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**TITLE: Are women empowered to make decisions about the use of antidepressants in pregnancy?**

**Abstract:**

**Background:** Untreated depression is related to adverse maternal mortality and morbidity. The most frequent treatment option for women is antidepressant medication. Women find decision-making about antidepressant usage in pregnancy difficult and confusing. There is a dearth of information to explain if women are empowered to make decisions around the use of antidepressants in pregnancy.

**Method:** A literature review was conducted using Cinahl Complete, Intermed, Proquest and Discover More.

**Results:** Information provision was inadequate and women experienced decisional conflict. Women wanted to be involved in a collaborative decision-making process.

**Conclusion:** Women want to be provided with clear and accurate information and follow a collaborative decision-making process when making decisions about antidepressants in pregnancy. More research is needed to explore demographic gaps within population samples. Women's experiences of decision-making about antidepressant usage need to be explored in depth. Undergraduate and postgraduate

health education should include conversation skills training, associated with collaborative discussion and informed choice around medication usage.

### **Key Points**

- There is a need to provide clear information about the risks and benefits of antidepressant usage during pregnancy.
- Women want their healthcare professionals to facilitate collaborative discussion with them about treatment options.
- Feeling informed has a clear association with feeling satisfied when women make decisions about anti-depressant usage.
- More research covering a wider demographic and with UK participants is necessary in order to better understand this topic.

**Keywords:** Empowered decision-making; pregnancy; depression; antidepressants

## **Background**

Depression and anxiety are two of the most common health problems in pregnancy in the UK, with 12% of women experiencing depression and 13% experiencing anxiety (Heron et al, 2004; Gavin et al, 2005; Vesga-Lopez et al, 2008). The most common treatment is antidepressant medication (McManus et al, 2016). In 2013, antidepressants were the most researched drugs during pregnancy, with over 30,000 potential outcomes examining the risk of adverse effects on the fetus (Einarson, 2013). Furthermore, antidepressant usage in pregnancy has been linked with spontaneous abortion, maternal morbidity and adverse neonatal outcome such as; low birth weight, pre-term delivery, congenital malformations, neonatal withdrawal syndrome and persistent pulmonary hypertension of the newborn (Bonari et al, 2004; Chan et al, 2014; UK Teratology Information Service (UKTIS), 2016). However, risks are difficult to quantify due to conflicting findings from teratological research (UKTIS, 2016) and the observational methods used, since pregnant women are not included in randomised controlled trials for antidepressant drugs (Einarson et al, 2015). Ambiguity around risk factors makes decision-making about antidepressant usage during pregnancy a complex process (Bonari et al, 2005; Patel et al, 2011; Stepanuk et al, 2013; Walton et al, 2014). Therefore, this literature review seeks to explore whether

women feel they are empowered to make complex decisions about antidepressants in pregnancy.

## **Method and results**

This literature review focussed on papers using Boolean logic to incorporate the use of the word “AND” within the search strategy. For Example, “Pregnancy AND depression AND decision\*\*” was used for the majority of the search. To enhance the search, reference lists from identified articles were reviewed for relevance. The search used Cinahl Complete, Intermed, ProQuest and Discover More data bases. The process to select relevant articles included screening by title and abstract (anonymised author initial). To add rigor, an independent review was undertaken (anonymised author). Selection revolved around the exclusion criteria and relevance to the topic.

The focus of this paper related to women’s decision-making regarding the use of antidepressants. Therefore, papers were excluded if the main focus was on decision-making by clinicians, postpartum depression, the teratogenic effects of antidepressants, or there was no analysis of how women are empowered to make a decision (See Figure 1 for detail). Countries similar to the UK in demographics were included. An expanded timeline was used to broaden the search due to the dearth of literature available (2000-2017). The selected articles were analysed using an appraisal tool adapted from CASP (2016) and Crombie’s (1996) checklists.

(PLACE FIGURE 1. HERE.)

