THE UNIVERSITY OF HULL

Understanding the Experiences of Pregnancy in Women with Epilepsy

being a Thesis submitted for the Degree of Doctorate of Clinical Psychology in the University of Hull

by

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Overview

This portfolio comprises of three parts: a systematic literature review, an empirical report and appendices.

Part one is a systematic literature review in which empirical literature relating to teratogenic risk perceptions of medication in pregnant women is reviewed and critically evaluated. The review attempts to determine how pregnant women perceive teratogenic risk associated with medication (over the counter and prescription) and reports on the intrapersonal factors associated with these perceptions. The review links the findings with theory and recommendations for clinical practice and future research are made.

Part two is an empirical paper which used qualitative methodologies to explore the lived experiences of pregnancy in women with epilepsy. To achieve this, seven women who were either pregnant or who had given birth to their babies within nine months attended a semi-structured interview with the main researcher which was analysed using Interpretive Phenomenological Analysis (IPA). Themes are discussed at length and considered within both a pregnancy and epilepsy context. The clinical implications and methodological limitations are also discussed and areas requiring further research are identified.

Part three comprises appendices and a reflective account of the research process.

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Part One: Systematic Literature Review

A Systematic Literature Review into the Perception of Teratogenic Risk associated with Medication in Pregnant Women and Intrapersonal Factors Associated with these Perceptions

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This paper is written in the format ready for submission to BioMed Central Pregnancy and Childbirth. Please see Appendix 2 for the guidelines for authors.

Abstract

Background: Despite a significant number of women consuming or needing to consume medication during their pregnancy, relatively little is understood as to how pregnant women perceive teratogenic risk associated with medication and factors associated with these perceptions. The purpose of this review was to collate research exploring teratogenic risk perceptions in pregnant women and to explore factors associated with these perceptions. It was hoped that this would further understanding of how women appraise medication taken during pregnancy and have implications for the provision of information about medication in health care settings. The review Methods: MEDLINE, PsycINFO, PsycARTICLES, Web of Science and CINAHL were systematically searched and twelve relevant papers were identified. To be included in the review studies had to explore the teratogenic risk perceptions associated with medication (over the counter and prescription) in pregnant women and be published in a peer reviewed journal. Qualitative and quantitative studies were included. The quality of each study was evaluated and the main findings were extracted and synthesised using a narrative approach. Results: Twelve studies were reviewed and overall demonstrated that

pregnant women overestimate the teratogenic risk associated with medication and in particular overestimate the risks associated with psychotropic medication. Factors positively associated with teratogenic risk perceptions included depression, advanced maternal age, higher education and use of medication during pregnancy. Conclusions: The findings of the studies reviewed suggest that pregnant women overestimate teratogenic risk associated with medication and fear harming their unborn child through the use of medication. Findings are discussed in the context of theory, research and practice.

Keywords: pregnancy; risk perception; medication; teratogenic; medication adherence

Background

Pregnancy is a time when many women may be required to take some form of medication; this may be for a condition that pre-existed the pregnancy (e.g. epilepsy), for a pregnancy-related condition (e.g. persistent nausea and vomiting), or simply for relief of a non-pregnancy related symptom (e.g. headaches) (Koren, Pastuszak & Ito, 1998). In some instances, medication use is necessary to maintain the health of both the mother and the fetus. For example, poorly managed epilepsy in pregnancy can place the mother at risk, but also increases the risk of miscarriage (Lupton, 1999). There are also adverse consequences associated with discontinuation of psychotropic medication during pregnancy, which has been shown to be associated with suicidal ideation and alcohol use to manage symptoms (Einarson, Selby & Koren, 2001).

Whilst taking medication during pregnancy is often necessary to maintain the health of both mother and fetus, medication management during pregnancy has been challenging to both pregnant women and their clinicians, given the potential for fetal harm (Lee et al., 2006). Lupton (1999) describes the risk discourse that surrounds pregnancy and notes how pregnant women, sharing their body with the fetus, are imbued with the responsibility for its health and are expected to be vigilant to any potential threats. These expectations of mothers during pregnancy are in line with the discourse around being a 'good mother', who protects her baby from harm and puts her children's needs before her own (Wright, 2001).

Within this context, many women avoid taking medications (both prescription and over-the-counter) during pregnancy, for fear of consuming an agent that is teratogenic – namely one that irreversibly alters growth, structure or function of the developing embryo or fetus (Buhimschi & Weiner, 2009). Therefore pregnancy can be a difficult period for women with established illnesses because suboptimal, or nonadherence with treatment can have detrimental effects on the health of both mother and fetus, and in some cases, can be life threatening (Lee et al., 2006). Therefore pregnant women must negate the moral work of the 'good patient' (p. 18, Thompson, Thomas, Solomon, Nashef & Kendall, 2008) who heeds the advice of their healthcare professional whilst simultaneously striving to be a 'good mother' who does no harm to her unborn baby (Thompson et al., 2008).

The discourse that surrounds medication during pregnancy is better understood when one considers the historical context of the thalidomide disaster in the 1950-60s. Since this tragedy occurred, there has been significant concern about the effect of medication on the fetus, which has resulted in a growing body of evidence examining the safety of these medications. However, evaluation of the risk of fetal malformations caused by medications is difficult to assess for a number of reasons. One difficulty is that there is a high prevalence of medication use in pregnancy, coupled with an overall low incidence of malformations in the general population, which has been estimated at 1-5% (Sanz, Gómez-López & Martínez-Quintas, 2001). Given this baseline risk, chance alone would account for a substantial number of children being born to mothers who took some medication in early pregnancy (Einarson et al., 2001). In addition, most of the data in teratologic studies is derived from animal experiments (Polifka, Faustman & Neil, 1997) or epidemiological studies of relatively small cohorts of pregnant and nonpregnant women. Finally, because it is unethical to use traditional methods of drugs testing with human subjects, it is virtually impossible to assert that a drug or chemical is not a teratogen (Polifka et al., 1997)

Despite the uncertainty that continues to exist around the safety of medications, and particularly over-the-counter medications (Werler, Mitchell, Hernandez-Diaz & Honein, 2005) it is important to remember that from the extant literature, less than 1% of drugs have been positively associated with major malformations (Haramburu, Miremont-Salamé & Moore, 2000). For those drugs considered teratogenic, the percentage of children born with a malformation is usually less than 50%. The true risk of malformations is associated with a very limited number of compounds (Sanz et al., 2001).

The literature on risk commonly defines risk in terms of "danger from future damage" (Joffe, 2003, p. 56). The ability to be aware of and avoid such dangers is essential to human survival and modern society is increasingly concerned with identifying and calculating potential risks with the use of sophisticated scientific methods (Slovic, 1987). The ways in which lay people make 'risk judgements' however, are through a number of psychological mechanisms and mental modes as risks "cannot be 'perceived' in the sense of being taken up by human senses" (Wachinger, Renn, Begg & Kuhlickpe, 2013, p.1049).

In this review, TRP refers to the judgement that pregnant women make about the severity of risk that a medication holds for creating a malformation in the fetus by irreversibly altering its growth, structure or function (Buhimschi & Weiner, 2009). This concept is distinct from teratogenic risk awareness, which refers to knowledge of the degree of teratogenic risk posed by a medication rather than the judgment of that risk.

The risk perception literature points to a number of factors that determine how risk is perceived. For example, individual factors such as parenthood has shown to be associated with increases vigilance to threat (Eibach & Libby, 2009) and risk-averse decisions (Cameron, DeShazo & Johnson, 2010). Risk perception is also sensitive to the age of the recipient (Walter & Britten, 2002; Berry, 2004); health risk perceptions made for children tend to be higher than those made for adults regardless of whether the person making the judgement is a parent or not, potentially because young children are perceived to be more susceptible to a health threat (Berry, 2004).

How risk information is presented (e.g. positive or negative outcomes emphasised) as well numeracy levels have been shown to affect risk perception (Edwards, Elwyn & Mulley, 2002; Keller & Siegrist, 2009). However, the ways in which risk information is received and presented varies greatly. For example, women with epilepsy will be offered preconception counselling where the risks and benefits of their medication during pregnancy will be discussed (National Institute for Health and Clinical Excellence, 2012). Other women, however, may rely on the drug labels or information on the internet, which is likely to be very variable in quality, to receive teratogenic risk information. In sum, risk perception does not depend upon objective probability estimates alone (Lee, Ayers & Holden, 2012) and how a pregnant woman perceives the teratogenic risk associated with the medication is likely to have significant bearing on her adherence to the medication (Nordeng, Koren & Einarson, 2010 a). Providing an understanding of how women perceive teratogenic risk, as well as the factors associated with risk perception may help health professionals to better understand risk perception and decision making in this population. Despite the implications of how teratogenic risk is perceived in pregnant woman, very little research has been conducted in this area. Therefore the main objectives of this review were to answer the following questions:

- How do pregnant women perceive teratogenic risk associated with medication?
- What intrapersonal factors are associated with these perceptions?

Method

Population

The reviewer selected to explore pregnant women's teratogenic risk perceptions (TRP) of medications (over the counter and prescription) rather than food, recreational drugs, herbal drugs, medical interventions (e.g. radiation therapy) or other exposures. Pregnant women (any stage of pregnancy) are the population of interest in this review, see Appendix 3 for a rationale of the background and population selected.

Search Strategy

A search was carried out for existing review papers in this area to ensure that this review would not be replicating previous work. This search did not identify any systematic literature reviews investigating the TRPs of pregnant women and factors affecting these perceptions. A systematic literature review was therefore employed as the appropriate methodology to efficiently integrate the existing information in this area. By exploring the data in a way that was critical and evaluative, the results of this review lend themselves readily to informing healthcare providers about the needs of pregnant women with regards to their risk perceptions around medication.

A systematic review was conducted to identify studies of the perception of teratogenic risk of medication in pregnant women. The primary search method was a review of the medical and psychological literature undertaken between June 2012 and November 2012 using the following computerised databases: MEDLINE, PsycINFO, PsycARTICLES, Web of Science and CINAHL. MEDLINE and Web of Science were chosen for their coverage of international peer-reviewed literature in the behavioural sciences, mental health and health sciences. PsychINFO and PsycARTICLES were selected provide a focus on psychological research and theory and CINAHL was included to provide access to nursing and allied health journals with multidisciplinary content.

A start date cut-off was not employed. A wide ranging definition of 'pregnancy' and 'medication' and 'teratogenic risk perception' was used to ensure as many articles as possible would be identified. See Table 1 for a full list of search terms and Appendix 4 for further information regarding the search strategy and inclusion criteria. Table 1: Search terms to identify studies included in the review

Concept	Search Term
Pregnancy	'pregnan*' 'maternal*' 'antenatal*'
	'prenatal*' 'perinatal*'
Medication	'medic*' 'drug*' 'treatment*'
Teratogen	'teratogen*' 'malformation*' 'f*etal toxi*'
	'f*tal malformation*' 'defect*'
	'congenital*' 'abnormalit*'
Risk Perception	'risk*' 'perception*' 'risk* perception*'
	'perceived' 'anxiet*' 'worr*' 'concern*'
	'expectation*' 'attitude*'

All possible combinations of these terms were systematically entered into each database to retrieve articles that featured the terms in their title, abstract, subject or keywords. Due to the broad search terms many articles identified were not relevant for

inclusion when the title and abstract were inspected. In the case of uncertainty, full copies of potentially suitable articles were obtained so that the selection criteria could be applied fully to assess the article's eligibility. Once key authors were identified, searches were also conducted under their names. Additional studies were located through inspection of the reference sections of relevant articles and key authors in the field were also approached to identify any further papers.

Inclusion and Exclusion Criteria

The selection criteria were developed and refined from reading abstracts retrieved from the scoping search. Studies were included if they:

• Reported a quantitative measure or qualitative description of perceived teratogenic risk of medication (prescription and over the counter) in pregnant women. Studies were included regardless of whether exploration of TRP was the primary aim of the research or not.

Studies were excluded if they:

- Did not include pregnant women
- Only provided information about pregnant women's TRPs in relation to some form of external comparator (e.g. the perception of healthcare professionals), condition (e.g. positively framed information) or intervention (e.g. counselling)
- Reported on teratogenic risk awareness rather than teratogenic risk perception
- Were literature reviews or case studies
- Were not peer reviewed
- Were not in English

Data Extraction and Data Synthesis

Data were extracted from studies using a pro-forma designed specifically for recording data for this review (Appendix 5). The heterogeneity of the studies' aims, design and outcome measures precluded a meta-analysis. Therefore narrative synthesis of the data primarily in terms of outcome was employed whereby the relevant data regarding the

perception of teratogenic risk was extracted from the studies and grouped in terms of subject. The findings were compared and discussed within and across groupings.

Quality Assessment

It was decided that the quality of each paper would be rated and reported in the data synthesis tables (Tables 2 and 3). Quality checklists were employed to enable the researcher to critically evaluate the strength of the findings. These were developed based on quality assessment measures by the National Institute for Health and Clinical Excellence (National Institute for Health and Clinical Excellence, 2009) and Downs & Black (1998). Due to the variation in study designs, two quality control tools were adapted; one for assessing the quality of qualitative studies (Appendix 6) and one for quantitative studies (Appendix 8). Please refer to appendices 7 and 9 for the ratings of the qualitative and quantitative studies against the quality checklists.

Studies were not excluded from the review based on quality as there was not a large database from which studies could be drawn to investigate the specific literature review whilst meeting all of the inclusion criteria. Instead, quality assessment is integrated throughout. Furthermore, the inclusion of studies of varying quality enabled a critique of the research literature available to be conducted and recommendations for future research to be made.

Results

Overview of Search Results

Both qualitative and quantitative studies were included in the review. Twelve studies obtained from database searches satisfied all the selection criteria and were therefore included in the review (for summary of studies see Tables 2 and 3). Study selection methodology is depicted in Figure 1.



Figure 1. Flowchart of article selection process

Summary of Studies

The process of study selection, shown in Figure 1, led to twelve being included in the review, ten of which employed a quantitative methodology and two employed a

qualitative methodology. The two studies that used a qualitative methodology explored experiences of teratogenic risk perception in relation to a chronic health condition (asthma and epilepsy). These studies explored women's experiences and risk perceptions of medication use during pregnancy as well as other issues. By contrast, the studies that took a quantitative approach mostly explored teratogenic risk perception directly in relation to a specific concept such as socio-demographic variables and beliefs about medication taken during pregnancy.

Measures

The majority of the quantitative studies included in the review (6/10) measured teratogenic risk perception using a risk analogue scale which gauges risk on a scale of zero (no risk) to one hundred percent (risk in every case). When interviews were conducted in person, TRP was measured by asking women to mark their estimates on a 10 cm horizontal line with short vertical line at each end; one marked 0% and the other 100% (n=5). The visual analogue scale (VAS) was developed and validated by researchers based at a Teratogen Information Service, 'Motherisk', in Canada. When telephone interviews were conducted, women were asked to estimate risk between zero and one hundred (n=1). One study quantified teratogenic risk perception on a 10-point scale, whereas one quantified the teratogenic risk in terms of the likelihood of a malformation occurring into the categories 'more likely', 'less likely' or 'unchanged'. One study explored TRP in relation to beliefs about medication during pregnancy, in this study women were asked to agree, disagree or state uncertainty in relation to a question or statement. Another study explored TRP by use of a standardised questionnaire to ask women about their perceptions about the potential risks of painkillers for the fetus, but did not specify exactly what was asked.

Whilst the quantitative studies tended to employ similar techniques for measuring teratogenic risk perception, there was great variety in the data that they produced owing to the variation in the concepts that were explored in relation to teratogenic risk perception. In comparison to the qualitative studies, the data were often less rich and consisted of comparisons between pre and post measures. However, many of these studies made it possible to directly compare the teratogenic risk perceptions of pregnant women with the actual risk cited in the scientific literature. Overall, for qualitative studies, data was mainly sought by interviewing a small number of participants and findings were presented in the form of themes or categories. In contrast, the quantitative studies typically recruited larger samples and presented findings statistically.

Quality

The qualitative studies were of a fairly consistent high quality. The main strengths of both studies were clearly focussed rationale and objective, and their appropriate choice of qualitative methodology. Areas of weakness tended to include a lack of triangulation in the data.

Quality of the quantitative studies was much more variable. Some of the studies did not state screening criteria for eligibility for the study and did not include specific information on the characteristics of the study population. Many of the studies also did not report the actual probability values for some of the main outcomes or directly report on the validity and reliability of the outcome measure used. This represented a particular area of difficulty for rating studies which employed a VAS or derivative or it, but did not make reference to its validity and reliability. Studies which did this were rated as 'unable to determine' for the item relating to validity and reliability.

For many of the studies, it was not possible to ascertain if the participants asked to participate were representative of the entire population from which they were recruited. In terms of strengths, all of the studies reported their main findings clearly and used appropriate statistical tests to assess the main outcomes and the majority of the studies clearly described principal confounders in their pool of participants.

Reference (Country) & Study Aims	Participant characteristics	Design and Analysis	Findings
Widnes, Schjøtt & Granas	<i>n</i> =10	Qualitative, semi-structured and	Risk perception:
(2012) (Norway)	Aged: 22–39 years 20–34 weeks	individual in-depth interviews.	Use of AEDs in pregnancy outweighed perceived risks, but dose adjustments
To explore risk perception and	gestation Diagnosed with	Experiences and thoughts on medicines and risking seizures	increased perceived risks of teratogenicity.
medicines information needs in pregnant women with epilepsy.	epilepsy; treated with one or more	in pregnancy and physicians' presentations of teratogenic	<i>Reducing Risk Perception:</i> Ultrasound examinations and regular controls of fetal
	antiepileptic drugs (AEDs)	risks.	heart rates and movements; preconception counselling; already having healthy children;
		Analysis in accordance with principles of systematic text condensation.	hearing about successful pregnancies among other women using AEDs; long-standing diagnosis of epilepsy.
Lim, Stewart, Abramson, Ryan	<i>n</i> = 23	Interviews (5 face-to-face and	5 major themes: Risks versus benefit; self-
& George	Aged: 21–43 years	18 by telephone)	efficacy; asthma as a priority; support and
(2012)	Pregnant: <i>n</i> = 4		guidance; influences on medication use.
(Australia)	Delivered: $n = 4$ Diagnosed with	Perceptions about asthma medications, asthma symptoms	
To explore the views and experiences of asthmatic pregnant women with a view to	asthma; prescribed medication; long term moderate-severe	during pregnancy, medication use, and support from health professionals.	
develop strategies to improve asthma management during pregnancy.	persistent asthmatics (<i>n</i> =13)	Framework approach	

 Table 2: Data from qualitative studies included in the review

Reference (Country)	Participants	Design and Analysis	Measures	Main Findings
æ Study Aims				
Nordeng, Ystrøm & Einarson (2010) (Norway) To evaluate the perception of risk of 17 commonly used drugs and other substances by pregnant women.	n=1793 Pregnant (48.3%) or had a child less than 5 years old (51.7%)	Anonymous self- completed online questionnaire at 1 time point Linear regression and Student's <i>t</i> -test	Study specific questionnaire: Socio-demographic and lifestyle factors; medication use during pregnancy and information requirements. Numeric rating scales ranging from 0 (no risk to the fetus) to 10 (fetal malformation following each exposure).	 83.9% reported having used drugs during pregnancy; 69.4% reported they had chosen not to use a drug because they were pregnant; 87.5% estimated correctly estimated the risk of a malformation. Risk of psychotropic drugs during pregnancy highly overestimated. Pregnant women and mothers had a similar perception of risk. Higher risk perception of drugs: associated with primiparity, older age, higher education and choosing not to use a drug in pregnancy.
Walfisch, Sermer, Matok, Einarson, Koren (2011) (Canada)	n=143 Mean age: 32.7 Pregnant (43.3%) Planning	Maternal risk perception in relation to a specific exposure was measured at 2	Edinburgh Postnatal Depression Scale (EPDS)	Older women (aged 40 years or older) had higher perceptions of teratogenic risk.
To explore the association between	pregnancy (56.7%)	time points: before and after counselling	(VAS) to determine maternal risk perception in relation to a specific exposure	Maternal education had a significant effect on personal risk perception.

