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Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes

Foong Ming Moy1, Amita Ray2, Brian S Buckley3

1 Julius Centre University of Malaya, Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia. 2 Department of Obstetrics and Gynaecology, Father Muller Medical College, Mangalore, India. 3 Department of General Practice, National University of Ireland, Galway, Ireland

Contact address: Foong Ming Moy, Julius Centre University of Malaya, Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, Kuala Lumpur, Wilayah Persekutuan, 50603, Malaysia. moyfm@um.edu.my. moyfm@ummc.edu.my.

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To compare the techniques of blood glucose monitoring and their impact on maternal and infant outcomes among pregnant women with pre-existing diabetes.
BACKGROUND

Description of the condition

Types of diabetes

There are three main types of diabetes mellitus: Type 1, Type 2 and gestational diabetes (GDM). Type 1 or insulin-dependent diabetes results from the body's failure to produce sufficient insulin and accounts for a minority of the total burden of diabetes in a population. Type 2 diabetes results from a failure of the body to utilise insulin, causing high blood sugar levels. In GDM, women who were not previously diabetic develop carbohydrate intolerance resulting in hyperglycaemia with first onset or detection occurring during pregnancy (HAPO 2002). GDM develops in one in 25 pregnancies worldwide and it can lead to the development of Type 2 diabetes post-pregnancy. Type 2 diabetes alone constitutes about 85% to 95% of all diabetes globally (IDF 2010). Type 2 diabetes is a serious and growing global health problem which has evolved in association with rapid cultural and social changes, ageing populations, increasing urbanisation, dietary changes, reduced physical activity and other unhealthy lifestyle and behavioural patterns (WHO 1994).

Prevalence of diabetes

Diabetes mellitus can be found in almost every population in the world and it is estimated that 6.6% of the global population in the age group of 20 to 79 years old had diabetes in 2010. By 2030, it is estimated that 7.8% of the adult population will have diabetes (IDF 2010). Diabetes mellitus complicates about 2% to 3% of all pregnancies. Approximately 90% of diabetes in pregnancy is accounted for by GDM. Pre-existing Type 1 and Type 2 diabetes account for the remaining 10% of diabetes during pregnancy (Moore 2010). This review considers only the management of pre-existing diabetes in pregnant women as there is an existing Cochrane review on gestational diabetes mellitus being prepared (Pelaez-Crisologo 2009).

Complications of diabetes in pregnancy: for mother and baby

Women with diabetes of any kind are at increased risk of morbidity and mortality during pregnancy. Pregnancy outcomes for women with pre-existing diabetes and their infants are poor compared to those for women who do not have diabetes (NICE 2008). The risks to both women and infants include fetal macrosomia, preterm birth, birth trauma (to mother and infant), induction of labour or caesarean section, miscarriage, congenital malformation, stillbirth, transient neonatal morbidity, neonatal death, obesity and/or diabetes developing later in the baby's life (Gonzalez-Gonzalez 2008; Kitzmiller 2008; NICE 2008). Women with diabetes have increased risk of an early miscarriage and are at increased risk of having a baby with malformations. Both of these risks are associated with less than optimal glycaemic control around the time of conception and in the first trimester. The risks appear to be approximately equivalent for women with Type 1 and Type 2 diabetes. The increased rate of spontaneous miscarriages and fetal malformation appear to be low when glycaemic control is moderately raised, and higher with increasingly poor glycaemic control (IDF 2010; Jensen 2009). Women with diabetes should be encouraged to obtain the best possible glycaemic control before conception (Kitzmiller 2010). Women with uncontrolled glycaemic levels should be discouraged from becoming pregnant until their control can be improved.

Macroismia, defined as infant birthweight greater than 4.5 kg, remains the commonest complication of pregnancy in women with diabetes (IDF 2010; Kitzmiller 2008; NICE 2008). Macrosomia occurs in 27% to 62% of infants of diabetic mothers compared with 10% of non-diabetic mothers (Gabbe 2003). Nationwide studies from the Netherlands, United Kingdom, and Denmark confirm that the risk of delivering a large for gestational age, or macrosomic infant in women with Type 1 diabetes ranges from 48.8% to 62.5% (Kitzmiller 2008). Recent data confirm that women with Type 2 diabetes have an equally high risk of delivering a macrosomic infant (ACOG 2005; ADA 2004; Roland 2005). For mothers with diabetes, macrosomia leads to an increased risk of perineal lacerations, complications in labour, and delivery by caesarean section (Slocum 2004). There are increased risks for the infants of intracranial haemorrhage, shoulder dystocia, neonatal hypoglycaemia, jaundice, and respiratory distress (Thomas 2006) as well as the longer term health risks of insulin resistance, obesity and Type 2 diabetes (McElduff 2005). Overt diabetes is an undisputed factor for preterm birth (Sibai 2000).

