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Helping pregnant women make better decisions: a systematic review of the benefits of patient decision aids in obstetrics

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ABSTRACT

Objectives: Patient decision aids can be used to support pregnant women engaging in shared decisions, but little is known about their effects in obstetrics. The authors aimed to evaluate the effects of patient decision aids designed for pregnant women on clinical and psychosocial outcomes.

Design: Systematic review. Data on all outcomes were extracted and summarised. All studies were critically appraised for potential sources of bias and, when possible to obtain, the reported decision aids were evaluated. Meta-analysis was not possible due to the heterogeneity of outcomes in primary studies and the small number of studies.

Data sources: Electronic searches were performed using Medline, Embase, the Cochrane Library and Medion databases from inception until December 2010. Reference lists of all included articles were also examined and key experts contacted.

Eligibility criteria for selecting studies: Eligibility criteria included randomised controlled trials, which reported on patient decision aids for women facing any treatment decision in pregnancy published in English. Studies evaluating health education material that did not address women's values and preferences were excluded.

Results: Patient decision aids have been developed for decisions about prenatal testing, vaginal birth after Caesarean section, external cephalic version and labour analgesia. Use of decision aids is associated with a number of positive effects including reduced anxiety, lower decisional conflict, improved knowledge, improved satisfaction and increased perception of having made an informed choice.

Conclusions: Patient decision aids have the potential to improve obstetric care. However, currently the evidence base is limited by the small number of studies, the quality of the studies and because they involved heterogeneous decision aids, patient groups and outcomes.

ARTICLE SUMMARY

Article focus

- Engaging pregnant women in shared decision making has become a priority for maternity care but remains a challenge for many health professionals.
- Patient decision aids can be used to facilitate patient involvement in decision making and improve clinical practice. They are interventions, which provide information about options and outcomes as well as clarifying the user's values. However, little is known about their effects in obstetrics.
- We aimed to evaluate the effects of decision aids designed for pregnant women on clinical and psychosocial outcomes.

Key messages

- Eleven randomised controlled trials were identified investigating the effects of patient decision aids on a range of outcomes.
- Use of patient decision aids was associated with a number of positive effects including: reduced anxiety (three studies), improved knowledge (seven studies), improved satisfaction (two studies), increased perception of having made an informed choice (one study) and lower decisional conflict (five studies).
- Further research is needed to expand this limited evidence base and to develop better outcomes to assess the quality of decision making.

INTRODUCTION

Shared decision making, the process of engaging patients in making decisions about their care in collaboration with their clinicians, is widely advocated as the ideal model of clinical decision making in many situations. By enabling evidenced-based medicine to be applied in a patient-centred way, it can improve the quality of consultations and enable clinicians to be more accountable to their patients.[1 2] The aim is to facilitate high-quality decision making, which has been defined as 'the extent to which the implemented decision reflects the considered preferences of a well-informed patient', rather than influencing clinical outcomes.[3] Nevertheless, it has been associated with

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first systematic review of patient decision aids in obstetrics and provides a comprehensive and critical review of the available evidence.
- A number of potential benefits supporting the use of decision aids in clinical practice were identified.
- The limited evidence base was demonstrated aiming to stimulate the development of further decision aids and research into evaluation and implementation of them.
- There is need to be cautious in interpreting the potential benefit of decision aids in routine practice in pregnancy due to the limitations of the small number of randomised controlled trials and the inconsistencies in their results.
- Meta-analysis could not be performed due to the small sample size and heterogeneity of primary outcomes chosen.

improved health outcomes, satisfaction and improvements in a variety of other psychosocial health status indicators.[4] Thus, shared decision making has become a key component of health policy in the UK[5 6] and internationally.[7]

Research has shown that young female patients are more likely to prefer involvement in decision making than other patient groups.[8] Therefore, the enthusiasm of pregnant women for shared decision making, together with sociopolitical change, has perhaps unsurprisingly led to a wide acceptance that obstetricians should enable pregnant women to share decisions about their care and treatment with them.[9] However, involving patients in decision making remains a challenge for many health professionals.[2 6]

Patient decision aids can be used to facilitate involvement in decision making and improve clinical practice.[10] They are 'interventions designed to help people make specific deliberative choices by providing information about the options and outcomes that are relevant to a patient's health status and by clarifying personal values. They are intended as adjuncts to clinical practice.[11] Decision aids differ from health education materials in that they aim to prepare people for decision making with a detailed, specific and individualised focus, rather than simply promoting understanding.[12]