 Table 3: Data from the quantitative studies included in the review

maternal depression, teratogenic risk perception and rated likelihood to terminate pregnancy as well as evaluate the possible benefits of counselling.		Mann- Whitney <i>U</i> test Spearman and Wilcoxon Simple and multiple regression analyses	(0% no risk, 100% risk) and the rated likelihood to terminate the pregnancy.	Depression: EPDS score of 13 or more independent predictor of higher personal teratogenic risk perception.
Powell, McCaffery,	<i>n</i> = 125	Questionnaires	MOS 12-Item Short-Form	The perception of the risk of asthma
Murphy, Hensley, Clifton, Giles & Gibson	Mean age: 28.3 years 12-20 weeks	administered at 1 time point	Health Survey version 1 (SF- 12v1)	medication on their unborn baby was overestimated compared to the actual risk, particularly in the case of oral
(2011)	gestation	Analysis was	Asthma Quality of Life	corticosteroids.
(Australia)	Diagnosis of	conducted using	Questionnaire-Marks	
To assess the	astnma Regular inhaled	SIAIAII	(AQLQ-M) Perceived Control	asthma were excessive and class
perception of asthma control, quality of life	asthma therapy in the past 3 months	Logistic regression	of Asthma Questionnaire (PCAQ)	dependent.
(QoL), and	or current asthma			Women significantly overestimated
perceived risks of therapy in pregnant women with asthma	symptoms		The Brief Illness Perception Questionnaire (Brief IPQ)	the teratogenic effects of oral corticosteroids (42%).
women with usunnu.			Six-Item Short-Form State Trait	
			Anxiety Inventory (STAI-6)	
			Perception of teratogenic risk: VAS from 0% (no side effects) to 100% (severe deformity to the fetus)	

Einarson, Jasper & Einarson (2005) (Canada) Objectives: 1) To determine perception of risk of antidepressant drugs by pregnant women with depression, 2) to determine the efficacy of evidence-based counselling, and 3) to identify determinants that influence women in their decision making regarding the continuation of antidepressants during pregnancy.	Pregnant or planning a pregnancy Women calling The Motherisk Program regarding the safety of their current medication: antidepressants (n=100) gastric medications (n=100) or antibiotics for a short term infection (n=100).	interview measuring risk perception of the medication before and after evidenced- based information. Student's paired t-test Wilcoxon signed ranks test ANOVA Kruskal-Wallis	Scale which measured perception of risk from zero (no risk) to 100 (risk in every case). 7-point Likert scale Center for Epidemiologic Studies Depression Scale (CES-D)	based reassuring information, 15% antidepressant users, compared to 4% using gastric drugs and 1% us antibiotics, chose to discontinue t medication.
Koren, Bologa, Long, Feldman & Shear (1989) (Canada)	<i>n</i> =80 Women calling The Motherisk Program regarding exposure	VAS administered pre- and post- counselling.	VAS: Feelings towards termination of pregnancy, 0= would terminate, 10= would not terminate.	Risk of the malformation in the general population was estimated close (5.6%) to the accurate percentage.

Risk Perception Analogue

Telephone survey and

Bonari, Koren,

n=300

Despite receiving evidencebased reassuring information, 15% of 0 ising their

To quantify women's perceptions of teratogenic risk (risk in the general population and personal risk) and to quantify tendency to terminate and to assess the impact of counselling on perception of personal risk and tendency to terminate.	n=11 exposed to a teratogenic substance n=79 exposed to non-teratogenic substance	T-test	VAS: Risk of malformation in current pregnancy: none- 100% Risk of malformation in the general population: none- 100%.	 Personal risk was estimated to be significantly higher than risk estimated to women in the general population, both before and after counselling in women exposed to teratogens and nonteratogens. Perceived teratogenic risk did not change for women exposed to agents known to be teratogenic. Single mothers showed a significantly higher tendency to terminate pregnancy before the interview when exposed to nonteratogens.
Sanz, Gómez-Lópes & Marínez-Quniatas (2001) (Spain) To access the perception of teratogenic risk of common medicines by professionals and lay people	General practitioners (n=15), gynaecologists (n=10), pre-clinical students $(n=105)$, students in their clinical training (n=150), pregnant women $(n=81)$ pon-pregnant	Measured the perceived percentage of mothers who will deliver a child with a malformation, including those exposed to a list of drugs at one point in time.	A VAS was used to measure the percentage of mothers who will deliver a child with a malformation, including those exposed to a list of drugs 0% the other marked 100%.	The perception of teratogenic risk related to medication used in pregnancy was higher than the recognised risk in all groups, for all drugs.
people.	women $(n=63)$	deviation		

Mazzotta, Magee, Maltepe, Liftshitz, Navioz & Koren (1999) (Canada) To determine the advice reported to be received by women suffering from nausea and vomiting of pregnancy from their caregivers regarding management, their teratogenic risk perception and their choice of antiemetic drug in pregnancy. A secondary objective was to determine prospectively the effect of counselling on malformation risk perception.	<i>n</i> =260 pregnant women suffering from nausea and vomiting of pregnancy under 20 weeks of pregnancy contacting Motherisk.	Prospective study questioned about use of pharmacotherapy and perception of teratogenic risk through structured telephone interviews. Analysed by correlation coefficient, Phi (ϕ), for nominal data.	Semi-structured data collection forms for demographic information, symptoms, advice received, actual use of drugs, other drug exposures, impact on emotional wellbeing, impact on social functioning. Teratogenic Risk Perception measured and categorised as: Increased risk for malformations "more likely", unchanged risk for malformations "unchanged" and decreased risk for malformations "less likely".	At the initial call, over three quarter of the 260 participants reported that therapy of NVP increased their teratogenic risk.
Nordeng, Koren & Einarson (2010) (Norway)	<i>n</i> =866 Pregnant women	Online Survey administered during 5- week period	'Beliefs about Medicines' questionnaire (Horne, Weinman & Hankins, 1999) and author developed	Most women had positive beliefs about medication, but believed pregnant women should be more restrictive regarding use than non-

To study pregnant women's beliefs about medication and factors that influence those beliefs.		<i>x</i> ² Test, Student's <i>t</i> -test	statements specifically designed for medication use during pregnancy.	pregnant women. Significant association between education, occupation and attitudes with less educated women believing that medications in general were harmful and more highly educated women being more reluctant to use medication during pregnancy.
De Santis, Straface, Cavaliere, Cinque, Carducci & Caruso (2006) (Italy) To evaluate the importance of the perception of the risk level in making the decision to end the pregnancy and the relevance that a teratology consultation can have in preventing unmotivated terminations of pregnancy.	n=350 women recruited from a hospital who had taken the decision to voluntarily terminate their pregnancy n=72 pregnant women who contacted a Teratology Information Service (TIS) wishing to terminate (voluntary abortion group, VA).	Survey administered to women who had decided to terminate their pregnancies. Studied the pregnancy outcomes, clinical, psychological and socio-economic factors of pregnant women who had contacted the TIS (VA and CG)	Author developed questionnaire to appraise the participants' teratogenic risk and to quantify and qualify the intention to terminate the pregnancy including a VAS regarding perception of risk of congential anomalies linked to the exposure and perception of risk of congenital abnormalities in the general population.	Pregnant women overestimate the risk of a congenital malformation occurring in the general population. The perceived risk associated with the exposure was ranked as considerably higher by the pregnant woman and her partner than the actual risk associated with the exposure in almost all cases. TRP was not related to pregnant women's tendencies to terminate and that 'personal choice' was associated with tendency to terminate rather than concerns regarding an exposure.

n=70 pregnant women in who

	contacted a TIS but did not declare such an intention (control group, CG).			
Damase-Michel, Christaud, Berrebi, Lacroix & Montastruc (2009) (France) To investigate pregnant women's knowledge of drugs used to treat pain and to evaluate their perception of the risk of NSAIDs during pregnancy and to check the sources of drug information that women use.	<i>n</i> =250 pregnant women in waiting for a consultation in selected maternity hospitals in Toulouse.	Standardised questionnaire administered at one time point Bivariate associations tested using x ² Test and the Fisher tests.	Author developed questionnaire – questions related to sociodemographic information, drug consumption pattern, knowledge about NSAIDs, pregnancy-related changes in drug consumption and sources of information on risk in pregnancy as well as potential risks of the drug for the fetus.	13, 10 and 6 percent of pregnant women thought that it is safe to take aspirin, ibuprofen and niflumic acid respectively on late pregnancy. 18% of the women did not know whether it was possible to take aspirin on the third trimester of pregnancy. The percentage of women who did not know was 26% for ibuprofen and 35% for niflumic acid.

Main Findings

The finding regarding how women perceive teratogenic risk were organised by TRPs in the general population, across a variety of medications and across women with concerns about exposure to a teratogen. The data were also grouped by medications to treat specific health conditions. There were other ways which the data could have been grouped, but this decision was led by the diversity of the data across the health conditions which warranted their individual discussions. Finally, data were presented in terms of intrapersonal factors associated with TRP.

Pregnant Women's Teratogenic Risk Perception (TRP)

Risk of Malformation occurring in the General Population regardless of Medication Use

It has been demonstrated in some studies that pregnant women are able to correctly estimate the risk of malformation in the general population (Koren et al., 1989; Nordeng et al., 2010 b). For example, a Norwegian study which explored the perception of risk of 17 commonly used drugs and other substances in pregnant women and mothers, 87.5% of pregnant women estimated correctly the baseline risk of a malformation occurring in pregnancy in the general population (Nordeng et al., 2010 b). Koren et al., (1989) reported that pregnant women who had contacted a Teratogen Information Service (TIS) because of concerns regarding a specific exposure were able to accurately estimate the risk of malformation in the general population. However, more recent research also employing pregnant women contacting a TIS because of concerns regarding an exposure found that these women overestimated the risk of a congenital malformation occurring in the general population (De Santis et al., 2006).

Whilst it is difficult to gauge the extent to which pregnant women are able to accurately estimate the risk of a congenital malformation in the general population, one finding that has been consistently reported is an excessively high TRP of drugs, regardless of actual teratogenicity (Nordeng et al., 2010 b; Koren et al., 1989; Sanz et al., 2001; De Santis et al., 2006; Powell et al., 2011; Mazotta et al., 1999; Bonari et al., 2005).

Estimation of Teratogenic Risk across a variety of Medications

There are two studies (Nordeng et al., 2010 b; Sanz et al., 2001) which provide data on pregnant women (not specifically selected for their concerns regarding an exposure) and their perceptions of teratogenic risk of a variety of common medications and other agents (both teratogenic and non-teratogenic). Sanz et al., (2001) measured the TRPs of pregnant women attending the regular obstetric follow-up in the out-patient clinic with a VAS (validated in Koren et al., 1989). For all of the medications, both teratogenic and non-teratogenic, with the exception of etretinate (a teratogenic drug used to treat psoriasis), the perception of risk was elevated above the actual risk stated in the scientific literature. Perhaps not surprisingly, the highest teratogenic risk (median=90%) was for thalidomide, although this is excessively higher than the actual teratogenic risk (11-35%). Other medications rated highly teratogenic included benzodiazepines (median=75%), despite the fact that benzodiazepines are considered safe when used occasionally and in low doses. Benzodiazepines were ranked higher than other known teratogenic medications including phenytoin, warfarin and etretinate.

Whilst the VAS is cited as being assessed as valid and reliable in the Koren et al., (1989) study, Sanz et al., (2001) note that it is difficult to be specific and precise on a VAS, which may make representing low percentages on the scale more difficult. This may have influenced the relatively high values of teratogenic risk reported by both pregnant and non-pregnant women.

Nordeng et al., (2010 b) recruited pregnant women or mothers with a child less than 5 years old to complete an online questionnaire (n=1793) about their TRPs of 17 drugs, foods, chemicals and radiation. Whilst the sample mixed pregnant women and mothers, it was noted that the risk perceptions between the groups were not significantly different; the results are therefore presented together. Risk perception was measured by a numeric rating scale ranging from 0 (no risk to the fetus) to 10 (fetal malformation following each exposure). Converting these scores of 0-10 to percentages enables a comparison with the estimates obtained from the Sanz et al., (2001) study. However, because the authors represented the median scores (0-10) graphically, a percentage derived from this has been put within a range of 10% as an exact score cannot be obtained. It must also be noted that Nordeng et al., (2010 b) make no reference to the validity and reliability of a numerical rating as a measure of risk perception, and therefore the results must be interpreted with caution.

Overall, the results concur with the Sanz et al., (2001) study, as the mean TRPs were above the 'true' risk described in the scientific literature for all exposures. All of the medications included in the study, excluding thalidomide, were considered 'safe' (<5% risk of congenital malformation); thalidomide was rated as highly teratogenic (median= 70-80%), comparable to the 90% observed in the Sanz et al., (2001) study. However, interestingly, antidepressants were ranked as equally teratogenic as thalidomide, and sedatives/ anxiolytics as more so, comparable to the 75% risk attributed to benzodiazepines in the Sanz et al., (2001) study. Paracetamol was ranked as less teratogenic for both the Sanz et al., (2001) (median= 10%) and Nordeng et al., (2010 b) (median=20-30%) studies, but again as excessively higher than the 'true risk'. Heartburn drugs, which are not recognised as teratogenic, were rated as the least teratogenic but were assumed to elevate the baseline risk from 5% to 15-20%. Pregnant women in the Sanz et al., (2001) study rated the teratogenic risk posed by 'general' medication at 10%, which means that pregnant women contemplating any form of medication will automatically assume that the medication will double the risk of their fetus developing a malformation.

An exception to the finding that pregnant women overestimate the teratogenic risk associated with medications has been reported in one study in relation to nonsteroid and anti-inflammatory drugs (NSAIDs) (Damase-Michel et al., 2009). The research aimed to investigate pregnant women's perceptions of the risk of NSAIDs in pregnancy and reported that more than one third of pregnant women did not know that NSAIDs are dangerous in late pregnancy. However, the measurement of risk perception in this study is limited to questions asking '*Is it is possible to take this drug on the 3rd trimester of pregnancy?*' which forces women to choose between 'yes', 'no' and 'I don't know'. Data generated from this question may greater reflect women's knowledge of other women who have used this drug during pregnancy ('*is it possible...?*') rather than quantifying how risky they perceive it to be. It is also noted that this is a French study which has been translated into English, and therefore the emphasis of the question may be slightly different in the French study and may have been lost in the translation over to English.

Estimation of Teratogenic Risk across Pregnant Women with Concerns Regarding an Exposure

Overestimation of teratogenic risk has also been observed in pregnant women contacting a TIS in the first trimester of pregnancy because of a suspected teratogen exposure. De Santis et al., (2006) measured the TRP associated with the exposure with a VAS. The research demonstrated that the perceived risk was ranked as considerably higher by the pregnant woman than the actual risk associated with the exposure in almost all cases (De Santis et al., 2006). Indeed, it has also been shown that pregnant women exposed to non-teratogenic agents contacting a TIS overestimate the teratogenicity and believe that they have a one in four chance of having a child with a major malformation, which is comparable to the risk posed by thalidomide (Koren et al., 1989). The study by Koren et al., (1989) also explored the TRPs of pregnant women who had been exposed to teratogenic agents (n=11); however, the research did not report how much the risk of malformation was elevated in this group of women, which means that it is not possible to assess the degree to which TRP is discrepant from the actual risk. Of these 11 women, 2 were exposed to valporic acid, which is commonly used as an anti-epileptic drug. However, it is now strongly recommended that women of childbearing age should not be prescribed valporic acid, owing to the associated developmental problems, manifested by decreased verbal intelligence observed in the infants exposed in utero (Ornoy, 2009). Furthermore, in both of these studies the groups of women selected for the study were women contacting a TIS because of concerns about an exposure, and therefore the TRPs ascertained across both studies are perhaps more reflective of the characteristics of the participants.

Estimation of Teratogenic Risk of Medications to Treat Conditions

Medications to Treat Nausea and Vomiting

It has been shown that the teratogenic risk ascribed to drugs to treat nausea and vomiting in pregnancy (NVP) is inflated beyond the risk described in the scientific literature. Mazzotta et al., (1999) reported that two thirds of the pregnant women suffering from NVP claimed that (safe) drugs used for NVP were more likely to increase their baby's risk for malformations, whereas approximately one percent attributed no increased risk to the fetus. However, this measurement of TRP

(categorised as either increased risk for malformations "More likely", unchanged risk for malformations "Unchanged" or decreased risk for malformations "Less likely") has not previously been demonstrated as a valid and reliable measurement of TRP. The overestimation of teratogenicity is perhaps not surprising, when one considers the historical discourse surrounding drugs to treat NVP stemming from the thalidomide disaster in the 1950-60's.

Medications to Treat Asthma

Powell et al., (2011) recruited pregnant women with asthma (*n*=125) who had been taking regular inhaled asthma therapy in the past 3 months or had current asthma symptoms from the John Hunter Hospital antenatal clinic prior to 20 weeks of gestation. Asthma medications have a generally low risk of teratogenic risks; both salbutamol (beta agonist) and inhaled corticosteroid (ICSs) are not recognised to increase teratogenic risk. Prednisolone (oral corticosteroid) does not represent a major teratogenic risk in therapeutic doses, but it does increase the risk of oral cleft by an order of 3- to 4-fold (Park-Wyllie, 2000). Women identified a greater risk associated with oral corticosteroid (42%) compared to ICS (12%) and beta-agonist (5%), but inaccurately identified a teratogenic risk associated with ICS and beta-agonist use and overestimated the magnitude of teratogenic effects for all classes of asthma drugs. The authors note that the majority of the women in this study had mild asthma in the community, but is less generalisable to those with moderate to severe asthma.

A qualitative study by Lim et al., (2012) has also demonstrated that women with intermittent to severe asthma who were pregnant or who had delivered their babies expressed concern for any medication at all use during pregnancy:

"Just the fact it was medication...I don't even take [paracetamol] when I'm pregnant" (33 years, severe persistent asthma, second trimester).

The women expressed particular concern around the use of steroids, and although could not name the specific effects of steroids, perceived them as detrimental to fetal growth and development. Despite the limited absorption and placental transfer likely to result from the inhaled route of their medications, this did not alleviate the concerns of many of the women, who continued to link adverse events with inhaled use. However, relievers (short-acting bronchodilators) were seen as completely safe to use or unavoidable; many participants did not check their safety during pregnancy. Whilst the study did have some variation in the degree of asthma severity, participants selfreported good adherence to their medication which is not likely to be representative of this population, as over one-third of women with asthma discontinue their medications during pregnancy (Sawicki et al., 2012).

Medications to Treat Depression, Gastric Conditions and Short-term Infections

TRP has also been shown to be excessively high in women who were pregnant or planning a pregnancy and were either taking antidepressants, gastric medications or antibiotics (Bonari et al., 2005). The women in the study were recruited through a TIS and had contacted the service because of a query regarding their medication. Despite the established safety of these medications, 87% of women on antidepressants and with an active diagnosis of depression rated risk of antidepressants as greater than 1-5% (malformation risk in the general population), 56% of women with gastric problems rated risk of medications as greater than 1-5% and 22% of women with infections rated the risk of medications greater than 1-5%.

Medications to Treat Epilepsy

TRP has also been explored in women with epilepsy. The treatment for epilepsy is typically a daily, long-term antiepileptic drug (AED) regimen to control seizures. Frequently, epilepsy requires continuous pharmacological treatment throughout pregnancy; AED use during pregnancy has attracted considerable attention because of teratogenicity and risk of adverse pregnancy outcomes associated with AEDs (Winterbottom, Smyth, Jacoby & Baker, 2009). In a qualitative study reported by Widnes et al., (2012), pregnant women with epilepsy expressed concerns regarding AED use and said that the risks could not be dismissed. However, all participants stated that the benefits of AEDs in controlling seizures clearly outweighed the risks. Several women appeared to have internalised the information received from their Neurologists, who had described an increased but small risk of a malformation occurring, balanced against the risk of seizures.

Intrapersonal Factors associated with TRP in Pregnant Women

Depression

It has been established that pregnant women taking medication for a variety of conditions express concern about teratogenicity and tend to overestimate adverse effects associated with the medication. Walfisch et al., (2011) demonstrated that depression is positively associated with TRP in women who were either pregnant or planning to be pregnant. The authors found that a score of 13 or more on the Edinburgh Postnatal Depression Scale was an independent predictor of TRP before counselling. However, the results are limited by their generalisability, as the researchers only recruited women who were utilising a teratogen counselling service because they either had a chronic medical condition, suspected a possible teratogenic exposure or simply because of a desire to be personally counselled by a professional in the field. However, the results do suggest that depression is a factor which is positively associated with TRP. Notably, use of antidepressants was associated with trend towards lower TRP, compared to women with depression but who were not using antidepressants. Whilst this finding did not reach statistical significance, it further implicates the potential role of active depression on TRPs (Walfisch et al., 2011).

Bonari et al., (2005) also reported on an association between depression and TRP, and showed that TRP was the highest in women taking antidepressants compared to women taking gastric medications and antibiotics, despite the fact that the all of the medications have been shown not to elevate the baseline risk of malformation. The authors reported that there were no major differences between the women in terms of self-rating of risk-taking ability, concern for the wellbeing of the baby, ability to cope with their condition without their medications agreed significantly less that all medications are harmful during pregnancy and significantly less that the potential consequences of taking their medication during pregnancy were too great to take a chance compared to women taking antidepressants.

Bonari et al., (2005) did not employ a power calculation, and therefore it is not apparent whether or not the sample size was sufficient to detect a different between the groups, or indeed what size difference the authors were interested in detecting. Moreover, the results did not enable a distinction between the responses of pregnant and non-pregnant women, which may have been an uncontrolled factor impacting on TRP. With these limitations in mind, it seems apparent that women taking antidepressants were more concerned than women on antibiotics or on gastric medication about the potential teratogenic effects of their medication.

Beliefs about Medication

Nordeng et al., (2010 a) assessed pregnant women's beliefs about medications. The study did not seek to explore TRP directly, but many of the questions allude to concerns of teratogenicity. The study, which employed an online questionnaire, showed that 43.4% of pregnant women reported 'yes' in response to the item that all medicines can be harmful for the fetus, with 29.1% disagreeing and 27.5% reporting uncertainty. The study also showed that the majority of pregnant women (87.4%) agreed with the statement that they were more cautious about using medications when they were pregnant. The majority of pregnant women (61.5%) reported agreement with the statement that even if a woman was ill and would have taken a medication if she had not been pregnant, it is better for the fetus to refrain from using medicines during pregnancy. Only 12.9% of women disagreed with this statement and 25.5% were uncertain. Whilst the study did not explore the association between beliefs and TRP directly, it can be assumed that beliefs should be considered when reviewing the factors impacting pregnant women's TRPs.