Glycemic control prior to pregnancy

Women with diabetes have an increased risk of an early miscarriage and are at increased risk of having a baby with malformations. Both of these risks are associated with less than optimal glycaemic control before or around the time of conception and in the first trimester. Maternal hyperglycaemia during the first few weeks of pregnancy is strongly associated with increased spontaneous abortions and major congenital malformations (Kitzmiller 1996; Ray 2009).
after 12 weeks' gestation, hyperglycaemia induces fetal hyperinsulinaemia, accelerated growth, and excess adiposity in animal models and diabetic women (Gabbe 2003). These risks appear to be approximately equivalent for women with Type 1 and Type 2 diabetes. The increased rate of spontaneous miscarriages appears to be low when the HbA1c is modestly raised, and higher with increasingly poor glycaemic control (Mills 1988; Rosen 1991). The same pattern is also found with respect to the rate of fetal malformations (Greene 1989, Suhonen 2000). Women who improve their glycaemic control before conception have a reduced rate of fetal malformation (Fuhrmann 1983). Therefore, women with diabetes should be encouraged to obtain the best possible glycaemic control before conception (IDF 2010; NICE 2008).

**Description of the intervention**

**Techniques of blood glucose monitoring**

Glucose readings supply trend information that helps to identify and prevent unwanted periods of hypo- and hyperglycaemia that can bring adverse effects to both mother and baby. Women with Type 1 and Type 2 diabetes are advised to self-monitor their blood glucose throughout pregnancy (IDF 2010). Techniques of blood glucose monitoring to be considered in this review will include self blood glucose monitoring, continuous glucose monitoring and clinic monitoring (for which timing and frequency of monitoring will also be considered).

Self Blood Glucose Monitoring (SMBG) - A glucose meter (glucometer), with or without memory, can be used to measure capillary glucose. Conventional intensified glucose monitoring is defined as three to four blood glucose measurements per day (ADA 2011). Postprandial glucose during pregnancy has been identified as the best predictor of neonatal macrosomia (de Veciana 1995; Moses 1999). Therefore, SMBG protocols for women with Type 1 or Type 2 diabetes during pregnancy stress the importance of measuring blood glucose after meals (Jovanovic 2009) while for non-pregnant diabetics, preprandial values are recommended (ADA 2011; NICE 2008).

Continuous Glucose Monitoring - The Continuous Glucose Monitors currently available measure glucose either with minimal invasiveness through continuous measurement of interstitial fluid (ISF) or with the non-invasive method of applying electromagnetic radiation through the skin to blood vessels in the body. The technologies for bringing a sensor into contact with ISF are minimal invasive technology and up to three months with the non-invasive technology. Continuous glucose monitoring can provide up to 288 measurements a day (Murphy 2007). Clinic Monitoring refers to routine glucose monitoring during ante-natal visits either using capillary or whole blood.

**Timing and frequency of glucose monitoring**

Postprandial glucose monitoring has been shown to be able to reduce the risk of neonatal hypoglycaemia, macrosomia and caesarean delivery (de Veciana 1995) as well as to reduce the incidence of pre-eclampsia and neonatal triceps skinfold thickness (Manderson 2003). Postprandial glucose values were most strongly associated with increased birth weight in the studies in which both pre- and post-meal glucose were measured (Mello 2000). According to NICE 2008, pregnant women with diabetes mellitus are advised to test fasting and one-hour postprandial blood glucose levels after every meal during pregnancy. Women taking insulin are encouraged to test their blood glucose before going to bed at night (NICE 2008). The American Diabetes Association also recommends SMBG before and after meals and occasionally at night time, to provide optimal results in pregnancy (Kitzmiller 2008). However, the frequency of glucose monitoring will greatly depend on the compliance of these women. Educational approaches incorporating additional glucose testing after meals to improve glycaemic control in late gestation have shown potential to reduce birth weight (Howorka 2001). The optimal frequency and timing of home glucose testing during pregnancy is, however, unknown with few women managing to carry out the 10 daily tests required to document most glucose estimations (Kerssen 2006).

**Glycaemic control during pregnancy among pre-existing diabetics**

Pregnancy profoundly affects the management of diabetes (Gabbe 2003; Jovanovic 2006). Pregnancy is associated with changes in insulin sensitivity which may lead to changes in plasma glucose levels. Hormonal changes during pregnancy cause a progressive increase in insulin resistance, necessitating intensive medical nutrition therapy and frequently adjusted insulin administration throughout the pregnancy. The control of hyperglycaemia in pregnant women with pre-existing diabetes is essential in order to avoid the above mentioned adverse maternal and infant outcomes (Kitzmiller 2008). Macrosomia and other neonatal complications are minimized with intensified glycaemic control (Kerssen 2007; Kitzmiller 2008; Suhonen 2000).

