

Women with epilepsy preparing for pregnancy: A qualitative analysis

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Abstract

Women with epilepsy (WWE) are frequently presented with information when preparing for pregnancy, much of this includes statements of risk either concerning the health of the woman or her future child. Little is known about how women consider, use, are influenced by, trust and either act on or disregard information provided prior to conception, how they make decisions about conception, and what might influence their pregnancy planning. Studies have told us the numbers of women not receiving advice prior to getting pregnant, but these studies do not help us understand why this occurs and little is known of the potential to influence the involvement of women in preconception counselling. The rationale for this project was to develop understanding of the views of WWE, their beliefs, attitudes and perceptions of future pregnancy.

Qualitative methods were applied to investigate the processes of WWE preparing for pregnancy. Purposive recruitment was undertaken for women aged 16 years to 45 years with a confirmed diagnosis of epilepsy of at least three months who have experience of being prescribed antiepileptic drugs for management of epilepsy. Women were recruited from regional epilepsy clinics across the NW of England, and invited to take part in either a focus group or clinic observation and follow-up interview. All interviews and focus groups were recorded and transcribed verbatim. All transcript data was managed using NVIVO 7 computer-assisted qualitative analysis software and analysis was informed by interpretative phenomenological analysis.

A total of 85 women participated within this study, and 12 clinicians provided consent for clinic observation. The results highlight the value of examining the subjective experiences of reproductive aged WWE, and contribute important insights into the part played by women within the decision-making process, and in the broader context of their personal experience, relationships, family and social life. The most significant finding from analysis was the inconsistent use of the term 'planning' both by women and their clinicians. Women frequently defined planning as the intention to conceive, implying activities to improve epilepsy management occurred before the planning stage. For those women who defined planning as involving more complex activities and commitment to improve preconception health, many also longed for a more natural approach to pregnancy of simply trying to conceive. Barriers to planning included misunderstandings about what interventions were required and the timing of implementation, in addition to the influence of significant others and past pregnancy experience including experience of miscarriage, pregnancy termination or abortion, and the likelihood of engaging in preconception interventions.

The presentation of risk information to women during their childbearing years presents a challenge requiring a careful balance between delivery of risk information and promotion of self-efficacy to successfully achieve planned pregnancy. It is contended that current practice fails to acknowledge women's active role in preconception decision-making. Risk information emphasises risks of harm to the unborn child heightening fear and worry and for some women perceptions of blame and selfishness when considering their needs above a future child. Future research is required to acknowledge the interconnectedness of factors likely to contribute or inhibit pregnancy planning, and the perceptions of risk, all of which were likely to act both independently and interdependently within the social context of the lives of WWE during their childbearing years.

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Author's Declaration

This thesis is the result of my own work. The material contained in the thesis has not been presented either wholly or in part, for any other degree or qualification.

I was solely responsible for the study design, all approvals obtained and all data collection and analysis.

Author's Declaration Date

Related Publications

Some of the material contained within this thesis has previously been published in the following papers:

Winterbottom J.B.; Smyth R.M.D.; Jacoby A; Baker G.A. Preconception counselling for women with epilepsy to reduce adverse pregnancy outcome. Cochrane Database of Systematic Reviews 2008, Issue 3. Art. No.: CD006645. DOI: 10.1002/1461858.CD006645.pub2.

Winterbottom J; Smyth R; Jacoby A; Baker G. The effectiveness of preconception counselling for women with epilepsy: What's the evidence *Epilepsy & Behavior* 14 February 2009

Iniesta I, Winterbottom J. Antiepileptic drugs: the risks and benefits during pregnancy. *Prescriber* 2010; 21(17):61-3, 65-6.

Shallcross R, Winterbottom J, Bromley R. Prenatal exposure to anti-epileptic drugs: the need for preconception counselling. *The Practising Midwife* 2011; 14(11):20-1

Related Awards

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1. Role of preconception counselling for women with epilepsy. 27th International Epilepsy Congress, Singapore, 2007.
2. The experience of being a woman with epilepsy: An interpretative account. The 2008 International Nursing Research Conference, Liverpool.
3. The role of preconception counselling for women with epilepsy: A systematic review. The 2008 International Nursing Research Conference, Liverpool.
4. The Phenomena of preparing for pregnancy challenged by risk. 9th Conference of European Sociological Association, Lisbon, 2009
5. Patient's perspectives: the experience of women with epilepsy. Communicating the Risks to Health-Whose responsibility is it? Royal Statistical Society, London, 2009
5. Developing a model for preconception counselling. Epilepsy Research UK Evening Lecture, ILAE UK meeting, Brighton, 2010
6. Developing a model for the preconception care of women with epilepsy. North West Epilepsy Group Meeting, Liverpool, 2011

Related Poster presentations

Winterbottom J, Jacoby A, Baker G. Preparing for pregnancy: The experience of women with epilepsy. *Epilepsia* 2009; 50:81-82.

Winterbottom JB, Jacoby A, Baker G. Risk Communication in the Preconception Counseling Visit. *Epilepsia* 2010; 51(Special Issue, Suppl 4):165.

Abbreviations

AED	Antiepileptic drug
AZM	Acetazolamide
CBZ	Carbamazepine
COZ	Clobazam
ENS	Epilepsy Nurse Specialist
FG	Focus group participant code
FU	Follow-up clinic appointment
HBM	Health Belief Model
HLC	Health Locus of Control
IO	Interview only participant code
IQ	Intelligence Quotient
ILAE	International league against epilepsy
LTG	Lamotrigine
LEV	Levetiracetam
MCM	Major congenital malformation
MRC	Medical Research Council
NICE	National Institute for Health and Clinical Excellence
NTD	Neural Tube Defect
NEAD	Neurodevelopment Effects of Antiepileptic Drugs
NP	New patient clinic appointment
OI	Observation and Interview participant code
QOL	Quality of life
SES	Socioeconomic status
TPB	Theory of Planned Behaviour
TRA	Theory of Reasoned Action
TPM	Topiramate
TTM	Transtheoretical Model
VPA	Sodium valproate
WWE	Women with epilepsy

Chapter 1 – Introduction: Women with epilepsy preparing for pregnancy

“Epilepsy and pregnancy. The shock of waking every morning to such a grim problem of life” (Evans, 1952, p.125)¹

Introduction

This thesis focuses upon how women with epilepsy (WWE) experience the communication of risk information and its influence upon their involvement in preconception care and decision-making during the stages of preparation for pregnancy. WWE are presented with risk information throughout their childbearing years through interactions between healthcare professionals, family, friends and the social media. National and International guidelines recommend the provision of preconceptual information and counselling (Crawford, 2005; Stokes et al., 2004; Delgado-Escueta and Janz, 1992; Centre for Maternal and Child Enquiries, 2011; National Clinical Guideline Centre, 2012), however little is known of how women use and interpret risk information, what factors influence their utilization of services and whether these factors influence changes in behaviour during the stages of preparation for pregnancy.

Epilepsy is a common neurological disorder affecting individuals who show a tendency to experience recurrent unprovoked seizures as a result of abnormal and excessive neuronal discharge (Sanders and Shorvon, 1996). The prevalence rate of epilepsy in the UK is approximately 0.97% based on 2010 population estimates (Joint Epilepsy Council, 2011). The incidence of epilepsy in the general population is estimated at 50 cases per 100 000 per year (MacDonald et al., 2002), with an age specific prevalence rate in women of between 6.9 and 7.9 per 1000 (12-50 years) (Purcell et al., 2002). This represents a population of 139, 000 women of childbearing age in the UK and more than 1,000,000 women in the United States (Vazquez et al., 2007; Joint Epilepsy Council, 2011). It has been estimated that twenty-three percent of

¹ Quotation by Margiad Evans’ an Anglo-Welsh author within her autobiographical book ‘A ray of darkness’ describing her journey into motherhood and her initial joy discovering her pregnancy, as fulfilling her role as a woman with epilepsy (p.120), tainted by her experience of seizures during pregnancy which led her to consider her own mortality (p.125). Evans, M. (1952) *A Ray of Darkness*, London, John Calder.

patients with epilepsy are women of reproductive age and 0.3% to 0.7% of all births are to mothers with epilepsy, most of whom require continuation of antiepileptic drugs (AEDs) during pregnancy because uncontrolled seizures might harm the mother and fetus (Lunardi et al., 2011; Tomson et al., 2011; Joint Epilepsy Council, 2011). This represents an estimated 22,800 children born each year following in utero AED exposure in the US (Meador and Zupanc, 2004); and in the UK, 2400 children born to mothers with epilepsy are exposed to AEDs in utero per annum (Kinney, 2011). The challenges facing WWE ‘and their supporters’ highlight the importance of adequate risk information prior to conception to inform reproductive decision-making and reduce risks including maternal mortality (Centre for Maternal and Child Enquiries (CMACE), 2011).

Whilst the outcome of pregnancy for the majority of WWE is normal, there is a two- to threefold increased risk of adverse pregnancy outcomes; these include risks of maternal mortality and morbidity, together with fetal risks of death, major congenital malformations, dysmorphism and long-term cognitive delay (Barrett and Richens, 2003; Yerby, 1997). The population frequency of newborn babies with one or more malformations secondary to in utero AED exposure has been calculated as 20/100 000. This falls within a similar range as the prevalence of phenylketonuria or congenital hypothyroidism, disorders at birth which are targeted by national screening programmes (Barrett and Richens, 2003). This comparison has been used by Barrett and Richens (2003) to highlight the inequitable service and research investment for WWE.

1.1 Preconception counselling principles

One of the principal goals of preconception care is the identification of and reduction in (modifiable) risk factors before conception in order to improve obstetric outcome. Therefore, the primary prevention of drug-induced teratogenic² exposure should be an important part of this new type of health care (Stegers, 2005, p.278).

² A teratogen is defined as an ‘agent or factor that can cause abnormalities of form, function (physically resulting in birth defect and altered central nervous system performance resulting in neurological dysfunction, behavioural and cognitive abnormalities) or both in an exposed fetus’ (Hanson, J.W. (1997) *Human Teratology*. In Rimoin, D. L., Connor, J. M., Pyeritz, R. E. & Emery, A. E. H. (Eds.) *Emery and Rimoin's principles and practice of medical genetics* (pp.697-700). 3rd Ed. New York: Churchill Livingstone.p.697)

Preconception care is based on the principle that “healthy mothers produce healthy babies who become healthy children and adults” (Department of Health, 2004). Preconception counselling has been defined by Chamberlain (1986) as a process of preparing for pregnancy through which physical, mental and emotional health is optimised before pregnancy. Preconception counselling offers women contemplating pregnancy the opportunity to avoid exposure to potential teratogens with the goal of improving the chances of a better outcome both for themselves and their child (Chamberlain, 1986; Steegers, 2005). Improvements in preconception health to increase awareness of modifiable risk factors has been identified by the Center for Disease Control and Prevention (2006) as a primary means of preventing major congenital malformations, thereby reducing societal costs. The provision of health information, including promoting folic acid supplementation, is reported to ‘reduce the occurrence of spina bifida and other nervous system defects by at least 50%’ (Koonin et al., 2001). The Centre for Maternal and Child Enquiries (2011) has extended this to include reduction in preventable indirect maternal deaths. The impact of substandard care received by WWE in the UK, was highlighted as being instrumental in the epilepsy-related deaths reported (de Swiet et al., 2011). Deaths to WWE during 2006-2008 represented a rate of 0.61 per 100, 000 mothers, many of whom did not receive preconception counselling. As a result, these women and their carers were unaware that closer surveillance or changes to medication during pregnancy were appropriate (Lewis, 2011, p.43; de Swiet et al., 2011). Promoting the benefits of preconception care of WWE, Kinney (2011) reports the potential cost reduction of preventing 31 children each year born to mothers with epilepsy being affected by major congenital malformations (MCMs) (from changes in prescribing practices). He identifies that avoidance of sodium valproate would reduce the economic burden by preventing 5 cases of spina bifida per year at an estimated cost saving of £1,746,000 (Kinney, 2011)³. Unplanned pregnancy represents a missed opportunity to prevent teratogen exposure. Improvements in pregnancy planning has been estimated to represent an unadjusted relative risk reduction of 3.0 (95% CI 2.0-4.5) for first trimester exposure to potential teratogenic medications (Han et al., 2005).

³ Poster presented at the ILAE UK Chapter Annual Scientific Meeting, York 2011 by Dr Michael Kinney on behalf of the UK Epilepsy and Pregnancy Register. Slides made available by personal communication with Dr James Morrow on behalf of the UK Epilepsy and Pregnancy Register (correspondence date 28-11-11).

Preconception care includes risk assessment, health promotion (involving screening and health education) and interventions to modify or eliminate risk factors in order to minimise the risk of adverse outcome (De Weerd and Steegers, 2002; Jack and Culpepper, 1990). Preconception interventions for WWE target the appropriate use of contraception to delay pregnancy until optimal health is achieved and improved adherence of preconception supplementation with folic acid (Pack et al., 2009; De Weerd et al., 2002). Risk assessment components of preconception counselling for WWE target review of diagnosis and AED regimen to ensure appropriate treatment prior to conception, focusing on drug choice and, for women experiencing frequent seizures, reduction of drug burden from polytherapy to monotherapy (Winterbottom et al., 2009; Bánhidly et al., 2011). The improvement of seizure control prior to conception is a primary objective of preconception epilepsy review. This requires a balanced discussion of both treatment and seizure-related risks, cautioning women of the risks of worsening seizures during pregnancy associated with abrupt withdrawal of AEDs (National Clinical Guideline Centre, 2012; de Swiet et al., 2011). The health promotion activities for WWE target improving health knowledge and awareness of the benefits of planned pregnancy, early booking into antenatal care, and use of individual risk information for the birth, neonatal period, breastfeeding, and care of infants (Winterbottom et al., 2009; Commission on Genetics et al., 1993).

1.2 The history and development of preconception counselling

Advice to women contemplating pregnancy to improve their ‘wellness’ and ‘avoid hazardous substances’ can be traced back to early civilisations, for example, within the Old Testament advising on women’s nutrition and the need to avoid alcohol prior to conception (Freda et al., 2006). The earliest reports of preconception care within a Medline search⁴ date back to 1957 (Bourquin and Bennum, 1957). The history of preconception counselling in the UK dates from 1978 with the establishment of clinics providing ‘specific medical advice concerning specific problems which might concern women and their partners before embarking in pregnancy’ (Chamberlain, 1980; Chamberlain, 1986; Bradley and Bennett, 1995; Lumley et al., 1980). The development of preconception counselling for women with chronic diseases including epilepsy was the primary intention of service developments in response to the first

⁴ Medline search completed January 2012.

reports of the teratogenic properties of AEDs (Meadow, 1968; Müller-Kueppers, 1963). However, Chamberlain reported that women with prior medical problems represented only 17% of the referrals to the clinic (Chamberlain, 1986, p.5-8). The importance of targeting preconception care at women at higher risk of adverse pregnancy outcomes was the intention of the House of Commons Health Committee reporting on the inclusion of preconception care into maternity services (Health Committee (Fourth Report), 1990-1991). Improvements in treatment for WWE highlighted the need for medical advice prior to conception and modification of drug treatment, placing responsibility on the woman to inform her doctor of her plans for a family before trying to conceive (Health Committee (Fourth Report), 1990-1991, p.xi and Volume II Minutes of Evidence p.163, para 3.28).

The first report on preconception counselling for WWE, entitled 'Problems counseling the epileptic mother', was published in 1979 by Char and colleagues, and reflected increased concern for the outcomes of pregnancy in women treated with phenytoin and phenobarbitone and the prevention of fetal hydantoin-barbiturate syndrome (Char et al., 1979). This was followed by the Advances in Epileptology Symposium in 1981, highlighting the importance of starting counselling early in the course of the disease and extending to include the patient's future as she contemplates decisions concerning marriage and parenthood (Andermann et al., 1981, p.219). This symposium focused on reducing the two-threefold increased risk of major congenital malformation by maintaining the lowest possible plasma levels of anticonvulsants compatible with good seizure control, avoiding polytherapy with three or more agents, changing to monotherapy whenever possible, and avoiding drugs known to be highly teratogenic (Andermann et al., 1981, p.225). The importance of preconception counselling was recognised by the International League Against Epilepsy (ILAE), which recommended the format for provision of information, care and treatment of WWE relating to contraception, pregnancy, prenatal counselling and treatment, birth, the neonatal period, breastfeeding and infancy (Anonymous, 1993a; Anonymous, 1989).