Gestation

The potential effect of weeks of pregnancy on TRP was not addressed directly by any of the studies included in the review. However, it was noted that for pregnant women with asthma, concerns surrounding the teratogenic effects of steroids used to treat asthma were most apparent in the first trimester, considered the critical period of development and growth. It is not clear from this research whether TRP of steroids reduced after the first trimester, or whether the TRP of steroids remained constant, but that concerns were alleviated as the pregnancy progressed.

Socio-demographics, Parity and Miscarriage

There are mixed findings with regards to socio-demographics and TRP. Koren et al., (1989) reported no association between TRP and age, parity and socioeconomic status, whereas Nordeng et al., (2010 b) reported that primiparity, older age and higher education level were associated with higher TRP, the latter two of which were also associated with higher TRP in the Walfisch et al., (2011) study. Moreover, qualitative analysis by Lim et al., (2012) noted that pregnant women with asthma were more cautious about using their medications during pregnancy if it was their first pregnancy. This was also observed with pregnant women with epilepsy, who reported a lower risk perception regarding possible negative effects if they had already had healthy children compared to nulliparous women (Widnes et al., 2012). With regards to a history of miscarriage, Lim et al., (2012) reported that pregnant women with asthma were more likely to be more cautious about their medication if they had a history of miscarriage.

When considering the reported associations, it is important to consider the quality of the studies and to give greater weight to findings from the more robust studies. None of the quantitative studies included a power analysis to calculate the sample size require to detect a difference of a given effect size but varied greatly in the size of their sample; Koren et al. recruited 80 participants, Walfisch et al. (2011) recruited 417 and Nordeng et al., (2010 b) recruited 1793. One potential explanation for the greater number of associations observed in the Nordeng et al., (2010 b) between TRP and socio-demographics may be owing to the larger sample size which enabled more subtle associations to be borne out that were not possible to detect with a much smaller sample size (n=80); although it is noted that an online questionnaire raises the question of whether participants are providing accurate information.

Interestingly, another Norwegian study by Nordeng et al., (2010 a) reported that women with a lower education level were more sceptical towards how physicians prescribe medication during pregnancy and agreed more often that medications did more harm than good and were addictive and poisonous; however, these women were more willing to use medication during pregnancy than those with a higher educational level. It is therefore apparent that the presence of certain beliefs does not necessarily dictate medication use. A reluctance to use medication in more highly educated women, despite a greater awareness of its benefits may be owing to a number of factors not explored in the study, such as inflated risk perceptions constructed on a number of factors other than beliefs.

Use of Medication during Pregnancy

Whether or not a woman uses a medication during pregnancy has also been shown to impact TRP. Nordeng et al., (2010 b) found that choosing not to use a drug was associated with higher TRPs amongst pregnant women and mothers. It was also shown that women who had used specific class of drugs during pregnancy rated risk of such drug use as less risky than those who had not used them. However, the authors note limitations on the external validity of the findings owing to the over-representation of more highly educated women compared to the general population. A similar association between use of medication and attitudes was reported by Nordeng et al., (2010 a) as use of penicillins was 19.7%, 9.4% and 4.8% among women who agreed, were unsure and who disagreed with the statement that it was better to use medication than to have an untreated illness during pregnancy. Therefore there appears to be a relationship between attitudes, use of medication and TRP, although this study also had an over representation of women who had completed postsecondary education.

Discussion

Overview of research findings

In reviewing the literature around the TRPs of medication in pregnant women and factors associated with these perceptions, several interesting findings have transpired. A trend emerged that pregnant women overestimate teratogenic risks associated with medication and that this is positively associated with depression, older age, high level of education and some studies have suggested a role of parity. There are mixed findings, however, as to whether pregnant women are able to accurately estimate the baseline risk for a malformation occurring in pregnancy in the general population.

Overall, it can be said that pregnant women at the very least tend to perceive teratogenic risk to be double that of what is recognised in the scientific literature. This finding is in disconnect to the finding that people generally rate their personal risk as much lower compared to the general population (Sjöberg, 2000). Inflated risk
perceptions have also been linked to volition and anticipated regret (Nordgren, Van Der Plight & Van Harreveld, 2007). It may be that pregnant women perceive that the teratogenic risks associated with medication use are generally avoidable; therefore those exposing themselves to these risks may be thought of as doing so at their own volition. It has been shown that risk estimates are raised when the risk is perceived to be voluntary because this leads to people anticipating experiencing regret (Nordgren et al., 2007); this highlights the role of emotion-specific influences on risk perception, which shall be discussed later on.

The majority of the findings in this review relate to an overestimation of TRP, generally denoted by percentage scores. It is worthwhile considering, therefore, how lay people use percentages and the potential impact of innumeracy on risk estimates. Firstly, it is noted that many people often use 50% to indicate uncertainty as to whether or not an event will occur, and that the use of an open-ended format which requires respondents to generate their own probability responses encourages this usage (Fischhoff, 1999). Many of the studies included in this review required participants to generate their own probability responses and therefore the possibility of overestimation occurring as a result of indicating uncertainty must be considered throughout. A further factor which may have affected the percentage scores generated is 'Probability neglect', which refers to probability estimates carrying very little weight when the consequences of an event carry strong affective meaning (Sunstein, 2001). For example, when considering whether or not a medication may increase the risk of a malformation, the probability of such an event occurring becomes relatively unimportant and an all or nothing mentality is evoked when the focus is on the potential negative consequence, regardless of its potentially small probability (Sunstein, 2001). Asking pregnant women to generate teratogenicity estimates may evoke strong affect and produce an all or nothing response, which may be communicated by the use of 50% to mean that it may or may not occur.

Whilst it is imperative to be aware of potential cognitive and affective processes influencing the generation of a risk estimate, there was variety in the estimates generated for different medications, which suggests that there is some form of discrimination occurring. It is curious to note commonalities in the medications rated as highly teratogenic; some of the most highly rated teratogenic medications included known teratogens and safe psychotropic medications. It is perhaps important to consider that risk is socially constructed and that responses to risk will always be influenced by societal culture and values (Nelkin, 1989); perhaps the heightened teratogenic risk associated with psychotropic medication may speak to the historical and current stigma associated with mental health problems and their treatment. It is not uncommon for individuals with mental health problems to be faced with fear and discrimination from the wider community (Komiti, Judd & Jackson, 2006); this fear may likely extend to the medication used to treat them. It is established that fear inflates risk perceptions (Sjöberg, 2000) and arises from appraisals of uncertainty (Lerner, Gonzalez, Small & Fischhoff, 2003), which may partially explain why the TRP is significantly elevated for psychotropic medication, the function and effects of which are not widely understood.

Thalidomide was consistently and accurately identified as increasing the baseline risk of a malformation, but was rated as exceeding its actual level of teratogenicity. The high risk attributed to thalidomide may be owing to some degree to the widespread public knowledge of the thalidomide disaster in the 1950-60s. The availability heuristic states that individuals make judgements about the probability of events occurring by the ease with which examples come to mind (Tversky & Kahneman, 1973). Knowledge of the thalidomide disaster continues to permeate public awareness; in 2010 the UK Government issued £20 million of compensation to victims and it was referred to as "one of the worst disasters in medical history" (Boseley, 2010). It is likely that to some degree individuals will be using this context to form the basis of their risk perceptions of medication use during pregnancy, as opposed to the less accessible scientific data.

Furthermore, 'knowledge' and 'seriousness of harm in the event of an accident or unfortunate event' are highly correlated with risk perception in the context of pharmaceuticals (Slovic, Peters, Grana, Berger & Dieck, 2007). Any internet search in relation to thalidomide produces a vast array of imagines of children with a variety of deformities. The 'seriousness of harm' associated with thalidomide is therefore likely to be extremely high, as the consequences of the drug are highly visible and emotive.

However, TRPs were overestimated for both teratogenic *and* non-teratogenic agents. Reasons for this may relate to the availability heuristic, or it may be that the

risks associated with thalidomide are generalised across to other medications down a gradient based upon perceived similarities between the two (Johnson & Tversky, 1983).

The theory around how risk perceptions are formed helps to make sense of why teratogenic risk is overestimated. It is established that risk is perceived in two central ways: one pathway relies on affect and utilises intuitive reactions to danger to guide perceptions; the other pathway calculates risk by using logic and reason and employs a 'scientific' approach (Slovic et al., 2007). Most risk analysis in day to day life employs the former approach to guide risk perceptions, as feelings provide the individual with a quick and efficient way to navigate a complex and sometimes dangerous world (Slovic et al., 2007). Individual emotions can have varying and opposing effects on risk; fear, which arises from appraisals of uncertainty, amplifies risk estimates and anger, arising from appraisals of certainty, diminishes them (Lerner et al., 2003). It is likely that pregnant women will use their emotions and intuition to guide their risk perceptions; this affect may be predominantly experienced as fear, grounded in uncertainty about the potential detrimental effects on the fetus.

Affect and preferences can also shape beliefs as uncertain outcomes that are unattractive will appear as more risky than uncertain outcomes that are attractive (Gaskell et al., 2004). In this way, risk perception can be seen as "an expression of already existing values and preferences" (p.186, Gaskell et al., 2004). The overestimation of teratogenic risk may therefore reflect the adverse reaction towards a malformation occurring in the fetus rather than the risk *per se*, which may be perpetuated by the fear of such an event occurring.

It has been demonstrated that pregnant women or women planning to become pregnant with a diagnosis of depression have higher TRPs than comparison groups. The authors suggest that women may infer that antidepressants damage the developing brain of the fetus, owing to their functioning on the central nervous system. Other potential explanations may speak to the role of depression itself, as people in negative moods are more likely to perceive the world as a threatening place and are more likely to process information systematically and carefully in order to avoid potential losses (Jorgensen, 1998). It is perhaps also worth revisiting the finding that psychotropic medication was appraised as highly teratogenic by pregnant women, potentially reflecting a societal level stigma (Corrigan, Kerr & Knudsen, 2005). The heightened TRPs amongst pregnant women with depression may represent a form of self-stigma, whereby stereotypes about mental illness and its treatment are enacted and the self is considered as devalued and different by society (Corrigan et al., 2005). On an intrapsychic level, this sense of unwanted difference may result in pregnant women with depression feeling that their baby, thought of as an extension of the mother during the first phase of pregnancy (Stainton, 1985), is at an increased risk of developing a malformation – a physical embodiment of the mother's sense of difference. In this regard, heightened TRP may be indicative of a number of factors including a general sense of heightened risk of malformation in pregnant women with depression, or an internalisation of the fear and stigma surrounding the use of antidepressants during pregnancy.

In general, the studies in the review did not explore weeks of pregnancy and TRP. Results regarding the effects of parity were mixed, although it was noted that the qualitative research revealed that primiparity and a history of miscarriage was linked with greater concern for medication use during pregnancy. It is well documented that experiences of previous pregnancy impact upon experiences of subsequent pregnancies; in particular, the experience of perinatal loss can result in a heightened sensitivity to the well-being of the baby as well as resigning oneself to the possibility of a 'bad outcome' (Côté-Arsenault & Morrison-Beedy, 2001). Moreover, anxiety has been identified as a coping mechanism in the face of previous perinatal losses (Lamb, 2002). Whilst anxiety is not necessarily a precursor to heightened TRPs, if women gauge TRP based upon affect, then it is possible that this may inflate risk perceptions.

Other findings that emerged from the review related to the role of older age and higher educational level in elevating TRP. Older age may be associated with increased teratogenic risk because of the significance of maternal age and its implications for the risk of chromosomal abnormalities. A higher level of education was positively associated with elevated TRPs, which is contrary to the literature which suggests that education does not exert a significant effect on risk perception (Sjöberg, 2000). The research also showed that women with higher TRPs were more likely to have beliefs about use of medication during pregnancy which were more in line with the medical literature than women with a lower level of education. Whist this finding is in keeping with the literature that suggests that education is a partly-independent contributor to health literacy (Paasche-Orlow & Wolf, 2007), it may seem contradictory that more highly educated pregnant women have elevated TRPs when they have more informed

beliefs about the use of medication during pregnancy. However risk perception is a construct which is formed of multiple components, of which knowledge is only one.

Use of medication during pregnancy has also been shown to affect TRP, with not consuming a medication associated with higher TRPs. One potential explanation for this effect is knowledge; individuals taking the medication may be more informed about the level of risk and therefore have lower TRPs. Those who are not taking the medication may rely more on affect than logic to guide risk perceptions, and it is known that fear appraisals often arise from uncertainty (Lerner et al., 2003). An alternative explanation considers the effect of attitudes on cognition and cognitive consistency theory suggests that people operate with a strong need for consistency among their beliefs and attitudes (Heider, 1946). It is therefore difficult for women to consume medication whilst holding the perception that it is potentially teratogenic; therefore in order to reduce this cognitive dissonance (Festinger,1957) women reappraise the medication as lower in teratogenic risk.

There are a number of other models and theories which could usefully applied to understand the role of factors other than risk perception in explaining medication use in pregnant women. These include the Theory of Planned Behaviour (Azjen, 1985) which describes the role of attitudes, subjective norms (expectations of significant others' responses to the performance of the behaviour) and perceived behavioural control in predicting behaviour.

Limitations of the Review and Implications for Future Research

Many of the studies included in the review were carried out in several different countries and a significant portion came from Motherisk, a TIS in Canada. Since risk is socially constructed (Lupton, 1999), there may be limitations in generalising conclusions to other cultures. Moreover, researchers at Motherisk used women contacting the service as their participant pool; it is likely that these self-selecting women are more anxious about use of medication in pregnancy by their very actions. Therefore future research should be aware of the extent to which the results could be generalised to other groups of pregnant women, and include pregnant women who are not accessing a TIS, which is likely to add more diverse data. Many of the studies also used a VAS to measure TRP. Whilst the VAS has been validated as an effective way of measuring TRP (Koren et al., 1989) the researchers did not specify how this validity was calculated, which is important as some methods for validating the VAS have been criticised for inflating correlations (Porter, 1999). It has also been suggested that the VAS is a highly subjective measure and therefore is more appropriately employed to measure change within individuals across time, rather than between groups (Wewers & Lowe, 1990). Future research should therefore critically evaluate the validity of the VAS in measuring TRP and consider how the VAS is appropriately utilised within this filed, as well as developing ways of measuring TRP that negate some of the difficulties inherent in the VAS, such as difficulty in being specific and precise (Sanz et al., 2001).

A further limitation of the research is that many of the studies in this review included women who were planning a pregnancy in their participant pool. This makes it difficult to assess how teratogenicity is appraised in pregnant women specifically. Furthermore, many of the studies did not compare the TRPs of different populations of pregnant women, or include a control or comparison group. Based on these limitations, future studies should incorporate control groups and control for confounding variables in order to understand how teratogenicity is appraised in different populations in order to target or tailor information to specific groups.

Defining inclusion and exclusion criteria for the studies was difficult due to the different ways of measuring TRP and whether or not it was stated as a research aim. Many of the quantitative studies used a VAS to measure TRP, but other studies explored beliefs associated with medication which included questions which alluded to concerns of teratogenicity. There were also differences in how teratogenicity was explored in the qualitative studies as one of the studies stated exploration of risk perception as research aim, whereas the other study explored experiences of pregnancy more generally, which led to the discussion of concerns about teratogenicity in some form would be included, regardless of whether or not this was initially stated as a research aim. Stricter and more defined inclusion and exclusion criteria could improve this review, although this would reduce the research base even further. The systematic collation of studies which discussed appraisals of teratogenicity of medication has enabled the identification of general trends within the literature.

The review did not employ a cut-off start date for the review and therefore included studies as far back as 1989. The decision was taken not to employ a cut-off date as the review sought to explore *perceptions* of teratogenic risk rather than how actual levels of risk associated with medications have changed with time. A further rationale for not employing a cut-off date was that the oldest paper included in the review (Koren et al., 1989) represented seminal work within this field and significantly shaped the field for subsequent researchers, many of whom have utilised the tool for measuring TRP originally validated in this research.

However, there have been considerable changes in the ways in which information is disseminated and obtained regarding teratogenicity since this pioneering research was conducted. With the widespread availability and use of the internet, women are increasingly doing their own online research (of varying quality) to inform themselves about potential teratogenic risks. Interestingly, despite significant changes in the ways in which women can receive information about teratogenicity, this review has demonstrated that there has not been significant change in the tendency for women to over-estimate teratogenic risk in research spanning over 20 years.

Future research should increasingly consider the changing ways in which information about teratogenic risk is obtained and the impact on risk perceptions. One example of a significant change which is currently unfolding in the United States of America regards the ways in which health care providers are informed about the safety of specific medications during pregnancy. Recent changes proposed by the Food and Drug Association means that pregnancy labelling of drugs will be required to include 3 major informational parts which include a risk summary, clinical considerations and data.

Currently drugs in the United States are classified according to the potential of the drug to cause birth defects and are rated by the reliability of research and benefit to risk ratio. The categories are 'A': adequate and well-controlled studies have failed to demonstrate a risk; 'B': animal studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women; 'C'; animal studies have shown an adverse effect on the fetus and there are no adequate and wellcontrolled studies in humans, but potential benefits may warrant use; 'D': positive evidence of human fetal risk but potential benefits may warrant use and 'X': there is positive evidence of human fetal risk and risks of this medication outweigh the benefits. This system, which has been extensively criticised as being largely misunderstood in terms of the risks that they present (Feibus, 2008) will be eliminated as part of the new approach. Potentially, this new system will help healthcare providers to more clearly and accurately present information about a medication, which is likely to have implications for how teratogenic risk is perceived and represents a rich area for future research.

Overall, this review has highlighted the shortage of studies in this field, particularly studies of a qualitative nature. Future research directly investigating how pregnant women appraise the teratogenicity of medication would therefore benefit from a qualitative approach in order to provide an insight into the experiences of medication consumption during pregnancy as well as an understanding of the values that pregnant attach to medication use during pregnancy. Deconstructing the processes that underpin pregnant women's tendencies to overestimate teratogenic risk could help to shape the development of information for pregnant women, particularly those who require the continuation of medication due to a chronic health condition.

Summary and implications

Since it is not uncommon for pregnant women to be required to consume a number of medications throughout their pregnancy, understanding how women perceive teratogenic risk and the factors affecting it holds important implications for a medication adherence. This review found that women tend to overestimate teratogenic risk associated with medication and in particular rate psychotropic medication as highly teratogenic. Older age, a higher level of education and a diagnosis of depression were factors associated with higher TRPs and some studies suggested primiparity and a history of miscarriage as linked with anxiety about the use of medication. When developing information about medication taken during pregnancy for pregnant women, care should be taken to highlight the processes that underpin many women's TRP, rather than simply stating data about the risk of malformation. By directly commenting upon the tacit beliefs that pregnant women hold about taking medication during pregnancy and the tendency for women to significantly overestimate the teratogenic effects of medication, pregnant women may be better able to reflect upon the role of

affect in their perceptions and choose to adopt a more 'scientific' approach to understanding the risks.

Pregnant women with depression, or other additional risk factors for heightened TRPs, would benefit from additional support to explore and reflect upon their TRPs. Healthcare providers should be aware of how pregnant women are likely to perceive teratogenic risk associated with medication and facilitate women's thinking about what may be impacting these perceptions so that women are able to make informed decisions about their healthcare. It is important that services do not overlook the individuality of each pregnant woman and support and care should be tailored towards the specific needs of the woman. Further studies which explore TRPs in specific populations would be valuable in order to be able to target and tailor support to specific populations of pregnant women.

Conclusions

It is apparent that there is a significant discrepancy between the level of teratogenic risk associated with medication in the scientific literature and pregnant women's perceptions of teratogenic risk. The discourses around pregnancy as well as the numerous factors involved in risk perception may contribute to teratogenic risks being overestimated. Estimation of teratogenic risk was exceptionally high for psychotropic medication, which points to the construction of risk discourses surrounding medication occurring within a societal context, in which mental health problems have been feared and stigmatised.

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Part Two: Empirical Paper

Experiences of Pregnancy in Women with Epilepsy - A Phenomenological Understanding

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This paper is written in the format ready for submission to BioMed Central Pregnancy and Childbirth. Please see Appendix 2 for the guidelines for authors.

Abstract

Background: There is limited knowledge about the lived experiences of pregnancy for women with epilepsy (WWE), despite the various reproductive challenges present. This study investigated how epilepsy impacts the experience of pregnancy as well as how pregnancy may impact the experience of epilepsy. Methods: Semi-structured interviews were conducted with seven WWE who were either currently pregnant or who had delivered a baby in the past 9 months. Data were analysed using Interpretive Phenomenological Analysis. Results: Four super-ordinate themes emerged: "Am I really able to do this?"; Experiences of Care; Living with Risk and "Information is quite hard work". Many of the themes reflected the usual psychological tasks of pregnancy, but were magnified or exacerbated due to the additional challenges of epilepsy. Unique challenges included promoting the health of the fetus whilst simultaneously identifying themselves as a source of risk. Living with the risk of seizures and/or risks associated with antiepileptic drugs (AEDs) was identified and approached by a weighing up process. Women felt that health professionals did not have enough understanding about issues relating to pregnancy and epilepsy; women described occupying the contradictory position of driving of their own care whilst feeling uninformed about their health. Conclusions: Health professionals working with pregnant WWE should provide a context for discussing risk and work to not situate it within the individual. Training may help professionals to work with women in a more sensitive, informed and holistic manner which empowers women by providing them with individualised information about their condition and care.

