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.

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
Improved health outcomes, satisfaction and improvements in a variety of other psychosocial health status indicators. Thus, shared decision making has become a key component of health policy in the UK and internationally.

Research has shown that young female patients are more likely to prefer involvement in decision making than other patient groups. 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. However, involving patients in decision making remains a challenge for many health professionals.

Patient decision aids can be used to facilitate involvement in decision making and improve clinical practice. 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. 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.

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.

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. The IPDAS checklist was published in 2006 and uses quality domains with a total of 41 criteria. 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. 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. 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), 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
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 and 70.5% for decision aid of Hunter et al), but they did not evaluate the other decision aids as they were unable to assess the booklet produced by Nagle et al and did not include the other four studies in their review.

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 found that the uptake of detailed anomaly scan was higher in the decision aid group, and Thornton et al 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. Pregnant
Table 1  Summary of studies included in the review

| Author          | Participants | Decision aid                               | Control                  | Outcomes                                      | Results                                                                 |
|-----------------|--------------|--------------------------------------------|--------------------------|-----------------------------------------------|-------------------------------------------------------------------------|
| Bekker et al¹⁶  | 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 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. |
| Graham et al¹⁷  | 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) Understanding of prenatal tests Satisfaction with information Anxiety Use of information leaflet | More women in the intervention group underwent detailed anomaly scanning. No difference in other tests No difference Reduced in the intervention group No difference |
| Author            | Participants                                                                 | Decision aid                        | Control          | Outcomes                                                                 | Results                                      |
|-------------------|-------------------------------------------------------------------------------|-------------------------------------|------------------|--------------------------------------------------------------------------|----------------------------------------------|
| Hewison et al⁸    | 2000 consecutive women referred for antenatal care at Hull Maternity Hospital | Video                               | Routine care     | Uptake of screening (second trimester serum screening) Knowledge          | No difference                                |
|                   |                                                                                |                                     |                  | Anxiety, Worries abnormalities, Worries about screening tests            | Improved knowledge in the intervention group |
|                   |                                                                                |                                     |                  | General worries about pregnancy/childbirth                                | No difference                                |
|                   |                                                                                |                                     |                  | Knowledge                                                                 |                                             |
|                   |                                                                                |                                     |                  | Anxiety                                                                  | No difference                                |
|                   |                                                                                |                                     |                  | Decisional conflict                                                        | Decreased with PDA                           |
|                   |                                                                                |                                     |                  | Satisfaction                                                              | Less satisfied with PDA than individual counselling |
| Hunter et al¹⁹    | 352 pregnant women aged ≥35 years                                              | Case examples and worksheet          | Individual or group genetic counselling                                  | Increased knowledge in all groups: highest knowledge levels with group counselling | No difference                                |
|                   |                                                                                |                                     |                  | Anxiety                                                                  |                                             |
|                   |                                                                                |                                     |                  | Decisional conflict                                                        | Decreased with PDA                           |
|                   |                                                                                |                                     |                  | Satisfaction                                                              |                                             |
| Leung et al²⁰     | 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) Initial decision about screening after intervention Understanding and satisfaction with the information they had received | No difference                                |
|                   |                                                                                |                                     |                  | No difference                                                             |                                             |
|                   |                                                                                |                                     |                  | Women who used the decision aid had fewer additional questions            |                                             |
|                   |                                                                                |                                     |                  | No difference in satisfaction                                             |                                             |