Preconception counselling developments have emphasised the complex and multifaceted health needs of reproductive-age WWE (Report of the Quality Standards Subcommittee of the American Academy of Neurology, 1998), together with the importance of missed opportunities for women to access counselling, or take folic acid

in the correct dose and at the appropriate time. WWE have been found to frequently experience unplanned pregnancy, forgetting preconception advice and information concerning malformation risks, and failing to recognise the benefits of preconception review of AEDs, improvements in seizure control and commencement of folic acid (Scottish Intercollegiate Guidelines Network, 2003 (Updated October 2005); Fairgrieve et al., 2000).

The benefits of preconception counselling are achieved by timely identification of risk, life-style modifications, informed decisions about pregnancy and the opportunity to plan pregnancy (Cefalo et al., 1995). The context of preconception counselling for WWE emphasises the chronic nature of epilepsy, in which women require an ongoing process of preparation and review of epilepsy management, to ensure they conceive with a minimum of risk factors, fully aware of any risks and benefits of treatment, and able to make informed decisions about future pregnancies (Crawford, 2005). The Health Committee's report on preconception counselling recommended that the Chief Medical Officer draw to the attention of GPs the need to advise people with existing medical problems (including epilepsy) of the implications of their illness for future pregnancies (Health Committee (Fourth Report), 1990-1991 v1 para 123, p.xxvii). The slow progress developing preconception services for WWE has been criticised (Pack et al., 2009), including in relation to contraceptive knowledge deficits as a method of preventing unplanned pregnancy for WWE (Davis et al., 2008).

The progress of history is reflected in the updated NICE clinical guidelines (2012) which place responsibility upon healthcare professionals to be knowledgeable about potential interactions between AEDs and contraception, to offer all women and girls taking AEDs the opportunity to commence folic acid 5mg/day before any possibility of pregnancy, and to provide accurate and tailored information and counselling, in advance of sexual activity, about the risk of AEDs causing malformations and possible neurodevelopmental delay to an unborn child (National Clinical Guideline Centre, 2012). The requirement for healthcare professionals be aware of the latest data on risks to the unborn child, and to assess the risks and benefits of treatment with individual AEDs is emphasised, with specific focus on the risk of continued use of sodium valproate, particularly at higher doses, and of polytherapy, particularly including sodium valproate (NICE, 2012).

1.3 Introduction to this thesis

1.3.1 Research question

How do WWE interpret risk information when presented within consultation? What factors influence their decision-making? Do women use risk information when making decisions, and following consultation, are women prepared to make a risk-benefit assessment and potential modifications to their epilepsy management and or health behaviour? What are women's perceptions of the influence of communication of risk upon decisions made?

These general questions inform the specific research question addressed here of how WWE perceive and communicate risk information, which in turn structures the aims and objectives of this study.

1.3.2 Aims and objectives

The main aims of the study were two-fold:

1. To explore in-depth the perceptions of risk and probability of adverse pregnancy outcomes for WWE in the context of their preparations for pregnancy, and
2. To explore how WWE interpret information about risk when making preconception decisions?

Specific objectives were to explore:

- i. What factors influence risk behaviour and perception of risk in reproductive-age WWE.
- ii. How risks and uncertainties are perceived and their potential influence on preconception decision-making.
- iii. The experiences of risk benefit assessment.
- iv. Women's involvement in shared decision-making with their clinicians.

1.3.3 Research context

This study was influenced by my undergraduate and postgraduate studies in nursing and ethics; and, my employment within the NHS as an Epilepsy Nurse Specialist since 1995, working alongside medical staff and psychologists to develop services for WWE

across Merseyside and Cheshire. This context influenced my approach to research, valuing evidence from randomised control trials, and the humanistic approach valued from my nursing perspective.

The research presented in this thesis was developed from my clinical practice with WWE during their reproductive years. My experiential knowledge gained from practice reveals the routine presentation of information, in which some women actively requested additional risk information from their GP, neurologist or epilepsy nurse specialist; while others did not take up the offer of information and presented during pregnancy unaware of potential risks. Focusing on the experience of WWE, there was acknowledgement of a number of factors influencing reproductive decisions, including the role played by a partner. The primary focus of this study is to explore how women consider, use, are influenced by, trust and either act on or disregard the information provided during preconception clinic attendance.

The study was also developed alongside the authorship of a Cochrane systematic review of the evidence of effectiveness of preconception counselling to reduce adverse pregnancy outcomes. Preconception counselling and care interventions can be characterised as complex interventions with no high quality evidence of effectiveness and, to-date, no theoretical underpinning (see Chapter 2.4). The study reported within this thesis was designed to gain insight into the experience of women receiving risk information as part of their preconception care; and to identify what factors influence decision-making with the goal of developing a theoretical understanding of how preconception interventions might bring about changes with preconception planning and decision-making.

1.4 Outline of thesis

In Chapter 2, the literature reviewing the gender-specific challenges experienced by WWE is outlined, highlighting how the experience of seizures and requirement for AEDs during their reproductive years is further challenged by knowledge deficits. The management of these reproductive challenges will be presented alongside the results of a Cochrane Systematic Review of the effectiveness of preconception counselling to reduce adverse pregnancy outcomes for WWE.

Chapter 3 examines the psychosocial impact of epilepsy and influences upon women's perceptions of risk and personal judgements concerning preconception decisions. In Chapter 4 the methodological issues concerning research in this field are discussed, prior to describing the application of qualitative methods to explore the experiences of women preparing for pregnancy.

Chapters 5 to 9 detail the findings of qualitative analysis. Chapter 5 introduces the women contributing their experiences of preparing for pregnancy. Chapters 6 to 9 explore the substantive themes of 'pregnancy planning', the 'communication of risk and uncertainty', and 'decision-making in preparation for pregnancy' as experiential accounts utilized in the development of a model of preconception care for WWE. The contribution of these findings to the extant literature is discussed in Chapter 10.

Chapter 11 presents the study conclusions within the context of the original research questions to critically review the strengths and weaknesses of the findings and their contribution to practice. Recommendations for preconception care are discussed in relation to the findings of the Cochrane Systematic Review into the effectiveness of preconception counselling to reduce adverse pregnancy outcome and the future research requirements in this area.

Chapter 2 Preconception counselling: A literature review

Introduction

WWE planning pregnancy can generally expect an uneventful pregnancy, resulting in a 'normal child' (Tomson and Battino, 2009). However, WWE face additional challenges as they consider the possibility of pregnancy, namely, potential changes in menstrual function and reduced fertility, potential interactions of AEDs with hormonal contraception, the risks of adverse pregnancy outcomes including maternal and fetal mortality, congenital malformations, dysmorphism, developmental delay and the risks of inheritance (Yerby, 1997). A review of the evidence of the impact of preconception care upon the reduction of adverse pregnancy outcomes for WWE and their children is the focus of this chapter.

2.1 Gender-specific challenges

For WWE, the experience of pregnancy takes on additional dimensions in which their own illness may compromise the health of the unborn baby and further reduce their ability to cope with the everyday work of motherhood (Thompson et al., 2008). This requires women who want to improve their chances of having a positive pregnancy outcome to take action to control their environment and minimise the associated risks (Corbin, 1987). Thompson et al (2008) referred to these requirements as 'moral work': to take action to avoid unplanned pregnancy; and, to both seek and comply with complex medical advice when considering pregnancy. The reproductive journey for WWE is 'strewn with social barriers of an attitudinal, ideological and material' nature (Thomas, 1997; Dansky et al., 1980), resulting in the lives of WWE being associated with psychosocial sequelae which can have major implications for overall quality of life (QOL) (Jacoby and Baker, 2008).

Yue and colleagues (2011) identified the strongest predictors of QOL for women as perceived AED side effects and the numbers of AEDs taken; suggesting fertile WWE may worry about the increased risks of treatment in three important areas: fetal health, reproductive health including endocrine disorders and fertility, and the impact on appearance due to weight gain or hair loss. All these place a great burden on the social lives of women (Yue et al., 2011). Aspects of QOL for reproductive-age WWE relate

to the regulation of fertility, and attempts to normalise lifestyle through reliable contraception, including oral contraceptives as the most effective and commonly used contraceptive method (Lader, 2009; Boon et al., 2004). Effective contraception for WWE is seen as important because of the increased risks of pregnancy, which are compounded for some women by interactions between AEDs and hormonal contraception (Weisberg, 2010).

Contraceptive interactions result in reduced contraceptive efficacy, accidental pregnancy and/or increased seizure activity (Gaffield et al., 2011). The most notable AED interactions are between hormonal contraception used concomitantly with enzyme-inducing AEDs: phenobarbital, primidone, phenytoin, carbamazepine, topiramate (mainly at higher dose), eslicarbazepine, rufinamide and oxcarbazepine (Joint Formulary Committee, 2011; Gaffield et al., 2011). The choice of contraception for some women is, therefore, influenced by AED selection, thus increasing their need for information and counselling to support informed reproductive health choices (Gaffield et al., 2011). For women taking the non enzyme-inducing AED, lamotrigine, recent evidence suggests a clinically significant risk of interaction with the combined oral contraceptive pill, lowering lamotrigine serum levels and increasing the risk of seizures (Sabers and Petrenaite, 2009; Gaffield et al., 2011). Women taking sodium valproate, or polytherapy regimens including sodium valproate, are advised of the importance of establishing 'highly effective contraception' to avoid unplanned pregnancy, due to the additional risks of adverse pregnancy outcomes (Stokes et al., 2004; Harden et al., 2009; National Clinical Guideline Centre, 2012). The importance of WWE controlling their fertility is emphasised by recommendations – to plan pregnancy which for some women may require changes of AEDs or involve additional risks of contraceptive failure (Aylward, 2008; Thompson et al., 2008; Crawford, 2005). The significance of unintended pregnancy for the health, economic, and social status of women and their families is a global challenge reflected within the United Nations Millennium Development Goals to reduce child mortality and improve maternal health (Singh et al., 2010).

Further, the reproductive health of WWE is influenced by gender-specific side effects of AEDs, in addition to endocrine and menstrual dysfunctions (Herzog, 2006; Morrell, 1998; Isojarvi, 2003; Taubøll et al., 2009). Isojarvi (2003) reported prevalence of

polycystic ovarian syndrome as higher among untreated WWE, while menstrual disorders are more common in women taking carbamazepine long-term. Those gaining weight with valproate are more likely to experience polycystic ovaries, hyperandrogenism, and menstrual disorders (Isojarvi, 2003). Menstrual disorders in WWE have been associated with an increased risk for infertility, migraine, emotional disorders, female cancers, and are neurologically important because they are associated with greater seizure frequency (Herzog, 2006).

Infertility in WWE is likely due to social as well as medical reasons – the ‘likelihood of women marrying and having children’ is ‘dependent on the nature, severity, and duration of the disease’ and the extent to which ‘existing medical, social, and legal conditions impede marriage’ - resulting in married WWE having fewer live-born offspring than expected for the general population (Dansky et al., 1980; Aylward, 2008). Women with active epilepsy requiring continued AEDs into adulthood have been shown to have lower than average numbers of deliveries, pregnancies, and spontaneous and induced abortions, compared with women who achieve remission before the age of 20 years (Löfgren et al., 2009). Further, the Kerala Registry of Epilepsy and Pregnancy prospectively evaluated fertility in WWE, finding 61.6% of registrants conceived within 12 months; 38.4% were classed infertile, with exposure to AEDs increasing the risk of infertility, and polytherapy carrying a seven-fold risk (Sukumaran et al., 2010). It is estimated one in 200 pregnancies are exposed to AEDs (Fairgrieve et al., 2000; Barrett and Richens, 2003).

2.2 Preparing for pregnancy:

The risk of adverse pregnancy outcomes for women with epilepsy

Most women with epilepsy today can conceive and bear normal, healthy children, but their pregnancies present an increased risk for complications. Pregnancy can exacerbate seizure frequency in some women with epilepsy, and both maternal epilepsy and in utero exposure to antiepileptic drugs can increase the risk of adverse outcomes in children born to women with epilepsy (Yerby et al., 2004).

2.2.1 Major congenital malformation and birth defects

In utero exposure to AEDs is associated with greater risk of MCMs. The size of risk is influenced not only by the type of AED, but also by dose and other variables, all of which need to be taken into account in the management of epilepsy in women of

childbearing potential (Tomson et al., 2011). AEDs taken as monotherapy are associated with a two- to three-fold increased risk of MCMs raising the background malformation risk within the UK population from 1-2% to 4-9% (Morrow et al., 2006). Earlier publications quote even higher AED-related risks, suggesting up to a sevenfold increased risk of MCMs (Oguni and Osawa, 2004). The variance between MCM risk estimates reflects a number of factors. These include drug-specific factors, such as, the nature of the drug, the dose, concomitant drugs (polytherapy AEDs are associated with increased MCM risk), timing of exposure, and the nature of MCMs (presenting as isolated defects or defects affecting several organ systems), together with methodological factors, such as, inclusion criteria and reporting of confounding factors of maternal age and parity (Czeizel et al., 1992). The hypotheses proposed to explain AED teratogenicity include: folate deficiency, interactions between AEDs, the effect of tonic clonic seizures, genetic factors, and other factors including alcohol, smoking, age and gestational age (Oguni and Osawa, 2004). The association of MCMs with in utero exposure to AEDs is the best known example of an irreversible side effect of AEDs (Perucca et al., 2000).

The spectrum of MCMs associated with the older AEDs includes neural tube defects associated with exposure to sodium valproate and carbamazepine; congenital heart defects and facial clefts associated with exposures to phenobarbital, primidone and phenytoin; and urogenital and skeletal abnormalities associated with all older AEDs (Morrow et al., 2006). The rapid extension of newer AEDs into the treatment armoury for WWE has added to the uncertainty of teratogenic potential for all but the most commonly used ones, due to the time required from initial licensure to establish common use in women of reproductive potential (Tomson et al., 2007). AED use by registrants within the UK Epilepsy and Pregnancy Register illustrates this point, with reporting of monotherapy outcomes for the four most commonly used AEDs in the UK (1996-2005) carbamazepine, sodium valproate, lamotrigine and phenytoin (Morrow et al., 2006) (table 2.1).

MCM risk information for the newer AEDs remains limited. For example, for topiramate licensed for use in the UK in 1995, only 35 pregnancy exposures were reported by Morrow et al (2006). A Danish cohort has contributed data on the newer AEDs, with reporting of pregnancy outcomes following in utero exposure to

topiramate (5 MCMs in 108 pregnancies, 4.6%), oxcarbazepine (11 MCMs in 393 pregnancies, 2.8%), gabapentin (1 MCM in 59 pregnancies, 1.7%) and levetiracetam (0 MCM in 58 pregnancies) (Mølgaard-Nielsen and Hviid, 2011). The UK Epilepsy and Pregnancy Register has reported further on the MCM risks of levetiracetam, an AED licensed for use in the UK in 2000, and widely used in clinical practice to manage both generalised and partial seizure disorders. The Register reported three MCMs in 117 pregnancies exposed to levetiracetam in combination with other AEDs (2.7%; 95% CI 0.9% to 7.7%) (Hunt et al., 2006).

Drug/ date of 1 st use in practice (Shorvon, 1995)	Number of MCMs / Informative Outcome*	MCM rate (95% CI)	Type of malformation		
			NTD	Facial cleft	Cardiac
Carbamazepine (1962)	20 / 900	2.2% (1.4 to 3.4)	0.2%	0.4%	0.7%
Sodium Valproate (1961)	44 / 715	6.2% (4.6 to 8.2)	1.0%	1.5%	0.7%
Lamotrigine (1992)	21 / 647	3.2% (2.1 to 4.9)	0.2%	0.2%	0.6%
Phenytoin (1938)	3 / 82	3.7% (1.3 to 10.2)	0.0%	1.2%	1.2%

* Pregnancy losses with no MCM excluded; NTD, neural tube defect

Table 2.1 Malformation risk of monotherapy AEDs (Morrow et al., 2006).

Polytherapy regimens have been found to represent a greater risk of MCMs compared to monotherapy, particularly for regimens including sodium valproate, associated with MCM rates as great as 16.7% (Mawer et al., 2010). The challenge for reporting polytherapy MCM risk information was illustrated by Morrow and colleagues (2006) who reported 126 different combinations among 770 registrants into the UK Epilepsy and Pregnancy Register, the most commonly used polytherapy combinations being carbamazepine and sodium valproate (62 pregnancies, 8.8% MCM rate) and sodium valproate and lamotrigine (141 pregnancies, 9.6% MCM rate).