Key findings from the literature review are outlined in Table 1, which reflect a significant weighting towards quantitative research, as three studies were quantitative (Stepanuk et al 2013; Patel and Wisner 2011; Bonari et al 2005) and one included a mixed methodology (Walton et al 2014). Available studies were set in the USA or

Canada. There was a lack of evidence around information provision and decision-making in the antenatal period in a UK setting. The findings suggested a need for clear risk-benefit information for antidepressant usage. There was a strong indication that women wanted collaborative discussion about their antidepressant treatment options. Two key themes emerged from this literature review related to information provision and collaborative decision-making, which will be discussed further.

(PLACE TABLE 1. HERE)

### **Information Provision**

Information provision was cited as an important aspect of the decision-making process in all four studies reviewed. A mixed method, cross sectional study (n=50), by Walton et al (2014) looked at decisional conflict among pregnant women who were considering antidepressant usage. The quantitative aspect of the study focused on the Decisional Conflict Scale (DCS), a validated tool for studying complex decisions (O'Connor, 1995; Stacey et al, 2012), which provides a score indicating the level of decisional conflict experienced by the user. A DCS score of >37.5 indicated a high level of decisional conflict, a score of 25 to 37.5 indicated moderate decisional conflict and a score of <25 indicated low decisional conflict. It was found that women who were antidepressant users (n=21) had a much lower state of decisional conflict (DCS mean=17.5) in the 'Informed' subscale than women who were non-users (n=19, DCS mean=42.1). This indicated that women who were antidepressant users felt more informed than women who were non-users. The difference in scores was statistically significant ( $p=0.001$ ), the low p value indicates there was little chance for error and is a robust finding (Crombie, 1996).

Semi-structured interviews with women (n=10) reported a lack of high quality information (n=5) about risk in relation to the health of their baby (Walton et al, 2014).

All of the women interviewed went on to express the competing requirement to weigh their own health against the health of their baby as a barrier to decision-making. This is in contrast to the previous quantitative finding from this same study that women felt less decisional conflict when they were informed. The number of participants involved (10) could be seen as limited, although Guest et al (2006) suggested that overarching themes can emerge from as few as six interviews. The limited number does impact on the generalisability of the findings, which is acknowledged by the authors.

Information provision was also tested by Bonari et al (2005) in their structured telephone survey (n=100) of women calling the MotherRisk Medication Help Line. They found a positive correlation (Pearson's  $r=0.391$ ,  $p<0.01$ ) between information received and continuation with antidepressant usage. However, there is no rationale given for the chosen sample size (n=100), therefore the correlation should be considered as weak because it may be underpowered (Bowling and Ebrahim, 2005).

In a further study, information provision by health care professionals was found to impact on the level of emancipation in the decision-making process, which was in turn linked to satisfaction about the decision made (Stepanuk et al, 2013). In addition, satisfaction with decision made was not significantly different between women who chose to take or not take antidepressant medication. Stepanuk et al (2013) also explored empowerment in decision-making using a cross-sectional, descriptive web based survey based on Wittman-Price's (2004) theory of emancipated decision-making (n=143). A statistically significant relationship between personal knowledge and satisfaction with decision ( $p<0.001$ ) was found. Personal knowledge was defined as the information women needed to weigh up the risks and benefits of taking antidepressant medication during pregnancy (Stepanuk et al, 2013). This finding can be treated as robust since the power calculation to define the sample size was set at

0.8, which is accepted as a good level in order to be able to detect statistically significant relationships (Sedgwick, 2011).