If it is safely achievable, women with diabetes should aim to keep fasting blood glucose between 3.5 and 5.9 mmol/litre and one-hour postprandial blood glucose below 7.8 mmol/litre during pregnancy (NICE 2008). HbA1c should be kept below 6.0% (ADA 2011). Excellent glycaemic control throughout the pregnancy is associated with the lowest risk for both maternal, fetal and neonatal complications (Kitzmiller 2008). On the other hand, the
targets of glycaemic control for non-pregnant women with Type 1 or Type 2 diabetes are less stringent, i.e.: fasting blood glucose to be 3.9 to 7.2 mmol/l and HbA1c < 7.0% (ADA 2011).

How the intervention might work

Maternal glucose levels in women with pre-existing diabetes directly influence those of the fetus. Fetal metabolic complications may give rise to macrosomia, congenital malformation, stillbirth and increased perinatal mortality (IDF 2010; Kapoor 2007; Kitzmiller 2008; NICE 2008). Blood glucose monitoring allows adjustment of insulin dosage in relation to meal size and type, physical activity, stress and time of the day for women with pre-existing diabetes during pregnancy (Davidson 2005). This will limit the maternal risk of hypoglycaemic episodes while avoiding prolonged periods of hyperglycaemia. However, the frequency and timing of glucose monitoring will also influence the maternal and fetal outcome.

Why it is important to do this review

Self-monitoring of blood glucose is recommended as a key component of diabetes therapy during pregnancy and included in the management plan (IDF 2010; Kitzmiller 2008; NICE 2008). However, unfavourable pregnancy outcomes are still more prevalent among women with pre-existing diabetes compared with those without diabetes (Modder 2008). Continuous glucose monitoring was introduced more than ten years ago but its utility is questioned. No existing systematic reviews consider the benefits of various techniques of blood glucose monitoring on maternal and infant outcomes among pregnant women with pre-existing diabetes. The effectiveness of the various monitoring techniques is unclear. This systematic review aims to generate information to guide pregnant women with pre-existing diabetes and their clinicians in their choice of monitoring techniques in order to optimise maternal and infant outcomes. All trials that evaluate any techniques of blood glucose monitoring among pregnant women with pre-existing diabetes will be considered.

O B J E C T I V E S

To compare the techniques of blood glucose monitoring and their impact on maternal and infant outcomes among pregnant women with pre-existing diabetes.

M E T H O D S

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials, quasi experimental trials and cluster-randomised trials. We will exclude trials using a cross-over design.

Types of participants

Pregnant women with pre-existing diabetes mellitus (Type 1 or Type 2). Women with gestational diabetes mellitus will be excluded.

Types of interventions

Techniques of blood glucose monitoring including self blood glucose monitoring, continuous glucose monitoring or clinic monitoring. We will also consider the timing and frequency of monitoring.

Types of outcome measures

Primary outcomes

Maternal

• Glycemic control (HbA1c, Fructosamine, fasting blood glucose, postprandial blood glucose)

Infant

• Birthweight
• Macrosomia greater than 4.5 kg

Secondary outcomes

Maternal

• Frequency of hypoglycaemia
• Antenatal hospital stay (% requiring admission, length of stay)
• Induction of labour
• Caesarean section rates
• Miscarriage
Infant

- Gestational age (at birth) or preterm birth < 37/34 weeks
- Frequency of neonatal hypoglycaemia
- Shoulder dystocia
- Major and minor anomalies
- Neonatal intensive care admissions
- Death of baby including stillbirth/neonatal death

Search methods for identification of studies

Electronic searches

We will contact the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group’s Trials Register. The Cochrane Pregnancy and Childbirth Group’s Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the ‘Specialized Register’ section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

Searching other resources

Where studies can be accessed only as abstracts, we will contact the authors for more details. We will include these trials in the review if sufficient information is provided to judge the quality and potential for bias of these trials.

We will also examine the reference lists of included studies and any relevant studies accessed.

We will not apply and language restrictions

Data collection and analysis

Selection of studies

Two review authors (Foong Ming Moy and Amita Ray) will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion or, if required, we will consult the third author (Brian Buckley).

Data extraction and management

We will design a data extraction form and pilot it to ensure its effectiveness in prompting the retrieval of appropriate data. For eligible studies, two review authors will extract the data using the agreed form. We will resolve discrepancies through discussion or, if required, we will consult the third author. We will enter data into Review Manager software (RevMan 2011) and check for accuracy. When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). We will resolve any disagreement by discussion or by involving the third author.