The influence of maternal tonic-clonic seizures as a causal factor for MCMs has been proposed. However, the evidence is refuted by claims that the fetus is 'remarkably resistant' to the influence of metabolic acidosis secondary to isolated seizures, although seizures are likely to influence the adverse outcome of pregnancies already complicated by pre-existing conditions (such as, placental insufficiency or chronic fetal hypoxia) (Barrett and Richens, 2003). The increased risk of MCMs in untreated WWE has led to suggestions of epilepsy itself as a causal factor (Czeizel et al., 1992;

Shapiro et al., 1976). Whilst the increased rates of major malformations, minor anomalies, intrauterine growth restriction and impaired psychomotor development among children exposed to AEDs is felt to be multifactorial, evidence of the pathogenesis of these adverse outcomes strongly suggests AEDs as the dominant cause at least for major congenital malformations (Perucca et al., 2000). The main focus of research has been to quantify the risks of WWE delivering a baby affected by MCMs, to categorise exposed infants by specific AED exposure into specific malformation syndromes and, to identify the frequency of specific congenital malformations and/or association with neuro-developmental delay into drug-specific syndromes. To a lesser extent research has focused on strategies to ameliorate the risks of adverse pregnancy outcome through preconception interventions. Strategies identified to reduce malformation risks within the general population, such as, preconception supplementation with folic acid, reduction of smoking, alcohol consumption, and obesity have been considered, albeit as confounding factors, within studies into the pregnancy outcomes of WWE.

The opportunity to influence the outcome of pregnancy and reduce MCMs for WWE is addressed by the recommendation for preconception folic acid supplementation, commencing prior to conception and continuing for a minimum of twelve weeks gestation (National Clinical Guideline Centre, 2012). Evidence of the effectiveness of folic acid in reducing the rate of AED-related MCMs, and specifically spina bifida, remains limited and is confounded by the variable uptake of folic acid either at the recommended doses or timings (Fairgrieve et al., 2000; Czeizel and Bánhidly, 2011). In the general population folic acid supplementation has been identified as having a primary preventive role for neural tube defects and other congenital defects (MRC Vitamin Study Research Group, 1991; De Weerd and Steegers, 2002). However, the ability to extrapolate this finding to treated WWE is unclear, with only limited evidence of its influence on reducing risks of spina bifida amongst sodium valproate exposed pregnancies (Craig et al., 1999; Morrow et al., 2009). WWE continue to be recommended folic acid supplementation, with benefit reported for reduction of congenital malformations in children unexposed to AEDs and those exposed in utero to carbamazepine, primidone, phenobarbital and phenytoin (Morrow et al., 2009; Jentink et al., 2010; National Clinical Guideline Centre, 2012; Kjær et al., 2008).

The potential teratogenic risks of all AEDs have been established, resulting in all older generation AEDs being classed as harmful to fetal health, and the majority of the newer AEDs classed as potentially harmful (Holmes, 2011). Assuming the effect of AEDs is important, then changes to newer AEDs may lead to changes in the risks of adverse pregnancy outcomes (Borthen et al., 2011). However, whatever reduction in specific MCMs changes to AEDs may afford, the ability to reduce the rate of MCMs is reliant on comprehensive changes in the medical care of preconceptual and pregnant women with epilepsy (Bánhidý et al., 2011). The value of research to inform on the MCM risks of AEDs is to assist both treating clinicians and individual women planning pregnancy, where ‘the goal for all concerned is a healthy, seizure-free mother and an undamaged child’ (Lander, 2008). MCM risk information serves to support epilepsy management decision-making, where the issues of maternal and fetal need require concurrent consideration, and a balance is likely required between acceptable MCM risk for a specific treatment regimen and the dosage required to establish effective seizure control (Lander, 2008). Data from the European Epilepsy and Pregnancy Register and UK Register have identified dose-dependent risks, supporting the recommendation to aim for lowest dose of an AED associated with optimum seizure control (Tomson et al., 2011; Morrow et al., 2006; Hauser, 2011).

2.2.2 Neuro-developmental delay

The longer-term implications for children born to mothers with epilepsy requiring AEDs throughout pregnancy is the influence upon their neurodevelopment and behaviour; early case reports indicate a relatively high incidence of ‘mental retardation’, intrauterine growth restriction and multiple minor anomalies as a marker for impairment (Barrett and Richens, 2003). Controversy exists pertaining to the existence of drug-specific risk and the frequency of neurodevelopmental effects associated with AED exposures, largely as a result of methodological concerns including study design, study size, control of confounding variables and duration of follow-up (Naghme Adab et al., 2004; Bromley et al., 2011). The Cochrane Systematic Review by Naghme Adab et al (2004) established the poor quality of evidence, revealing little evidence to guide drug selection, and caution interpreting the results. At

the time of completing the systematic review⁵, few studies reported outcomes for children exposed to sodium valproate, finding polytherapy to be associated with poorer neurodevelopmental outcomes (Naghme Adab et al., 2004).

Investigation to classify the neuro-cognitive effects of in utero AED exposure has been the focus of several national and international study groups including the Neurodevelopment Effects of Antiepileptic Drugs (NEAD) Study Group (Meador et al., 2009; Meador et al., 2011; Cohen et al., 2011), the Australian Pregnancy Register for Women with Epilepsy and Allied Disorders (Nadebaum et al., 2011) and the UK Epilepsy and Pregnancy Register (Cummings et al., 2011). The Manchester and Liverpool Neurodevelopmental Study Group has extended the phenotype of sodium valproate exposed infants to include specific verbal deficits and autism spectrum disorder (Shallcross et al., 2011; N. Adab et al., 2004; Bromley et al., 2008; Adab et al., 2001; Bromley et al., 2010; Vinten et al., 2009; Kini et al., 2006). Drug-specific risks have been established, reporting a dose-dependent influence of valproate for both lower verbal and non-verbal abilities, and the dose of carbamazepine influencing lower verbal performance. These findings have led to the hypothesis that fetal drug exposure may alter normal cerebral lateralization of language (Meador et al., 2011). Attempts at prolonged follow-up of neuro-cognitive adverse effects of in utero exposure to AEDs into adolescence and adulthood have revealed an increased risk of cognitive delay following polytherapy exposure and a crude recurrence risk of 29% (Dean et al., 2002; Titze et al., 2008).

The Liverpool and Manchester Neurodevelopment Group have added to methodological refinement in their prospective study of long-term risks following in utero AED exposure, confirming the overall development of children exposed to AEDs in monotherapy was statistically poorer than control children; and children exposed to valproate at doses >900mgs/day assessed younger than 24 months had a relative risk of 3.6 for below average developmental scores on the Griffiths Mental Development Scale [Confidence interval 1.760-7.571, $p < 0.001$] (Bromley et al., 2010). A significant dose-related decline in motor functioning is reported for valproate and

⁵ The review revealed 31 studies meeting the inclusion criteria reporting on 18 independent cohorts. The recruitment for these studies spanned from 1959 through to 1999 reflecting the variable AED prescribing practices.

carbamazepine, with a significant dose-related performance decline in parental ratings for adaptive functioning following valproate exposure. In addition, based on parental ratings for attention span and hyperactivity, children exposed in utero to valproate were at significantly greater risk for a future diagnosis of attention-deficit/hyperactivity disorder (Cohen et al., 2011). These findings are in keeping with others reporting on the additional educational needs of children exposed to sodium valproate (Adab et al., 2001) and valproate-specific language delay requiring speech therapy interventions (N. Adab et al., 2004). The odds ratio for detrimental effect of valproate upon neurodevelopment is reported as OR 26.1 (95% CI: 4.9-139) $p > 0.001$ by Cummings et al. (2011).

The identification of long-term developmental effects of in utero exposure to the newer AEDs is limited by the latent period from drug licence to adoption in practice and prescription within the childbearing population, as well as limitations in post-marketing surveillance. Bromley et al (2010) reported delayed development following exposure to less commonly used AEDs in a sub-group of 13 children exposed to phenytoin (7), topiramate (2), gabapentin (2), vigabatrin (1) and oxcarbazepine (1). They found no statistical significance compared with control children and were unable to draw conclusions due to the small size of this group (Bromley et al., 2010). Shallcross and colleagues (2011), on behalf of the Liverpool and Manchester Neurodevelopment Study Group and UK Epilepsy and Pregnancy Register prospectively investigated one of the newer AEDs, levetiracetam, finding exposed children did differ significantly from controls and had higher scores for overall development quotient when compared to children exposed in utero to valproate.

Alternative non-AED mechanisms influencing neurodevelopment of children born to WWE have been proposed, including a detrimental effect of maternal tonic clonic seizures during pregnancy (Titze et al., 2008). Adab et al (2004a) identified women experiencing five or more tonic clonic seizures in pregnancy as having a similar size effect upon child verbal IQ as exposure to sodium valproate. The potential mechanisms for convulsive seizures to influence neurodevelopment include fetal hypoxia and prolonged exposure to acidosis (N. Adab et al., 2004). Consistent with the majority opinion, Bromley et al (2010) and others have found no statistically

significant difference between children exposed to seizures and those not (Thomas et al., 2007; Meador et al., 2009; Titze et al., 2008).

The opportunity to influence neurodevelopmental outcomes has been proposed by Meador and colleagues (2011) who report preconception folate as positively associated with higher verbal outcomes in AED-exposed children. This finding is supported by the general population prospective observational Norwegian Mother and Child Cohort, which identified maternal use of folic acid supplements in early pregnancy as associated with a reduced risk of severe language delay in children at age 3 years (Roth et al., 2011). Meador et al (2011) support the need for additional research to both confirm the findings of drug-specific dose-dependent risks for neurodevelopmental delay and understand the underlying mechanisms associated with the effect of AEDs on the immature brain. In addition, the potential influence of environmental factors upon neurodevelopment also requires attention, to examine the implications of maternal stress secondary to worries concerning the risk of malformations, as potential confounders (Van den Bergh et al., 2005; Turner et al., 2008; Nicolai et al., 2008).

2.2.3 Adverse neonatal outcomes

Adverse outcomes of neonates were reported by Lin and colleagues (2009), suggesting WWE have a greater tendency to have low birth weight, preterm and small for gestational age babies, which is counteracted by AED therapy. These results were contested by the Liverpool and Manchester Neurodevelopment Study Group. Their controlled observational study found no significant differences in the frequency of preterm birth or low birth weight babies between WWE receiving treatment and controls, whilst babies of untreated WWE did not differ from those of the control group in relation to gestational age at birth or birth weight (Mawer et al., 2010).

2.2.4 Adverse antenatal outcomes

Adverse antenatal outcomes include changes to seizure frequency. The Australian Register of Antiepileptic Drugs in Pregnancy suggest the risk of seizures during pregnancy is 50-70% less if WWE are seizure free one year before pregnancy (Vajda et al., 2008). Seizure-related risks in pregnancy have been reported in the literature, ranging from no changes in seizure frequency and improvements in control reported in 83% of women with active epilepsy (Viinikainen et al., 2006), to infrequent seizure-

related injuries reported by the Liverpool and Manchester Neurodevelopmental Study Group (Mawer et al., 2010). The implications of a single breakthrough seizure during pregnancy as posing serious consequences for everyday social life are considered by Sabers (2009). Findings from a UK prospective study of the care of WWE in pregnancy found 71% of women experiencing ongoing seizures at the time of pregnancy, while incomplete adherence with medication was reported in 62.3% of women, a factor likely to have influenced the continued experience of seizures during pregnancy (Fairgrieve et al., 2000). Women who abruptly withdraw AEDs within pregnancy have been found to be at increased risk of worsening seizure control and a ten fold increased risk of maternal mortality, the latter felt to be preventable in the majority of cases through adequate preconception and pregnancy patient and carer education (de Swiet et al., 2011; Barrett and Richens, 2003). Maternal mortality includes cases of sudden unexpected death in epilepsy (SUDEP), and other preventable causes such as drowning (de Swiet et al., 2011). Status epilepticus as a complication of pregnancy accounted for 1.8% of all pregnancies monitored within the European register, which concluded that the outcomes of status epilepticus were not associated with maternal mortality or miscarriage (though there was one case of stillbirth in a woman experiencing status epilepticus) (The EURAP Study Group, 2009).

Obstetric complications associated with pregnancies in WWE taking AEDs throughout pregnancy include an increased risk of severe pre-eclampsia, early bleeding in pregnancy, induction of labour and caesarean delivery, and the increased risks of complications associated with AED use, the epilepsy itself being less influential (Borthen et al., 2011). Further, women with active epilepsy (seizures <5 years before conception) experienced planned caesarean sections more frequently. Rates of pre-eclampsia, early bleeding, induction and caesarean were not different between women with active or inactive epilepsies, and women not using AEDs had no increased risk of pregnancy complications (Borthen et al., 2011). The Kerala Registry of Epilepsy and Pregnancy prospectively followed WWE from preconception/first trimester throughout pregnancy, confirming no excess in intrapartum complications (severe bleeding and prolonged labour) or postpartum problems (postpartum haemorrhage and puerperal infections) compared to a matched control group of women without epilepsy (Saramma et al., 2011).

2.3 Preparing for pregnancy: Information needs

WWE require information concerning the increased risks associated with the management of epilepsy and its treatment throughout their reproductive years. This information is crucial to support their involvement in making informed reproductive decisions (Crawford and Lee, 1999). A number of studies have surveyed the information needs of WWE, identifying the extent of knowledge deficiency experienced by women and their poor satisfaction with service provision (Bell et al., 2002; Crawford and Hudson, 2003; Crawford and Lee, 1999; Wallace and Solomon, 1999; Fairgrieve et al., 2000). The significance of knowledge deficits were for women's inability to avoid accidental pregnancy and their lack of awareness of the potential risks associated with their treatment (Madden, 1999). Accidental or unplanned pregnancy secondary to contraceptive failure has the potential to create continued anxiety about the risks of AEDs, and to result in women seeking information from other less creditable sources because of conflicting medical advice (Wallace and Solomon, 1999).

The disparity between women's concerns about pregnancy and their awareness of effective contraception were the focus of the cross-sectional survey sampling WWE attending routine epilepsy care within the Columbia Comprehensive Epilepsy Centre (Davis et al., 2008; Pack et al., 2009). Of women who reported being sexually active, only 53% used effective methods of contraception (defined as contraception $\leq 10\%$ experience of pregnancy in the first year of typical use) and 17% relied on unorthodox methods and the unsafe method of 'withdrawal'. Of those women who had been pregnant, 61% reported at least one unplanned pregnancy (Davis et al., 2008). Women's knowledge of AED-related risks was found to be limited and inaccurate for the majority, with some women reporting AEDs as either having no effect on fetal development or a 'good effect'. For those women reliant on older AEDs (phenytoin, phenobarbitone, primidone, carbamazepine and sodium valproate) 40% were unaware of the potential teratogenic potential of their treatment, and 50% of women reliant on enzyme-inducing AEDs were incorrect about the potential for their treatment to reduce the effectiveness of oral contraceptives (Pack et al., 2009). History of pregnancy was not found to be associated with increased knowledge of AED-oral contraceptive interactions, leading to the authors to underscore the significance of knowledge deficits

for WWE as resulting in preventable morbidity including unplanned pregnancy, fetal exposure to teratogenic AEDs, and maternal stress (Pack et al., 2009).

The standard of care of WWE aged 14-55 years was examined as part of the Department of Health Clinical Standards Advisory Group (CSAG) questioning the information received on preconception and pregnancy topics. They found 40% of women recalled being advised of the need for pregnancy planning, 38% recalled being advised to commence folic acid prior to pregnancy and 48% of women recalled being advised of teratogenic risks (Bell et al., 2002). The results of the 'Ideal World' survey of female member of the UK charity Epilepsy Action, reinforced the value of written information about the effects of epilepsy on pregnancy and the risks to the unborn child being provided to support decision-making about adjusting AEDs when considering pregnancy (Crawford and Hudson, 2003). The potential improvements in epilepsy services for WWE were the focus of qualitative enquiry by Vazquez and colleagues (2007) who identified the level of dialogue between women and their physicians as insufficient to alleviate concerns.