A Cochrane review showed that the benefits of patient decision aids used in a variety of clinical settings included the following: improved patient knowledge, more realistic expectations of the benefits and harms of options, reduced decisional conflict (a measure of uncertainty about making a particular choice), improved involvement in decision making and reduced uptake of invasive surgical options.[12]

In response to increasing interest and development of decision aids, the International Patient Decision Aids Standards (IPDAS) Collaboration was established to produce a quality framework, which could be used to assess the quality of decision aids.[11] The IPDAS checklist was published in 2006 and uses quality domains with a total of 41 criteria.[13] Currently, the International Patient Decision Aids Standards instrument (IPDASi) is being validated which aims to quantitatively assess the quality of decision aids (http://ipdasi.org) as the checklist is limited by providing only limited quantitative assessment and because not all criteria are relevant to all decision aids.[14] The IPDASi will provide a summative assessment (a numerical figure which can be used to compare patient decision aids (PDAs)) and a formative assessment of content, which can be used to improve an individual patient decision aid.

The aim of this systematic review was to identify and critically appraise all randomised controlled trials evaluating patient decision aids in obstetrics and to evaluate their effects on decision-making processes and a range of clinical and psychosocial outcomes. Clinical outcomes were included as, although the aim of decision aids is to improve decision quality rather than influencing patients' decisions or health, it was valuable to ascertain whether their use had any effect on the choices women make and relevant health outcomes such as anxiety.

METHODS

Electronic searches were performed targeting citations on decision support techniques for pregnant women (key words decision support techniques, shared decision making, pregnancy, parturition, prenatal diagnosis see online appendix 1). We searched Medline, Embase, the Cochrane Library and Medion databases from inception until May 2011. The reference lists of all included primary and review articles were examined to identify cited articles not captured by electronic searches. As this is an emerging field of research, we attempted to address publication bias by contacting experts in the field of decision support techniques to enquire if there were any unreported trials that we had not identified.

Study selection is summarised in figure 1.[15] The first stage involved assessing the titles and abstracts of the results of electronic searches. In the next stage, full papers of potentially relevant citations were obtained and reviewed. Eligibility criteria included randomised controlled trials that reported on patient decision aids for women facing any treatment decision in pregnancy published in English. Studies evaluating health education material that did not address women's values and preferences were excluded. As the small number of studies identified were heterogeneous in design, all reported outcomes were included. Data on all outcomes were extracted and summarised by the first author and checked by the other authors. All available summary measures were included (see table 1 and results below).

All studies were critically appraised for potential sources of bias by all three authors particularly considering issues included in the Jadad scale (randomisation, blinding, description of withdrawals),[27] allocation concealment and follow-up and analysis (table 2). When possible to obtain, the reported patient decision aids were evaluated using the IPDAS checklist. As the IPDASi