continued
| Author          | Participants                                                                 | Decision aid                                                                 | Control     | Outcomes                        | Results                                                                 |
|-----------------|------------------------------------------------------------------------------|------------------------------------------------------------------------------|-------------|---------------------------------|-------------------------------------------------------------------------|
| Montgomery et al | 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              | Decreased with both decision aids                                       |
|                 |                                                                              |                                                                              |             | Mode of delivery                | No difference                                                          |
|                 |                                                                              |                                                                              |             | Anxiety                         | Decreased with both decision aids                                       |
|                 |                                                                              |                                                                              |             | Knowledge                       | Increased with both decision aids                                       |
|                 |                                                                              |                                                                              |             | Satisfaction with the decision  | Satisfaction higher in decision analysis group than with usual care. No other differences |
| Nagle et al     | 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                             | 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 |
|                 |                                                                              |                                                                              |             | Intention to have screening     | No difference                                                          |
|                 |                                                                              |                                                                              |             | Decisional conflict             | No difference                                                          |
|                 |                                                                              |                                                                              |             | Anxiety                         | No difference                                                          |
|                 |                                                                              |                                                                              |             | Depression                      | No difference                                                          |
|                 |                                                                              |                                                                              |             | Attitudes to pregnancy/fetus    | No difference                                                          |
|                 |                                                                              |                                                                              |             | Acceptability of resource       | No difference                                                          |
|                 |                                                                              |                                                                              |             | Acceptability of screening      | No difference                                                          |

Continued
| Author       | Participants                                                                 | Decision aid                                                                 | Control          | Outcomes                                                                 | Results                                                                 |
|--------------|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------|------------------|--------------------------------------------------------------------------|-------------------------------------------------------------------------|
| Nassar et al<sup>23</sup> | 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                                                                | Increased with PDA                                                     |
|              |                                                                                |                                                                                |                  | Decisional conflict                                                      | Decreased with PDA                                                     |
|              |                                                                                |                                                                                |                  | Anxiety                                                                  | No difference                                                          |
|              |                                                                                |                                                                                |                  | Satisfaction with decision making                                        | No difference                                                          |
|              |                                                                                |                                                                                |                  | Participation in decision making                                        | More women in the PDA group had a positive attitude towards ECV       |
|              |                                                                                |                                                                                |                  | Attitudes of the importance of undergoing an ECV                        | PDA group more likely to favour ECV                                  |
|              |                                                                                |                                                                                |                  | Intended choice                                                          | No difference                                                          |
|              |                                                                                |                                                                                |                  | ECV uptake                                                                | No differences                                                         |
|              |                                                                                |                                                                                |                  | Maternal and perinatal outcomes (presentation at birth, mode of delivery, Apgar scores, infant sex, gestational age, infant birth weight, maternal length of stay) | No differences                                                         |

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                                                          |
|                         |                                                                               |                                                   |                                                  | Intended choice of analgesia               | No difference                                                          |
|                         |                                                                               |                                                   |                                                  | Analgesia use                              | No difference                                                          |
|                         |                                                                               |                                                   |                                                  | Participation in decision making           | No difference                                                          |
|                         |                                                                               |                                                   |                                                  | 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**                              |                                                                        |
| Author         | Participants                                                                 | Decision aid                                                                 | Control                                                                 | Outcomes                                                                 | Results                                                                 |
|---------------|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|-------------------------------------------------------------------------|
| Thornton et al²⁶ | 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.
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women with a previous section may be offered either a planned trial of vaginal birth (VBAC) or elective repeat caesarean section (ERCS). The Royal College of Obstetricians and Gynaecologists 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.

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.

Two decision aids have been trialed in this context, both of which improved knowledge and decreased decisional conflict (table 1). 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 IPDAS gave the PDA developed by Shorten et al a score of 64.0%.

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. Reported success rates of ECV vary from 18% to 76%. The Royal College of Obstetricians and Gynaecologists recommends that ECV should be offered in all hospitals where there is adequate expertise.

Despite the evidence supporting ECV, reported uptake is low (24%–54%) 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. None of the respondents commented on having discussed the risks and benefits of elective caesarean section. 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 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. There was no difference in the proportion of women actually choosing ECV or in anxiety levels. 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. 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 preferences.