Bagshaw et al (2008) reviewed women's information needs concerning childcare and the potential seizure-related risks of accidents and injury to their infant. These authors found only 50% of women recalled being provided with information about caring and managing childcare risks. The implications of maternal knowledge deficits for the psychomotor development of children have been raised, with both the childcare environment and maternal abilities identified as important determinants. These studies highlighted mothers' anxiety about their 'mothering' skills and lack of confidence in their abilities to protect their baby from harms (Hirano et al., 2004; Saramma et al., 2006; Bagshaw et al., 2008). The Kerala Registry of Epilepsy and Pregnancy group found a significant association between childrearing knowledge and practices, with WWE having significantly lower scores for childrearing knowledge, childcare monitoring and specific impairments of infant stimulation than women without epilepsy. The hesitations of WWE to actively involve themselves in cleaning and bathing their baby were felt to be due to the perceived fears both of the women themselves and family/carers concerning the risks of dropping the baby or causing injury (Saramma et al., 2011).

Improvement in women's knowledge is contingent on the availability of information services and knowledgeable healthcare professionals. However, healthcare professionals have been found to lack the skills necessary to advise women of teratogenic risks (Hancock et al., 2007). Morrell and colleagues (2000) surveyed 3535 healthcare professionals across a wide range of specialities, finding 50% of respondents uncertain about the frequency of birth defects of children born to WWE, and most not knowing the recommended minimum dose of folic acid supplementation. Around three-quarters of pharmacists were aware of enzyme-inducing AEDs reducing the efficacy of contraceptives; but neurologists were found to have significant knowledge gaps. Only 33% correctly identified the increased risks associated with sodium valproate, and even fewer responded correctly about the older AEDs (Roberts et al., 2011; McAuley et al., 2009). The majority of neurologists recognised the potential benefit of folic acid supplementation, despite lack of awareness of the additional risks for neurodevelopmental deficits in children exposed to AEDs (Roberts et al., 2011). These findings are significant for the care of WWE, given their reliance on healthcare professionals as first contact when considering pregnancy (Vazquez et al., 2007). This is reflected within NICE clinical guidance (2012), which requires those responsible for prescribing AEDs to be aware of the 'latest data' concerning risks to the unborn child when prescribing to any woman or girl with current or future childbearing potential (National Clinical Guideline Centre, 2012).

The need to reduce the health inequalities that result in an increased risk of adverse pregnancy outcome for WWE served as rationale for a formal systematic review to evaluate the evidence of effectiveness of preconception counselling for WWE, as part of The Cochrane Library series (JB Winterbottom et al., 2008).

2.4 Preconception counselling for women with epilepsy – A Cochrane Review

The objectives of completing this systematic review were two-fold; to establish the effectiveness of preconception counselling interventions for WWE, measured by a reduction of adverse pregnancy outcomes for both mother and child, increased knowledge of preconception issues and increased intentions to plan pregnancy; and to determine the level of evidence and primary research in the area (JB Winterbottom et al., 2008). The review has been completed in three stages:

- 1) Review protocol (first published in the Cochrane Library Issue 3 2007)
- 2) Complete review (first published in the Cochrane Library Issue 3 2008)
- 3) Update of review

The review methods⁶ complied with The Cochrane Library and involved a systematic search and appraisal of all published and unpublished work in the field. The types of studies included: randomised control trials - including quasi-randomised and cluster randomised trials; prospective cohort studies; controlled before and after studies and interrupted time series studies. Participants of interest were women of childbearing potential aged 12-50 years, with a confirmed diagnosis of epilepsy, experiencing two or more seizures in the last two years, on or off treatment. Preconception counselling interventions included any educational and/or counselling interventions targeting WWE before conception with the intention of improving pregnancy outcomes. Preconception defines the time leading up to a pregnancy, starting from the decision to have a baby up until becoming pregnant, with interventions involving assessment of lifestyle, health and fitness by a healthcare professional (NHS Direct, 2009). Studies were considered relevant if they compared usual care (defined as no targeted intervention) with any combination of the recommended components of preconception care.

Outcomes of interest included, as primary maternal outcomes, increased knowledge of pregnancy and treatment-related risks; and as secondary outcomes, reduction in maternal mortality and morbidity, reduction in unplanned pregnancy, improvement in rates of commencement of folic acid, increased uptake of breastfeeding, increased satisfaction with care, and increased concordance with treatment/intervention regimens. Primary fetal outcomes included reduced incidence of major malformations (minor anomaly) and developmental delay, while secondary outcomes included reduced infant mortality and morbidity (reduced admission into Special Care Baby Unit, reductions in preterm births and reductions in baby born small for gestational age). An essential component of evaluating the effectiveness of health promotion interventions is the measurement of cost effectiveness, requiring both immediate and

⁶ Winterbottom, J.B., Smyth, R.M., Jacoby, A. & Baker, G.A. (2008) Preconception counselling for women with epilepsy to reduce adverse pregnancy outcome. *Cochrane Database of Systematic Reviews Issue 3*, Art.No.: CD006645.doi: 10.1002/14651858. CD006645.pub2. Review methods and results are presented acknowledging my contribution as main author.

long-term measurement of direct and indirect costs. Economic measures of cost-effectiveness and cost-utility analysis were included in the review protocol as essential measures to estimate the likely benefits, harms or costs to reduce adverse pregnancy outcomes in WWE and their children (JB Winterbottom et al., 2008).

2.4.1 Complete review results – Description of studies

The search strategy⁷ identified 225 citations of which 211 were excluded (65 were guidelines or narrative reviews, and the remainder included non-interventional surveys of information needs). No study met the eligibility criteria for inclusion in the review (see 'Characteristics of excluded studies' table, within JB Winterbottom et al., 2008). The review identified several studies that attempted to provide evidence of the effectiveness of preconception counselling and reported positive outcomes, but caution is required interpreting these study findings due to their methodological weakness and failure to meet the predetermined inclusion criteria. Four studies identified improved fetal outcomes, reporting reduced incidence of MCMs (Betts and Fox, 1999; Oguni et al., 1992); reduced perinatal deaths (Martin and Millac, 1993); and one study⁸ reported improvements in live birth rate (Cox et al., 1992; Smith et al., 1987). Betts and Fox (1999) identified no cases of MCM in the preconception intervention group who had benefited from epilepsy review resulting in changes in AEDs, notably withdrawing or switching from valproate, and switching to monotherapy. Data were unavailable to ascertain the effectiveness of counselling to promote preconception folic acid supplementation, although no MCMs were recorded for WWE taking folic acid before conception (Betts and Fox, 1999).

2.4.2 Updated review results – Description of studies

The present literature review updates the previously published one in The Cochrane Database of Systematic Reviews (Issue 3, 2008) on 'Preconception counselling for women with epilepsy to reduce adverse pregnancy outcome', using the same search methods for identifying studies for inclusion and the same assessments of methodological quality (see JB Winterbottom et al., 2008, Methods & Appendix 1 Search Strategy). Three studies awaiting classification at the time of the original

⁷ A search of electronic databases included Medline (OVID) (1950-February 2008); Scopus (1966-March 2008); CINAHL (1982-March 2008); PsycINFO (1806-March 2008); and ASSIA (1987-March 2008)(Winterbottom et al., 2008).

⁸ One study reported findings in two papers.

review have now had their status updated. Contact was made with one author (Nguyen, 2007) and retrieval of full text articles by Shafer and Santilli (1996) and Beffa Negrini, et al.(1998) confirmed them as opinion papers only describing service developments. Assessment of a paper by Beffa Negrini and colleagues (1998) identified a further publication describing a non-intervention retrospective study reporting pregnancy outcomes following development of an outpatient service for pregnant women with epilepsy (Franza et al., 1998). In addition, the update includes appraisal of two studies, updating their status following assessment of the complete published data. The study by Mawer and colleagues recruited women into a prospective pregnancy cohort evaluating pregnancy outcomes. Communication with the author revealed that preconception interventions were not included within analysis of outcomes, and recruitment occurred during the index pregnancy (Mawer et al., 2010). The study by Miškov and colleagues (2009) was included for assessment of quality.

The updated electronic and hand searches were re-run including dates between March 2008 and February 2012, with 73 new citations identified including one from the Cochrane Pregnancy and Childbirth Group. Sixty-eight papers were discounted as not relevant, of which 37 were guideline documents and narrative review articles. From those discounted; five surveyed information needs (three of professionals; two of WWE); one reviewed a midwife intervention in a non-epilepsy population; four were non-interventional, surveying genetic risk perceptions and fears concerning childbearing; two reported fertility rates. Three studies (four papers) were discounted due to study design, including the Hungarian case-control study which concluded that preconception folic acid supplementation reduced, but did not eliminate, the increased MCM risk for children exposed to AEDs (Kjær et al., 2008; Bánhidly et al., 2011); and the qualitative papers by Thompson and colleagues (2008) and Pashley and O'Donoghue (2009). Of note, Thompson et al (2008) provided an additional perspective on women's experience of the 'hard work' coping with the uncertainties of reproduction, which result in few seeking specialist advice in advance of planning pregnancy; and on the dissonance between specialist advice and women's internalization of health messages advising against drug use in pregnancy as a barrier when considering engaging in preconception counselling. In the study by Pashley and O'Donoghue (2009), women experiencing unplanned pregnancy were found to be less likely to worry about AED-related risks and to judge their ability to influence

pregnancy outcomes with a degree of fatalism. These qualitative papers provide insight into the problems faced by WWE, and provide rationale for the undertaking of a systematic review of the effectiveness of preconception interventions to influence pregnancy outcome.

Assessment of selection of studies was completed with the search results classified as relevant, possible or rejected. One study met the inclusion criteria (Miškov et al., 2009)(see table 2.2 Risk of Bias); the rationale for exclusions are shown in table 2.3 Characteristics of excluded studies.

2.4.3 Included studies

The prospective cohort study by Miškov, et al. (2009) reported on the outcomes of 23 women taking lamotrigine (mean age 27.14±3.15) recruited at Sestre milosrdnice University Hospital, Zagreb (May 2003- May 2008) and followed prospectively throughout pregnancy, including outcomes for their infants up to one year of life. The problem of incomplete reporting on the outcomes of interest has been resolved by writing to the study author.

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	All women enrolled in first trimester, "most of them had been surveyed at the same hospital before their index pregnancies occurred".
Allocation concealment (selection bias)	High risk	One third of participants presented for first time in the Centre for counselling during pregnancy. No evidence of concealment.
Blinding of participants and personnel (performance bias)	High risk	No evidence of blinding
Blinding of outcome assessment (detection bias)	High risk	No evidence of blinding
Incomplete outcome data (attrition bias)	High risk	Ascertainment of exposure to the preconception interventions restricted due to pooled data.
Selective reporting (reporting bias)	High risk	The published description of the methods and results prevented complete assessment of methodological quality, since no description was provided of the derivation of the intervention and control groups.
Other bias	High risk	Reported results of preconception counselling for only a subset of the main sample of women (those who had attended the hospital before their index pregnancy).

Table 2.2 Risk of bias (non-randomised studies)

Eleven women were reported to have planned pregnancy (defined as deciding to achieve pregnancy and considering changing dietary habits prior to conception); 16 women took folic acid at least four weeks before pregnancy and continued throughout pregnancy. The higher intake of folic acid was attributed to the ‘proper preconception counselling’ and repeated recommendations. However, the lack of baseline data means this conclusion is unsupported. Preconception switch of AEDs was completed by 17 women, seven switching between 10 days and 1 month before pregnancy, of whom four planned pregnancy, and two experienced deterioration in seizure control during pregnancy. Adverse outcomes were reported in six pregnancies, no MCMs: there was one intrauterine death (without evidence of MCM), two spontaneous abortions (one excluded due to diagnosis of toxoplasmosis), and one elective termination (reasons not related to epilepsy or AEDs). Eight women experienced seizures during pregnancy, and two experienced preterm deliveries (Miškov et al., 2009).

Study ID	Reason for exclusion
De Santis et al 2010	Study design: Prospective cohort of callers to the Teratology Information Service. Participant: 344 non-pregnant women taking AEDs (10% of calls to TIS were doctors, 7% relatives), 3733 non-pregnant women taking non-AED therapeutic chemicals. Intervention: risk information concerning drug exposure in pregnancy. Main findings: 54% of all women callers had folic acid, compared to 12% of WWE. Reason for exclusion: Unable to differentiate AED use for WWE or other indications.
Kazandi et al (2010)	Study design: Retrospective cohort Participant: 66 pregnant WWE. Intervention: Provision of preconception counselling. Main findings: No MCMs or minor anomalies; 57% counselled WWE commenced preconception folic acid. All counselled women remained on prescribed AEDs throughout pregnancy compared to 60.71% of non-counselled women. Reason for exclusion: Retrospective study design.
Mawer et al (2010)	Study design: Controlled observational study Participant: 277 WWE, 315 controlled matched for age and parity. Intervention: Prospective review of pregnancy outcomes, no preconception intervention. Main findings: No association between MCM and dose of preconception folic acid. Reason for exclusion: Non-interventional.
Rück & Bauer (2008)	Study design: Retrospective cohort of patients referred into the Epileptology Clinic. Participant: 118 WWE attended for ‘special pregnancy planning advice’. Intervention: Preconception advice and changes to AEDs, commencement of folic acid. Main findings: 31.2% of counselled women took preconception folic acid. 35.5% planned pregnancy. 35.5% counselled WWE had increased seizure frequency. Reason for exclusion: Retrospective study design.
Sabers et al 2009	Study design: Retrospective chart review. Participant: 99 Pregnant WWE registered in European Epilepsy and Pregnancy Register. Group 1- 46 WWE receiving preconception review, Group 2- 44 WWE referred pregnant. Intervention: Preconception counselling delivered as routine care for all women. Main findings: 78% of counselled women versus 41% pregnant women took preconception folic acid. Counselled women were less likely to be seizure free prior to pregnancy. Reason for exclusion: Retrospective study design.

Table 2.3 Characteristics of excluded studies

2.4.4 Discussion of review findings

Caution is required when interpreting the results for the included study, due to the high risk of bias. There was little evidence to confirm the effectiveness of preconception counselling interventions to improve pregnancy outcomes in WWE. Several studies attempted to show evidence of effect. However, due to methodological weaknesses, no firm conclusions or implication for practice can be drawn.

The study by Miškov and colleagues (2009) identified the ‘continuous processes of planning and preparing for pregnancy’ as reliant on a multidisciplinary approach. Their findings were supported by Sabers (2009), in that not all women referred to the epilepsy clinic before conception experienced a planned pregnancy (48%) or commenced folic acid (70%) (Miškov et al., 2009). This highlights the potential influence of other factors affecting pregnancy outcomes such as socioeconomic status, educational attainment and preconception knowledge deficits. Of note, from those studies excluded, Sabers (2009) described systematic delivery of preconception counselling information including about ‘adequate contraception’, and evaluation and/or adjustment of AEDs ‘aimed at therapeutic low-dose monotherapy regimens’, and reported counselled women as less likely to experience an increased seizure frequency during pregnancy. Sabers (2009) suggested preconception folic acid intake was not an accurate marker for receipt of preconception counselling, as not all counselled women commenced supplementation prior to conception. Sabers proposed preconception commencement of folic acid as more predictive of intention to conceive, as not all women followed medical advice. The goals of preconception counselling were extended by Kazandi and colleagues to include alleviation of pregnancy-related stress by improving folic acid supplementation, coordinating pregnancy care, providing ultrasound scans and information about the risks of seizure in pregnancy. Kazandi et al (2010) found preconception counselling was associated with complete adherence to treatment advice and women maintaining AEDs throughout pregnancy, when compared to non-counselled women who were at increased likelihood of discontinuing AEDs during the first trimester and of experiencing seizures during pregnancy.

The methodological challenges raised by the results of this systematic review, alongside concerns about methodological quality of studies identified highlight the

need for caution interpreting the results. Others investigating the potential to recruit and retain women participating in preconception interventional studies, have demonstrated the ability to achieve an adequate rate of study completion and representative sample posing few threats to study validity (Brown et al., 1997). These authors highlight the potential barriers to recruitment included the tentative nature of pregnancy plans requiring adjustments of the data collection protocols and the importance of maintaining contact with participants throughout the study (Brown et al., 1997). The Cochrane Effective Practice and Organisation of Care Group; in their work to review the effectiveness of complex interventions that involve both patients and professionals and organisational change, highlight the importance of a control group and pre-intervention data collection (Ballini et al., 2011). Evaluation of preconception counselling interventions represented a challenge, due to the complex nature of interventions involving several interconnected components; both pharmacological and educational, and the interdependence of interventional components dependent on organisational structures, personnel and service delivery; in addition to patient variables. Evaluation of the effectiveness of preconception counselling interventions is reliant on appropriately powered studies designed to eliminate the risk of confounding.