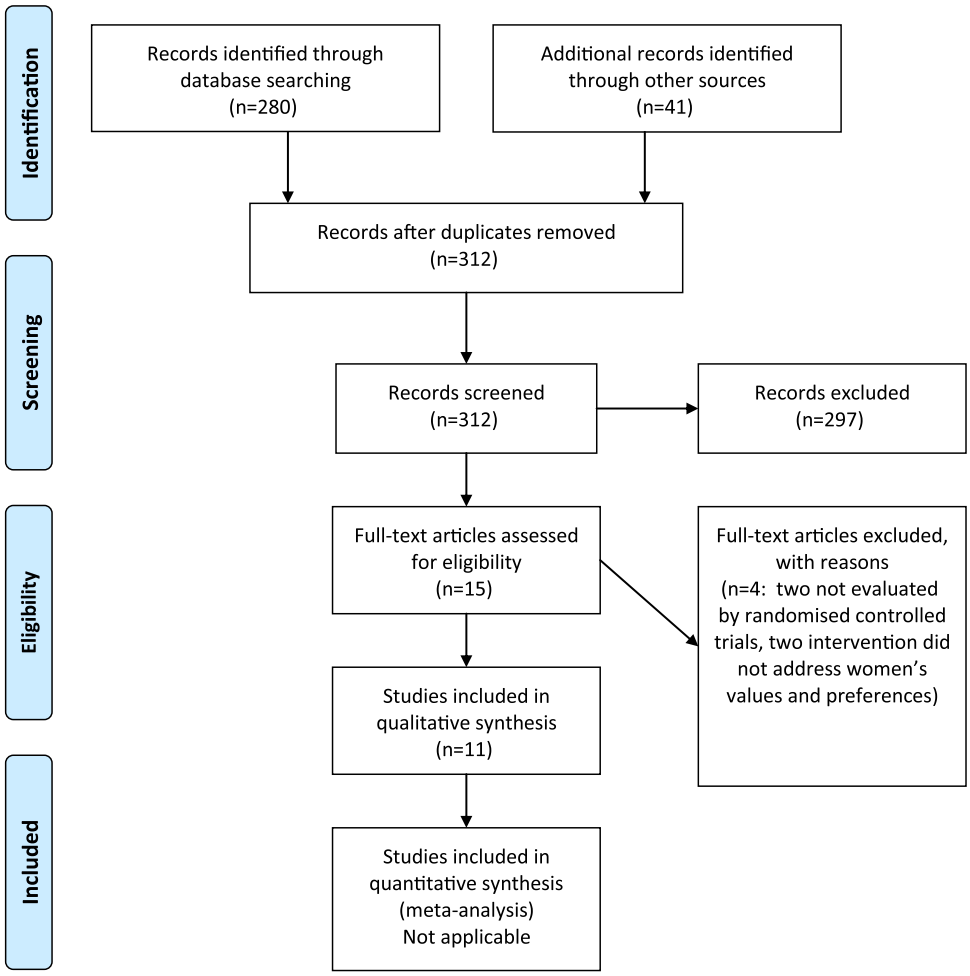

Figure 1 PRISMA 2009 flow diagram, from Moher *et al*.[15] Visit http://www.prisma-statement.org for more information.

was not available for use, any IPDASi scores available in other publications for the included studies were identified.

RESULTS

Eleven studies were identified (table 1) and will be discussed in relation to the clinical decision they addressed.

Prenatal screening

Communication about screening for Down's syndrome presents a challenge for health professionals as they guide women through the process of understanding the risk and consequence of a fetal abnormality, explaining the difference between screening and diagnosis, advising about screening results and describing the benefits and risks of subsequent diagnostic tests. Understanding about how best to present this information is limited. A patient decision aid could provide individualised unbiased information with the aim of helping women make more informed choices and reducing anxiety.

Seven studies evaluating a variety of decision aids (including a touch screen information system, video, booklet and modified consultations) were identified (table 1). An evaluation of potential sources of bias is summarised in table 2. A recent review which evaluated decision support technologies for amniocentesis gave high IPDASi scores for two of these studies (70.8% for decision analysis consultation of Bekker *et al*[16] and 70.5% for decision aid of Hunter *et al*[19]), but they did not evaluate the other decision aids as they were unable to assess the booklet produced by Nagle *et al*[28] and did not include the other four studies in their review.[29]

The results of these studies suggest that using decision aids for prenatal screening for Down's syndrome can reduce anxiety, improve knowledge, improve satisfaction and increase women's perception of having made an informed choice (table 1). However, these effects were not consistent across studies.

The decision aids also had different effects on the decisions women make. Graham *et al*[17] found that the uptake of detailed anomaly scan was higher in the decision aid group, and Thornton *et al*[26] found that there was increased uptake of serum screening (and decreased uptake of cystic fibrosis testing). The other studies showed no effect on the decision made.

Vaginal birth after caesarean section

Concerns about the rising caesarean section rate are widespread. With increasing rates of primary caesarean section, an increasing number of women are pregnant with a history of prior caesarean delivery.[30] Pregnant

Table 1 Summary of studies included in the review

Author	Participants	Decision aid	Control	Outcomes	Results
Bekker *et al*[16]	117 women receiving a screen- positive maternal serum test for Down's syndrome (risk ≥250) at Leeds General Infirmary over 15 months. NHS patients, literate in English.	Decision analysis consultation	Routine consultation	Decision whether or not to have diagnostic test (amniocentesis or CVS)	No difference
				Subjective expected utilities	No difference in expected utility values (other than terminating a baby with Down's syndrome which women in the intervention arm valued more highly) Women in the intervention arm evaluated information in relation to their own values more than those in the control arm.
				Knowledge	No difference
				Informed decision making	Decision analysis women evaluated more information
				Risk perception	More decision analysis women perceived their screening test to be medium rather than high risk
				Decisional conflict	Decreased over time with intervention
				Anxiety	No difference
				Perceived usefulness of consultation	No difference
				Perceived directiveness of consultation	No difference
				Length of consultation	Decision analysis longer
Graham *et al*[17]	1050 women booking antenatal care at Aberdeen Maternity Hospital between April 1997 and January 1998	Touch screen information system	Information leaflet	Uptake of prenatal tests (booking ultrasound scan, serum screening, detailed anomaly scan, amniocentesis, chorionic villus sampling)	More women in the intervention group underwent detailed anomaly scanning. No difference in other tests
				Understanding of prenatal tests	No difference
				Satisfaction with information	No difference
				Anxiety	Reduced in the intervention group
				Use of information leaflet	No difference

