbane, Australia
Ms Liz Conway	Stillbirth and Neonatal Death Support (SANDS) Queensland; Brisbane, Australia.
Ms Laura Koopmans	Fetal movement study group coordinator, Mater Medical Research Institute, Mater Health Services; Brisbane Australia
Ms Tomasina Stacey	Senior lecturer, School of Midwifery, Auckland University of Technology; Auckland, New Zealand

## Appendix F. Conflict of Interest statement

The working party feels strongly that the identification and management of conflicts of interest are of central importance, to ensure that there is no influence by competing interests that could erode the integrity of recommendations. Under the *Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines* (the 2011 NHMRC Standard<sup>125</sup>), this working group has been required to identify, document and manage potential competing interests through adherence to the following NHMRC principles:

- transparency in the disclosure of any interests
- managing interests in a manner consistent with the NHMRC policy
- balance and diversity of expertise and perspectives
- balancing the benefit of having persons with expertise against the risks of their interests biasing a process
- the focus on technical knowledge should not override or dominate all other considerations
- the committee or working group is chaired by someone who has no conflicts of interest that could, or could be perceived to, erode the integrity of the recommendations
- ensuring the integrity of the guidelines.

Each member of the group has agreed to comply with the principles about disclosure of interests and also follows their own internal institutional procedures in relation to declaration, identification and management of interests.

### Appendix G. Stakeholder consultation

Once the working party had achieved consensus around recommendations, consultation was undertaken including the following organisations and individuals:

- 1. Perinatal Society of Australia and New Zealand (PSANZ), Policy Committee
- 2. PSANZ Consumer Advisory Panel
- 3. PSANZ SANDA membership
- 4. Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)
- 5. Australian College of Midwives (ACM)
- 6. Royal Australian College of General Practitioners (RACGP)
- 7. New Zealand College of Midwives
- 8. National SIDS Council of Australia Ltd (SIDS and Kids)
- 9. Stillbirth Foundation Australia
- 10. SANDS Australia
- 11. Still Aware