The implication for practice is that there are major limitations to available evidence of the effectiveness of preconception interventions, and a need to evaluate the cost-effectiveness of service developments. NHS maternity care for WWE is associated with additional care requirements, resulting in antenatal costs estimated at £660 higher per woman than for women overall (Mistry et al., 2007). However, no study reviewed included cost analysis of preconception care. In addition, uncertainty surrounds the effectiveness of one of the most commonly and widely applied primary preventive strategies: preconception folic acid supplementation (Kjær et al., 2008); and preconception health education to increase appropriate use of folic acid (Czeizel and Bánhidy, 2011). Preconception care aims to increase awareness of WWE of the importance of seizure control, together with knowledge of role AEDs play in maintaining optimal control both prior to and during pregnancy (Kalviainen and Tomson, 2006). Achieving this requires improvements in shared information concerning all aspects of reproduction (NICE, 2012).

The driver for future research is the need to understand the unique challenges faced by WWE throughout their childbearing years. Prospective investigation of factors that influence pregnancy planning, and sufficient long-term follow-up of WWE who have received preconception interventions are required so that the influence of risk information on risk framing and decision-making, and clarification of the meanings of risk for WWE and their likely motives for taking action, can be evaluated (Winterbottom et al., 2009).

2.5 Summary

Women with epilepsy preparing for pregnancy are required to manage a range of gender-specific challenges, including contraception, fertility, and the need for AEDs during their childbearing years. Whilst the majority of women achieve a desired pregnancy and good outcome, some face additional risks of congenital malformation and neuro-cognitive delay affecting their offspring. Clinical practice has addressed these challenges through provision of preconception counselling. However, current literature reveals limitations in the evidence of the effectiveness of preconception interventions. Future research should include prospective evaluation of primary and secondary outcomes of preconception counselling with pre-intervention measures of knowledge and health behaviours of WWE to reduce the potential bias reported by observational studies. To achieve this goal, research is first required to investigate the women's perceptions of pregnancy-related risks and the influence upon reproductive decision-making and pregnancy planning. This thesis presents research that addresses this goal.

In the next chapter, the contribution of social-cognitive theories and the psychosocial literature to understand reproductive health behaviour is considered.

Chapter 3 Reproductive health behaviours

Introduction

Preconception care is the physical and mental preparation for childbearing of both parents before pregnancy. It has a large component of health education, one facet of the total education of living, and a smaller medical component specifically for identifiable problems. Pregnancy is a load and probably is better coped with if preparations have been made (Chamberlain, 1986, p.1).

WWE preparing for pregnancy face two sets of challenges: those common to any woman (deciding to have a child including negotiation with a partner, and setting time aside to prepare and optimise health prior to conception), and those specific to their condition. Managing pregnancy-related risks for WWE includes: the importance of optimising seizure control and the need for AEDs throughout childbearing years, non-drug concerns about epilepsy inheritance, and epilepsy-specific knowledge deficits. WWE may experience additional psychosocial challenges, reflecting the additional responsibilities they face during their reproductive years. The challenges faced by WWE negotiating preconception decisions are highlighted, acknowledging the influence of a partner as implied by Chamberlain's quote, in addition to external social factors all likely to influence pregnancy planning. In this chapter, I will examine the determinants of reproductive decision-making and risk perceptions considered by WWE, reviewing the literature both from the perspective of social cognitive theories and the wider psychosocial literature.

3.1 Social cognitive theory

Social cognitive theories and models have emerged to help explain and predict health behaviours and thereby assist the development of interventions to produce improvements in individual and populations' health (Conner and Norman, 1995, p.1,7). Health behaviours are assumed to be the end result of rational decision-making, based upon elaborate subjective cost-benefit analyses of the likely outcomes, valued and associated with the highest expected utility (Conner and Norman, 1995, p.7). A literature search reveals the application of social cognitive theories across a wide range of health conditions, describing how the preparedness of an individual to action behaviour change is a consequence of a complex of variables and/or stages (Marks,

2008). This literature review will focus on application of social cognitive theories in the fields of preconception and epilepsy-related healthcare illustrated in table 3.1.

Preconception Intervention	Social Cognitive Theory	Evidence of application
Epilepsy management review Seeking preconception review	Self-efficacy, self-management. Extended Health Belief Model	General epilepsy population (DiIorio et al., 2003). Teenagers with diabetes (Charron-Prochownik et al., 2001)
Improved contraception use Condom use consistency	Composite model (perceived barriers, cues to action, self-efficacy). Theory of planned behaviour	Preconception diabetic population (Wang et al., 2006). Teenage non-epilepsy population (Abraham et al., 2011)
Planned pregnancy	Theory of planned behaviour. Locus of control	Preconception non-epilepsy population (Lifflander et al., 2007). Preconception diabetic population (Holing et al., 1998)
Adherence to intervention (switch to alternative treatment, withdrawal, dose reduction)	Self-efficacy and self-management of medications. Theory of planned behaviour. Maternal & fetal health locus of control	General epilepsy population (DiIorio et al., 2004; Kobau and DiIorio, 2003). General epilepsy population (Kilingç and Campbell, 2008). Pregnant women with diabetes (Spirito et al., 1990)
Initiation of folic acid	Health belief model. Health belief model & 'Fetal Health Locus of Control Scale'. Transtheoretical model	Non-epilepsy pregnant population (Kloeblen and Batish, 1999). Non-epilepsy population 17-50 year olds (Quillin et al., 2000). Non-epilepsy population (Milan and White, 2010)
General preconception health improvements. Stopping smoking.	Locus of control & self-efficacy. Transtheoretical model.	Preconception non-epilepsy population (Bastani et al., 2010). Pregnant non-epilepsy population (Haslam and Draper, 2000).

Table 3.1 Application of social cognitive theory

3.1.1 Health Belief Model

The health belief model (HBM) assumes that individual beliefs concerning personal susceptibility to, and severity of, a health concern (e.g. unplanned pregnancy) serve to motivate actions to reduce the threat through a person's desire to avoid the area of concern and maintain wellness (Stretcher and Rosenstock, 1997, p.43). An individual's level of readiness to respond to health concerns is motivated by their ability to take the necessary action and their perceptions of benefits weighed against perceived barriers. Barriers are seen to direct an individual's decisions and course of action, whilst 'cues for action' serve as triggers to prompt an individual to feel ready to address the health concern (Stretcher and Rosenstock, 1997, p.45-6; Rutter and Quine, 2002, p.10).

Kloeblen and Batish (1999) tested the utility of the HBM to predict low income pregnant women's intentions to follow a high folate diet, finding the perceived benefits of supplementing their diet were the strongest predictor of this outcome. Quillin et al (2000) identified four potential health belief variables predicting adherence to preconception folic acid intake, including, perceived susceptibility of having a baby affected by NTD if not complying with folic acid supplementation; perceived seriousness of NTDs; perceived benefits of supplementation to prevent occurrence of NTD; and, perceived barriers to compliance with folic acid supplementation (Quillin et al., 2000).

Investigating reproductive health attitudes and behaviours of adolescent females with type 1 diabetes, Wang et al (2006) found perceived susceptibility to becoming pregnant had a significant positive relationship with perceived barriers and cues to use of birth control. Further, perceived benefits of birth control were significantly related to positive personal attitudes towards using birth control, and 'cues to action' were significantly related to intentions to perform reproductive health behaviours. Charron-Prochownik et al (2001) applied an Extended Health Belief Model, and found a strong association between teenagers with diabetes' initial awareness of preconception care and their later utilization of services, suggesting the timing of health messages and motivational cues by healthcare professionals played an important role triggering action and promoting positive reproductive health behaviours.

3.1.2 Self-Efficacy Theory

Perceived self-efficacy refers to beliefs in one's capabilities to organize and execute the courses of action required to produce given attainments. The events over which personal influence is exercised vary, and influence may entail regulating one's own motivation, thought processes, affective states, and actions, or it may involve changing environmental conditions, depending on what one seeks to manage (Bandura, 1997, p.3).

Perceived self-efficacy is a good predictor of adherence to self-management regimens; predicting how well a person might stick to a particular health behaviour and manage their own health (Bandura, 1997, p.288). Bandura suggests chronic disease management requires the person not only to 'alleviate symptoms that are more or less personally controllable but also exercise personal control over medical care and treatment that are prescribed for them' (p.299). Schwarzer and Fuchs (1995, p.165)

propose that adoption of health promotion recommendations relies on three sets of cognitions, (adapted here to reflect the needs of WWE):

1. an expectancy that one is at risk ('my epilepsy might deteriorate in pregnancy' or 'my baby might be affected by my drugs');
2. an expectancy of reducing the threat by behaviour changes ('if I seek epilepsy review to optimise my epilepsy control, I will reduce the risks to me and my future baby'); and
3. the expectancy that one is sufficiently capable of making positive changes or avoiding risky habits ('I can avoid accidental pregnancy and access preconception review')

Epilepsy self-management is achieved by the individual taking steps to control seizures and manage the consequences or effects of having a seizure disorder, finding 'perceived' self-efficacy and patient satisfaction directly influencing perceived self-management of medications and abilities to manage epilepsy and optimise seizure control (DiIorio et al., 2004). Those confident to manage their medications were more likely to believe the benefits associated with taking treatment and practice self-management strategies. Further, the development and maintenance of self-management practices emphasises the importance of social support (DiIorio et al., 2004). Self-efficacy beliefs are behaviour specific, with high levels of self-efficacy associated with confidence in performing behaviours prescribed to control seizures (Dilorio et al., 1992). Amir et al (1999) found the level of perceived control to achieve mastery in dealing with epilepsy encouraged an individual's coping, medication taking, and performance in self-management actions. Self-efficacy and its influence upon epilepsy self-management, in addition to social support and locus of control, were found to impact quality of life (Amir et al., 1999).

3.1.3 Health Locus of Control

Health locus of control (HLC) emphasises perceptions of control, mastery and self-efficacy beliefs, focusing on expectancies that one's actions are instrumental in goals attained (Norman and Bennett, 1995, p.63). Individuals with an internal locus of control are identified as assuming responsibility for their health, and more likely to engage in health-promoting activities than those with an external locus of control, who believe events occur outside their control, by chance, or the control of powerful others

(Norman and Bennett, 1995, p.63). The HLC model has been applied to epilepsy self-management programmes. It suggests locus of control is a useful measure of an individual's perceptions of their ability to change or control their lives, and is a predictor of a person's willingness to comply with medical treatment. The HLC model supports interventions to empower people to better deal with the ramifications of living with a seizure disorder (Dechman, 1992). In a study by Asadi-Pooya, et al (2007) patients with good seizure control were found to have higher internal health locus of control scores on the multidimensional health locus of control scale compared with patients with uncontrolled seizures. Patients with epilepsy held stronger beliefs in powerful others influencing their health (external HLC), and tended to believe internal factors were unimportant for health control. They found significant interrelationships between HLC and health attitudes, behaviours, coping styles and outcomes, highlighting the strong role to be played by healthcare professionals influencing the health-related beliefs of patients accessing their care (Asadi-Pooya et al., 2007). Specific features of coping behaviours found among WWE were greater reliance on religion/faith, and fewer problem-solving strategies to help them overcome the problems they faced in daily life compared with pregnant healthy controls (Sachin et al., 2008).

Assessment of HLC in pregnant women found those abstaining from smoking during pregnancy held significantly higher perceived internal control scores, and believed themselves responsible for the health of their unborn child, compared to women with external locus of control, who believed health professionals or chance factors determined their newborns' health (Labs and Wurtele, 1986). Spirito et al (1990) found women with diabetes were more likely than non-diabetic women to believe the health of their unborn baby was under the control of powerful others such as healthcare professionals. Perceived internal control in relation to birth outcomes has been strongly associated with socio-demographic variables and physical health status; women perceiving greater control over future birth outcomes were older, more highly educated, married or living with a partner, and in better physical health (Weisman et al., 2008). Women with diabetes attributing their health outcomes to the control of powerful others were more likely to experience unplanned pregnancy (Holing et al., 1998). Preconception interventions aimed at empowering women by increasing their awareness of the risks of unhealthy lifestyles and the benefits of health improvements

upon pregnancy outcomes; and at influencing beliefs of personal health as less dependent on influential others, were likely to improve health decisions and increase preferences for information seeking (Bastani et al., 2010).

3.1.4 Theory of Planned Behaviour

The theory of planned behaviour (TPB) assumes an individual holds beliefs which influence their intentions to perform particular behaviours (Ajzen, 1988, p.132-3). In this model three independent determinants influence a person's intention to perform a particular behaviour; subjective norms, attitudes towards the behaviour, and the individual's perceived control to be able to perform the behaviour (Ajzen, 1988). Perceived behavioural control is an important extension of the TPB, reflecting theoretical developments from the theory of reasoned actions (TRA), concerning the influence of behaviours not entirely under volitional control, and proposing a direct causal effect of perceived control on intentions and behavioural goals (Ajzen, 1988, p.136-7). The TRA was the basis for the analysis by Austin (1989), which showed that subjective norms predicted parental adherence to AED regimens, and influenced by negative beliefs based on inaccurate information. In relation to contraceptive practices, perceived behavioural control predicts intentions to use condoms and actual condom use (Conner and Sparks, 1995, p.129). The impact of social structures, such as socioeconomic status (SES), gender and aspirations pertaining to lifestyle, employment and education, upon condom use has been explored. Mother's SES and aspirations were found to have independent unmediated effects on consistent condom use, and educational aspirations and gender affecting condom specific cognitions and consistency of use (Abraham et al., 2011).

Describing women's motives and behaviours surrounding pregnancy planning, Lifflander et al (2007) identified three different dimensions: the decision to have a child; taking steps to increase the likelihood of conception; and making plans for childcare. Conflicting desires for pregnancy introduced uncertainty about the timing of conception, in which women wanting a child at a younger age, despite also wanting to complete their education or establish their career, were found to be less motivated to plan and more willing to leave the outcome of childbearing to chance (Lifflander et al., 2007).

Perceived behavioural control has been associated with the uncertainty of predicting the benefits of withdrawing AEDs weighed against the risks of seizure relapse, with planning behaviours influenced by normative beliefs and social pressures including the embarrassment associated with a diagnosis of epilepsy, problems associated with medication taking, timing of the decision to withdraw medication and perceived support (Kilinç and Campbell, 2008). Motivations to withdraw AEDs were found to reflect personal experience and a wider awareness of others successfully achieving the planned outcome (Jacoby et al., 1992). In addition, decision-making processes unique to women were found to be influenced by subjective norms about achieving pregnancy off medications (Kilinç and Campbell, 2008).

3.1.5 Stage theories of health behaviour change

A number of differing stage theories have been developed to predict and explain health behaviour change, emphasizing the dynamic and temporal perspective of behaviour change reliant upon different cognitions at the different stages of change (Norman and Conner, 1995, p.213). The ‘contemplation ladder’ was developed by Biener and Adams (1991) as a single item self-report measure of a person’s motivation stage, and applied to measure readiness to take action to stop smoking, identifying a person in the ‘precontemplative stage’ with ‘no thought of quitting’ at stage 0-1. It is assumed a level of threat must exist before a person contemplates the benefits of taking action, and ruminates about their competence to perform the behaviour (Schwarzer and Fuchs, 1995, p.177). The Transtheoretical Model (TTM) was developed to include the stages of precontemplation and contemplation to help explain an individual’s readiness to plan a specific behaviour change (Prochaska and DiClemente, 1983). The stages of change are defined by the time between thinking about change and taking action. The preparation stage is the time immediately before taking action, and the action stage is the time immediately after having made the overt change of behaviour (Prochaska et al., 1994).

Milan and White (2010) evaluated a web-based folic acid intervention based on the TTM, establishing that the majority of participants were not taking folic acid supplements at baseline, with greatest improvements following completion of the tailored intervention, based on self-efficacy and weighing the pros and cons for adopting a change in behaviour. ‘Precontemplative’ individuals experienced the

greatest impact, as they had no motivation to change prior to the intervention (Milan and White, 2010). In contrast, the health risk assessment of pregnant smokers was explored by Haslam and Draper (2000), identifying precontemplative women less convinced of the health risks associated with smoking compared to women in the contemplative, preparation or action phases. The importance of stage-specific interventions were highlighted, suggesting that women in the ‘contemplative’ and ‘preparation’ stages held more conviction and, therefore, would benefit more from skills training, whilst those in the ‘precontemplative’ stage required consciousness-raising health information to convince them of the risks of smoking in pregnancy (Haslam and Draper, 2000).