Continued

Table 1 Continued

Author	Participants	Decision aid	Control	Outcomes	Results
Hewison *et al*[18]	2000 consecutive women referred for antenatal care at Hull Maternity Hospital	Video	Routine care	Uptake of screening (second trimester serum screening)	No difference
				Knowledge	Improved knowledge in the intervention group
				Anxiety	No difference
				Worries abnormalities	No difference
				Worries about screening tests	No difference
				General worries about pregnancy/childbirth	No difference
Hunter *et al*[19]	352 pregnant women aged ≥35 years	Case examples and worksheet	Individual or group genetic counselling	Knowledge	Increased knowledge in all groups: highest knowledge levels with group counselling
				Anxiety	No difference
				Decisional conflict	Decreased with PDA
				Satisfaction	Less satisfied with PDA than individual counselling
Leung *et al*[20]	201 low-risk Chinese women attending prenatal clinic in Hong Kong before 20 weeks of gestation Chinese speaking	Interactive multimedia decision aid	Information leaflet and 30 min video	Uptake of screening tests (integrated screening test <15/40, serum screening >15/40, amniocentesis/ CVS for women >35)	No difference
				Initial decision about screening after intervention	No difference
				Understanding and satisfaction with the information they had received	Women who used the decision aid had fewer additional questions
					No difference in satisfaction

Continued

Table 1 Continued

Author	Participants	Decision aid	Control	Outcomes	Results
Montgomery *et al*[21]	742 pregnant women with one previous lower segment caesarean section and delivery expected >37 weeks	Two computer-based interventions. 1) Information programme: descriptions and probabilities of clinical outcomes 2) Decision analysis mode of delivery was recommended based on utility assessments combined with probabilities of clinical outcomes within a decision tree	Usual care	Decisional conflict Mode of delivery Anxiety Knowledge Satisfaction with the decision	Decreased with both decision aids No difference Decreased with both decision aids Increased with both decision aids Satisfaction higher in decision analysis group than with usual care. No other differences
Nagle *et al*[22]	Community (Australia). 55 clusters, 467 low-risk women aged >18 years, ≤12/40, English speaking, able to give informed consent	Booklet—24 pages designed using Ottawa Decision Framework	Standard pamphlet	Informed choice including knowledge subscale Intention to have screening Decisional conflict Anxiety Depression Attitudes to pregnancy/fetus Acceptability of resource Acceptability of screening	OR making an informed choice with decision aid 2.08 (95% CI 1.14 to 3.81). More women had 'good' levels of knowledge on the knowledge scale No difference No difference No difference No difference No difference No difference No difference

Continued

Table 1 Continued

Author	Participants	Decision aid	Control	Outcomes	Results
Nassar *et al*[23]	200 women with a singleton breech pregnancy at term, clinically eligible for ECV, four tertiary obstetric units Australia	24-page booklet with 30 min audio CD and worksheet	Standard care	Knowledge Decisional conflict Anxiety Satisfaction with decision making Participation in decision making Attitudes of the importance of undergoing an ECV Intended choice ECV uptake Maternal and perinatal outcomes (presentation at birth, mode of delivery, Apgar scores, infant sex, gestational age, infant birth weight, maternal length of stay)	Increased with PDA Decreased with PDA No difference No difference in satisfaction with decision making but more women in the PDA group were satisfied with the amount of information they received No difference More women in the PDA group had a positive attitude towards ECV PDA group more likely to favour ECV No difference No differences

Continued

Table 1 Continued

Author	Participants	Decision aid	Control	Outcomes	Results
Raynes-Greenow *et al*[24]	Primiparous women in the third trimester planning a vaginal birth of a singleton infant in two obstetric hospitals, Sydney Australia	55-page booklet with worksheet and 40 min audio CD	Four-page pamphlet developed and endorsed by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Australian Society of Anaesthetists	Knowledge	Increased knowledge with PDA use
				Decisional conflict	No difference
				Anxiety	No difference
				Satisfaction with decision making	No difference Women using PDA were more likely to report that they had sufficient information to make decisions
				Intended choice of analgesia	No difference
				Analgesia use	No difference
				Participation in decision making	No difference in preferred role. Women using PDA more likely to report seriously considering their care providers opinion
				Adherence and acceptability	No difference
				Impact on service outcomes (analgesia, maternal and perinatal outcomes including mode of delivery)	No difference
Shorten *et al*[25]	227 Women with one previous caesarean section and medically eligible for a trial of vaginal birth	Decision-aid booklet	Usual care	Knowledge	Intervention increased knowledge
				Decisional conflict	Intervention decreased decisional conflict
				Preferred mode of delivery 36 weeks	No difference
				Satisfaction 6–8 weeks postnatally	No difference
				Mode of delivery	No difference