Keywords

Pregnancy, Epilepsy, Risk, High-risk pregnancy, Qualitative

Background

Epilepsy is defined by the presence of recurrent, unprovoked seizures and every 3-4 pregnancies in 1000 occur in women with epilepsy (WWE) (Royal Society of Medicine Epilepsy Guidelines Group, 2004). For many women, their epilepsy requires continuous pharmacological treatment throughout their pregnancy (Pennell, 2005), and in the United Kingdom, approximately 1 in 200 pregnancies are exposed to antiepileptic drugs (AEDs) (Adab, 2006). The issue of AED-exposed pregnancies in women with epilepsy, amongst other issues, has attracted considerable research attention because of the potential risk of adverse pregnancy outcomes associated with the teratogenic effects of AEDs (Winterbottom, Smyth, Jacoby, & Baker, 2009).

Although the outcome of pregnancy for most WWE is normal (Winterbottom et al., 2009), change of treatment may be necessary to promote healthy development of the fetus both pre-conceptually and during pregnancy and to enable successful breastfeeding and safe childcare after (Thompson, Thomas, Solomon, Nashef, & Kendall, 2008). Guidelines emphasise the importance of pre-conception counselling and pregnancy pre-planning (National Clinical Guideline Centre, 2012) owing to the increased risk of adverse pregnancy outcomes which includes an increased risk of maternal-fetal mortality and morbidity, major congenital malformations and long-term developmental delay in the fetus for WWE on AEDs (Veiby, Daltveit, Engelsen, & Gilhus, 2009). Other concerns during pregnancy include altered seizure frequency and intensity and an increased risk of pregnancy-specific disorders such as eclampsia (Kaplan et al., 2007).

As half of all pregnancies are unplanned, it has been recommended that WWE should be offered preconception counselling throughout their reproductive years (Winterbottom et al., 2009). Unfortunately for this group of women, preconception counselling services have often not been widely available, and the lack of evidence supporting its use has been highlighted (Winterbottom et al., 2009). When an unplanned pregnancy occurs, women, regardless of any health condition, are potentially faced with a myriad of practical, emotional and financial dilemmas. For WWE, this is further complicated by the necessary consideration of how the management of their condition may have impacted on the developing fetus, which is most vulnerable to the effects of AEDs in the first 3 months (Crawford et al., 2009).

How epilepsy is experienced during pregnancy is also likely to be affected as seizures during pregnancy are very variable: some women experience a reduction in seizures, others have an increase, and for some women frequency stays the same (Chen, Chiou, Lin, & Lin, 2009). During pregnancy the body is transformed physiologically, and for WWE this transformation may be even more marked by a change in the frequency or intensity of their seizures.

In sum, epilepsy, with many of its wide ranging effects, including both physical and psychosocial, may be conceptualised as a chronic stressor (Lee, Lee, & No, 2010). Epilepsy involves a loss of consciousness, is unpredictable and is episodic; recurrent seizures may also serve as acute stressors (Lee et al., 2010). Likewise, pregnancy is an event that involves several psychological and somatic changes and it can also be a potent stressor, and involves coping with uncertainty and unpredictability (Sowden, Sage, & Cockburn, 2007).

Despite the number of challenges that WWE potentially manage during pregnancy, the personal experience of pregnancy in WWE has received little research attention. A recent review by Weckesser & Denny (2013) highlighted the dominance of research employing quantitative methods in this area, compared to the paucity of literature which has attempted to gain an insight into the experiences of women with epilepsy. Although limited, research in the experiences of pregnancy and epilepsy has described how WWE must negate the moral work of being a 'good patient' who heeds the advice of their healthcare professional while also striving to be a 'good mother' who does no harm to her unborn baby (Thompson et al., 2008). A further study focussed on how WWE perceived the risks associated with AEDs and found that women felt that the risks posed by AEDs were outweighed by the benefits and that dose adjustments during and after pregnancy increased perceived risks of teratogenicity or seizure (Widnes, Schjøtt, & Granas, 2012). This work offers an initial insight but overall relatively little is known about the personal experience of pregnancy in WWE, and how women make sense of and understand this experience. Gaining a detailed understanding is likely to be useful in developing appropriate and effective support for this group of women.

The current study used Interpretative Phenomenological Analysis (IPA) (Smith, Flower & Larkin, 2009). IPA aims to understand the meanings ascribed to experiences, and takes an interpretive as well as a phenomenological (descriptive) stance. Specifically, the current study had two specific aims:

- a) To understand how epilepsy impacts on the experience of pregnancy, labour and birth
- b) To understand how pregnancy impacts on the experience of epilepsy

Methods

Participants

Inclusion criteria were developed by the researcher and participants were eligible if they met the following criteria:

- Diagnosed with epilepsy
- Pregnant (up to 29 weeks) or had delivered their baby within the past 9 months
- Aged 18 or over
- English speaking

A cut off point was employed for number of weeks in pregnancy as it was felt that it may not be appropriate to interview women who are in the latter stages of their pregnancy and may find sitting and discussing potentially emotive topics for a prolonged period uncomfortable. Women were also recruited up to 9 months postdelivery in order to gain an insight into the experiences of later stages of pregnancy as well as labour and birth.

Measures

Qualitative, semi-structured and individual in-depth interviews were employed. In order to allow each participant to describe their experience of pregnancy, a semi-structured interview schedule was developed and used flexibly, as suggested by Smith et al. (2009). The schedule was devised by trawling the epilepsy and pregnancy literature and putting together questions which either reflected the issues highlighted in the literature or attempted to bridge the gaps in the understanding of the experiences of pregnancy in women with epilepsy. The drafted questions were then posted on an Epilepsy Action forum, from which the author did not receive any feedback. In the interview participants were asked about whether or not their pregnancy was planned and their experience of pregnancy pre-planning, the impact of epilepsy on their pregnancy and the impact of pregnancy on their experience of epilepsy. If women had more than one child, the researcher emphasised that the study was about their most recent pregnancy.

Procedure

Ethical approval was gained from a local research and ethics committee and the research and development departments of two local NHS Trusts in the North of England. Epilepsy Action also approved the study to be advertised through their website and magazine. Written, informed consent was obtained from all participants.

Two clinician pathways for recruitment were devised: either a Midwife or Epilepsy Nurse in participating NHS trusts invited women who met the inclusion criteria to participate and gave them a poster of information about the study. If these women expressed an interest in participating in the research they were given a form to provide their contact details which was passed onto the researcher. Those women who consented to be contacted by the researcher were provided with more information about the study and an interview was scheduled if the women agreed to participate.

Women were also recruited by advertising the research poster through the charity Epilepsy Action. In these instances, women who were interested in the study contacted the researcher themselves who provided more information about the study and scheduled an interview if the women agreed to participate. Participants were recruited during October 2012-April 2013. The sample was opportunistic.

Data Collection

All but one of the women, who chose to be interviewed in a café, were interviewed in their own homes for approximately one hour. The interviews were initiated with a short questionnaire where the participants were asked to provide information regarding age, weeks of gestation or age of baby, type of seizures, date of last seizure, number of years since diagnosis, type of seizure experiences during pregnancy (if any), treatment during pregnancy, whether or not the pregnancy was planned and if it was the participant's first pregnancy.

The recorded interviews were stored securely on encrypted and password protected computer hardware and destroyed after they were transcribed. Names and distinguishing features were anonymised and pseudonyms provided. Participants were given a unique identifying number and the master list was kept separate from the data.

Analysis

IPA was chosen as an appropriate methodology as it was consistent with the aim of the study, to explore in detail participants' personal experiences of pregnancy and epilepsy, and the meanings they ascribed to this. IPA is an idiographic approach, concerned with the human experience of the world in particular contexts at particular times. Small sample sizes are typical, thus enabling a detailed case by case analysis. All interviews were recorded and transcribed verbatim with identifying material removed/disguised. The data were analysed according to the principles of IPA (Smith et al., 2009). Each transcript was read several times, emerging themes were identified and those that seemed connected were grouped into related clusters. Master/subordinate themes which incorporate these clusters were then identified. A cross case analysis was undertaken in order to identify overall subordinate themes. The significance of these themes to the research questions was then assessed. An example of data analysis using an extract from one transcript is provided in Appendix 10.

Quality

Attention was paid to the validity of the findings by addressing the issues of transparency and credibility. To increase the validity of the interpretations, members of an IPA group as well as an academic supervisor were involved in the process of analysis

by examining transcripts, identifying initial themes and reviewing the thematic structure to ensure that the interpretations were grounded in the research data. IPA recognises that a participant's reality is not explored in isolation and the process is inevitably influenced by the researcher's perceptions, biases and previous experiences (Smith et al., 2009).

The interviewer (SGB) was aware that her personal experiences and preconceptions could influence the data collection and analysis. Having explored epilepsy literature in developing the interview schedule, the researcher entered into the interviews with a heightened awareness of the issues that may affect women with epilepsy during pregnancy. In addition, familial experience of a 'high-risk' pregnancy meant that the researcher had preconceptions about some of the broad issues that can affect women with 'high-risk' pregnancies which could colour interpretations of women's answers and make the researcher more likely to perceive the presence of certain issues.

Safeguards against this included a standard set of questions as well as the use of a reflexive journal throughout the study for the researcher to explore her position in relation to the research process and findings to foster awareness of researcher-bias. Transparency was addressed by providing an extensive list of quotes for each theme generated which were shared within a supervisory context. Additional supporting quotes for purported themes may be found in Appendix 11.

Results

Background information on participants

Seven women of Caucasian ethnicity consented to the interview and were interviewed. Five of the women were recruited through epilepsy nurses or midwives in the North of England and two were recruited via advertisement of the study through Epilepsy Action. Demographic and epilepsy- or pregnancy-related characteristics of the participants are presented in Table 1.

Alice, 25-30	Emma, 31-36	Naomi, 25-30	Sara, 31-36	Orla, 31-36	Eve, 37-42	Amy, 25-30	Name* and age
23 weeks	2.5 months	8.5 months	4 months	25 weeks	29 weeks	7 months	Weeks of Pregnancy Or Age of baby (months)
Unsure	Nocturnal	Focal, tonic-	Tonic-	Tonic-	Unsure	Tonic-clonic	Types of Seizures
	tonic-clonic	clonic and	clonic	clonic			experienced
		absent					
12	> 10 years	9 years	> 10	> 10	> 10	> 10 years	Time since diagnosis
months			years	years	years		
1 year 7	19 days	2 weeks	2.5 years	5 months	16-17	1 year	Time since last Seizure
months					years		
None	Tonic-	1 x tonic-clonic,	None	1 x tonic-	None	2 x tonic-	Seizures experienced
	clonic	'a few' focal		clonic		clonic	during pregnancy?
None	None	Lamotrigine	Tegretol Retard	Levitera- cetam	Keppra	Lamotrigine	Treatment
Z	Z	Y	Υ	Υ	Υ	Y	Planned?**
Y	Y	Y	Y	Y	Z	Y	First Pregnancy?**

Table 1: Demographic and epilepsy- or pregnancy-related characteristics of the participants

* Names, along with other significant identifying details, have been changed throughout this report.** Y= yes, N= no

All of the participants were cared for by a Neurologist, Obstetrician and Midwife. Five of the women also had the support of an Epilepsy Nurse whom they could contact over the phone with questions and concerns. Two of the women were not in contact with an Epilepsy Nurse as they had not had this service offered to them. Whilst the women shared many of the same disciplines involved in their care, experiences of this varied widely with the approach taken.

Five women felt that they had received 'some' information about the issues relating to epilepsy and pregnancy prior to conception or that it had been 'touched on' by their clinicians. Two of the women had stated that they had not received any information prior to becoming pregnant; these were the same two participants who did not have contact with an Epilepsy Nurse. Women were not able to clearly answer whether or not they had received 'preconception counselling'. Some said that they had received 'information' about pregnancy but that it had not been discussed particularly in depth. All of the women who were on AEDs had planned pregnancies whereas the two women who had chosen not to take AEDs had unplanned pregnancies.

Most women (n=6) did not disclose any other significant health problem; one participant reported that she also had another health condition. The pregnant women and mothers had similar views on their experiences of pregnancy and epilepsy.

Main Themes

Analysis generated eleven sub-ordinate themes which were clustered into four superordinate themes which can be seen in Figure 1.

Super-ordinate Theme 1: "Am I really able to do this?"

- a) "I'm going to be such a risk" vs "It kind of doesn't really feature"
- b) "Part of being a mother is being able to do that"
- c) "If I do have a seizure, there's no way I can give birth normally"

Super-ordinate Theme 2: Experiences of Care

- a) Epilepsy gets in the way of good care
- b) "I...needed to see her"
- c) Empowering Care vs "you have a path that you have to take"

Super-ordinate Theme 3: Living with Risk

- a) "Now...I weigh up the risks"
- b) "I'm more wary of it" vs "live your life"

Super-ordinate Theme 4: "Information is quite hard work"

- a) "It's the lack of understanding"
- b) "That was me who had to find it out"
- c) "Unanswered questions"

Figure 1: Super-ordinate themes with corresponding sub-ordinates

Super-ordinate theme one: "Am I really able to do this?"

All participants expressed having some concern during their pregnancies about how their epilepsy and/ or its treatment would affect their ability to be a mother. These concerns covered a range of issues relating to pregnancy and the post-natal period but were characterised by a fear of harming the baby or not being able to fulfil some of the 'tasks of motherhood'. During pregnancy fears of harming the baby related to direct or indirect harm to the unborn baby caused by seizures and or concerns regarding teratogenic effects of medication. Concerns in the post-natal period also related to harming the baby as a result of seizures, but in addition related to not being able to breastfeed or manage night-feeds. Despite these concerns, many of the women also expressed a strong and positive identification with becoming a mother and in some ways did not feel different for having epilepsy.

"I'm going to be such a risk"

All of the participants reflected upon the potential for their condition and/or its treatment to impact on the health of the baby and participants held many fears that epilepsy made them a risk to their baby both during pregnancy and after the baby was born:

"it [medication] stops me from having fits so it must affect the baby as well" (Orla, 255-256)

" if something happens to me it will affect me and it will affect her" (Eve, 52-53)

Fears about harming the baby seemed to be magnified after experiencing a seizure when Naomi felt unsure about how it would have impacted upon the baby:

"I had the seizure at 4 weeks it made me really scared because I I had really bad seizures I go purple and I stop breathing so I was thinking what has it done to her" (63-65)

For Naomi, these fears extended to worrying about whether or not the baby would have epilepsy as well:

"could she have epilepsy or could she have something wrong with her because I had epilepsy" (179-180)

For one participant, a seizure at 18 weeks could have been fatal for both her and her baby:

"I was driving when I had my first seizure when I was pregnant and I could have lost my baby" (Amy, 64-65)

As well as the potentially fatal consequences of seizures, Amy also had concerns about the risk of sudden unexpected death in epilepsy; this was also concern which became particularly poignant during pregnancy:

"one percent there's not it's really low percent but there is a percent and we could die in having epilepsy" (492-494) Concerns were also held about coping with the risk of seizures after the baby is born:

"...what if I drop her and I injure her or worse...I just burst out crying and I said I'm so worried if anything happens what do I do"(Amy, 458-459)

"I think I'm worried as well... if I have a seizure or if when she's born if I brought her downstairs" (Eve, 87-89)

Again, these concerns seemed to be amplified by the experience of a seizure during pregnancy, which had led one participant to question whether she was able to manage becoming a mother:

"I do feel down just like am I really able to do this" (Orla, 204-205)

For one of the participants these concerns were reinforced by policies to manage the risk presented by her epilepsy at work:

"at work I was being told you can't do this you can't do that...I was thinking oh my god I'm going to be such a risk to my baby if I'm such a risk to all of the children here" (Naomi, 199-204)

Another participant also experienced reinforcement of her own fears through other's perceptions of risk and harm, as a neighbour enquired about the risks of taking AEDs during pregnancy:

"she said...oh well will that not go to the baby? And I said well a small amount does" (Amy, 373-374)

Amy described a general sense that other people were making judgements about her as a pregnant woman and the impact of her epilepsy and its treatment on the baby's health:

"you felt kind of you know paranoid that people were talking about you and making comments about the baby's health and the impact of the medication" (352-353)

All of the women discussed their babies in terms of having an individual identity and the very nature of being pregnant and 'sharing' a body with their baby led to an anxiety about how their condition and its treatment could impact the baby:

"I was worried with the Keppra in my system how it would affect him" (Eve, 215-216)

The women tended to express a strong sense of responsibility for the pre-natal health of the baby:

"if anything happened and I missed out on a day [medication] then I'd blame me" (Eve, 349-350)

For one participant, knowing that medication taken during pregnancy would also go to the baby confirmed her decision not to take medication:

"It's not something I'm going to put into somebody else" (Emma, 77-78)

Vs "It kind of doesn't really feature"

Whilst women expressed their fears around risk of harming their babies, they also expressed joy at becoming a mother and felt that epilepsy had not overshadowed their pregnancies:

"I didn't feel like my epilepsy made me any more different than any other woman who's pregnant" (Naomi, 158-160)

Some expressed pride in having had a smooth pregnancy and or delivery:

"there were no problems due to my epilepsy and even by normal standards I had a really good pregnancy" (Sara, 373-374)

"I had a natural delivery I only had gas and air" (Amy, 443)

Others thought about their epilepsy as an additional factor to consider during pregnancy, rather than a dominant feature of it:

"pregnancy's quite a stressful time and you're concerned about any aspect of anything affecting your baby so I think epilepsy was just an additional thing to be concerned about" (Emma, 362-365)

"pregnancy is probably the same for me as it is for others erm but I've just got the risk that and the worry that something may happen in the 9 months or during birth" (Eve, 451-454)

One participant in particular expressed a much stronger identification with becoming a mother than the concerns around her epilepsy:

"Part of being a mother is being able to do that"

Most of the women had been advised about what they should avoid doing after the baby is born, such as bathing the baby alone, or had an awareness of some of the restrictions that their epilepsy may place on their ability to carry out certain tasks, such as nighttime feeds.

One participant felt that the advice that she had been given to her was so restrictive that it wasn't feasible:

"he said don't watch TV on your own, don't walk up and down the stairs with baby in your arms on your own, don't bath the baby on your own...that's impossible it's just not going to happen" (Alice, 154-156)

Some women felt concerned that their epilepsy would hold them back from being able to do things that 'mothers do'; one participant in particular had been told that she would not be allowed to breastfeed on her medication which had left her feeling upset and disappointed:

"I really shouldn't get upset about it butI kind of feel it's part of being a mother is being able to do that" (Orla, 213-214)

Orla also expressed a concern that the restrictions of her epilepsy and not being able to hold a driving licence would impact negatively on her child:

"Before being pregnant it didn't affect us so much it didn't affect that you couldn't drive and stuff that wasn't an issues but when you've got somebody else to look after" (200-203)

"I mean psychologically that's one of the things that you worry kind of about doing the best for your baby" (107-108)

Other women expressed concerns about feeding their baby, either because of the medication they were taking or because of tiredness or sleep deprivation being a trigger for a seizure:

"I always wanted to breastfeed but we were like a bit worried about night time feeds and whether or not I'd get too tired feeding at night" (Naomi, 348-349)

"I worried that the medication I take (Lamotrigine) would cause issues in breastfeeding" (Amy, 643)

"If I do have a seizure, there's no way I can give birth normally"

Some of the women discussed their concerns they had about how their epilepsy would impact upon their experience of labour and birth.

Alice expressed concern about how sleep deprivation associated with labour could serve as a trigger for her epilepsy:

"the concern for me is if it gets to the 40 hour plus bit how will I react" (Alice, 296)

Naomi reporting feeling worried that her epilepsy would hijack her experience of labour and birth by removing her consciousness:

"when I have a seizure it's like a big chunk of time has been taken away...I was worried that would happen when I had her then I would never have known"(159-164)

One participant recounted her experience of having a seizure during labour and the subsequent sense of powerlessness that she experienced:

"I wasn't in a position to be able to fight for what I wanted because I wasn't you know...conscious in enough and not vocally not enough to be able to do that so I just got taken away with what they wanted"(Emma, 252-255)

Super-ordinate theme two: Experiences of Care

All of the women discussed their experiences of care from Neurology and Maternity services when discussing their pregnancies. Whilst experience varied greatly, similar

themes were generated regarding professionals' as well as the system's response to managing a pregnancy alongside epilepsy.

Epilepsy gets in the way of good care

For some women, the experience of being pregnant and having epilepsy led healthcare professionals not directly involved in the management of it either to be unable to engage in conversations about it, or to overly focus on it as a source of risk.