3.1.6 The role of social cognition to explain preconception health behaviours

The health behaviours associated with preparations for pregnancy are assumed in-part under volitional control (securing effective contraception, taking AEDs as prescribed, accessing the epilepsy clinic and requesting information). Other aspects of psychosocial experience, for example, life with epilepsy, risk perceptions, and outcome expectancies are assumed as under incomplete personal control, representing internal issues such as limited knowledge, uncertainty, emotional factors and dependence on others. Additionally, the influences of socioeconomic factors need recognition. All of these factors may act to constrain implementation of intended behaviours (Ajzen, 1988, p.127-133), and may help explain poor adherence by WWE to preconception recommendations. There is increasingly acknowledgement of the importance of assessing risk as a socially constructed phenomenon (Slovic, 2000b), an issue relevant for reproductive aged WWE due to the complexity of preconception interventions – a point extended in the following section.

3.2 Psychosocial influences upon reproductive health behaviour

The psychosocial burden to women during childbearing can be substantial, with mixed messages from different physicians, nurses, family, and friends, about the risk that she is “placing” on her unborn child by exposure to known teratogens. Although there are increased maternal and fetal risks compared to the general population, these risks are often over-exaggerated and are not presented in the context of the risk of recurrent and uncontrolled seizures (Pennell and Thompson, 2009, p.S21)

Pennell and Thompson (2009) identify four types of 'psychological burden' facing WWE preparing for pregnancy: the first concerns their childbearing status and decisions to plan pregnancy; the second relates to their perception of pregnancy-related risk; the third concerns the influence of risk communication; the fourth, to women's preference for involvement in decisions concerning their treatment.

3.2.1 Pregnancy planning

The challenge facing WWE making pregnancy decisions is the extent to which their decisions extend beyond the duration of pregnancy to influence pre-pregnancy decisions (Thomas, 1997), and motivate them to seek preconception review and secure highly effective contraception until completion of the recommended interventions. The decision to plan pregnancy has been proposed as a process moving from underlying motivations, attitudes and beliefs to desires and the active formation of reproductive intentions, through to the implementation of a decision and the resultant behaviours (Miller, 1994). In this process WWE must also respond to the specific-to-epilepsy risks of unplanned pregnancy and the benefits of planning (Pashley and O'Donoghue, 2009).

The affective and psychological dimensions influencing ambivalence towards contraceptive use have been used to explain happiness or dismay about the discovery of pregnancy as stages along a continuum of planning (Bachrach and Newcomer, 1999). From a sociological perspective, becoming a mother has been constructed in terms of a life 'transition', in which motives for having children may not have been considered or discussed, and the questions of whether pregnancy was planned are complex, tapping into a 'minefield of unexplored or half-explored motives and reasons' (Oakley, 1979, p.33). These can be framed broadly as: expectations; the results of a 'long process of critical self-examination'; the weighing up advantages and disadvantages; and the influence of images of family life (Oakley, 1979, p.30-35). Earle and Letherby (2002) identify the medical and lay discourses around women intentionally trying to conceive as creating an illusion of control, which fails to match the reality of the ability to conceive when desired, occurring earlier or later than anticipated, if at all. The experience of an earlier than planned pregnancy has been described within patient groups of WWE; with pregnancy in teenage years or when not ready, as a result of inadequate advice leading to contraceptive choices being ineffective (Wallace and Solomon, 1999).

Barrett and Wellings (2002) emphasise the importance of women's definitions of pregnancy planning. They suggest that the term 'unplanned pregnancy' may fail to capture the positive pregnancy intentions expressed by some women. Earle (2004) presented a typology of pregnancy intentions identifying four categories: the planned pregnancy, the 'laissez-faire pregnancy', the 'recalcitrant pregnancy', and the accidental pregnancy. Earle (2004) considers the planned and accidental categories as unambiguous, describing women as either 'following advocated health professional' recommendations, or describing an 'unexpected pregnancy due to contraceptive failure'. The categories of 'Laissez-faire' and 'recalcitrant' are seen as ambiguous: the former describing women's experience of stopping contraception and adopting a more relaxed approach to pregnancy, the latter describing the experience of women who want to be pregnant but for whom planned pregnancy would be socially unacceptable (Earle, 2004). For others, ambivalence towards pregnancy has been linked to inconsistent contraceptive use and proposed as an alternate explanation for the poor predictive power of 'pregnancy timing intentions' (Zabin, 1999). Poor utilisation of contraception methods has been proposed as an important factor in the experience of unplanned pregnancy among WWE (Pennell and Thompson, 2009). A lack of planning surrounding contraception may be reflective of personality traits and a general disinclination to plan ahead on wide variety of issues in daily life (Brown and Eisenberg, 1995, p.170). The term 'recalcitrant pregnancy' highlights the affective dimensions of pregnancy desires, where past experiences can create barriers to seeking preconception care (Earle, 2004). Barriers to discussing pregnancy intentions with either a partner or healthcare professional are associated with WWE experiencing unplanned pregnancy, highlighting misunderstandings about fertility (Pashley and O'Donoghue, 2009).

Analysis of women's pregnancy intentions distinguishes a subset of women who knowingly take chances through ineffective contraceptive practices. These women in effect adopt a tactic of 'contraceptive roulette', in which 'non-decisions' are seen as valid alternatives to deliberate reproductive or contraceptive choices (Lippman-Hand and Fraser, 1979c, p.81; Pashley and O'Donoghue, 2009). Holing et al (1998) questioned why women with diabetes chose not to plan pregnancy, identifying unplanned pregnancy as often not due to contraceptive failure, but more closely classified as conscious or subconsciously intended. These authors highlighted the

complex ‘web of circumstances associated with poor pregnancy planning’, including poorer SES and, significantly poorer relationships with healthcare professionals and perceptions of discouragement (Holing et al., 1998). Extending the analysis within a General Practice population Hosli et al (2008) identified factors deterring women from participating in preconception counselling including: perceptions of having sufficient knowledge to make the necessary preconception health improvements, perceptions of low risk of adverse pregnancy outcome, and misunderstandings about the aim of preconception counselling. An important finding from these authors related to the influence of risk perception upon reproductive decision-making, suggesting women who felt they had already achieved a healthy lifestyle and perceived low personal and familial risks of congenital malformations were less likely to decide to participate in preconception counselling (Hosli et al., 2008).

3.2.2 Perception of pregnancy-related risk

The term ‘risk’ is often used to denote a phenomenon that has the potential to deliver substantial harm, whether or not the probability of this harm eventuating is estimable (Lupton, 1999, p.9).

Lupton (1999) suggests pregnancy exemplifies the impact of the advance in risk-related knowledge and technology, with advice constructed to regulate a woman’s body from the time she may be considering the idea of childbearing. The aim is to ensure she is at a peak state of health at the time of conception, and able to care for the fetus, which is portrayed as highly fragile and susceptible to risk throughout development (Lupton, 1999, p.89). For many women, the presentation of risk information as part of their medical care and communication with specialists defines their risk status as their individual responsibility (Parsons and Atkinson, 1992, p.438).

Pregnancy risk perceptions have been judged major influences upon the lives of women with disability and chronic health conditions such as epilepsy (Lyerly et al., 2009; Thomas, 1997; Douglas, 1990). In these circumstances women are seen to adopt ‘protective governing’ strategies in order to exert some control over the potential harms threatening their pregnancy (Corbin, 1987). Corbin (1987) identified a number of strategies used by pregnant women to assess their level of risk in response to information, to balance available management options in terms of potential benefits

and risks, and to control risks through adoption of shared management processes in which management actions were taken by women alongside their clinician.

Since the thalidomide disaster in the 1960s, fears about medicine use in pregnancy persist. Differing sources of risk information (social media, friends, family, healthcare professionals etc) may provide women with misleading information, further provoking anxieties and fears (Hancock et al., 2007). Assessment of therapeutic risk has been explored by Slovic (2000a), finding public perceptions of the likelihood of harm and seriousness of harm due to taking therapeutic drugs was highly correlated to perceived risk. Within patient groups, those experiencing adverse drug reactions were more likely to blame a lack of information about the drug as the cause of the reaction, in addition to inadequate monitoring by the doctor (Slovic, 2000a, p.261).

3.2.3 The influence of risk communication

Pennell and Thompson (2009) suggest the psychosocial issues facing WWE require attention by clinicians when counselling and considering treatment, as the content of risk information has far reaching consequences for the range of decisions made by women concerning pregnancy and life-style, before, during and after pregnancy. The potential influence of framing risk information is significant, a point explored by Parsons and Atkinson (1992) in their research of women receiving genetic counselling. Exploring the meanings of risk, these authors found that whilst some women retained mathematical risk information (such as percentage risk), others translated their risk into descriptive categories (such as, 'high' or 'low') and in doing so, shifted from the delicacy of 'risk values' originally communicated by the clinician into a binary statement of something that was either going to happen or not (Parsons and Atkinson, 1992). Being offered treatment options in addition to the level of descriptions of potential drug side-effects (including negative descriptions) has been presented as a desirable approach to assisting medication/intervention decision-making (Toerien et al., 2011; Berry et al., 1997). Recent research shows that use of the internet to search for information about teratogenic risks of AEDs has resulted in many women remaining uncertain, confused and experiencing increased anxiety (De Santis et al., 2010). De Santis and colleague's (2010) highlight the importance of 'health professionals directing women towards high quality websites', and recommend women are 'provided instruction about how to locate information, how to check its credibility,

and the need to discuss the information during consultation' (p.157). The potential for women to benefit from a tailored internet intervention was reported by Milan and White (2010). These authors found female college students were receptive to an internet based intervention, tailored to their stage of change and able to promote self-efficacy and perceived pros for commencing folic acid supplementation.

The importance of frank discussion about drug risks regardless of whether health professional or patient feel comfortable has been identified as a crucial characteristic of satisfactory teratogenic risk counselling (Santucci et al., 2010). May et al (2009) identified WWE held differing perceptions of risks which were influenced by past experiences of pregnancy, and associated with expressions of 'great worry during pregnancy about risks to their newborn child'. Perceived drug risks influenced women's decisions about whether to have children or not, finding the potential risks of malformations caused by their treatment as instrumental in their conscious abstaining from having their own children (May et al., 2009). Perceptions of genetic risks were investigated by Helbig and colleagues (2010) who found perceived risks of epilepsy affecting the child to be overestimated, with a four-fold increase in risk estimated by parents with epilepsy. The implications of such overestimation were apparent in women's perceptions of the abilities to care for a child and resulted in decisions to have fewer children (Helbig et al., 2010). Further, patients undergoing genetic investigations experienced intensified fears about the possibilities of their child developing epilepsy, with the potential for both positive and negative emotional impact upon the family (Hammond et al., 2010).

Turner et al (2008) investigated prevalence of fears in pregnant WWE, and found women with higher seizure frequency during pregnancy were more fearful of childbirth; WWE were significantly more fearful about possible fetal malformations than were healthy controls, but less fearful of pain during delivery. May and colleagues (2009) identified fears during pregnancy as contributing to a fifth of women stopping or reducing AEDs during pregnancy without consulting their physician. The consequences of fear resulted in a third of women having great reservations about becoming pregnant because of their epilepsy (May et al., 2009; Helbig et al., 2010). This last point is exemplified by a sociological analysis of the medical discourse around 'Fetal Alcohol Syndrome' by Armstrong (2003). Armstrong notes the 'tragedy'

of birth defects associated with teratogen exposure and women's 'weighty' responsibility towards the fetus has defined the woman as a 'fetal vessel' requiring careful risk management (p.117, 137,195). This may, in turn, lead to extensions of the 'ritual prohibitions' of pregnancy to women who are no more than potentially pregnant (Armstrong, 2003, p.197).

The unpredictability of patient responses to risk information has been reported either as emphasising 'chance' and 'opportunity', or accentuating 'uncertainty' and 'danger' (Wilkinson, 2010; Heyman and Henriksen, 1998). The disparity between lay and professional interpretations of perceived risks of seizure relapse have been studied in families and clinicians caring for children with epilepsy (Gordon, 1994), with the finding that clinicians are often unable to predict a family's response to risk information (Gordon et al., 1996). Individual variance in views about acceptable seizure relapse risks have also been shown for adolescents with epilepsy when compared to their parents (Pogančev, 2011), and in the context of women's perceptions of teratogenic risks in relation to their requirement for medical treatment during pregnancy (Jasper et al., 2001). Examining women callers to the Motherisk teratogen information service, Jasper et al (2001) found teratogenic risk information presented as the probability of giving birth to a normal child lowered perceptions of risk and influenced decisions to use a drug in pregnancy. Negative presentation of drug risk (e.g. "there is a 1-3% chance of having a child who has a major birth defect") influenced women's perceptions of higher teratogenic risks when compared to positively framed messages (e.g. "97-99% chance of having a normal child"), resulting in negative framing reducing the likelihood of wanting to take the medication (Jasper et al., 2001). Even among women counselled with positively framed information, more than 65% chose not to take their medication (Jasper et al., 2001). An alternate explanation of risk framing was presented by Jacoby's et al (1993) analysis of counselling patients about AED withdrawal, identifying negative framing of risk information was more likely to influence decisions to remain on treatment in patients initially uncertain of their treatment preference. The clinician's neutrality was felt to inadvertently 'reflect a high magnitude of risk' (Jacoby et al., 1993). That patients with epilepsy are more susceptible to framing bias places them at risk of making uninformed decisions and emphasises the decisions they face as complicated by the uncertainties involved in differing drug choices and their short- and long-term risks and benefits

(Choi et al., 2011). Wallace and Solomon (1999) identified WWE as concerned by conflicting advice which, they felt, left women unclear of exactly what risks they might face, anxious about the risks of AEDs in pregnancy, and philosophical about achieving a balance of seizures and side-effects that least interfered with their lives. The potential for 'risky' decisions about stopping treatment on discovery of pregnancy, and issues of women's ability to perform their 'moral work of avoiding unplanned pregnancy' as being highly contingent upon their receipt of accurate and timely information, remains a concern in practice (Thompson et al., 2008, p.59).

The experience of pregnancy for women with chronic illness requires effort and focus, keeping the condition closely monitored and under control, not only to maintain their own health 'but for the safety of her developing fetus' (Corbin and Strauss, 1987, p.266), and emphasising the probability of an abnormal process and the need for women to be dependent on medical care (Oakley, 1980, p.21 & p.215). The overall experience of pregnancy represents a transition period reflecting changes in biological, social and psychological makeup (Pennell and Thompson, 2009; Turner et al., 2008). This can, for WWE who interpret pregnancy as a stressor, result in additional worry and lack of control over their bodies (Lunardi et al., 2011). Knowledge as a prerequisite for psychosocial wellbeing for persons with epilepsy has been reviewed by Collings (1999), who positioned knowledge as central in the reduction of uncertainty. Psychosocial well-being is best achieved by the combination of effective AEDs and the provision of as much information as possible regarding epilepsy and its treatment (Collings, 1990). Collings (1990) proposed that a lack of information places the person with epilepsy unable to make realistic adjustments in their lifestyle, and more likely to fall victim to myths and other inaccurate information, in turn resulting in increased health worries and less fulfilment. Meeting women's information needs requires their current beliefs, ideas and knowledge to be explored, challenging professionals not simply to dismiss erroneous beliefs, but to offer convincing alternative explanations (Wallace and Solomon, 1999). Having adequate knowledge and a stock of management strategies helps women to manage pregnancy risks; the greater the knowledge about their condition and about the purpose and implications of treatment plans in contrast to normal pregnancy, the better able WWE will be to accurately assess risk levels and adopt a position of control in making use of available support (Corbin, 1987).

3.2.4 Involvement in treatment decisions

The challenge for WWE making reproductive decisions is their concerns about the continuation of medication during pregnancy. The importance of establishing ‘the right drug for their seizures’ was revealed in women’s accounts of a frustrating ‘trial and error’ process, in which they accepted lengthy and laborious changes in medication in the hope of gaining seizure control (Wallace and Solomon, 1999). The study of patient involvement in the AED decision-making reveals a widespread ‘paternalistic’ approach, in which patients attending routine epilepsy clinic consultations relinquish control of treatment options being presented, in favour of the clinician’s expertise (McCorry et al., 2009). In contrast to the literature in other fields of medicine elevating the patient as expert (Tuckett et al., 1985; Lowe, 2005), few patients held specific treatment preferences. Whilst the majority had ‘hopes and expectations’, including a keenness to try new treatments if recommended by their doctor, few expressed concerns about potential adverse side effects (McCorry et al., 2009). The case of a reproductive aged woman was exemplified by McCorry et al (2009), where the patient’s ‘risky decision’ to withdraw sodium valproate, had failed to take account of her personal risks, if her actions had resulted in worsening seizures. The patient’s account was influenced by her perceived ‘high chance’ if she had experienced pregnancy of causing ‘damage’ to her child (McCorry et al., 2009).