Continued

Table 1 Continued

Author	Participants	Decision aid	Control	Outcomes	Results
Thornton *et al*[26]	3368 Women attending antenatal clinics in Bradford Infirmary and Leeds General Infirmary between <15/40	Additional individual information at an extra hospital visit supported by extra written information or extra class supported by extra information	Information sheet and routine consultation	Uptake of prenatal tests (detailed anomaly scan, serum screening, amniocentesis)	No difference in uptake of ultrasound or amniocentesis. Increased uptake of Down's syndrome serum screening with individualised information (no difference with group with extra information) Decreased uptake of cystic fibrosis testing with both interventions
				Knowledge	Women felt that they understood information better in both intervention groups
				Anxiety	Anxiety reduced with individual information at 20/40, 30/40 and 6 weeks post partum
				Anxiety measure specific to pregnancy and fetal abnormality	Women offered individual information were less worried about the baby at 20/40 than those offered classes

CVS, chorionic villus sampling; ECV, external cephalic version; PDA, patient decision aid.

women with a previous section may be offered either a planned trial of vaginal birth (VBAC) or elective repeat caesarean section (ERCS).[30] The Royal College of Obstetricians and Gynaecologists[30] recommends that 'women with a prior history of one uncomplicated lower segment transverse caesarean section, in an otherwise uncomplicated pregnancy at term, with no contraindication to vaginal birth, should be able to discuss the option of planned VBAC and the alternative of a ERCS'.

This discussion requires women (and clinicians) to consider complicated information about risks and benefits in order to make a decision. It is known that women's decision making about mode of delivery may be influenced by cultural norms, family situation and the way risk information is presented to them by clinicians.[31 32]

Decision aids about mode of delivery may benefit women by presenting risk information in a clear and unbiased way and by eliciting women's values, helping them to make a decision consistent with their values.[21 31]

Two decision aids have been trialed in this context, both of which improved knowledge and decreased decisional conflict (table 1).[21 25] Neither decision aid had any effect on mode of delivery. Potential sources of bias are summarised in table 2. A study of the development and validation of the IPDASi[25] gave the PDA developed by Shorten *et al* a score of 64.0%.[14]

External cephalic version

External cephalic version (ECV) is a cost-effective intervention associated with a reduction in non-cephalic birth and caesarean section; it is not associated with increased perinatal morbidity or mortality.[33] Reported success rates of ECV vary from 18% to 76%.[33–37] The Royal College of Obstetricians and Gynaecologists recommends that ECV should be offered in all hospitals where there is adequate expertise.[38]

Despite the evidence supporting ECV, reported uptake is low (24%–54%)[37 39] and women's preferences for and against ECV are not clear. Women may not be accurately or adequately counselled about the risks and benefits of ECV compared with elective caesarean section; one cross-sectional survey showed that approximately one-quarter of eligible women were counselled against ECV and gave their doctor's advice as the reason for declining ECV.[40] None of the respondents commented on having discussed the risks and benefits of elective caesarean section.[40] A decision aid for women with a breech presentation at term would facilitate counselling regarding management options, aiming to present the available evidence in a way that women can understand and use to make their decision.

Nassar *et al*[23] conducted a randomised controlled trial of a decision aid which consisted of a 24-page booklet, 30 min audio CD and worksheet in 200 women with a singleton pregnancy diagnosed antenatally with a breech presentation from 34 weeks, clinically eligible for ECV and able to read and write English (table 1). Women in the intervention group had higher knowledge scores, lower decisional conflict scores, were more satisfied with the amount of information they had been given and were more likely to state that they intended to have an ECV.[23] There was no difference in the proportion of women actually choosing ECV or in anxiety levels.[23] Potential sources of bias are considered in table 2.