For some participants, healthcare professionals who were not directly involved in the management of their epilepsy would often close down and redirect conversations relating to it. Amy experienced this after sharing with her Midwife at a check-up that she had recently had a seizure:

"I said I've had a seizure and she literally she never went into detail she said oh well you've got your specialist nurse for that" (609-611)

Eve felt that the division between who knew and understood about her epilepsy was stark and that epilepsy appeared to leave certain professionals unable to support her:

" as far as my GP and my Midwife were concerned it's another world" (5)

In contrast, Alice's experiences were that her epilepsy was overly focussed upon by her Obstetrician, despite the fact that it was being well managed by the Neurology services:

"he didn't ask me any questions relating to my pregnancy and any questions relating to the baby, the only questions he asked me were to do with epilepsy" (198-200)

This left Alice feeling frustrated and that it detracted from finding out more about her baby:

"I feel like I've missed like I should be getting something from him that every other pregnancy person's getting" (222-224) Similarly, Sara felt that her epilepsy and risks associated with it became a significant focus for healthcare professionals not involved in managing her epilepsy:

"everybody to do with epilepsy...treat me as a very low risk patient but as soon as I go to my other Doctors my epilepsy becomes a kind of high risk thing" (441-445)

"I...needed to see her"

Many of the women spoke about anxieties that they had experienced during pregnancy and the responses of healthcare professionals which had been ineffective in allaying their fears.

For Emma, being reassured that her epilepsy would not affect the baby without sufficient explanation or reference to any medical information or research did not alleviate her concerns:

"it's concerning you have a condition that can affect the baby and he just seemed to dismiss that oh you know it's not going to affect the baby you don't even need to think about it and that wasn't enough information for my liking" (319-322)

Orla felt slightly sceptical about the information that seizures would not affect the baby:

"they say it doesn't affect the baby you know...but you don't really know" (100-102)

Some of the women discussed feeling uncertain about how the baby was developing and having very little information to base this on:

"you have little doubts in your mind I can't see her I can feel her and now my tummy is growing but but that's it" (Eve, 337-339)

Managing having very little information about the health of the baby was particularly poignant for Orla after experiencing a seizure early on in her pregnancy:

"they listened to the baby's heartbeat and that was the only the only knowledge that I knew it was still alive" (168-169) Many women felt that whilst technologies such as ultrasound scans were useful in calming some of their anxieties, only the experience of seeing their baby for themselves would reassure them of the health of their baby:

"I think the scans helped but I felt that I still needed to see her and know that she was fine" (Naomi, 311-312)

Empowering care

The women described their experiences of healthcare throughout their pregnancies. Themes emerged with regards to care that was flexible and individually tailored to the needs and wishes of the women; in contrast were experiences of care whereby the preferences of the woman could not be considered or accounted for.

For Orla, having dynamic two-way conversation and being invited to take an active role rather than simply being a passive recipient of information was a refreshing and encouraging experience:

"he did ask a good question which you don't often get asked he said 'what are your concerns?"" (373-372)

Amy also valued a collaborative relationship where there was freedom for expression of preferences and flexibility to accommodate for them:

"she increased it [Lamotrigine] to by 25 miligrams and she said you can, you can, do that now at 10 weeks because the fetus, at the time, you know, is practically fully formed but I said I'd prefer to wait until 12 weeks...she understood that"(84-90)

For other women, having a shared goal with their clinician was an important aspect of feeling confident and supported in their care:

"I felt like there was a plan in place and that was the best that could be done" (Naomi, 271-272)

For Sara, positive experiences of care were associated with pacing of information and not being dictated to:

"I wasn't ever told within one appointment this is what can happen you must come off this drug or something where you're instantly told what to do without time to think about it it wasn't the case like that" (417-420) Other women described clinicians recognising and allowing expression of the emotional impact of epilepsy during pregnancy as an affirming experience:

"she was very kind of erm er supportive of me and empathetic of me and I felt really reassured by that" (Orla, 328-330)

"cried with her a couple of times and she was really supportive" (Amy, 459-460)

Vs "You have a path that you have to take"

For some of the women, the experience of being pregnant with epilepsy meant that choices became restricted and that decisions about care were made without the woman's input.

Many of the women felt that not being able to have as much choice in their care was a necessary provision for the safety of their health and their baby's. It was acknowledged, however, that having epilepsy in services that are designed to support non-disabled women removed the freedom to make decisions about their care:

"your care plan is pretty much set in stone you don't have a lot of say" (Naomi, 239-240)

Emma in particular experienced services as extremely restrictive and inflexible in relation to her epilepsy:

"and just assuming you know 'oh you've got epilepsy, this is going to happen and you can't do that no' and not really being open to discussion just 'these are the rules, we follow them and you will as well '" (80-83)

Sara described feeling disappointed and frustrated that despite having a pregnancy that had not been dominated by epilepsy she was refused the water birth that she had hoped for:

" everything had been completely fine through my pregnancy and my epilepsy really didn't come into it at all so suddenly to have my epilepsy to come up as a barrier" (460-464)

Orla also expressed her sadness and disappointment at the news that she would not be able to breastfeed on her medication:
"when you're expecting to be able to [breastfeed] because of the medication that I'm on when a choice is taken away from you" (211-212)

However, limited choice was not always experienced as a negative thing, as trust was placed in the health professionals to make the safest decisions for mother and baby:

"there was very little of my birth plan that I got to choose ... it didn't bother me too much because I just wanted to have her safely" (Naomi, 243-244)

Super-ordinate theme three: Living with Risk

All of the women interviewed linked the concept of risk with certain aspects of pregnancy whether it related to the risks associated with the direct and indirect risks posed by seizures, the teratogenic risks associated with medication or how they anticipated that their epilepsy may impact upon labour and delivery. Whilst all of the woman showed an awareness of increased risk in their pregnancies and changes in their behaviour as a result, there was also a sense of resuming normal life and not living in a totally risk-averse way.

"Now...I weigh up the risks"

For many of the women taking medication during pregnancy, the risks associated with medication was appraised by weighing it up against the risks posed by uncontrolled seizures. For Eve, taking medication presented the possible risk of a malformation, whereas not taking medication was equated with risking going into a seizure and causing certain harm to her baby:

"I'd rather take them than risk going into a fit or going into a seizure and harming her" (Eve, 376-377)

As a result, the process of weighing up risk was much more straightforward:

" it's very black and white. I take them and [I'm] lowering the risks and I don't take them and increase my risk factor"(381-383)

The sense that the risk of malformations was a much smaller risk to take was shared by many of the women after a similar weighing up process:

"am quite happy to be taking medication during pregnancy I know in an ideal world I'd rather not but I'd much rather take it than not and risk having more fits" (Orla, 301-304)

This weighing up process also occurred for women who had chosen not to use medication throughout pregnancy:

"this is a risk that I've weighed up and I'm not prepared to have all of the side effects of the medication" (Emma, 500-502)

"More wary of it"

All of the women explained that how they thought about their epilepsy had changed during pregnancy and described a heightened awareness of it, which translated into changes in their health behaviour.

For some women this meant being more attentive to taking their medication than they previously were, which was experienced as a way of controlling or reducing their risk:

"I take it every day now whereas before I was pregnant I was a bit lax with it" (Eve, 343-345)

Other women described being more aware of possible triggers to a seizure and working to control these:

"I'm not getting overtired I've sort of taken a cut back in working hours" (Orla 143-145)

For some women the experience of being pregnant had created significant changes in how they approached their epilepsy and the risks associated with it. Naomi described an overall shift from previously living her life with her epilepsy in the background to it being more in the foreground:

"I think before I was pregnant I didn't think about the risks as much like there was very little I wouldn't do because of my epilepsy"(225-226)

Vs "Live your life"

As well as describing how pregnancy had created shifts in their thinking and behaviour in relation to epilepsy, the women also described continuity with their lives before becoming pregnant and an ability to 'carry on' with life.

For Emma, epilepsy was simply another thing to think about during pregnancy, rather than a condition that defined her or her experience of pregnancy:

"it was just another thing on the list really" (368)

For Naomi it was important not to pathologise her pregnancy and there were parallels with how she approached her epilepsy in terms of it not holding her back from living her life:

"I'm not going to be one of those people who sits around all day complaining the whole time so I just kept busy doing what I was doing before" (152-154)

Eve summed up managing the balance between being aware of risks and managing them, but not compromising significantly on her approach to life:

"you kind of have to take a stand back erm but also live your life at the same time" (98-99)

Super-ordinate theme four: "Information is quite hard work"

A theme throughout the interviews was a lack of understanding amongst healthcare professionals about epilepsy and the specific issues raised with pregnancy. Women described having to be very forward in seeking out information and at times driving aspects of their own care. Despite this, many of the women shared the experience of not feeling informed themselves and information not being particularly accessible.

"It's the lack of understanding"

Many of the women felt that the issues pertaining to pregnancy and epilepsy were not well understood by most healthcare professionals.

This was particularly pertinent for Emma, who had nocturnal epilepsy and felt that epilepsy was often thought about solely in terms of waking seizures:

"I think the health professionals in general need more information about epilepsy and the different types" (601-603)

This was shared by Orla who felt that unless you were medically trained then epilepsy evaded most people:

"nobody else really knows a huge amount about it" (186-187)

For Naomi, this extended to Neurologists who did not specialise in epilepsy who she felt did not have a real depth of understanding:

"I think a lot of Neurologists don't have a lot of information about epilepsy they're just general neurologists...my other Neurologist who didn't seem to care and didn't seem to know anything about women and epilepsy and the challenges they face I couldn't really believe anything what he was saying because it would just feel like it was coming out of a textbook" (33-440)

There was the sense that pregnancy brought with it particular issues that required additional expertise:

"at the time I got pregnant I was seeing a Doctor in [location] but because you probably know Doctor [name] specialises in women with epilepsy and so the antenatal clinic said we will get you referred back" (Sara, 131-133)

Having an expert in managing the issues relating to pregnancy was also necessary for questioning the appropriateness of medications prescribed by other healthcare professionals who did not know enough about epilepsy and its treatment:

"I rang my nurse to see to make sure that it was ok to take...she said she'd spoken to Doctor[name] and I don't need to be on Vitamin K...and taking this could cause a seizure. You couldn't believe it...they don't know enough about the epilepsy or the medication I'm taking" (207-226)

"That was me who had to find it out"

Alongside feeling that most healthcare professionals did not have much understanding of epilepsy, many of the women also described being the drivers and having to take the lead on their own care.

In most instances, women had to contest with health care professionals because of a lack of understanding on their part about the care of women with epilepsy during pregnancy:

"when my folic acid ran out after 3 months I had to fight to get my folic acid because they reckoned that I didn't need it" (245-246, Eve)

Amy described a very active role in her care, co-ordinating between the Obstetrician and Neurology services and acting as the gate-keeper for her own health:

"I wanted to make sure that anything that I was taking wasn't going to make me have a seizure" (209-211)

One aspect of driving their own care involved actively seeking out information that is not freely available:

"I've always made an effort to get as much information out of the Doctors as I can" (Sara, 235-236)

Emma also described taking an active role in her care by equipping herself with information that was not provided by her Neurologist:

"researching myself using the internet looking up different things that I hadn't been given information about like from the Neurologist" (395-397)

Overall, Orla described her experience of getting information from healthcare professionals as a taxing process:

"trying to find out the information is quite hard work" (410-411)

It was felt that driving one's own care required certain characteristics, but that these characteristics generally were perceived as being quite negative:

"I think I would never have got an epilepsy nurse if I hadn't been so pushy" (452-454, Naomi)

There was also the sense that without actively fighting for what was needed the system would forget about you:

"if you're the one who is one of those very quiet people that just tells them that everything is fine you could be just signed off" (Eve, 417-419)

"Unanswered questions"

In addition to being drivers of their own care, many of the women reported themselves feeling generally uninformed about managing their condition alongside pregnancy:

"I don't feel much wiser having become pregnant you know about the epilepsy than I knew at the beginning" (Orla, 179-181)

Some women identified feeling uniformed about the effects of seizures on the baby, and Emma in particular felt that she was not provided with enough information to appraise the risks of seizures herself:

" he'd just said you know as long as you don't fall out of bed or injure yourself, injure your stomach then there's no issue with having a seizure and being pregnant...that was all the information he gave me I did think he could have had more information to give me because it didn't seem sufficient" (Emma, 313-318)

Other women identified medication as something which they did not feel they understood enough about:

"something for me was knowing about my medication and I didn't know enough about that" (Amy, 8-9)

Discussion

This small exploratory study has provided a unique insight into the lived experiences of pregnancy in women with epilepsy; a perspective which has not been readily sought out in a field dominated by medical literature. Rubin's (1984) theory of maternal identity provides a framework for thinking about adjustment to motherhood and proposes four psychological tasks of pregnancy, namely ensuring safe passage, gaining acceptance, binding in and giving oneself. The themes will be discussed within the context of the tasks of pregnancy, with a focus on how these processes may be affected in WWE.

"Am I really able to do this?"

"I'm going to be such a risk" vs "It kind of doesn't really feature"

The first task of ensuring 'safe passage' involves the pregnant woman focusing on her health and safety which then progresses to concerns for both herself and her unborn child. All of the women expressed a strong and positive identification with becoming a mother and at times diminished the extent to which epilepsy impacted upon their identities as mothers. However, worries about the health and wellbeing of the baby were a common thread running across all of the interviews. Fears about fetal abnormalities are recognised as a common source of anxiety for women during pregnancy (Schneider, 2002) and in particular for primiparous women (Melander, 2002), of which six out of seven women were. Therefore concerns about the health of the fetus are fairly typical and represent a common psychological process, but are potentially exacerbated in this group of women who may consume medication which increases their baseline risk of a malformation occurring.

Perhaps more unique to this population of women were concerns about 'being' a risk to the baby, either during pregnancy or in the post natal period. The risk discourse that surrounds pregnancy imbues pregnant women with the responsibility for the fetus' health (Lupton,1999); the expectations of mothers during pregnancy are around being a 'good mother' who protects her baby from harm (Wright, 2001). Tsing (1990) describes the rise of the commonly held discourse in the 20th century that fetuses are vulnerable and that the female body represents a source of threat; those women who were perceived to be causing harm to the fetus were held up as 'monster mothers'. Whilst societal condemnation of pregnant women who expose their fetus to risk of harm is generally targeted at women where the risk is perceived as intentional or avoidable (e.g. smoking), this stigma seemed to resonate for WWE who expressed a form of self-condemnation for exposing their fetus to any risks at all. The nature of epilepsy and its treatment left some women in a 'double bind' whereby it was felt that either using or abstaining from AEDs presented some form of risk to the fetus.

Concerns about 'being' a risk to the fetus or baby was not just something that women experienced on their own, as it was sometimes reinforced by other people or systems. The second task of pregnancy concerns gaining support and validation from those around the individual (Rubin, 1984). Whilst for the majority of women this was positive, concerns expressed by individuals or systems within the woman's social sphere could be quite damaging. Many of the women appeared to have internalised the message of risk and constructed it as an inherent aspect of themselves, rather than a hypothetical future event which is determined by a number of factors (Adelswärd and Sachs, 1998).

"Part of being a mother is being able to do that"

A further dilemma for women during pregnancy regarded formation of their maternal identity, holding in mind the restrictions that their epilepsy and its treatment placed on their ability to complete tasks typically associated with motherhood, such as breastfeeding. Rubin (1967) described one of the processes underlying maternal role attainment as including fantasising about oneself as mother and Mercer (1995) described 'competency testing' of self in the new role as a strategy that women may employ when faced with the unknown reality of becoming a mother. Forming an idea about oneself as a mother was a common theme across the participants; for some of the women this was accompanied by difficult feelings because of the discrepancy between the fantasy of motherhood and the reality of how they felt they measured up to this ideal.

"If I do have a seizure, there's no way I can give birth normally"

Anxiety about labour and delivery was another area of concern for the women in this study. Generally, this related specifically to the fear of a seizure, which was assumed to complicate the delivery and diminish the mother's ability to give birth naturally. The association between epilepsy and external health locus of control (the notion that one's health outcome is under the control of powerful others such as health professionals or is determined by fate, luck or chance) has been noted in the epilepsy literature (e.g. Asadi-Pooya, Schilling, Glosser, Tracy & Sperling, 2007) and may serve to perpetuate women's anxieties about birth if it is perceived that the likelihood of a seizure occurring is outside of the individual's control. Loss of consciousness that can occur during a seizure was also discussed as a fear, in the sense that epilepsy would 'hijack' the experience of birth. Again, this fear was very much linked with being out of control and essentially at the mercy of a potential seizure. The need for women to feel in control and to have choice in their labour is something that has been reported widely across the pregnancy literature (e.g. Gibbins & Thomson, 2001; Dahlen, Barclay & Homer, 2010) and may represent a universal need in women that is particularly threatened in WWE.

Fears associated with the actual birth of the baby is one of the most common fears during pregnancy (Melender & Lauri, 1999) and primiparous women (predominately this sample) have been found to experience more fear than multiparous women (Bernazzani, Saucier, David & Borgeat, 1997). It has been shown, however, that women with epilepsy experience a significantly higher rate of fear of childbirth when compared with healthy controls (Turner, Piazzini, Franza, Canger, Canevini & Marconi, 2008). This fear, however, was shown to relate more specifically to fear of offspring malformations rather than labour pain, which suggests that the fear is due to epilepsy rather than pregnancy and labour factors (Turner et al., 2008).

Experiences of Care

"I...needed to see her"

In keeping with the fear around potential malformations, it was noted that many of the women did not feel reassured by health professionals about their concerns and had to manage living with the uncertainty until they could be with their baby. Rubin (1984) described 'binding in' as one of the tasks of pregnancy whereby the mother invests not only in the idea of a baby, but in this particular baby. This process may have occurred in the women interviewed, whereby as their emotional connection with the baby grew so did the need for reassurance regarding the health of the baby. High-risk pregnancy is associated with psychological distress and an increased level of uncertainty regarding the pregnancy and its outcomes (Gray, 2001) and therefore women with epilepsy may be less effectively reassured about the health of their baby than women with low risk pregnancies.

Epilepsy gets in the way of good care

Within a health care discourse, pregnant women are considered at risk and in need of medical supervision and monitoring (Reissman, 2003). If an unpredictable outcome happens, it can be perceived as a failure of the health care providers

(Crawford, 2004). Within this study, how epilepsy and its associated risks were constructed varied significantly amongst professionals not embedded within Neurology services. A common theme was that epilepsy was perceived as a tricky and anxiety provoking area which meant some health professionals discarded it as an area that fell outside of the perimeter of their expertise, a tactic that is used by healthcare professionals when they feel that they have no way of offering assistance (Sugg, Thompson, Thompson, Maiuro & Rivara, 1999). Other professionals approached the topic of epilepsy by giving it undue focus, which led some women to speculate on the extent to which fear of litigation coloured their actions. Adelswärd and Sachs (1998) describe how risk in health care is often constructed as existing within the individual and is given "as a diagnosis, something that a patient has and suffers from. Risk then becomes what has to be treated" (p.200). The authors note how risk poses a dilemma for professionals; to talk about risks may exacerbate tensions concerning risk, yet avoiding talking about risk may also lead to anxiety.

Empowering Care vs "you have a path that you have to take"

Empowerment in health care has been described as mutual participation, knowledge acquisition, equal partnership (Ellis-Stoll & Popkess-Vawter, 1998) and mutual decision-making regarding health issues and goals (Rodwell, 1996). For some women, choice and collaboration resulted in a positive experience of care, and more negative experiences were defined by restrictions in choice and being dictated to about one's own care. However, some women seemed satisfied to take a less active role in decision-making and to put their trust in health professionals. It has been recognised that in high-risk pregnancies there can be a preference for the health professionals to make decisions about care, which is felt to be due to the increased concern that women with high-risk pregnancies perceive for their infants and themselves (Harrison, Kushner, Benzies, Rempel & Kimak, 2003). Satisfaction with care in pregnant WWE may therefore depend somewhat on the congruence between individual preference for either active or passive decision making and her experience (Harrison et al., 2003).

"It's the lack of understanding"

In order to complete the task of 'safe passage' Rubin (1984) postulates that women become informed by accruing information including written literature, advice and reassurance from health professionals. A shared experience was that epilepsy was not generally well understood and that little discrimination between the epilepsies occurred. Several women described critically evaluating information received from health professionals, a phenomenon supported by the increased access of lay people to professional and institutional knowledge (Sarangi & Clarke, 2002). As increasingly informed consumers of health care, the combination of quasi-professional knowledge alongside experience occasionally elevated the women to expert status. However, occupying the expert role was not described as desirable, potentially because women with higher risk pregnancies have been shown to prefer to place their trust within health professionals and show a readiness to accept medical authority (Harrison et al., 2003).

"That was me who had to find it out"

As well as occasionally occupying an expert role in relation to their own health and care, women were also often forced to be the drivers of it in the form of actively seeking information and questioning professionals' actions. The act of pursuing aspects of one's care was generally described in relatively aggressive terms, suggesting an awareness of the pervasive ideas that non-compliance is associated with deviance and that the reciprocal role of a patient is to comply with treatment (Playle & Keeley, 1998).

"Unanswered questions"

Lack of access to information that is tailored to the individual woman was also a common experience, and does not represent just a recent issue for disabled women (Becker, Stuifbergen & Tinkle, 1997; Lipson & Rogers, 2000; Walsh-Gallagher,Sinclair & Mc Conkey, 2012). In this regard, women were expected to occupy the contradictory position of driving their care whilst being uninformed about their health. It has been shown that pregnant women need information to help them to feel confident about understanding their pregnancy (Luyben & Fleming, 2005). Therefore access to information during pregnancy is required for empowering women and underpins a psychological process. This need may be greater in pregnant WWE as they attempt to understand not only about their pregnancy but also how their pregnancy may be affected by epilepsy, as well as how epilepsy may be affected by pregnancy.