An alternative approach to women’s role in AED decision-making was presented by Pashley and O’Donoghue (2009). They identified women who planned pregnancy as more articulate and determined, taking a central role in the decision-making process, both in relation to instigating referral for counselling, and in asserting their opinions upon the available treatment options. The epilepsy-specific factors influencing treatment decisions have been found to include the potential loss of driving licence, ‘fears of seizures because of past seizures and their after-effects’, and the gender specific factor of the ‘implications of continued AED treatment for contraception and pregnancy’ (Jacoby et al., 1993). Offering women the opportunity to withdraw AEDs may be controversial, highlighting that in the context of pregnancy, WWE need to be cautioned about the importance of weighing up the uncertain teratogenic risks of AEDs against the physical risks to them of experiencing a seizure, and the social penalties

such as loss of driving or employment (Williams et al., 2002). In this sense, Thomas (1997) proposes that women's pregnancy decisions take into account their concerns about the implications of disability and/or treatment upon perceptions of themselves as 'good enough mothers'. Thomas (1997) highlighted the responsibilities placed on medication decisions for WWE and their needs to avoid the potential outcome of having a disabled child, based on their perception of being seen by others as 'irresponsible' and 'unfair' to the child.

3.3 Summary

In this chapter, social cognitive theories have been shown to offer the potential to predict health behaviours, such as epilepsy self-management and AED adherence, and health promoting behaviours, such as securing effective contraception, commencement and maintenance of folic acid supplementation, and seeking preconception counselling. The psychosocial literature has illuminated many of the challenges facing WWE. These include the need to plan pregnancy and manage the risks associated with taking medication during pregnancy, and managing a seizure disorder, in which decisions made, could have far reaching consequences. The potential for 'risky' decisions to be influenced by misperceptions, the influence of framing bias, and the added influences of perceived judgements of others have been explored within the literature.

Review of the literature reveals limited application of both social cognitive theories and psychosocial literature to account for the experiences unique to the population of WWE. A number of unanswered questions have been raised, including the continued struggle faced by WWE to adequately prepare for pregnancy, which can result in women experiencing pregnancy unaware of potential risks and resorting to stopping AEDs without discussion with their clinician. In Chapter 4, I will present the methods employed to address this thesis research question.

Chapter 4 Methodology and methods

Introduction

This chapter will outline the research methodology and methods used within this qualitative study to answer the research question of how WWE perceive and communicate risk information during preparation for pregnancy. I will describe the development of the approach taken within this study, and the rationale for selecting a qualitative approach. The final section of this chapter will describe the practical application of the study methods; detailing the recruitment of research participants, methods of data collection, and the processes of analysis.

The author, Janine Winterbottom was responsible for the design and execution of this study, and was awarded The Sir Desmond Pond Fellowship from Epilepsy Research UK in 2006 to conduct it.

4.1 The methodological approach

This section will highlight the importance of methodology within health research, bringing together ‘two ways of knowing’ in which both medical and social science have influence (Oakley, 2000, p.20).

4.1.1 Developing the methodological approach

The primary focus of this study was to explore the context of women’s experience of preparing for pregnancy, and to develop a theoretical understanding of how preconception interventions might bring about changes in pregnancy planning and decision-making. The study protocol was written alongside a detailed literature review of the subject area, including a review of the effectiveness of preconception interventions to reduce the risk of adverse pregnancy outcome for WWE. The review was published within the Cochrane Library of Systematic Reviews and the results presented in Chapter 2. The review identifies the limitations of existing evidence, both to describe what constitutes preconception care and what factors were likely to influence its effectiveness. These factors influenced decisions concerning the research question and study design, and required choices to be made between a qualitative and/or quantitative methodology. The key characteristics of quantitative and

qualitative research are presented in table 4.1. My prior experiences working with WWE created a tension between selecting a quantitative objective approach, as against a qualitative paradigm which valued experiential knowledge. These competing interests were recognised during the process of study design, and highlighted the importance of selecting a ‘reflexive’ approach which acknowledged my prior knowledge of the subject and position within the research process.

Referring to table 4.1 the following account is presented to situate this study within the broader health research paradigm, and to highlight the selection of research approach.

	Quantitative	Qualitative
Dominant Paradigm:	Positivist, Empirical-analytical Epidemiology	Interpretivist, Constructivist Humanistic or Naturalistic
Research aim / stance:	‘Outsider’ - Testing hypotheses / generalizing. Reductionist / inferential / hypothetico-deductive / outcome orientated.	‘Insider’ - Generating hypotheses / describing. Exploratory / inductive / process-oriented / oriented to understanding.
Question:	How many Xs? (enumeration)	What, Why and How?
Contextual:	Extent of difference & characteristics of phenomena.	Classifying difference, meanings of phenomena or experience.
Explanatory:	Causal analysis & statistical associations.	Examining reasoning descriptions & interpretations.
Evaluative:	Extent of outcome achieved. Prediction.	How? Appraisal of interventions.
Generative:		Develop theory, policy solutions.
Research relationship:	Distance between researcher & subject. Relation between theory & research - confirming theory.	Closeness between researcher & subject. Relation between theory & research - emergent theory.
Sampling method:	Respondent, participant. Random, statistical or probabilistic sampling. Frame fixed before start.	Participant, informant. Theoretical or purposive sampling. Sampling units flexible before & during.
Data collection:	Experiment, survey, structured interview, questionnaire.	Observation, semi-structured/in-depth interview, focus group
Analysis:	Specified in advance.	Worked out during the study.
Ethics:	Appropriateness of standardized techniques.	Intrusion, sensitivity or intimacy of subject
Quality criterion:	Rigour, proof, evidence, statistical significance.	Relevance, plausibility, illustrativeness/ responsiveness to subject’s experience.
Adapted from the following sources: Bryman (1988); Oakley (2000); Pope and Mays (1995); Ritchie (2003)		

Table 4.1 Key distinctions between quantitative and qualitative study design

4.1.2 Dominant Paradigm

Research in the field of epilepsy has been dominated by an empirical quantitative research paradigm, focusing upon questions of causality, statistical associations,

predictions and frequencies. This approach has resulted in an expedient increase of antiepileptic drug development, confirmation of the influence of genetics, and an emphasis on quantitative measurement of 'quality of life' as a determinant of treatment success (Baker et al., 1993; Baker et al., 1998). Qualitative research has supported extending understandings to achieve substantive and formal theoretical advancement, such as, the advancement of a model for 'epileptic stigma' (Scambler and Hopkins, 1990; Jacoby et al., 1996; Jacoby et al., 2004). The value of conducting qualitative health research is its ability to bridge the gap between scientific evidence and clinical practice through a commitment to understanding health behaviours in everyday context and acknowledgement that subjective meanings are crucial (Green and Britten, 1998; Atkinson, 1995).

4.1.3 Research Aim / Stance

The focus of interest was to seek to understand the meaning of experiencing preparing for pregnancy from the perspective of the women themselves (Chapter 1). Review of the literature (Chapter 2) reveals few studies have sought to understand the beliefs and perceptions of women concerning their preconception care needs during their reproductive life, and therefore have failed to answer why many WWE do not utilise available services. The study objectives were to expand understanding and have direct applicability to the development and evaluation of preconception interventions to reduce the risks of adverse pregnancy outcomes for WWE.

The researcher stance requires an interaction between the 'researcher and participant' with the intention of increasing understandings and generating theoretical concepts (Holloway and Wheeler, 2010). From a quantitative paradigm, deductive approaches are used by the researcher to test existing theory or hypotheses, with the findings either supporting or negating the hypothesis leading to extrapolation to larger populations (Broom and Willis, 2007). In contrast, the qualitative research paradigm acknowledges the limitations of striving for objectivity. Snape and Spencer (2003) acknowledge that the qualitative research process is interactive, with a dynamic relationship between the 'researcher' and the 'participant' jointly creating understandings of the phenomena of interest.

While one attempts to get close to the participant's personal world, one cannot do this directly or completely. Access is both dependent on, and complicated by, the

researcher's own conceptions which are required in order to make sense of the other personal world through a process of interpretative activity (Smith, 1996:264).

4.1.4 Research Question

The present study questioned the experience of WWE preparing for pregnancy. Punch (1998) judges the research question as giving direction to the research context, identifying the boundaries of investigation and the type of data to be collected, and finally, maintaining the researcher's focus and providing a framework for writing. The research question was developed within clinical practice in response to the need to gain understanding of women's experience of preparing for pregnancy, perception of risk information and decision-making within the context of epilepsy review, and more specifically preconception counselling, all of which might shape reproductive behaviour, information seeking and access to epilepsy review.

4.1.5 Research relationship

In setting out to examine the problems faced by women preparing for pregnancy, my concern was essentially with capturing the 'essence' of their reproductive experience as part of their wider social existence and concerns of everyday life. This approach is in sharp contrast to a positivist/quantitative approach, where the goal of research is to gather objective knowledge gained through impartial and 'outsider' observation. Oakley (2000) is critical of quantitative approaches which attempt to 'imitate' the natural sciences by creating the illusion of barriers between the researcher and the researched leading to a 'dangerous disengagement' positioning the researcher as expert:

The idea of a world to be known about implies a knower; the knower is the expert, and the known are the objects of someone else's knowledge, rather than their own. This is where power comes in. The notion of expertise, intrinsic to the 'quantitative' model of how research is done, means a hierarchy of power relations; where there are the powerful, there are also the powerless (Oakley, 2000:36).

Oakley reveals an important issue concerning the relationship between my position as a female researcher and clinician researching the experience of WWE, and the moral obligation 'to treat others as one would oneself wish to be treated' by avoiding the imposition of 'the theorist's' (my) own views upon the female subject (Oakley, 2000, p.36). Holloway and Wheeler (2010) acknowledge the potential for the qualitative

researcher to influence the process of the research and the findings, requiring explicit scrutiny of the research process, including both the interactional and interpersonal aspects of the research.

In recognition of these methodological assertions, decisions were made to situate this research within an interpretivist paradigm. The essential quality of the relationship between the 'interpretivist' researcher and participant is its ability to get close to 'view the world as a participant in that setting' to gather rich and detailed data (Bryman, 1988), which in turn supports analysis, theorising and inference. The relationship of the qualitative researcher to theory relates to its purpose as a framework for 'critically understanding' the data, with existing theories illuminating the findings, which in turn might be modified through the findings (Holloway and Wheeler, 2010). The relationship to theory has also been suggested as an 'orientating or theoretical lens' guiding the researcher 'as to what issues are important to examine, and the people who should be studied' (Creswell, 2009).

This opening section has outlined the nature of the debate surrounding the qualitative-quantitative divide. My relationship to the participants and the research questions being asked led to my decisions to take an interpretative phenomenological analytic approach. The decisions concerning analysis will be presented in the following section.

4. 2 Qualitative research methods

A good qualitative research study design is one which has a clearly defined purpose, in which there is coherence between the research questions and the methods or approach proposed, and which generates data which is valid and reliable. (Lewis, 2003:47)

4.2.1 Sampling methods / study population

Holloway and Wheeler (2010) suggest the identification of the study population and the context and settings of the research refer both to the environment and conditions in which the study takes place, and to the culture of the participants and location of the research. Sampling methods were required to be purposeful as a means of recruiting individuals able to grant access to a particular perspective on the experience at the heart of the investigation (Langdrige, 2007). The study sample for an interpretive phenomenological analysis is most frequently limited in size and calls for a

homogenous sample. Homogeneity requires definition, as its use in interpretative phenomenological analysis refers to the selection of participants ‘for whom the research question is meaningful’ (Smith et al., 2009, p.49). Therefore, in relation to the current study, a homogeneous sample would select women of childbearing age (see inclusion criteria).

The size of the study population was judged adequate by the participants being able to ‘represent a particular perspective on the phenomenon of interest’ (Smith et al., 2009, p.49)(see Appendix 3 Stages of Analysis). The term representativeness within phenomenology refers to:

...not seeking the human common differences, but seeking the differences that make us common, that make us human. (Morse, 1992:92)

The importance placed on maximising opportunities for transfer of the findings to the wider population of reproductive age WWE preparing for pregnancy was a reflection of the commitment to the funding organisation and was addressed through careful selection of the recruitment site.

4.2.2 Data collection techniques

Qualitative data collection techniques have been divided into two approaches: those that allow investigation of the phenomena in their natural settings, and those that generate data through the interventions of the researcher (Ritchie, 2003). The selection of naturally occurring data (observation of clinic consultation) and generated data (focus groups and in-depth interview) were felt to reflect the descriptive and interpretative experiences surrounding preparation for pregnancy.

Data that reflected the reproductive careers of WWE and invited women to offer a rich and detailed ‘first-person’ account of their experience was required to gain an understanding of the personal context of the reproductive decisions faced by women (Lewis, 2003). Focus groups represented the opportunity to collect data reflecting the normative influences, self-identity and shared meanings which likely shape perceptions of experience and understandings in the social world of WWE (Finch and Lewis, 2003). WWE rarely have opportunities to meet each other; and as no naturally occurring groups were available, the focus groups were convened specifically with the

purpose of the research project. Qualitative research can rely on a single source of data, however, the opportunity for a 'mixed method' approach to data collection can benefit a study, with each method bringing a particular insight to the phenomena of interest (Ritchie, 2003). The choice of 'mixed methods' or triangulation in relation to this study refers to the processes by which several methods (focus group methods, in-depth interviews and non-participant observation) and sources of data have been used to study the phenomenon in order to ensure validity (Holloway and Wheeler, 2010)(see also section 4.2.5 Quality Criteria).

4.2.3 Qualitative analysis

There are many ways of analysing qualitative data ... what links all the approaches is a central concern with transforming and interpreting the qualitative data – in a rigorous and scholarly way – in order to capture the complexities of the social world we seek to understand. (Coffey and Atkinson, 1996:3)

Decisions concerning the selection of analytic approach were made in collaboration with my academic supervisors and through formal research training which widened my appreciation of alternative approaches⁹. The selection of analytic approach resulted in a comparison between discourse analysis and interpretative phenomenological analysis (Table 4.2). Although discourse analysis has relevance to the epilepsy clinic consultation, and could be used to explore the discursive context of women attending the epilepsy clinic, it was felt to limit the scope of exploring experience and focus attention on the act of communication rather than the processes and products of the communication of risk and its influence upon decisions made by woman preparing for pregnancy, the majority of which lie outside of the influence of the consultation.

Interpretative phenomenological analysis requires further distinction, as a number of approaches have been developed within health and social research (Smith et al., 2009; Benner, 1994; Van Manen, 1990). The approach selected recognised the necessity to value the social-cognitive paradigms, to explore the content of particular individuals' beliefs and responses, and draw attention to the process operating between cognitions and behaviour consistent with the research objectives (Smith, 1996; Smith et al., 1997). The main assumptions of interpretative phenomenological analysis place

⁹ Research training 'The design, conduct and analysis of qualitative research using depth interviews' (4-8th July 2005) was provided by the National Centre for Social Research in London (NATCEN) and was invaluable in informing the writing of the study protocol and selection of methodology and methods.

interest in learning something about the participant's psychological world in the form of beliefs and constructs; placing 'meaning' as the central aim of analysis – to try and understand the content and complexity of those meanings (Smith and Osborn, 2008). This quality was the main attraction, and was seen to offer a unique insight into the research subject:

...the participant, like me, is a unique individual worthy of an idiographic, holistic analysis. At the same time, however, there is the possibility of bridging the divide between selves because we are all at the same time part of a larger whole, a collectivity that allows the possibility of mutual understanding. (Smith, 2007:5)

Key features	Discourse Analysis	Interpretative Phenomenological Analysis
Philosophy	Knowledge and meaning produced through interaction with multiple discourses.	People as psychological entities, able to reflect on actions which have existential consequences.
Goal	Understand how people use language to create and enact identities and activities.	Exploring, describing, interpreting and situating the means by which individuals make sense of their experience.
Data	Observation of participants in conversation in their natural environment. Participant and researcher engage in dialogue, interviewer probes for inter-textual meaning.	Observation of participants in the context where the phenomenon is experienced. Participants describe their experiences; interviewer probes for detail and clarity.
Analytic methods	Examine how understanding is produced through a close look at the words. Interested in how the story is told, what identities, activities, relationships, and shared meaning are created through language.	Examine personal perceptions of the phenomenon to understand the participant's point of view (the particular) with focus on personal meaning-making in particular contexts (an interpretative activity).
Analytic Relationship	Examine own place in the discourse(s).	'Bracket' or distance background beliefs and preconceptions, becoming open to the 'insider perspective'.
Product	Description of language-in-use; identify how different discourses shape how identities, relationships, and social goods are negotiated and produced.	Commitment to the person as a cognitive, linguistic, affective and physical being and assumes a chain of connection between people's talk and their thinking and emotional state.
Application	Broad application within the discourses of doctor-patient communication (Silverman, 1987; Mishler, 1984). In epilepsy research; focusing on the epilepsy clinic consultation (McCorry et al., 2009), and as a method to analyse the discursive terms of epilepsy (Valachovic et al., 1999).	Applied use: risk perception and chronic illness (Senior et al., 2002); risk perception and decision-making in genetic counselling (Smith et al., 2002). Epilepsy research: experience of stigma (Kilinc and Campbell, 2009); patient involvement informing the epilepsy research agenda (Thomas et al., 2010).