(1) Random sequence generation (checking for possible selection bias)

We will describe for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We will assess the methods as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); or
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We will describe for each included study the method used to conceal allocation to interventions prior to assignment and will assess whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We will assess the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.
(3.1) Blinding of participants and personnel (checking for possible performance bias)
We will describe for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We will consider that studies are at low risk of bias if they were blinded, or if we judge that the lack of blinding would be unlikely to affect results. We will assess blinding separately for different outcomes or classes of outcomes.
We will assess the methods as:
- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)
We will describe for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We will assess blinding separately for different outcomes or classes of outcomes.
We will assess methods used to blind outcome assessment as:
- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)
We will describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We will state whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake.
We will assess methods as:
- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; ‘as treated’ analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)
We will describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We will assess the methods as:
- low risk of bias (where it is clear that all of the study’s pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study’s pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)
We will describe for each included study any important concerns we have about other possible sources of bias.
We will assess whether each study was free of other problems that could put it at risk of bias:
- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias
We will make explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). With reference to (1) to (6) above, we will assess the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We will explore the impact of the level of bias through undertaking sensitivity analyses - see Sensitivity analysis.

Measures of treatment effect

Dichotomous data
For dichotomous data, we will present results as summary risk ratio with 95% confidence intervals.

Continuous data
For continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Trials with more than two intervention groups
If we identify trials with more than two techniques of glucose monitoring, they will be analysed as per Higgins 2011 - the relevant pair of intervention will be selected and the others will be excluded.

**Cluster-randomised trials**

We will include cluster-randomised trials in the analyses along with individually-randomised trials. We will adjust their sample sizes using the methods described in the Cochrane Handbook for Systematic Reviews of Interventions using an estimate of the intra-cluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

**Dealing with missing data**

For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we will carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we will attempt to include all participants randomised to each group in the analyses, and all participants will be analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

**Assessment of heterogeneity**

We will assess statistical heterogeneity in each meta-analysis using the T², I² and Chi² statistics. We will regard heterogeneity as substantial if the I² is greater than 30% and either T² is greater than zero, or there is a low P value (less than 0.10) in the Chi² test for heterogeneity.

**Assessment of reporting biases**

If there are 10 or more studies in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually, and use formal tests for funnel plot asymmetry. For continuous outcomes we will use the test proposed by Egger 1997, and for dichotomous outcomes we will use the test proposed by Harbord 2006. If asymmetry is detected in any of these tests or is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

**Data synthesis**

We will carry out statistical analysis using the Review Manager software (RevMan 2011). We will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and the trials’ populations and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials is considered clinically meaningful. The random-effects summary will be treated as the average range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials.

If we use random-effects analyses, we will present the results as the average treatment effect with its 95% confidence interval, and the estimates of T² and I².

**Subgroup analysis and investigation of heterogeneity**

If we identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.

We plan to carry out the following subgroup analyses.

1. Types of diabetes mellitus (Type 1 versus Type 2 diabetes)
2. Glycaemic control prior to pregnancy (pre-pregnancy HbA1c within target range versus pre-pregnancy HbA1c out of target range)

Subgroup analysis will be restricted to the review’s primary outcomes. For fixed-effect inverse variance meta-analyses, we will assess differences between subgroups by interaction tests. For random-effects and fixed-effect meta-analyses using methods other than inverse variance, we will assess differences between subgroups by inspection of the subgroups’ confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

**Sensitivity analysis**

We will carry out sensitivity analysis for aspects that might affect the results, for example, when there is risk of bias associated with the quality of some of the included trials. Studies with a high risk of bias such as quasi-randomised designs or those assessed as having specific sources of bias risk as per the Cochrane ‘Risk
of bias' instrument will be excluded from the analyses to assess their effect, if any, on the overall results. We will also carry out a sensitivity analysis to explore the fixed-effect or random-effects analyses for outcomes with statistical heterogeneity.

ACKNOWLEDGEMENTS

As part of the pre-publication editorial process, this protocol has been commented on by three peers (an editor and two referees who are external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

REFERENCES

Additional references

ACOG 2005

ADA 2004

ADA 2011

Choleau 2002

Davidson 2005

de Veciana 1995

Egger 1997

Fetita 2006

Fuhrmann 1983

Gabbe 2003

Gonzalez-Gonzalez 2008

Greene 1989

HAPO 2002

Harbord 2006
Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes (Protocol)

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Pelaez-Crisologo 2009

Ray 2001

RevMan 2011

Roland 2005

Rosenn 1991

Sibai 2000

Slocum 2004

Suhonen 2000

Thomas 2006

WHO 1994

* Indicates the major publication for the study

**HISTORY**

**CONTRIBUTIONS OF AUTHORS**
Foong Ming Moy (FMM), the contact person, is the guarantor of the review. This protocol was drafted by FMM. All three authors provided co-ordination, methodological prospective, clinical prospective and policy prospective of the review. All three authors contributed to developing and writing the protocol.

**DECLARATIONS OF INTEREST**
None known.
sources of support

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External sources

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