Living with Risk

"Now...I weigh up the risks"

Women's expectations of pregnancy risk are closely aligned with those of their care providers (Seale, 1996). The women on AEDs described their heightened risks of fetal abnormalities but balanced this against the risk of uncontrolled seizures, which represents the same process of weighing up risks as reported by Widnes et al., (2012). As also found in the Widnes et al. (2012) study, women appeared to have internalised messages that they had received from their Neurologist, whom they perceived as trustworthy and an expert in the field. These women's readiness to comply with advice on medication may be in part explained by the notion that if a woman believes herself to be at greater risk in pregnancy, then the tendency is to see the health care provider as an authority for direction to reduce perceived risks. Interestingly, the two women who chose not to use medication throughout their pregnancies were the most sceptical about use of the term 'high-risk' to describe their pregnancies.

"I'm more wary of it" vs "live your life"

As the final task, Rubin (1984) describes the sacrifices that a woman makes during pregnancy as 'giving of oneself'. Women generally described being more aware of their epilepsy during their pregnancy and making changes in their behaviour and/or lifestyle in order to promote the health of the fetus. The Health Belief Model (Rosenstock, 1966) can be used as a framework for understanding changes in women's health behaviour as a result of pregnancy. Generally this model is used to consider the impact of threat on the individual's health, but can be extended to considering threats in terms of the impact on the fetus. The model states that perception of a health behaviour threat is influenced by general health values (e.g. concern about health of fetus), beliefs about vulnerability to a health threat (a seizure may cause direct or indirect harm to the fetus) and beliefs about the consequences of a health problem. Once the threat is perceived the individual is cued to action and is more likely to undertake a recommended preventive health action (e.g. greater adherence to medication). The task of 'giving oneself' may therefore be exaggerated in women with epilepsy who may reevaluate the approach taken to the management of epilepsy in order to promote the health of the baby.

Alongside being flexible to reorganise oneself in relation to the world, a further competing challenge of pregnancy is to maintain equilibrium in the existing self and family system (Rubin, 1984). This was reflected in women's accounts of maintaining some of their approaches to living life with epilepsy prior to becoming pregnant. Some women also showed a resistance to conceptualise their pregnancy as a problem which required medical intervention, despite pregnancy and birth increasingly being defined within medical domains (Conrad, 1992).

With regards to pregnancy planning and preconception care, there was variation in what care and information women had received prior to and during their pregnancies. Some of the women reported receiving this information prior to pregnancy, but the depth of this information was unclear, as was whether this would be classified as 'preconception counselling' as recommended by NICE (2012). Whilst some women did not report receiving information prior to conceiving, all of the women who were using AEDs had planned pregnancies. This potentially suggests that the women in this study were taking a more cautious approach to pregnancy and had some awareness of the need for pregnancy pre-planning, but did not readily associate knowledge with information provided by services. Rather, women recounted being aware that they needed to contact the relevant services if they were planning to become pregnant rather than having a particular knowledge about the issues in pregnancy.

Whilst one possibility is that the information was not made available, another possibility is that this information was provided, but that timing is a factor in terms of what information was taken in and retained. Petty & Cacioppo's (1986) Elaboration Likelihood Model provides a way of thinking about how health information is processed and describes how people are more likely to thoughtfully process information if they perceive it to be relevant. The authors describe that individuals process information via the 'central' or 'peripheral' route; when a message is processed peripherally the message is not considered thoughtfully and occurs when the individual has little interest in the message. By contrast, central processing occurs when there is motivation and ability to think about a topic and involves the individual listening to and evaluating the content of a message (Petty & Cacioppo, 1986). Therefore if women were presented with pregnancy specific information prior to contemplating pregnancy then it is likely that they will not have actively processed and retained much of the pregnancy information. This model may partly explain why some of the women were

not able to recall many of the key messages that they had been presented with prior to conception about the issues relating to pregnancy and epilepsy.

Strengths and Limitations

The sample size in this exploratory interview study is relatively small, however, the indepth material generated offers important insight into women's experiences. Participants varied in the type and frequency of seizures, how long they had been diagnosed with epilepsy as well as duration of time since their last seizure and whether or not they used AEDs throughout their pregnancies. One of the women had nocturnal epilepsy which meant that her seizures only occurred during sleep and another had another health condition. Variation in these factors are likely to have had implications for the experiences of pregnancy and epilepsy it might have been important to distinguish more between participants in terms of these factors.

Whilst some homogeneity is important in IPA (Smith & Osborn, 2003) it is known that people with epilepsy are more likely to have comorbid physical or mental health problems (Strine et al., 2005). Moreover, there are more than 40 different types of seizures and that a person may have more than one type ("Epilepsy facts, figures and terminology", 2013). Therefore selecting a sample which controlled for all of these factors may prove problematic and may not accurately represent the diversity that exists within this population. Moreover, controlling for these factors would have required a larger sample size than recruited here in order to make comparisons. The research also included women who had delivered their babies within the past 9 months and therefore included retrospective accounts of pregnancy which may have made for less accurate accounts. However, IPA would suggest that no one 'true' version of reality exists (Smith & Osborn, 2003) and therefore would not necessarily consider this problematic. The sample did not include women of diverse ethnicity and including women with different ethnicity could enrich the sample.

A limitation of the study is that it represents the reviews of a self-selecting sample of Caucasian women predominately primiparous women, none of whom reported a previous history of miscarriage or the presence of a malformation in the fetus. However, the lack of diversity within the participants may have been a strength in the relatively small sample size. A further limitation is that women who were over 29 weeks of pregnancy were excluded from the study and no women participated who were currently pregnant were in the first trimester; therefore these stages of pregnancy were only discussed in retrospect.

The researcher did not receive any feedback on the draft interview questions posted on the Epilepsy Action forum. This may have reflected the fact that the questions did not generate a particularly strong reaction from people within the forum which meant that they did not feel motivated or obliged to contact the researcher. Alternatively, it may have been felt that the research area and or questions were not of particular relevance to individuals within the forum, or indeed that the forum itself was not particularly active. For future research, face to face contact with women with epilepsy or who are pregnant may provide a better avenue for gaining feedback on the appropriateness and usefulness of the research questions.

Implications for Clinical Practice and Future Research

The study highlights how epilepsy can impact a woman's perception of herself as a mother, particularly in terms of risk. It is important therefore, when discussing risk with women, that it is not situated within the individual, but rather discussed in terms of a potential future event. Clinicians should not dismiss elevated risks that women and their unborn babies are exposed to, but should provide a context for thinking about the risk in terms of the risks that we may all encounter on a daily basis (e.g. travelling by car). In this way, clinicians can work with women to support them to reduce potential risks without reinforcing the identification with 'being' the risk and provide a context to appraise potential risks.

It may also be of benefit for clinicians to recognise the limitations that epilepsy can place on women's ability to manage certain tasks associated with motherhood (such as breastfeeding) and the associated emotional impact on women and their identities as mothers. Clinicians should give women the opportunity to explore some of their feelings in relation to the potential loss of some of these ideals and should work with women to support them to feel confident in their journey into motherhood. When giving advice about what tasks should be avoided or approached in a different way it is essential that the woman's individual circumstances are understood so that advice given can be practically applied. Further training about epilepsy and the specific issues that are raised in pregnancy may be useful for health professionals working with pregnant women with epilepsy who do not have specific expertise in epilepsy. Further training may create a number of benefits; namely it may reduce the burden on pregnant women to critically evaluate the actions of those who are not 'in the know' about epilepsy because of greater competency; it may help clinicians to discriminate between the different types of epilepsy and equip them to have a more informed understanding of risk that is based upon the individual and not simply generated from a diagnosis and label of high-risk; finally, it may enable health professionals to engage to some degree in conversations about epilepsy and pregnancy without immediately redirecting the mother to her Neurologist or Epilepsy Nurse. As a result, women are more likely to experience more holistic and individually tailored care as health professionals will have more of a rudimentary understanding about epilepsy and its treatment.

Information needs to be readily available and accessible to women through a number of sources. This study also highlighted the need for individually tailored advice and it was noted that women who had more positive experiences of care tended to have contact with an Epilepsy Nurse. Epilepsy Nurses can provide accessible, expert information on the issues relating to pregnancy and epilepsy in a way that is tailored to the individual and can work in a joined up manner with Neurologists as well as Maternity or Obstetric services when required.

With regards to pregnancy pre-planning and pregnancy care, some women recalled being given information, whereas others reported not knowing that preconception counselling was available or recommended for WWE. Therefore information about pregnancy and pregnancy preplanning needs to be more widely available to women than was found in this study. Timing needs to be a consideration in terms of what information will be attended to and retained if it is felt to be of little personal relevance. Clinicians should seek to work in a collaborative manner with women about issues relating to preconception care and pregnancy. Health professionals should be aware that information presented may not be retained over time and so should discuss this information with women on a number of occasions.

Given the added concerns that WWE have about their risks in pregnancy and the fact that WWE are only 37% as likely to have a pregnancy compared to controls

(Schupf & Ottman, 1994), future research could explore the decision to have children in WWE. Equally, an insight into lived experiences of WWE in the postpartum period may be important to facilitate an understanding of how WWE can be supported during this period, particularly in view of the fact that WWE experience higher rates of postpartum depression than the general population (Galanti et al., 2009).

Conclusion

This study explores pregnancy in WWE and provides a valuable insight into the lived experiences of these women whose pregnancy is labelled by health professionals as 'high-risk'. The analysis describes how the presence of epilepsy can exacerbate or magnify some of the common psychological tasks of pregnancy, as well as presenting unique challenges. Whilst there was significant variation in the women's experiences, several themes reoccurred which suggested that there is some universality in the challenges that epilepsy can present both to the mother and the system caring for her. Strategies are suggested for improving the care of this group of women whose needs are not adequately described or accounted for within the label 'high-risk'.

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Part three: Appendices

Appendix 1: Journal Choice

I chose to submit A Systematic Literature Review into the Perception of Teratogenic Risk associated with Medication in Pregnant Women and Intrapersonal Factors Associated with these Perceptions and Experiences of Pregnancy in Women with Epilepsy- A Phenomenological Understanding to the BioMed Central Pregnancy and Childbirth journal. I felt that the paper is clinically relevant to a number of professionals working in health care with pregnant women. The journal accepts papers that cover any aspect of pregnancy and childbirth and had an impact factor of 2.83

Appendix 2: Guidelines for Authors for the Systematic Literature Review and Empirical Report

Instructions for authors

Criteria

Research articles should report on original primary research, but may report on systematic reviews of published research provided they adhere to the appropriate reporting guidelines which are detailed in <u>'About this journal'</u>.

Submission Process

Manuscripts must be submitted by one of the authors of the manuscript, and should not be submitted by anyone on their behalf. The submitting author takes responsibility for the article during submission and peer review.

Files can be submitted as a batch, or one by one. The submission process can be interrupted at any time; when users return to the site, they can carry on where they left off.

During submission you will be asked to provide a cover letter. Use this to explain why your manuscript should be published in the journal, to elaborate on any issues relating to our editorial policies in the <u>'About BMC Pregnancy and Childbirth'</u> page, and to declare any potential competing interests. You will be also asked to provide the contact details (including email addresses) of potential peer reviewers for your manuscript. These should be experts in their field, who will be able to provide an objective assessment of the manuscript. Any suggested peer reviewers should not have published with any of the authors of the manuscript within the past five years, should not be current collaborators, and should not be members of the same research institution. Suggested reviewers will be considered alongside potential reviewers recommended by the Editorial team, Editorial Advisors, Section Editors and Associate Editors.

Overview of manuscript sections for Research articles

Manuscripts for Research articles submitted to *BMC Pregnancy and Childbirth* should be divided into the following sections (in this order):

Title page

The title page should:

• provide the title of the article

- list the full names, institutional addresses and email addresses for all authors
- indicate the corresponding author

Please note:

- the title should include the study design, for example "A versus B in the treatment of C: a randomized controlled trial X is a risk factor for Y: a case control study"
- abbreviations within the title should be avoided

Abstract

The Abstract of the manuscript should not exceed 350 words and must be structured into separate sections: **Background**, the context and purpose of the study; **Methods**, how the study was performed and statistical tests used; **Results**, the main findings; **Conclusions**, brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract. **Trial registration**, if your research article reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number (e.g. **Trial registration**: Current Controlled Trials ISRCTN73824458). Please note that there should be no space between the letters and numbers of your trial registration number. We recommend manuscripts that report randomized controlled trials follow the <u>CONSORT extension for abstracts</u>.

Keywords

Three to ten keywords representing the main content of the article.

Background

The Background section should be written in a way that is accessible to researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where appropriate, include a summary of a search of the literature to indicate why this study was necessary and what it aimed to contribute to the field. The section should end with a brief statement of what is being reported in the article.

Methods

The methods section should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses in the Methods section.

For studies involving human participants a statement detailing ethical approval and consent should be included in the methods section. For further details of the journal's editorial policies and ethical guidelines see 'About this journal'.

For further details of the journal's data-release policy, see the policy section in <u>'About</u> this journal'.

Results and discussion

The Results and discussion may be combined into a single section or presented separately. Results of statistical analysis should include, where appropriate, relative and absolute risks or risk reductions, and confidence intervals. The Results and discussion sections may also be broken into subsections with short, informative headings.

Conclusions

This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.

List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations can be provided, which should precede the competing interests and authors' contributions.

Competing interests

A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organizations. Authors must disclose any financial competing interests; they should also reveal any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript.

Authors are required to complete a declaration of competing interests. All competing interests that are declared will be listed at the end of published articles. Where an author gives no competing interests, the listing will read 'The author(s) declare that they have no competing interests'.

When completing your declaration, please consider the following questions:

Financial competing interests

• In the past five years have you received reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? Is such an organization financing this manuscript (including the article-processing charge)? If so, please specify.

- Do you hold any stocks or shares in an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? If so, please specify.
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Non-financial competing interests

Are there any non-financial competing interests (political, personal, religious, ideological, academic, intellectual, commercial or any other) to declare in relation to this manuscript? If so, please specify.

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In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section.

An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study. To qualify as an author one should 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; and 3) have given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

We suggest the following kind of format (please use initials to refer to each author's contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a

person who provided purely technical help, writing assistance, or a department chair who provided only general support.

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You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies, or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

Acknowledgements

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The role of a scientific (medical) writer must be included in the acknowledgements section, including their source(s) of funding. We suggest wording such as 'We thank Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd.

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Endnotes

Endnotes should be designated within the text using a superscript lowercase letter and all notes (along with their corresponding letter) should be included in the Endnotes section. Please format this section in a paragraph rather than a list.

References¹

All references, including URLs, must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends¹. Each reference must have an individual reference number. Please avoid excessive referencing. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission.

Only articles, datasets, clinical trial registration records and abstracts that have been published or are in press, or are available through public e-print/preprint servers, may be cited; unpublished abstracts, unpublished data and personal communications should not be included in the reference list, but may be included in the text and referred to as "unpublished observations" or "personal communications" giving the names of the involved researchers. Obtaining permission to quote personal communications and unpublished data from the cited colleagues is the responsibility of the author. Footnotes are not allowed, but endnotes are permitted. Journal abbreviations follow Index Medicus/MEDLINE. Citations in the reference list should include all named authors, up to the first 30 before adding '*et al.*'.

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Illustrations should be provided as separate files, not embedded in the text file. Each figure should include a single illustration and should fit on a single page in portrait format. If a figure consists of separate parts, it is important that a single composite illustration file be submitted which contains all parts of the figure. There is no charge for the use of color figures.

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Each table should be numbered and cited in sequence using Arabic numerals (i.e. Table 1, 2, 3 etc.). Tables should also have a title (above the table) that summarizes the whole table; it should be no longer than 15 words. Detailed legends may then follow, but they should be concise. Tables should always be cited in text in consecutive numerical order.

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Abbreviations

Abbreviations should be used as sparingly as possible. They should be defined when first used and a list of abbreviations can be provided following the main manuscript text.

Typography

- Please use double line spacing.
- Type the text unjustified, without hyphenating words at line breaks.
- Use hard returns only to end headings and paragraphs, not to rearrange lines.
- Capitalize only the first word, and proper nouns, in the title.

- All pages should be numbered.
- Use the BMC Pregnancy and Childbirth reference format.
- Footnotes are not allowed, but endnotes are permitted.
- Please do not format the text in multiple columns.
- Greek and other special characters may be included. If you are unable to reproduce a particular special character, please type out the name of the symbol in full. Please ensure that all special characters used are embedded in the text, otherwise they will be lost during conversion to PDF.

Appendix 3: Population and Background Rationale

The reviewer chose to focus on pregnant women, rather than women planning to become pregnant or women who have delivered their babies because it was felt that the very experience of being pregnant may intensify, or bring into awareness, the conflict between the discourse that mothers should protect their unborn child from any risks and being faced with the reality of a condition or symptom that requires treatment. The review focused on 'medication' because data from the united States suggests that pregnant women receive an average of 3 to 5 drug prescriptions and that 64% of pregnant women use at least 1 prescription drug (Andrade et al., 2004). The review also focussed on 'intrapersonal' factors associated with TRP as it was felt that there would be too much variety by including all exposures and factors, and that the results would be more useful in terms of their implications for health care providers by limiting the focus to medication.

Pregnant women (any stage of pregnancy) are the population of interest in this review. This includes pregnant women who may or may not use or have used medication (prescription and over the counter) during pregnancy (both teratogenic and non-teratogenic). Some studies include pregnant women and non-pregnant women in their results; these findings were included but it was specified that the sample included is not entirely representative of the population in question. Equally, some studies included teratogenic risk perception in relation to drugs not used as medication (e.g. nicotine). In these instances, the reviewer only included the findings relevant to the question and highlighted the finding as a mixed result when separation from other non-medicinal substances was not possible.

References

Andrade, S., Gurwitz, J., Davis, R., Chan, K., Finkelstein, J., Fortman, K. & Platt, R. (2004). Prescription drug use in pregnancy. *American Journal of Obstetrics and Gynecology*, *191*, (2), 398–407.

Appendix 4: Search Strategy and Inclusion Criteria

The author sought to explore how the teratogenic risk associated with medication is perceived in pregnant women and the intrapersonal factors associated with these perceptions. The researcher systematically and critically evaluated the results produced by the search terms and included research articles which stated the exploration of teratogenic risk as a specific aim, but also included studies which explored teratogenic risk perceptions within the results section but did not specifically state it as a research aim. The researcher is aware that there may be other papers which discuss concerns about medication consumption during pregnancy as part of their results section which have not been captured within the specified search terms. However, it was felt that attempting to include these papers which may have not been captured by these search terms would require extensive scouring of the health and pregnancy literature, which was felt may dilute the focus of the review.
Appendix 5: Data Extraction Sheet

Study Title

Authors

Year of Publication

Reference and Country of Origin

Study Characteristics:

- Research question/aims
- Quality Scores

Concept Deconstruction:

- Is exploration of 'teratogenic risk perception' or 'risk perception' of medication or drugs stated as a research aim?
- Are the concepts of 'risk perception' and 'teratogenicity' or potential harm to the fetus linked in the introduction or just discussed in the results?

Study design:

- Qualitative or Quantitative

Participant Characteristics:

- Number of women
- Ages of women
- Pregnant? Weeks of gestation
- If participants are not pregnant are they planning a pregnancy or have they previously been pregnant?
- Is it stated whether participants have used any medication during pregnancy?
- Is it stated whether the participants have been exposed to a medicinal teratogenic substance during pregnancy?
- Ethnicity
- Geographical Region
- Diagnoses?
- Other significant demographic variables

Participant Recruitment:

- Recruitment methods
- Inclusion criteria
- Exclusion criteria
- Participation rate:

Procedure:

Details of Data Collected:

- What was measured?
- Which outcome measures were used?
- Is the validity and reliability of the measure of teratogenic risk perception stated or referred to?
- Number of times data collected

Results and Analysis:

- Analysis method
- Theoretical perspective (qualitative only)
- Statistical tests (quantitative only)
- Main findings
- Do the results enable a distinction between the risk perceptions of pregnant women who have been exposed to a substance versus those who have not?
- Is the actual risk of malformation of the medication included in the study stated?