Labour analgesia

Childbirth can be an extremely painful experience, and it has been established that unmet expectations about pain relief can impact on women's satisfaction with their birth experience.[41] However, women have a range of options to consider for pain relief. These range from non-pharmacological methods such as continuous support in labour through to invasive pharmacological methods such as epidural analgesia. These alternatives have very different risks and benefits, which women need to evaluate, and their choice will depend on their own values and expectations. Unfortunately, there appears to be a mismatch between women's expectation and experiences of pain in labour with women underestimating the pain they go on to experience.[41]

Previous research identified that ways to better prepare women for the pain of labour, to give them more information to support their choices about pain relief and to help them to make a decision would be useful.[24 41] Raynes-Greenow *et al*[24] designed a decision aid for labour analgesia for women in their first pregnancy planning vaginal birth (table 1). It consisted of a 55-page booklet, worksheet and 40 min audio CD, which was compared with a pamphlet. Women using the decision aid had higher knowledge scores, were more likely to consider they had enough information to make decisions about labour analgesia and were more likely to report considering health professionals' opinions rather than making the decision alone.[24] There was no difference in decisional conflict, anxiety, satisfaction, choice of analgesia or discrepancies between analgesia intentions and use.[24] Potential sources of bias are considered in table 2.

DISCUSSION

This systematic review demonstrates that patient decision aids have the potential to improve obstetric care as they are associated with a number of positive effects, similar to the benefits established by the Cochrane review of decision aids in other clinical specialties.[12] These benefits include reduced anxiety, lower decisional conflict, improved knowledge, improved satisfaction and increased perception of having made an informed choice. However, while these positive effects are attractive, we must be cautious in interpreting their potential benefit in routine practice due to the limitations of the small number of randomised controlled trials which have been undertaken in obstetrics and the inconsistencies in their results, particularly as we were not able to perform meta-analysis due to the small sample size and heterogeneity of primary outcomes chosen.

Table 2 Summary of the quality of studies included in the review

Author	Randomisation	Blinding	Follow-up and analysis	Included in Cochrane review?
Bekker *et al*[16]	Simple randomisation with numbered sealed opaque envelopes Allocation concealment adequate	Not described	Number of withdrawals stated but reasons not given Intention-to-treat analysis	Yes
Graham *et al*[17]	Simple randomisation with numbered sealed opaque envelopes Allocation concealment adequate	Not described	Data entry checked for accuracy Number of withdrawals stated and that there were no significant differences between women followed up and women withdrawing Intention-to-treat analysis	Excluded (general information with lack of focused decision)
Hewison *et al*[18]	Pseudo-randomisation with women allocated on the basis of having either an odd or even unit number Women were pseudo-randomised without consent (sent a letter with either intervention/control leaflet stating that new methods of information provision were under evaluation and that women may be asked to complete questionnaires during their pregnancy) State that unit numbers were allocated consecutively by staff not participating in the study Allocation concealment not adequate	Not described.	No flow chart Psychological endpoint and demographic questionnaire only sent to first 1200/2000 women randomised because of limited time for follow-up Number of withdrawals stated but reasons not given No CIs	Excluded (did not meet criteria for definition of decision aid as no values clarification)
Hunter *et al*[19]	Randomised in blocks of 30 (10 women into each intervention group) using allocations in opaque envelopes Allocation concealment adequate	Not described	Non-participants were compared with participants across a variety of criteria. Significant differences included: more non-participating women had children prior to prenatal diagnosis counselling; more participating women disclosed exposure to alcohol, cigarettes, medication (including chemotherapy and radiotherapy) or street drugs in pregnancy; more participating women brought their partner to prenatal diagnosis counselling No flow chart No CIs	Yes

Continued

Table 2 Continued

Author	Randomisation	Blinding	Follow-up and analysis	Included in Cochrane review?
Leung *et al*[20]	Simple randomisation with numbered sealed opaque envelopes Allocation concealment adequate	Not described	Number of withdrawals stated but reasons not given Intention-to-treat analysis	Yes
Montgomery *et al*[21]	Computer-generated block randomisation with allocation stratified by maternity unit and baseline preference for mode of delivery Allocation concealment adequate	Not described	Intention-to-treat analysis Number of withdrawals stated Compared women who did and did not consent (participants older and less deprived) but no statement of withdrawals	No (published after last update)
Nagle *et al*[22]	Computer-generated cluster randomisation using individual general practitioners as the unit of randomisation Allocation concealment adequate	Not blinded	Intention-to-treat analysis Number of withdrawals stated and reasons given	No (published after last update)
Nassar *et al*[23]	Computer-generated block randomisation stratified by parity and centre allocated via remote telephone Allocation concealment adequate	Women and research team not blinded Antenatal staff blinded	Intention-to-treat analysis No difference in maternal age, level of education, parity or treatment allocation between responding participants and those lost to follow-up	No (published after last update)
Raynes-Greenow *et al*[24]	Computer-generated block randomisation allocated via remote telephone Allocation concealment adequate	Women not blinded but unaware that the control pamphlet was not the interventionAntenatal staff blinded to format and content of the decision aid	Intention-to-treat analysis Number of withdrawals stated but reasons not given	No (published after last update)
Shorten *et al*[25]	Computer-generated block randomisation Allocation concealment adequate	Participants initially blinded to their allocation but use of decision aid as specified would potentially negate blinding	Intention-to-treat analysis Number of withdrawals stated but reasons not given	Yes
Thornton *et al*[26]	Simple randomisation with numbered sealed opaque envelopes Allocation concealment adequate	Not described	No statement of withdrawals Intention-to-treat analysis Included Urdu-speaking women as trained an Urdu-speaking doctor	Excluded (authors unable to evaluate if met criteria for decision aid)