### **Collaborative Decision-making**

It was apparent that women wanted to be actively involved in collaborative decision-making about anti-depressant usage (Patel and Wisner, 2011; Stepanuk et al, 2013 and Walton et al, 2014). Collaborative decision-making was tested in Patel and Wisner's (2013) study, in which pregnant women (n=100) completed a structured online survey using three validated tools (1) The Decisional Conflict Scale (DCS), (2) The Control Preferences Scale (CPS) and (3) the Problem Solving Decision Making Scale (PSDMS) (O'Connor, 1995; Deber et al, 1996; Degner et al, 1997). This survey split the decision-making process into two parts; Problem Solving (PS) and Decision-Making (DM). With regard to problem solving, the study found that 72% of women wanted to defer; 24% wanted to share, and only 4% wanted to keep sole responsibility for solving the problem. In comparison, in relation to decision-making, only 4% wanted to defer; 41% wanted to share and 55% wanted sole responsibility for the decision-making process. A potential interpretation of the findings suggest that women see the clinician as playing a crucial role in helping to understand how to weigh risk and benefit associated with treatment options and would like to take a passive role in this process. However, women would like the stance taken by the clinician to be the basis of a conversation related to helping women decide to take them or not. Regardless of the interpretation, the findings demonstrated a clear desire from women surveyed to play an active role in decision-making around usage of antidepressant medication.

### **Strengths and Limitations**

There was an imbalance of available evidence to critique, since 3 studies were quantitative and 1 study used mixed methods. The balance within the mixed method study reflected a weighting towards 40 quantitative responses and only 10 qualitative

responses. Therefore, the perspective within this literature review reflects that imbalance of evidence, commenting on quantitative findings mostly and adding context and depth from the small amount of qualitative information available. All studies demonstrated a structured approach in their analysis and highlighted information about a topic that is little known about, specifically, how women make decisions about the use of antidepressants in pregnancy. To our knowledge there are no comparable studies in the UK specifically related to how women decide to use antidepressants in pregnancy, with all four of the studies reviewed being set in the USA or Canada. It was apparent that bias was identified in all four of the studies as demographics suggested that the majority of participating women were described as white, married or living with a partner, or educated to a high school diploma level or higher. A comparison of the demographic details can be seen in Table 2.

(PLACE TABLE 2. HERE.)

## **Discussion**

This literature review has provided current and robust information reflecting that women are not empowered to make decisions about the use of antidepressants in pregnancy. Walton et al.'s findings (2014) show that women wanted clearer information from a source they trust, and identified that there is a proven relationship between feeling informed and having less conflict when deciding to take antidepressants. Walton et al's (2014) finding that there was a significant difference in decisional conflict with between antidepressant users and non-users differs from Stepanuk et al.'s (2013) research, which found no statistically significant difference. Unfortunately, Stepanuk et al (2013) do not provide any qualitative data, so it is not possible to look in any depth at the reason behind this differing result. Therefore, there is a need for researchers to explore in depth how women decide to take antidepressant medication in pregnancy, especially in a UK setting.



In addition, Walton et al.'s (2014) qualitative research suggests that many women perceived receiving information from a specialist mental health clinic to be more helpful to their decision-making process. Unfortunately, Walton et al (2014) do not provide the number of women that reported this finding and therefore the finding should be treated with a degree of caution. However, in the UK there are gaps in service provision related to support from mental health practitioners which has been associated with lack of funding, shortage of appropriately qualified staff and poor resources (Hogg 2013).

Corroboration that women wanted information provided by specially trained mental health professionals is evidenced by the Guideline Development Group in their systematic review of qualitative research of UK women's experience of antenatal and postnatal care around mental health (The British Psychological Society and The Royal College of Psychiatrists, 2015). The report suggested that there was a lack of information provided, the consequences of which were that many women stopped taking their medication on finding they were pregnant. This evidence formed the basis of the NICE (2014) recommendation that women should be provided with information on the risks and benefits of medication, the consequences of no treatment, and what might happen if medication is stopped. Evidence within that guideline relating specifically to information provision was UK based, but focussed on postnatal mental health only and was therefore excluded from this review. This finding highlights the lack of current research situated in the antenatal period around how women are empowered to make decisions about whether to use antidepressants or not. Therefore, it is easy to understand why women find decision-making difficult in the antenatal period (Walton et al 2014).

Both Bonari et al (2005) and Walton et al (2014) found a relationship between information provided and continuation with antidepressant usage. Despite the

weakness of correlation and small sample sizes involved in the studies, it is important to acknowledge the link between information received and the decision to take antidepressant medication. This is particularly important in light of the known risks of untreated depression, such as reduced ability to form attachment to infants (Hayes et al, 2013), increased rates of premature delivery, increased frequency of NICU admission (Engelstad et al, 2014) and suicide, one of the largest contributors to maternal death (MBRACE-UK, 2016).