Conclusions

- Interpretation of results
- Limitations
- Key links to theory/literature
- Implications
- Further research

Notes/ comments:

Appendix 6: Quality Checklist for Qualitative Studies

Qualitative Research Quality Checklist

Paper title:	
Author (s):	
Date:	Journal:

Quality Assessment Questions

Quality Rating

Yes= 1; No= 0; U/D= unable to determine; P*=partially

Research Design

1. Are the study's purpose and research aims clearly stated?

2. Are qualitative methods of inquiry are appropriate for the study aims? (*The research sought to understand, illuminate, or explain the subjective experience or views of those being researched in a defined context or setting.*)

3. Do the authors discuss why they decided to use qualitative methods?

4. Are underpinning values and assumptions discussed?

Ethical Approval

5. Is ethical approval reported?

Sampling

6. Is participant selection clearly described and appropriate?

7. Is the sample size discussed and justified?

8. Is an inclusion and exclusion criteria stated?

9. Is the sample representative to the population being assessed?

Data Collection

10. Are data collection methods clearly described and justified?

11. Are the methods appropriate given the study aims and research questions?

Data Analysis

12. Is the analytic process clearly described?

13. Is the data analysis appropriate to the data collected?

14. Did the study include triangulation (namely, comparison of different sources of data re: the same issue)?

15. Were study findings generated by more than one analyst?

Findings/ Results

16. Is there a clear statement of findings?

17. Are the study findings discussed in terms of their relation to the research questions posed?

18. Is sufficient data presented to support findings?

19. Are potential researcher biases taken into account?

20. Are conclusions explicitly linked with exhibits of data?

Research Value

21. Did the authors identify new research areas?

22. Did the authors discuss how the research findings could be used for and what populations?

Quality Assessment Questions	Studies			
	Lim, Stewart, Abramson, Ryan & George (2012)	Widnes, Schjøtt & Granas (2012)		
Author (Independent rater) scores: Yes= 1; No= 0; U/D= unable to determine; P*= partially				
1. Are the study's purpose and research aims clearly stated?	1	1		
2. Are qualitative methods of inquiry are appropriate for the study aims?	1	1		
3. Do the authors discuss why they decided to use qualitative methods?	0	1		
5. Is ethical approval reported?	1	1		
6. Is participant selection clearly described and appropriate?	1	1		
7. Is the sample size discussed and justified?	0	1		
8. Is an inclusion and exclusion criteria stated?	1	1		
9. Is the sample representative to the population being assessed?	U/D	U/D		
10. Are data collection methods clearly described and justified?	1	1		
11. Are the methods appropriate given the study aims and research questions?	1	1		

Appendix 7: Quality Scores for Qualitative Studies

12. Is the analytic process clearly described?	0	1
13. Is the data analysis appropriate to the data collected?	1	1
14. Did the study include triangulation?	0	0
15. Were study findings generated by more than one analyst?	1	1
16. Is there a clear statement of findings?	1	1
17. Are the study findings discussed in terms of their relation to the research questions posed?	0	1
18. Is sufficient data presented to support findings?	1	1
19. Are potential researcher biases taken into account?	0	1
20. Are conclusions explicitly linked with exhibits of data?	1	1
21. Did the authors identify new research areas?	0	0
22. Did the authors discuss how the research findings could be used for and what populations?	1	1

Appendix 8: Quality Checklist for Quantitative Studies

Quantitative Research Quality Checklist

Paper title:

Author (s):

Date:

Journal:

Quality Assessment Questions

Quality Rating

Yes= 1; No= 0; U/D= unable to determine; P*=partially

Reporting

1. Is the hypothesis/aim/objective of the study clearly described?

2. Is the underlying theory described?

3. Do the hypotheses or questions follow from the theoretical background and literature review?

4. Are the main outcomes to be measured clearly described in the Introduction or Methods section?

5. Are the characteristics of the study population included in the study clearly described?

6. Did the report adequately describe the measures used?

7. Are the procedures/methods clearly described?

8. Are the distributions of principal confounders in each group of study participants to be compared clearly described? *E.g. gender, age, education. If there is only one group, score yes.*

9. Are the main findings of the study clearly described? *Simple outcome data reported so that the reader can check main analyses and conclusions (this question does not cover statistical tests).*

10. Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001? *If probability scores are not reported, score yes.*

External validity

11. Are the study participants asked to participate representative of the entire population from which they were recruited? *The study must identify the source population for study participants and describe how the study participants were selected. Study participants*

would be representative if they comprised the entire source population, an unselected sample of consecutive participants, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the study participants are derived, the question should be answered as unable to determine. 12. Are study participants who agreed to participate representative of the entire population from which they were recruited? The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

Internal Validity

13. Were the screening criteria for study eligibility specified?

14. If any of the results of the study were based on "data dredging," was this made clear? Any analysis that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported answer yes.

15. Were the statistical tests used to assess the main outcomes appropriate?

16. Were the main outcome measures used accurate (valid and reliable)?

17. Where suitable, was an appropriate control or comparison group used? *If not appropriate, score yes.*

18. Were participants randomised into groups? *Studies that state participants were* randomised should be answered yes except where methods of randomisation would not sure random allocation e.g. alternative allocation would score zero because it is predictable. If the study did not have separate groups to randomise participants to score yes

Power

19. Did the study mention having conducted a power analysis to determine the sample size needed to detect a significant difference in effect size for one or more outcome measures? If the study did not conduct a power analysis but had a sufficiently large sample size then score 'P*' for partially. If the study did not attempt to report on a difference then score yes.

Ethical Approval

20. Is ethical approval reported?

ality Assessmen	t Items				St	tudies			
Damase- Michel, Christaud, Berrebi, Lacroix & Montastruc (2009)	Nordeng, Ystrøm & Einarson (2010)	Walfisch, Sermer, Matok, Einarson, Koren (2011)	Bonari, Koren, Einarson, Jasper & Einarson (2005)	Koren, Bologa, Long, Feldman & Shear (1989)	Powell, McCaffery, Murphy, Hensley, Clifton, Giles & Gibson (2011)	Mazzotta, Magee, Maltepe, Liftshitz, Navioz & Koren (1999)	Sanz, Gómez- Lópes & Marínez- Quniatas (2001)	De Santis, Straface, Cavaliere, Cinque, Carducci & Caruso (2006)	Nordeng, Koren & Einarson (2010)

Appendix 9: Quality Scores for Quantitative Studies

Author (Independent rater) scores: Yes= 1; No= 0; U/D= unable to determine; P*=partially

											-
1.	1	1	1	1	1	1	1	1	1	1	
2.	1	1	1	1	0	1	1	1	1	1	
3.	0	1	1	1	0	1	1	1	1	1	
4.	1	1	1	1	1	1	1	0	1	1	
5.	1	1	1	0	0	1	1	0	1	1	
6.	1	1	1	1	1	1	1	1	1	1	

7.	1	1	1	1	0	1	1	1	1	1
8.	1	1	1	1	1	1	1	0	1	1
9.	1	1	1	1	1	1	1	1	1	1
10.	1	0	1	0	0	1	0	1	1	0
11.	1	0	1	U/D	0	U/D	U/D	U/D	U/D	0
12.	1	0	0	U/D	P*	U/D	1	U/D	U/D	P*
13.	0	1	0	1	0	1	1	0	0	0
14.	1	1	1	1	1	1	1	1	1	1
15.	1	1	1	1	1	1	1	1	1	1
16.	U/D	P*	1	U/D	1	1	U/D	U/D	U/D	P*
17.	1	1	1	1	1	1	1	1	1	1
18.	1	1	1	1	1	1	1	1	1	1
19.	1	Р*	0	0	0	0	0	0	0	P*
20.	U/D	1	1	0	0	1	1	0	0	1

Appendix 10: Example of Data Analysis.

Naomi, lines 232-264

Exploratory	R: How do you think your pregnancy	Emergent
comments	affected your experience of your	themes
	epilepsy?	
Risks always been there but not thought about?	P5: I think before I was pregnant I didn't think about the risks as much like there was very little I wouldn't do because of my epilepsy like climbing a ladder do	Motherhoo d= becoming 'risk focussed'
You can also put others at	you know what I mean like with other	
risk	people I would never put anyone else at risk but as far as I was concerned I didn't	Two bodies in one
	really think about what if I had a seizure right now whereas now I've had I weigh up the risks. I think I've sort of proved	Weighing up process
Sense of triumph	that I can carry on and have a normal life and this is what I've always wanted, a family and my epilepsy hasn't stopped me so I feel quite good about that	Live your life
	R: And then how do you think your epilepsy affected your experience of pregnancy?	

Others have	P5: I think you don't have a lot of	Rigid, non-
the freedom	choice in what you know like people	negotiable
to choose	choose water births home births lots of	care
	sort of yeh lots of sort of newer ideas	Epilepsy
Previous experience of	whereas when you have epilepsy you	restricts choice
testing out the	have a path that you have to take your	
flexibility?	care plan is pretty much set I stone you	
Choice=	don't have a lot of say I mean you	
superfluous	probably if you have better controlled	Perceived
ianai y .	epilepsy you might have more of a say	accepting of
	but as far as I was concerned there was	medical
	very little of my birth plan that I got to	authority
	choose on my birth plan but it didn't	Trust in
	bother me too much because I just	health professionals
Epilepsy	wanted to have her safely whether or	
presents a threat and	not I had a water birth or things it	Am I able to
diminishes	didn't bother me that much because I	do this?
other concerns-	suppose I had bigger problems to	
others don't have this?	worry about and I just wanted to go	Fear of
	through labour without having a	epilepsy 'hijacking'
	seizure so. Having a seizure during	labour
	labour was one if the things that	
	worried me because I think I kind of	Beyond
	link my seizures to tiredness whether	individual
	or not that is there's no link it' a not	control
	easy to pinpoint that as a link I think if	

Seizures upset the system

Epilepsy takes away being able to do things 'normally'

How can I make sense of my experience without being 'present'?

Have 'a' baby there- would it even feel like mine?

Impairs sense making

I'm more tired I'm more likely to have a seizure so it was yeh I was scared of having. Having a seizure is not very nice, it's worse for other people but I thought if I do have a seizure there's no way I can give birth normally because I'm so confused I don't know what is going on when I come round so I suppose I was scared of having a seizure and then having to have a caesarean straight away and also kind of not knowing what's happened. I know a lot of women probably have that if they have emergency caesareans but I was worried I'd have a seizure and wake up and have a baby there and not really understand what's happened or because when I have a seizure it's like a big chunk of time has been taken away so it's like nothing it's like I can remember being awake and then I wake up and there's a gap in time where I

have no idea what's happened and I

when I had her.

guess I was worried that would happen

Epilepsy takes away control and hijacks experience

Out of control of own body

Seizures can take away choice of how mother is delivered

Appendix 11: Supporting Quotes

Super-ordinate	Sub-ordinat	e Supporting Quotes
Themes	Themes	
"Am I really able to do this?"	"I'm going to	"after the birth as well that worries me a bit because obviously you're going to be knackered most of the time because you don't get much sleep"
	be such a risk" "there's that extra worry then you know so sort of after the baby or it's left alone because you can't look after it "you felt kind of you know paranoid that people were to the baby's health and the impact of the medication" "I felt like people were sayingthere might be somethin "anxious about having a fit and falling down" "I was also worried about because Lamotrigine can lear	"there's that extra worry then you know so sort of after I've had the baby if I've had a fit and harmed the baby or it's left alone because you can't look after it or whatever that worries me too"
		"you felt kind of you know paranoid that people were talking about you and making comments about the baby's health and the impact of the medication"
		"I felt like people were sayingthere might be something wrong with the baby"
		"anxious about having a fit and falling down"
		"I was also worried about because Lamotrigine can leave to cleft palate deformities"
		"I was anxious about seizures during pregnancy"
		"Worried that I'd have a seizure and the worry about birth defects especially after my seizure at 4 weeks so that worried me. They're probably my 2 biggest worries during pregnancy"

Vs "It kind of	"I did feel like I was just a normal pregnant woman"
doesn't really feature"	"I didn't really see it as an illness it was just something really positive that had happened"
	"even though I've got I've got medical conditions it didn't seem to make any you know [difference]"
	"at the birth I wasn't thinking about oh I wonder if I'll have a fit it was the last thing on my mind it really was"
	"I've sort of proved that I can carry on and have a normal life my epilepsy hasn't stopped me"
	"it was all a bit desperate [delivery] at the end but it had nothing to do with my epilepsy"
	"I gained confidence throughout my pregnancy because I thought despite all these possibilities of things going wrong nothing has"
"Part of being a mother is	"you're told if you have epilepsy to not bath them on their own that's another you know after the birth another thing to worry"
being able to do that"	"I saw somebody a while ago a Neurologist who said if you do have children maybe you can get your husband to do sort of the feeding at night"
	"the Doctor saidwhen you've had the baby don't bath it on your own, don't put it obviously in a high chair or anything don't leave it anywhere high up"

"If I do have a seizure, there's no way I can give birth normally"	If I do have a eizure, there's	"I was told it's quite common to fit when you're in labour" "My sister was worried that I'd had a fit during labour"
	ive birth ormally"	"that was one worry that I would have a fit because I had got so overheated"
	ý	"I haven't got any recollection of this and they had to hoist me out of the pool erm and then they called the ambulance to take me to the hospital and I think if I wasn't out of it I would have resisted that but I wasn't conscious at the time"
		"I just wanted to go through labour without having a seizure"
		"but I thought if I do have a seizure there's no way I can give birth normally because I'm so confused"
		"I was scared of having a seizure and then having to have a caesarean straight away"
		"but I was worried I'd have a seizure and wake up and have a baby there and not really understand what's happened"
Experiences	s Epilesy	"I told her about the epilepsy (pauses) but you know that was it"
of Care	gets in the way of good	"when he said is there any questions you'd like to ask me I asked 'yeh what would you have asked me if I wasn't epileptic?'"

"the maternity Doctor who I see on the maternity ward he's very anxious"

"all the questioned he asked me were 'oh so you've not had any seizures then, everything's going ok, when are you seeing the Epilepsy Nurse, when are you seeing your Consultant'...We're here to talk about pregnancy and baby, if we want to talk about epilepsy we'll be going to see our consultant"

"most people were saying that there was no risk and that it would be ok but the obstetrician who said who just put her foot down and just said no"

"Ineeded to see her"	"from 16 week to 30 it's it's it's a long time and I know there are people on the other end of the phone but it's not quite the same. Erm and as I said before it's the actual scans that make everything real and safe"
	"unless I go private I have no idea how she's doing"
	"but you have little doubts in your mind I can't see her I can feel her and now my tummy is growing but but that's it"
	"being a bit concerned about that because if there wasn't enough fluid for the baby then that could have been a problem that wasn't taken seriously"
	"I don't think it is until you actually see her that I was"

Empowering Care	"I didn't want my tablets to increase erm she did recommend another tablet"		
	"she was very kind of erm er supportive of me and empathetic of me and I felt really reassured by that she actioned something straight away and so as a result I feel confident in her";		
	"myNeurologist was so on the ball me not having a seizure during labour"		
	"midwife I had as well was really good even though he was born at 2.30am and she was obviously on night shift she was really really good so that was reassuring"		
	"You ring them like 9-5 and they will ring you back within 24 hours so you've always got someone to talk to so"		
	"I quite like the fact that I can just phone them [Epilepsy Nurses] up"		
Vs " You	"[obstetrician] just didn't take that on board and just said no absolutely not."		
have a path	"and I was told that I had a high-risk pregnancy and that I wouldn't be able to do that"		
that you have to take"	"my Consultant in [location] wrote a plan for my labour"		
	"and just assuming you know 'oh you've got epilepsy, this is going to happen and you can't do that no' and not really being open to discussion just these are the rules, we follow them and you will as well '"		

Living with	"NowI weigh up the	"I didn't really think about what if I had a seizure right now whereas now I've had I weigh up the risks"
Risk	risks"	"I'd rather take the drugs and risk birth defects than have a big seizure and it affect her like if I fell down the stairs or something because I have no warning so I'd rather take the medication and risk the very small likelihood that it could cause a birth defect and risks if I had a seizure"
		"to say it's [deformities from medication] not going to happen well it's a lie it's a possibility and it's an increased risk and the Doctor should be somebody saying that it's an increased risk and if you weigh up the pros and cons it may be better to take the medication because you're not going to have as many seizures hopefully but it wasn't delivered like that at all"
		"I'd rather not be taking it the medication because that way I would be pregnant and not taking it but obviously I don't want to risk having more fits"
	"More wary of it"	"I take it every day now whereas before I was pregnant I was a bit lapse with it" "I am taking my pills at the right time and doing the right thing there""
		"it's just making sure I'm making my pills on time"

"I think once you become pregnant you realise that it's no longer just you and your actions impact others"

"I was more focused on right I need to go to bed and I will turn off the computer"

"there were a few times when I was really tired and maybe I had a bit of a worry that I mustn't get too tired in case that makes me have a fit"

Vs "Live	"When I was in the first so basically I was 18 weeks pregnant and prior to that I was you
your life"	know, I had been obviously working and I had been doing 10 hour shifts"
	"there's not a huge amount you can do"
	"my pregnancy went really smoothly I just carried on doing everything I was doing"
	"I missed one day of work erm the whole time I was pregnant I didn't have loads of time off
	and I certainly didn't have any off because I was tired"

"Information is quite hard work"	"It's the lack of understanding"	"I'm not even sure I'd have rung the Midwife I'd probably just gone to A&E but yeh it wasn't a source of information that I felt reliable to be honest" "Pregnancy issues were with the epilepsy and erm people I'd say not really being aware of epilepsy erm and what it might present as problems during labour"
		"you kind of come out of your appointments just feeling very unsure about the whole thing and do the medicals actually know what they're doing"
		"they don't know enough about the epilepsy or the medication I'm taking."
		"but in terms of their knowledge of people having seizures in pregnancy I don't think they had any knowledge of that to even be able to make that judgement."
		" I don't ever recall any 'health professional' discussing the 'emotional' side to epilepsy and pregnancy"
		"think it's it's kind of mentally how it affects you isn't managed"

"That was me who had to find it out"	"so that's my aim of the next meeting to kind of find out a bit more information and find out how that's going to be managed in light of my epilepsy because that hasn't really been mentioned yet by any of by the Midwife"			
	<i>"I've been really sort of trying to ask questions when I saw the Neurologist yesterdaywhat happens after the birth it's not just the pregnancy and the labour"</i>			
	"and I had to chase it up and I ended up ringing the outpatient clinic in [location] and saying I need an appointment now I'm already pregnant and they said oh we don't have any appointment for 2 months"			
	" I was on the contraceptive pill at the time and I read somewhere that I reacted with the Lamotrigine that I was on and asked him about it and he said oh no it doesn't and then I kind of went on the drug company's website and they said it could"			
"Unanswered	"you're not really told much until something happens"			
questions"	"There isn't anything out there"			
	"side effects weren't really even mentioned"			
	"they don't really give you a huge amount of information"			
	"they don't give you very much information"			

"the medication I was on or I am on I thought was safe in pregnancy and having children and I was told yesterday that it's not recommended to breast feed"

"they tend to listen to your history but don't necessarily give you any advice"

"the Neurologists you see you see for a short amount of time very infrequently so it's hard to kind of you know it's nice to be able to get you know questions answered"

"you have to be very specific with your questions to get the kind of answers that you need"

"and I've gone along with a notepad with questions in it as well and and written down answers so that you know so I've always made an effort to get as much information out of Doctors as I can"

Appendix 12: Epistemological Statement

Epistemological Statement

As researchers, the decisions and actions we make are inevitably influenced by the ways in which we experience the world (Crotty, 2003). Therefore selecting the most appropriate methodology for the research involved consideration of the researcher's ontological and epistemological stance. Epistemology refers to the basis of knowledge, how it can be acquired and how it can be communicated to others and ontology is concerned with what entities are real or said to exist. Positivist quantitative methodologies acquire knowledge via scientific methods in order to test a predetermined hypothesis or theory and therefore reflect a realist ontology, which assumes that there is an independent social reality which can be objectively measured (Cohen, Manion, & Morrison, 2007). Conversely, qualitative research attempts to understand experiences rather than predict outcomes, it therefore more aligned with relativist ontology as it understands meaning to be subjective and dependent on a frame of reference, rather than absolute truths (Smith, 2008).

The underlying ideologies of these research methods were considered alongside the context of the phenomena which the researcher sought to investigate. It was felt that the experience of pregnancy in women with epilepsy was something that was likely to be influenced by a number of factors, as our realities are constructed by our culture, ethnicity, place in society, our age, the time we live in and our past experiences (Willig, 1999). Therefore whilst there may be similarities or parallels in some aspects of experience, the meanings that are ascribed to these experiences are individual. Reflection on these relativist considerations, alongside the dearth of extant research into the experiences of pregnancy in women with epilepsy led to the selection of a qualitative methodology with an exploratory approach. The researcher felt that an exploratory approach would be most appropriate in a vastly under-researched area and that quantification of the experience of pregnancy would likely be reductionist.

The researcher gave consideration to four qualitative approaches; content analysis, discourse analysis, Grounded theory and Interpretative Phenomenological Analysis (IPA). IPA was selected as the most appropriate methodology for the reasons described below.

Content analysis allows quantitative analysis of qualitative data (Willig, 2001) and requires the researcher to define concepts and words to be quantified. This methodology can be described as somewhat reductionist as it reduces the complexity of phenomena into simplified categories. This method was therefore considered unsuitable for this research study since the data may not provide a true representation of individual experiences. Moreover, defining concepts and words to be quantified would be very challenging in an area which has attracted very little research.

Grounded theory draws themes based on theoretical ideas from initial interviews or another data source and compares these with new data generated from further interviews, checking for similar or conflicting themes (Willig, 2001). Grounded theory is designed to facilitate the process of theory generation from data (Charmaz, 2006). It is argued that discovering theory from data indicates that the researcher uncovers something that already exists (Willig, 2001), reflecting a positivist epistemology. This methodology was therefore deemed unsuitable as the researcher sought to explore the lived experience of participants rather than create theory.