We were able to identify only 11 randomised controlled trials to date involving heterogeneous decision aids, patient groups and outcomes. These studies varied in quality (table 2). For example, none of the women participating in these studies were blinded, although some blinded clinical staff. Hewison *et al*[18] used pseudo-randomisation, allocating women depending on whether they had an odd or an even unit number. The other studies were randomised and had adequate allocation concealment. Five studies specified that they used computer randomisation. Follow-up was generally well documented (although some older studies did not include a flow chart), and intention-to-treat analysis was used. Two studies did not include confidence intervals (table 2).

None of the positive effects of decision aids were seen in all studies. With so few and such heterogeneous studies, no obvious patterns of association relating to clinical context or the type of decision aid used could be identified. For some outcomes, only a positive effect or no effect was found. For example, three of 11 studies demonstrated that patient decision aids were associated with reduced anxiety; six found no effect on anxiety, while two did not include anxiety as an outcome. In relation to decisional conflict, five studies demonstrated that patient decision aids decreased decisional conflict, two studies showed no effect and four studies did not include this as an outcome. At present, it may be that these inconsistencies can be explained by the limitations and heterogeneous nature of these studies and their effects may become clearer as the body of evidence grows.

Consistent with the wider Cochrane review, decision aids in obstetrics also had variable effects on the final decision made.[12] Possible explanations for this include that the trials were not sufficiently powered; that high-quality information was routinely provided in the control arms; that women had a high baseline level of knowledge; that effects depended on the acceptability of the intervention being considered; women's perception of screening tests as 'normal' and subsequent 'compliant' behaviour or the timing of the decision aid in relation to the intervention. Alternatively, decision aids may not impact on intervention rates (albeit they may improve decision quality), but again, further research is needed to clarify this.

When evaluating future studies, an important factor will be selecting appropriate outcomes. At present, there appears to be no ideal method of evaluating decision quality, defined as follows: 'the extent to which a decision reflects the considered preferences of a well-informed patient and is implemented' or alternatively 'whether the right person is being matched with the right treatment'.[42] The Decisional Conflict Scale measures uncertainty and includes a subscale, which measures 'perceived effective decision making'.[12 12a] While this provides a numerical score by which intervention groups can be compared with control groups (or each other) and has been found to be reliable and sensitive to change,[12] This should be the same additional reference. it is limited by lacking clinical applicability—it is not clear what a particular score means in practice and it does not encompass the concept of matching patients' choices to their values and preferences.

Uptake rates for interventions are also likely to be poor markers for decision quality as they do not discriminate between 'warranted' and 'unwarranted' variation.[42 43] Unwarranted variation is defined as that which results from care being less evidence based such as inequalities in resources or expertise, insufficient research, clinician bias, poor communication and confusion in the roles of health professional and patient.[42 43] Warranted variation is that which improves the patient centeredness of care by matching patients to the interventions most suitable for them based on clinical or psychosocial differences between patients and variation in patients' preferences for taking risks, their attitudes towards particular clinical outcomes or the time-frame for outcomes and their preferred role in decision making.[42 43] Decision quality instruments which assess decision-specific knowledge, patients' values and preferences and whether there is concordance between patients' goals and the treatments available have been developed.[42] However, while at present none have been developed for decisions in obstetrics, the potential of these to match interventions to patients' goals appears attractive.

The studies reviewed also involved heterogeneous decision aids. The most appropriate type and format of decision support might well vary depending on the clinical context, but little is known about which methods of decision support are most effective or what context or patient-specific factors are relevant. Raynes-Greenow *et al*[44] found no additional benefit of the audio component of their decision aid for labour analgesia compared with the booklet component alone. Future research could further address whether there is any variation in effects depending on the medium chosen or whether specific decisions or patient groups might benefit from different approaches to decision support.

A component of this is how best to communicate risk. At present, women are often provided with information framed in different ways from a number of healthcare professionals. Patient decision aids may help to reduce the confusion this can generate by standardising information and allowing it to be presented framed in several ways (eg, a 90% chance of X or a 10% chance of Y) to suit different women's preferences.