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. Raynes-Greenow et al 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. There was no difference in decisional conflict, anxiety, satisfaction, choice of analgesia or discrepancies between analgesia intentions and use. 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. 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.
| Author          | Randomisation                                                                 | Blinding                  | Follow-up and analysis                                                                                   | Included in Cochrane review? |
|-----------------|--------------------------------------------------------------------------------|---------------------------|----------------------------------------------------------------------------------------------------------|-----------------------------|
| Bekker et al.   | Simple randomisation with numbered sealed opaque envelopes                     | Not described             | Number of withdrawals stated but reasons not given                                                      | Yes                         |
|                 | Allocation concealment adequate                                                 |                           | Intention-to-treat analysis                                                                               |                             |
| Graham et al.   | Simple randomisation with numbered sealed opaque envelopes                     | Not described             | Data entry checked for accuracy                                                                         | Excluded (general information with lack of focused decision) |
|                 | Allocation concealment adequate                                                 |                           | Number of withdrawals stated and that there were no significant differences between women followed up and women withdrawing |                             |
|                 |                                                                                |                           | Intention-to-treat analysis                                                                               |                             |
| Hewison et al.  | Pseudo-randomisation with women allocated on the basis of having either an odd  | Not described.            | No flow chart                                                                                           | Excluded (did not meet criteria for definition of decision aid as no values clarification) |
|                 | or even unit number                                                            |                           | Psychological endpoint and demographic questionnaire only sent to first 1200/2000 women randomised because of limited time for follow-up |                             |
|                 | Women were pseudo-randomised without consent (sent a letter with either        |                           | Number of withdrawals stated but reasons not given                                                      |                             |
|                 | intervention/control leaflet stating that new methods of information provision  |                           | No CIs                                                                                                  |                             |
|                 | 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                                             |                           |                                                                                                         |                             |
|                 | Randomised in blocks of 30 (10 women into each intervention group) using      |                           |                                                                                                         |                             |
|                 | allocations in opaque envelopes                                                |                           |                                                                                                         |                             |
|                 | Allocation concealment adequate                                                 |                           |                                                                                                         |                             |
| Hunter et al.   | Randomised in blocks of 30 (10 women into each intervention group) using      | Not described             | Non-participants were compared with participants across a variety of criteria. Significant differences    | Yes                         |
|                 | allocations in opaque envelopes                                                |                           | included: more non-participating women had children prior to prenatal diagnosis counselling; more      |                             |
|                 | Allocation concealment adequate                                                 |                           | 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                                                                                                  |                             |

Continued
| Author          | Randomisation                                                                 | Blinding                  | Follow-up and analysis                                                                 | Included in Cochrane review? |
|-----------------|-------------------------------------------------------------------------------|---------------------------|----------------------------------------------------------------------------------------|-----------------------------|
| Leung et al     | Simple randomisation with numbered sealed opaque envelopes                    | Not described             | Number of withdrawals stated but reasons not given                                      | Yes                         |
| Montgomery et al| Computer-generated block randomisation with allocation stratified by maternity unit and baseline preference for mode of delivery | Not described             | Intention-to-treat analysis                                                             | No (published after last update) |
| Nagle et al     | Computer-generated cluster randomisation using individual general practitioners as the unit of randomisation | Not blinded               | Intention-to-treat analysis                                                             | No (published after last update) |
| Nassar et al    | Computer-generated block randomisation stratified by parity and centre allocated via remote telephone | Women and research team not blinded | Intention-to-treat analysis                                                             | No (published after last update) |
| Raynes-Greenow et al | Computer-generated block randomisation allocated via remote telephone       | Women not blinded but unaware that the control pamphlet was not the intervention, Antenatal staff blinded to format and content of the decision aid | Intention-to-treat analysis                                                             | No (published after last update) |
| Shorten et al   | Computer-generated block randomisation                                        | Participants initially blinded to their allocation but use of decision aid as specified would potentially negate blinding | Intention-to-treat analysis                                                             | Yes                         |
| Thornton et al  | Simple randomisation with numbered sealed opaque envelopes                    | Not described             | Number of withdrawals stated but reasons not given                                      | 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 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. 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’. The Decisional Conflict Scale measures uncertainty and includes a subscale, which measures ‘perceived effective decision making’. 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, 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. 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. 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. 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. 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 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
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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
| 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., I²) for each meta-analysis.                                                               | N/A               |
| 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.
For more information, visit: www.prisma-statement.org.

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