Discourse analysis examines how language is used in the construction of social realities (Willig 2001). However, language is taken at face value and it is assumed that what is said is what the individual meant. The approach favours participants who are more able to articulate their experiences and does not accommodate for deeper interpretation which may be required.

IPA methodology allows for a more interpretative stance and attempts to understand lived experience and how an individual ascribes meaning to that experience (Smith, Jarman & Osborn, 1999). One of the central tenants of IPA is that it is phenomenological, namely that it explores an individual's perception of an event and attempts to get to a close to it as possible (Smith et al, 1999). It is recognised that the researcher's conceptions will inevitably affect how these perceptions are perceived; however, a degree of interpretation is required in order to make sense of the participant's world. Smith & Osborn (2003) describe this as a two-stage interpretation process or 'double hermeneutic' whereby the researcher attempts to make sense of the individual who is attempting to make sense of their experience. Thirdly, IPA is idiographic as it is concerned the perceptions and understandings of the particular group being researched rather than trying to make generalisations (Smith & Osborn, 2003).

After consideration of the four possible methodologies, IPA was selected owing to its primary emphasis on experience. The researcher felt that the central components of IPA were aligned with the how the researcher wanted to explore pregnancy and epilepsy, particularly with the emphasis on understanding individual experiences. The researcher selected this method as each participant's views and experiences are considered important, without the need to create generalisations which felt inappropriate to the phenomena being researched. IPA was also selected as its roots in relativism were in keeping with the researchers own ideological perspective which is that reality is subjectively constructed and that "social actors are seen to jointly negotiate the meanings for actions and situations" (Blaikie, 1993, p.96). Moreover, IPA fits with the researcher's experience of clinical training which emphasises subjective interactivity and encourages a careful consideration of an individual's experiences and perceptions, which could be described as idiographic. IPA was therefore adopted the most appropriate methodology to explore the lived experiences of pregnancy in women with epilepsy.

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Appendix 13: Semi-structured interview schedule

Thank you for agreeing to take part in this study. It should last no longer than 1.5 hours. I'm going to ask you some questions around your experience of pregnancy (and labour and birth if delivered). I am interested in your experiences of your current or most recent pregnancy and so it would be useful if we could keep focussed on your experience of this pregnancy, although of course you are welcome to draw comparisons if you feel it would be helpful. Before we start do you have any questions? Let's begin.

- Were you aware of some of the issues relating to pregnancy and epilepsy before becoming pregnant?
- What were the sources of this information?
- What impact has your epilepsy had on your experience of pregnancy?
- What impact has your epilepsy had on your experience of labour and birth?
- What have been the main challenges of your pregnancy?
- What has helped you to manage these challenges?
- Has becoming pregnant changed how you see or experience your epilepsy?

Is there anything you'd like to add?

Are there any questions you would like to ask about the study before we finish?

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Appendix 14: Participant Demographic Form

Date: 01/04/2012 Version Number: 1.1

Participant Identification number for this study:

Title of project: Experiences of Pregnancy in Women with Epilepsy

Researcher: Stephanie Boardman

Please read and fill out the information below and bring to the interview. If you do not know the answer to any of the questions then leave them blank. If you prefer, you are welcome to complete the questionnaire during the interview.

1)	Age
2)	Weeks of pregnancy
	OR Age of baby (months)
3)	Epilepsy Diagnosis
4)	Years and months since diagnosis
5)	Treatment during pregnancy (if any)
6)	If you are pregnant, how long has it been since your last seizure?
7)	Type of seizures experienced during pregnancy (if any)
8)	Was your pregnancy planned? Yes / No

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Appendix 15: Participant Information Sheet

Participant Information Sheet

Experiences of Pregnancy in Women with Epilepsy

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1:

What is the purpose of the study?

Pregnancy for women with epilepsy can be challenging for a number of reasons including concerns about medication and seizures. The purpose of this study is to increase our understanding of the experiences of women who have epilepsy and who are pregnant. This could lead to the development of better care and support for pregnant women with epilepsy in the future.

Why have I been invited?

Women who have epilepsy and are pregnant or who have had a baby within the past 9 months have been invited to take part in this research. You have been invited because a health worker who works directly with you thought that you may be interested in taking part. If you are not interested in taking part, your details will not be passed on.

Do I have to take part?

It is up to you to decide to join the study If you decide that you would be interested in taking part in the study, or would like more information about the study, we will ask you to sign a consent form to be contacted by the researcher. Giving your consent to be contacted by the researcher is not giving your consent to participate in the research it is simply agreeing to find out more and think about taking part. If you would like to participate in the research after being contacted by the researcher then we will then ask you to sign a consent form. You do not have to take part and you are free to withdraw at any time, without giving a reason. Whether or not you take part would not affect the standard of care you receive.

What will happen to me if I take part?

• The study will take between 1-2 hours in total and during that time you will have an interview with the researcher

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- You will be asked to talk about your experience managing both your epilepsy and your pregnancy. At the beginning of the interview you will be asked a number of questions about your pregnancy, such as the number of weeks of your pregnancy or age of your baby, whether or not it is your first child and about any previous pregnancies. You will also be asked some questions about your epilepsy, including your diagnosis and number of years since diagnosis, your seizure frequency and intensity.
- During the interview, yourself and the researcher will be present. You will not meet other research participants.
- An audio copy of the interview will be recorded using a digital Dictaphone.
- After the interview is complete, the researcher will type up the interview and destroy the audio copy.
- After the interview has been completed you will not be approached again, or asked to provide follow-up information.
- This study is using a qualitative research design which means that the researcher will study the interviews to gain an understanding of the experiences of pregnancy and epilepsy.

Expenses and payments

Unfortunately, expenses or payment are not available for this study.

What will I have to do?

If you agree to be contacted by the researcher, you will have the opportunity to find out more information about the study, or to organise a convenient time and a place for the interview if you would like to take part. Interviews may take place in your own home or at the hospital managing your care.

The interview will last between 1-1.5 hours and you will be asked questions relating to your experiences of managing your epilepsy and your pregnancy. You will carry on with any medical or psychological treatments as usual.

What are the possible disadvantages and risks of taking part?

You may find talking about your pregnancy and epilepsy distressing. You will also be asked about whether or not you have any previous pregnancy experiences, but will not be asked to expand upon anything that you do not feel comfortable discussing.

What are the possible benefits of taking part?

We cannot promise the study will help you but we hope that the information we get from this study will help improve the care of pregnant women with epilepsy.

What happens when the research study stops?



At the end of the study you will be able to

ask any questions that you have. After this, there will be no further contact, unless you have indicated that you would like to be informed of the results of the study.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

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What will happen if I don't want to carry on with the study?

You may withdraw your participation at any stage of the study, up to seven days after completing the study. Following this time, your data may still be retained as it may not be possible to remove your data from the analysis. If you decide you would like to withdraw from the study before this point, any data collected from you will be destroyed and will not be used in analysis of the results. There will be no negative consequences of withdrawal from this research.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers on 07891111111 who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this via the NHS Complaints Procedure. Details of this will be available from your local hospital.

Will my taking part in this study be kept confidential?

- Your participation in this study will be kept confidential.
- Research data will all be collected during the study. Other sources of information, e.g. medical records will not be used.
- All data will be anonymised and identified only by a participant number that is assigned at the beginning of the study. Your name will not be used in any report or published document.
- All data will be stored in a secure place for 5 years, whilst the results of the research are being prepared for publication. After this, all data will be destroyed. Quotations from the interviews may be used but these will be anonymised.

What will happen if I become distressed during the interview?

The researcher will sensitively handle any distress that may arise and may remind you that you have the right to withdraw at any time. The researcher will offer any support that they are able to, and may suggest you contact other forms of support and provide information on these. If the researcher is particularly concerned about your distress then these concerns will be brought to the attention of a health worker involved in your care. This will only be done with your permission and your GP will not receive any personal information that you give to the experimenter as part of the study. All study information will remain confidential. Confidentiality will only be broken if you disclose something which the researcher feels puts you or others at significant risk. Under these circumstances, the researcher will be required to report the disclosure to the appropriate authorities.

Your participation in this study will not affect your current or future medical or psychological treatment.

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What will happen to the results of the research study?

It is intended that this research will be published in a peer-reviewed journal, which is accessible to the public. If you would like to be informed of the results of the research, we will keep your personal details on file, and send you information about the results of the research.

Who is organising and funding the research?

The chief investigator is being paid to carry out this research by the Humber NHS Foundation trust as part of their job role. However, this piece of research is receiving no external funding, and there are no identified conflicts of interest.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed by the NRES Committee Humber Bridge REC.

Further information and contact details

If you would like further information on taking part in research you may wish to look at the NHS Choices website: <u>http://www.nhs.uk/Conditions/Clinical-</u><u>trials/Pages/Introduction.aspx</u> or the National Research Ethics Service: <u>http://www.nres.npsa.nhs.uk/</u>

For further information, you can also contact the primary researcher by post, telephone or e-mail with any questions:

Stephanie Grace Boardman Trainee Clinical Psychologist Department of Clinical Psychology and Psychological Therapies Hertford Building University of Hull HU6 7RX

Telephone number: 07846864159

E-mail: s.g.boardman@2010.hull.ac.uk

Thank you for considering taking part in this study and taking the time to read this information sheet.

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Appendix 16: Participant Consent Form

Participant Identification number for this study:

EXPRESSION OF INTEREST

Title of project: Experiences of Pregnancy in Women with Epilepsy

Name of Researcher: Stephanie Grace Boardman	Please initial the box
1. I confirm that I have read and understand the information sheet dated 09 June 2012 (version 1.2), for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	ne d 🗆
2. I understand that my participation is voluntary and that I am free withdraw at any time without giving any reason, without any medi care or legal rights being affected.	e to cal
3. I understand that relevant sections of my medical notes and data collection during the study may be looked at by individuals from the regulatory authorities or NHS trust, where it is relevant to my takin part in this research. I give permission for these individuals to have access to my records.	ne ng 🗆
4. I understand that the researcher is obliged to break confidentialit should I disclose anything that suggests that I or others are at risk o harm.	y of □
5. I am aware of the potential risks and benefits of taking part.	
6. I agree to the interview being audio-taped.	
7. I agree to take part in the above study	

Name of participant

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Name of person

Date

Signature

Taking consent
Appendix 17: Ethical Documentation

REMOVED FOR HARD BINDING

Appendix 18: Reflective Statement

Reflective Statement

In this statement I intend to provide an overview of undertaking this research beginning with the formulation my research question and the systematic literature review, through to the empirical research. I will provide my personal reflections on the research process in terms of the decisions that I have made, the challenges as well as strengths that I have encountered and finally the advice that I would offer to others.

Formation of Research Question

At the very beginning of the research process I had not envisioned researching into epilepsy and pregnancy specifically and felt very open to a number of research projects with varying focuses and methodologies. However, the area of motherhood and epilepsy was presented at the University's research fair as a vastly under researched area. Initially, I was not sure what had attracted my attention to this area but I felt enthusiastic and excited about having such a broad area from which I could carve my own project. Whilst having such free range to formulate a research question felt very positive, I also felt that I needed to be focussed in what specific aspect I wanted to research.

I began by increasing my understanding of epilepsy and skimming the literature for challenges facing people with epilepsy, as well as some of the broad psychological constructs that have been linked with epilepsy. Once I felt that I had a grounding in some of these broad issues I began to narrow my focus to issues relating to women specifically. Bearing in mind my understanding of the difficulties that epilepsy could present in day to day life, I began to think more about what raising a child must be like for a woman with epilepsy and sought out research into the experiences of mothers with epilepsy. I shortly discovered that this area was overwhelmingly dominated by medical literature, and was not particularly easy to digest, but did provide me with a greater depth of understanding in terms of the causes and treatment of epilepsy, as well as the specific challenges facing women during their reproductive years.

I found learning about management of epilepsy during pregnancy from a medical perspective very interesting as not only did the condition present complex challenges prior to conception and during pregnancy, but it also required the health professional and the mother to weigh up the risks of treatment on the health of the fetus. The management of 'two bodies in one' struck me as very interesting, and made me wonder more about the experiences of women with epilepsy during their pregnancies. As there a paucity of literature in this area I developed a very exploratory question which sought to gain insight into the experiences of pregnancy in this group of women.

Choice of Methodology

The choice of a methodology was a relatively simple one after I had discarded the idea of using a quantitative methodology to explore the experiences of women in terms of their levels of anxiety of depression. I had initially toyed with this idea because I was aware that anxiety and depression are more prevalent in people with epilepsy and thought that epilepsy and pregnancy can both be conceptualised as types of stressors and I wondered whether this would be reflected in the data. However, this idea was discarded because I did not want to impose my hypothesis onto this population and felt that it would be much more interesting to take an explorative approach that would not place *a priori* constraints on the data.

Systematic Literature Review

Having never previously undertaken a systematic literature review, I approached this new methodology with some enthusiasm but also a degree of caution. I began the process as early as I could in order to give myself sufficient time to complete the process which has been lengthy. My first task was to identify an area of research that would inform my understanding of my empirical research. However, the area that I was researching has attracted little attention and so it was not possible to conduct a review of the extant literature. I then considered the two major components to my research ('pregnancy' and 'epilepsy') which could lead to very different reviews, both of which could inform my understanding of my empirical data. I selected to focus on the pregnancy rather than epilepsy literature as I felt that I had a lot more that I would like to understand about the psychological processes of pregnancy, after already having spent considerable time researching epilepsy. More specifically, I chose to explore teratogenic risk perceptions in pregnant women because it enabled me to learn more about pregnancy whilst linking it with a number of components present in my empirical research.

I was initially quite surprised that this area did not boast a wealth of research and had not previously been reviewed. It is well known that risk perception holds significant implications for behaviour and decision making, and in a health context, for medication adherence, which in pregnancy is complicated by the need to balance the health of the mother against the health of the fetus. Considering how common medication use during pregnancy is, I felt that it was really important to gain an understanding of some of the psychological processes occurring when a woman makes an assessment of the risk that a medication poses to her unborn child. I find this area fascinating because it taps into so many discourses that we hold around motherhood, pregnancy and the fetus, as well as the ideas and values that we attach to certain medications and the historical discourses around use of medication during pregnancy.

I chose to focus my review on teratogenic risk perceptions in pregnant women and the intrapersonal factors associated with these perceptions. First I decided to narrow this to medication (either over the counter or prescription) rather than recreational drugs, food or other medical interventions. This felt like a relatively easy decision to make as I wanted to keep it as relevant to my empirical paper as possible, but also so that it would have some relevant clinical implications for both women and health providers. Initially I had also considered including external factors (e.g. language used, influence of clinician); however, narrowing my focus meant that the review could be focussed and would allow for sufficient depth of exploration of findings, rather than simply providing a broad overview.

I would encourage future researchers to aim to create a focus within their literature search that gives enough room for a wealth of results to be discussed, but to balance this with not overwhelming the reader. Through discussions with my supervisor, I found it useful to remind myself of the position of the reader and to think about what the main points to be conveyed are, and implications for clinical practice. If I were to conduct another review I would be more disciplined in carving a very specific focus earlier on in the stages in the review. By creating this focus early on, it removes the need for shedding areas of your review later on which you have spent time analysing and linking with theory. A clear focus will ultimately make for a more digestible review which has better scope for analysis and interpretation of the results.

A further learning point from this process would be to become more adept at saving previous searches and the search terms used to produce the results as the literature I was trawling through was expansive and ever changing. I learnt relatively quickly that not keeping a log of the search terms used to produce the literature resulted in a lot of repetition of future searches.

Ethics

I initially applied for proportionate review, but as my study was not deemed appropriate for this my study was reviewed by a full ethical committee. Whilst this was a daunting process, having to answer questions about the rationale for certain decisions made me critically evaluate and justify the steps that I was taking and ultimately gave me greater confidence in my research. Whilst gaining ethical approval was relatively straightforward, I submitted two amendments along the way, both with the view to increase chances of recruitment. One amendment was to expand my inclusion criteria to also include women 9 months post-delivery in order to be able to increase chances of recruitment. My second amendment was for Epilepsy Nurses to write to women to invite them to participate in the research rather than waiting to see them in the clinic.

I learnt along the way that I needed to be flexible and open to ways of changing the procedure after some experience of 'on the ground' recruitment. I would therefore advise other researchers not to conceptualise gaining ethical approval as a linear process, but rather something that one may need to go back and forth with as ideas about how the procedure or recruitment could be developed emerge. I would also say that it is not necessarily easy to design the 'perfect' procedure to a study without experience of implementing it and then reflecting upon what aspects are and aren't working. In order to minimise the number of times that one may need to return to ethics with amendments it is advisable at the beginning of your research project to have a number of potential pathways of recruitment embedded within your design so that other routes of accessing participants can be mobilised when required without delay. This is best achieved by working closely with the clinicians who you may be relying upon to recruit your participants, as the people who work within that particular system may be best placed to put forward suggestions.

Empirical Study

I would describe the recruitment of participants as the most challenging aspect of my research. One particular challenge was recruiting participants from two different trusts with different care pathways for managing women with epilepsy who were pregnant. There was variation between the two sites in terms of the clinicians involved in the care and as a consequence there were differences in how women could be approached. In one site, pregnant women with epilepsy were cared for by an Obstetrician but also had regular appointments with the Epilepsy Nurses, of which there were two. The women also were cared for by the Epilepsy Nurses and Neurologist prior to becoming pregnant and as a result, the two Epilepsy Nurses were in contact with all of the women who were either pregnant or who had delivered their babies in the past 9 months. In contrast, in the other trust there was much less clarity about how pregnant women with epilepsy were managed. Eventually it was understood that a pregnant woman with epilepsy may either be referred directly to an Obstetrician by her GP, or would be referred by a Midwife at her 12 week appointment. Therefore the pathway for recruitment at this site was via Midwives and Obstetricians.

Gaining clarity about care pathways may seem like a simple task but should not be underestimated in terms of how difficult it can be, particularly when there have been recent changes to the pathways. I would advise researchers to reflect on this process and spend time thinking about the culture of conducting research within that service and how this may impact how smoothly the project runs. I would also encourage researchers to think about how the number of clinicians involved and how engaged they are with the research in relationship to rate of recruitment. Working alongside the Epilepsy Nurses proved relatively straightforward, and the fact that there were just the two of them made it easy to discuss and receive feedback on the proposed procedure in face to face meetings. In contrast, information about the procedure needed to be disseminated to a significant number of Midwives working across the area as any one of them could potentially come into contact with a pregnant woman with epilepsy at her initial appointment. Unfortunately, the researcher did not have an opportunity to meet with all of the Midwives as a group and as a result, this information was shared via email, which may not have been a particularly effective way of engaging Midwives with the research. Equally, it proved very difficult to contact the Obstetricians in the service and set up a face to face meeting, and so again, information about the study was shared over email.

Overall, I feel that having a clear understanding of pathways, working with a small number of clinicians with a clear focus and engagement with the research is key to recruiting successfully. Where it is necessary to involve a larger number of clinicians I would advise attending any meetings where there is a small opportunity to direct people's attention to the research and to provide a 'face' to the name and project. I would also encourage researchers to think about clinician workload and how likely this is to impact upon recruitment. I thought about how recruitment rates were likely to be low amongst Midwives as they often have very short appointments with women in which they are required to gather a significant amount of information. I would say that

recognising and naming this, even if it is has to be over email, can help to bring clinicians alongside your research.

The process of interviewing my participants was both more challenging and enriching than I had anticipated. Before beginning the interview process I had spent time reflecting upon my own preconceptions and how these might influence my approach to the interviews and their subsequent analysis. Having previously immersed myself in the epilepsy literature, I entered into the interviews with a heightened awareness of the issues that may affect women with epilepsy during pregnancy. In addition, having a sister who has a disability and who had recently been pregnant meant that I felt that I had some degree of some of the broad issues that can affect women with 'high-risk' pregnancies. I was aware that both this knowledge and experience may colour my interpretations of women's answers and make me more likely to perceive the presence of certain issues. I would advise all researchers to spend time thinking about how their knowledge and experience will affect all aspects of their research. I found it helpful to remind myself that that research was exploratory without any prior hypothesises which meant that I was free to be genuinely curious about what pregnancy was like for these women.

The process of interviewing felt like an enormous privilege, as my participants shared with me their personal accounts of what can be a highly emotive periods of their lives. The interview process was not always an easy one and amidst the collection of data I struggled to see how I would pull together the highly individual experiences and create some coherence. I also grappled with concerns about how my interview style or approach may have been changed with greater experience of conducting the interviews and gaining a greater understanding of some of the issues. I found it helpful to remind myself of the principles of interviewing in IPA and that interviewing can be modified in light of participants' responses and that the interviewer is free to probe at interesting and important areas as they arise (Smith & Osborn, 2003). I would advise any researcher embarking on an IPA project for the first time to frequently remind oneself of the principles of this methodology, as it is radically different both in terms of its theoretical underpinnings and approach than to quantitative methodologies.

I feel that my experiences have equipped me well for future research endeavours and have helped me realise my genuine interest in this field, which I hope to translate into my clinical practice. •

Smith, J. & Osborn, M. (2003). Interpretative phenomenological analysis. In J. A. Smith (Ed.), Qualitative Psychology: A Practical Guide to Methods. London: Sage.