One of the potential attractions of patient decision aids is that they provide evidence-based information in a way that avoids clinician bias. Pregnant women are often young, fit and motivated to seek information. Some will have prepared for the clinic visit on the internet. While inequalities in education and access to computers persist, using alternative media to written information may prove to be more inclusive. This is another potential benefit decision aids could offer. Those that could be regularly updated may be especially

useful as they could also help clinicians have current data at their fingertips. Thus, decision aids should not be seen as an alternative to the clinician in the decision-making process, rather that the decision aid may enhance the care provided by a clinician as an adjunct to good clinical practice; by explicitly eliciting women's values and providing consistent current information they may reduce the time needed to make a decision and facilitate communication and guideline implementation.

Nevertheless, it may be challenging for clinicians to accept that if a woman's preferences do not match with the best available evidence, she might still make a 'high-quality' decision because it agrees with her values, particularly, and perhaps more controversially, if the decision does not appear to be in the best interest of the fetus. Obstetrics is unique in that there is a third silent party involved directly in the clinical scenario: the fetus. By eliciting women's values and preferences, PDAs may facilitate decision making when difficult trade-offs between the advantages for mother and baby have to be made.

While the potential benefits of patient decision aids can be demonstrated in a research setting, the next stage is implementing and evaluating them in routine clinical practice. Outside of obstetrics, research has shown that barriers to using decision aids include lack of support from doctors (including concerns about data quality and time constraints), lack of an organised system to distribute decision aids (and lack of awareness of their existence) and clinician's perceptions about patients' attitudes towards participation in decision making.[45–50] Within obstetrics, one qualitative study has looked at healthcare professionals' views on two computer-based decision aids for women choosing mode of delivery after previous caesarean section.[51] While the majority of health professionals interviewed were positive about the decision aids, perceived barriers were similar to those in other clinical contexts, including service issues, communication issues and people issues.[51] Overcoming these barriers may necessitate cultural changes and system adaptations.

In this systematic review, we have discussed the potential beneficial effects which decision aids may have for women making decisions in pregnancy, accepting the limited evidence base. We have also identified a number of areas for future research including: how best to measure decision quality, investigating women's preferences for decision support and risk communication and how to implement decision aids into clinical practice in obstetrics. We believe that these questions should be addressed as part of our commitment to improving women's care by facilitating their involvement in decision making and improving their decision-making experience.

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Competing interests None.

Ethics approval Ethical approval was not required for this systematic review.

Contributors All three authors conceived and designed the study, analysed and interpreted the data, revised the article and approved the final version. RS drafted the article and will act as guarantor.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data available.

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Appendix 1: Search strategy for ‘Helping pregnant women make better decisions: a systematic review of the benefits of patient decision aids in obstetrics’

MEDLINE (inception until May 2011)

1. (Pregnancy OR pregnan* OR Prenatal Diagnosis OR Parturition)
2. (Decision Support Techniques OR patient decision aid.mp OR decision aid.mp OR shared decision making.mp)
3. 1 and 2

Following the submission of the revisions for our paper 'Helping pregnant women make better decisions: a systematic review of the benefits of patient decision aids in obstetrics' bmjopen-2011-000261, and in particular the addition of Table 2 summarising the quality of the studies, we have re-reviewed our tables.

As all the studies are included together in Table 2, we propose to combine the other two summary tables and add-in the studies by Nassar et al and by Raynes-Greenow et al (which were not previously summarised in table form) as Table 1. I have attached the amended table as a word document.

I am really sorry to suggest this after I had submitted the revisions but believe it would be clearer than the existing tables. I have made a few minor changes to clarify/ add detail to the text in the table. I have also changed the 'population' heading to 'participants' and have amended numbers so that they reflect the number of women randomised for consistency (as previously participants approached had been included for some studies depending on how the numbers were reported). I have also corrected a few typos I had found.

Please advise if you would like me to resubmit this through the Author Centre. In terms of affects on the main document, if you accept this revised table I will need to change any references to Table 3 to Table 2.

Again many apologies for submitting this after the revisions but having had further time to reflect on them and the paper I do think this table would be an improvement.

Best Wishes

Rebecca Say

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3-4
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	7-9
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	8-9
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	9-10
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	9-10
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	9-10
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	9-10
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	9-10
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	9-10
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	9-10
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	9-10
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	9-10
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	10-14 and Tables 1-2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	10-14 and Tables 1-2
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	10-14
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	14-17
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	19
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	2

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097.

PRISMA 2009 Checklist

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