Providing clear information about antidepressant usage in pregnancy is difficult for health care professionals to facilitate effectively due to the complexity of evidence surrounding the use of antidepressants in pregnancy (Einarson et al, 2015). Therefore, it is necessary for health care professionals to consider deeply how information is communicated. The need for a considered approach is echoed by Stepanuk et al (2013), who found that women were more satisfied with their decision when they felt more informed. Therefore, providing information in an accessible way that empowers women during the decision-making process makes a difference to the decision they make and to the satisfaction that they feel; even if the woman opts for no medication.

The link that Patel and Wisner (2011) found between complex information and a desire to defer the problem solving aspect of the decision making process must also be acknowledged. Only 4% of women wanted sole responsibility for this aspect, which included weighing risk and considering treatment options. This indicates that women did not feel empowered at this stage of the process but did not want to relinquish the decision making since 96% of women (41% wanted shared and 55% wanted sole responsibility) in actually making the decision whether or not to use antidepressants. Active decision-making reflects a level of empowerment that can influence positive treatment outcomes, ranging from impact on the satisfaction with the decision made (Bruera et al, 2002 and Kunneman et al, 2014) to findings of a more positive outcome

in health up to 3 years after treatment (Hack et al, 2006). Patel and Wisner (2011) recommended that it is important to explore the woman's expectations of the decision-making process to improve communication and satisfaction with the process.

A key finding within the studies reviewed focussed on the limited demographics (see Table 2). Patel and Wisner's study (2011) found that younger women surveyed had a higher score in the 'Informed' subscale of the Decisional Conflict Scale ( $p=0.02$ ), showing that younger women experience more conflict when they make decisions about antidepressant usage due to feeling uninformed. This highlights the need for further research encompassing a much wider demographic. Younger women were also identified by De Jonge (2001) as a group who needed specific and relevant information about mental health. This finding poses an important consideration around those who identify themselves as part of minority groups related to ethnicity, sexuality, learning disability or those who are less educated.

It is important to take into account that all women participating in the evidence presented in this review had actively sought further advice or information about their depression diagnosis (Bonari et al, 2005, Patel and Wisner, 2011, Stepanuk et al, 2013, Walton et al, 2014). It could be suggested that the nature of this self-help, coupled with the narrow demographic, might make the participants more motivated to gather information and share or take control of their situation. The general high level of education could also be said to contribute to a stronger need for detailed information. Further research with a wider demographic is needed to better understand this potential source of bias before a firm conclusion could be made.

## **Conclusion / Recommendations**

It was clear from this analysis that women in the USA and Canada are not empowered to make decisions about the use of antidepressants in pregnancy. This

conclusion was underpinned by a robust literature review. Four studies identified that information provision and a collaborative decision-making process emerged as the two most important factors for women. Women requested clarity of information, which was undermined by complexity when interpreting current research about risks and benefits of taking antidepressants during pregnancy. It was apparent that contradictory information confuses women and health professionals. Midwives should consider that when women feel informed there is a clear association with feeling satisfied with the decision made (Stepanuk et al, 2013). Therefore, the impact of unclear information given to women about using antidepressant medication needs more in depth qualitative research not only in the UK but also globally. Further research would help to identify accessible information that women will find useful. There is a need to understand more about how women problem solve around the uptake of antidepressants, as the topic is crucial to the health and wellbeing of women and their families when depression in pregnancy is experienced.

In addition, it was found that women wanted to actively participate in their treatment decisions (Patel and Wisner, 2011). Midwives need to have clear instruction about how to achieve collaborative discussions with women in a sensitive and caring way, which could be facilitated in undergraduate and postgraduate health education. In addition, to improve standards of care, provision needs to address service gaps in providing appropriately trained Health Care Practitioners within perinatal mental health services.

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