(Adapted from the following sources: Starks and Trinidad, 2007; Smith and Osborn, 2008)

Table 4.2 Comparison of analytic approaches

4.2.3.1 Consideration of 'fit' between data collection techniques and analysis

In-depth interviews provide a detailed account of personal disclosures made within a closed setting. In contrast, the more public forum of focus group discussions results in

data reflecting debate between group members and disclosures between participants (Flowers et al., 2000). The potential value of multiple data sources, was balanced against the requirements for additional analytic commitment directed towards group process (Smith et al., 2009). My selection of approaches draws influence from the application of interpretative phenomenological analysis applied to focus group data (Flowers et al., 2000; Dunne and Quayle, 2001) and observation data (Larkin and Griffiths, 2002) (discussed further in Section 4.3.4 Methods of Analysis).

4.2.3.2 Selection of computer-assisted qualitative analysis methods

A number of different computer-assisted qualitative data analysis software packages are available, and their application is guided by pragmatic concerns surrounding data management and storage (Flowers et al., 2000). The adoption of computer-assisted methods here was based on their ability to support my analysis, by allowing different levels of investigation to be achieved, such as, coding and connecting ideas using memos and annotations, and data management supporting storage and retrieval of data (Spencer et al., 2003). NVivo 7 software was selected following formal training and discussions with my academic supervisors¹⁰.

4.2.4 Ethical considerations

Attention was focused on the central ethical issues of respect for the research participant. These included respect for autonomy, the provision for informed consent, anonymity and confidentiality, and protection from harm. These principles ensured the study process and outputs reflected the codes of both professional practice and the research governance framework (Department of Health, 2005), and met the requirements of the relevant Multi-Centre Ethics Committee as directed by the Central Office of Research Ethic Committees¹¹.

4.2.4.1 Informed Consent

The provision of informed consent is central to the ethical conduct of all research and respects participant autonomy to make informed decisions whether to take part, whether to withhold or whether to later withdraw consent from participation within a

¹⁰ NVivo 7 training via The University of Liverpool Deanery & Departmental Postgraduate training providing the opportunity for regular updates (23-24th Nov 2006; 29-30th Nov 2007; 9-10th June 2008).

¹¹ CORECs were replaced by the National Research Ethics Service in the 2nd year of study reporting.

study. Study documentation packs¹², including participant/clinician information sheets, letters of invitation to participate and consent forms were developed conforming to the recommendations within the COREC Guidelines for Researcher's Version 2.0 November 2005 (Davies, 2005).

The approach of potential recruits was by invitation letter from their treating clinician. A returned reply slip was taken as implying agreement for contact to be made. Informed consent was supported by encouraging women read the study documentation in their own time. Stamp-addressed reply envelopes were provided with each study documentation pack and women could both indicate interest and provide consent during clinic attendance or by returning the reply slip on the invitation letter/consent form. The approved research protocol placed responsibility on the recruiting clinicians to identify and approach patients who met the inclusion criteria; this restricted my direct contact with potential recruits. Study documentation was distributed by clinical staff to female patients who met the eligibility criteria. The exact number of study documentation packs distributed was not known, preventing writing to women who had not replied to the first invitation. This potential limitation was balanced by the duration of recruitment (September 2006 – July 2009) allowing potential recruits to be approached on several different clinic visits, therefore providing an opportunity to revise their initial decision concerning participation. Contact was maintained with all women who returned a reply slip/signed consent form.

All women were required to provide consent prior to their involvement in the study, and consent was reaffirmed prior to commencing digital recording. Consent for clinic observation, both participants and the clinicians were made aware of each other's consent. Consent was re-confirmed as arrangements were made for the follow-up interview, and again prior to beginning the interview.

4.2.4.2 Confidentiality and anonymity

Anonymity is defined as the means of securing the identity of those taking part in the study from anyone outside of the research team¹³ (Lewis, 2003). While clinicians were

¹² See Appendix 1 Study Documentation.

¹³ The research team refers to myself (Janine Winterbottom) and my two academic supervisors (Professor Gus Baker and Professor Ann Jacoby).

aware of women they had selected as meeting the inclusion criteria (and those observed in consultation), it was only the research team who knew the final study population. It was acknowledged within the study documentation that absolute anonymity could not be offered or guaranteed.

Confidentiality in the context of qualitative research means the avoidance of attributing individual participant comments within any report, presentation, publication or the final submitted thesis. This includes both direct attribution, such as comments linked to a name or role, or place of residence, and indirect attribution such as by reference to a collection of characteristics that might reveal the identity of the participant (Lewis, 2003). These issues were managed at the point of transcription, with all names removed and replaced by descriptors, such as [location]. Participants were assigned an alphanumeric reference. The ID code was recorded and only accessed by the study author, or academic supervisors if required, following ethical codes of practice. Digitally recorded audio files and transcripts were stored electronically and access to all computerised stored and generated data was password protected. Data collection, storage and disposal conformed to the Ethics and Clinical Governance approval warranted, and conformed to the Data Protection Act.

Issues of confidentiality and the potential for indirect attribution were acknowledged as harder to guarantee and, therefore, the study documentation drew attention to this risk. Attempts to minimise the potential indirect breach of confidentiality was managed through the scrutiny of all reports and documentation (either verbal presentation, or in written form) by proof reading by the research team. The use of textual quotes when reporting the results reflects the need to sufficiently represent the links between the data and analysis, and the ability to portray meaning and understanding (Langdridge, 2007; White et al., 2003).

4.2.4.3 Protecting participants from harm

The potential for harm fell into three main areas: sensitivity of topic; confusion surrounding the clinician-researcher role; and, managing disclosures which might indicate the participant's risk of harm (Lewis, 2003).

1. Sensitivity of topic – The potential for causing distress, either by the probing nature of interview/focus-group questions, or by the intrusion of the researcher

observing the participant's clinic appointment, were addressed by the careful construction and revision of the topic guide (see Appendix 2), and by the explicit provision of support from a clinical psychologist being made available. Patient educational literature and details of the local patient voluntary services were also provided at the close of participant contact.

2. Confusion surrounding the clinician-researcher role – My professional and employment background was made explicit within the study documentation to protect against the risk of exploitation through any confusion concerning the researcher role (Arthur and Nazroo, 2003). The non-interventional basis of the research was emphasised, with participants informed that the study was not therapeutic.
3. Managing disclosures – Study documentation (see Appendix 1) defined the circumstances when interventions to manage disclosures would be justified. Consent to disclose information felt to be in the best interests of the participant was required; initially encouraging the participant to take action, and if necessary agreeing the content of any communication with their epilepsy clinician or General Practitioner. Duty to adhere to the guidelines for disclosure of suspicion of abuse was maintained by my substantive and honorary NHS contracts. Disclosures within the focus groups represented an additional challenge and was managed during focus group introductions, covering topics of disclosure and maintaining the privacy of fellow focus group participants as a form of respect (MW Smith, 1995).

4.2.5 Quality Criterion – Methods of appraising quality and validity

The methods for evaluating the quality of the study findings were informed by the characteristics of 'good qualitative research' established by Yardley (2000), and the methods of 'ensuring rigour in qualitative research' established by Seale and Silverman (1997) (Table 4.3). These two sources of quality criteria were felt sensitive to the study methodology and appropriate to support the final critical appraisal of the results of this study (presented as part of the Discussion – Chapter 10).

4.2.5.1 Validity and Reliability

The terms 'validity' and 'reliability' within qualitative health research have been interpreted as having different meanings to their traditional use within quantitative

research (Murphy et al., 1998). The reinterpretation of the traditionally quantitative definition of validity (a truthful correspondence of results with an objective reality) has been proposed – a useful alternative term ‘to avoid confusion’ is ‘credible’ which reflects the importance of credible qualitative findings emerging from systematic observations, and competent interpretations which correspond to the social reality experienced by the participants, and which in turn have meaning to those who read the results (Giacomini et al., 2000).

Quality criteria	Characteristics	Measurement techniques
Sensitivity to context	Theoretical; awareness of relevant literature used to corroborate &/or discriminate against interpretations. Focus on participant perspectives.	Reflexivity. Representativeness of cases Detail of unexpected findings.
Commitment to rigour	In-depth engagement in field & data immersion. Completeness of data collection & analysis. Methodological competence/skills.	Theoretical sampling. Triangulation. Deviant case analysis. Key word counts. Detailed transcription display systematic analysis.
Transparency & coherence	Clarity and power of description/argument. Transparent methods/data presentation. Fit between theory and method.	Audit trail. Systematic data management. Reflexive to influences of external pressures or constraint.
Impact & importance	Plausibility of the results. Theoretical – Enrich understandings. Socio-cultural – impact upon practice. Practical application – for community, policy makers and health care.	Testing hypothesis in data analysis and analytic induction. Generalisations supported by adequate evidence, counts of events, instances or themes.
Adapted from the following sources: Bramley and Eatough (2005), Lewis and Ritchie (2003), Ried et al (2005), Seale and Silverman (1997) and Smith et al (2009)		

Table 4.3 Methods for evaluating the research quality

The traditional quantitative measure of reliability (as the consistency of the research instruments and their ability to replicate the research findings) has been reinterpreted to appraise qualitative research, such as, ‘trustworthiness’, ‘consistency’ and ‘authenticity’, inferring that the internal elements, dimensions or meanings found within the study data are expected to recur outside of the study population (Lewis and Ritchie, 2003). Internal validity (referring to the ‘internal’ aspects of validity and internal logic of the research) is essential to expand upon the descriptive and explanatory accounts (Silverman, 2005). Triangulation as a method of testing emerging themes across the different study sites, testing findings from different methods to support comparison of different cases is felt to improve validity (Maxwell, 2002). The extent of external validity (or generalisability) has been proposed as more adequately measured through the criterion of ‘transferability’ in which the ability to

evaluate the possibility of transferring findings across the wider community is dependent upon the researcher providing ‘thick descriptions’ of population studied (Murphy et al., 1998).

4.2.5.2 Generalisation

The term generalisation within qualitative research refers to either empirical or theoretical generalisations (Hammersley, 1992); where empirical generalisations are refer to the ‘transferability’ of the findings, and theoretical generalisations refer to the ability to build theory for wider, or even universal application (Lewis and Ritchie, 2003). The use of generalisation within interpretative research is seen as inevitable, desirable and possible. It is defended by the cultural consistency within the social world studied by the interpretivist researcher as being the same cultural consistencies that make social life possible (Williams, 2000).

4.3 Women with epilepsy preparing for pregnancy – Study methods

This section will detail the application of methods through an audit trial of activities and decisions made during the conduct of the study. The study employed a qualitative design consisting of triangulation of both data source (interaction between patient and clinician plus participant accounts) and of method (gathering data by focus group method, interview and observation).

4.3.1 Ethical approval

This study was approved by Newcastle and North Tyneside 1 Research Ethics Committee (NRES reference number: 06/Q0905/62)¹⁴. Research and Development approval was granted from all recruiting centres: The Walton Centre NHS Foundation Trust; The Liverpool Women’s Hospital NHS Foundation Trust; Salford Royal NHS Foundation Trust; Wrightington, Wigan and Leigh NHS Trust, and Salford Primary Care Trust.

4.3.2 Sampling and recruitment

Decisions concerning recruitment were guided by the study objectives and pragmatics, which resulted in a study sample defined broadly as WWE of reproductive age (16-45

¹⁴ Application for Ethical approval was submitted outside of the region to prevent delay in commencing data collection.

years¹⁵) and, more specifically, as women who had experience of pregnancy, women currently considering pregnancy, and women who identified pregnancy as a future aspiration. Pragmatic consideration of the extra costs of travel for a study based outside the region where the researcher lives, and the time anticipated as needed to successfully recruit eligible women led to the decision to locate the study population to the Northwest of England. The study locations were selected to reduce the potential variability between the types of service delivered, with the epilepsy clinics based at Salford Royal Hospital and The Walton Centre NHS Foundation Trust providing a regional multi-disciplinary epilepsy service. Liverpool Women's Hospital was selected as providing access to WWE during pregnancy.

Staged recruitment involved selecting women for involvement in either stage 1 (focus group discussion) or stage 2 (observation and interview). The initial goal of stage 1 recruitment was to recruit sufficient participants to convene a minimum of four focus groups, reflecting a broad range of experience to capture women's experience of preparing for pregnancy as it unfolded in their lives, in addition to the anticipation of events (capturing the stages of planning behaviour) and reflection of past experience (experience of unplanned and planned pregnancy) (Smith et al., 2009). Ongoing review of the recruitment process was iterative, providing the opportunity to focus recruitment on groups of 'special interest' (teenagers and mature women) convening additional focus groups to test emerging themes (Ritchie et al., 2003, p.84). The sample selected for observation of an epilepsy consultation involved WWE preparing for pregnancy, and anticipated the presentation of pregnancy-related risk information. By conducting staged recruitment, the findings from interim analysis of the focus group discussions could be used to structure and inform recruitment into stage two (theoretical sampling). The final composition of the study sample was not known until interim analysis revealed a detailed picture of the experience of WWE preparing for pregnancy and no new insights or themes emerged.

Sampling involved attempts to ensure those selected reflected the wider UK population of reproductive aged WWE (see Appendix 2 Focus Group sampling frame). This was supported by use of published statistics, a method recommended by Hammersley

¹⁵ Decisions concerning the age range are discussed in section 4.3.2.1 Inclusion criteria.

(1992), and achieved by gathering participant background information, including antiepileptic drug use, to compare with the UK Epilepsy and Pregnancy Register database (Morrow et al., 2006). The UK Epilepsy and Pregnancy Register was felt to represent a contemporaneous account of AEDs used among pregnant WWE. The nature of antiepileptic drug use was felt to influence the type of risk information presented to women preparing for pregnancy, and the range of prescribing decisions faced both by women and the clinicians they consulted.

4.3.2.1 Inclusion criteria

The study sample was defined through the application of the following purposive selection criteria, which addressed the demographic, diagnostic and personal characteristics of the intended study population:

- Women aged between 16 years and 45 years.
- Confirmed diagnosis and history of epilepsy of at least 3 months.
- Experience of being prescribed antiepileptic medication for treatment of epilepsy.
- Be able to participate verbally in a group (focus group recruitment only).
- Able to converse in English.
- Provide signed informed consent.

The study objectives reflected the need to explore the lifecycle transition into motherhood. As preparation for pregnancy was implicit within the research question, it was felt justifiable on ethical and legal grounds to limit the age of selection to women 16 years and older. An upper age was set at 45 years, reflecting the potential for increased age-related congenital malformation risks, and reduced likelihood of fertility neither of which were the focus of the research objectives¹⁶.

Women were selected to reflect a range of different stages of their reproductive lives. However, it was not an explicit criterion to include women who had experienced either planned or unplanned pregnancies. Therefore, women aged 16-45 years were selected with the assumption that they would reflect a range of reproductive life experiences, including the use of contraception, experience of contraceptive failure, adverse

¹⁶ The risk of Down's Syndrome increases with age; estimated at maternal age 20 years- 1:1500 risk, compared to maternal age 35 years- 1:270, maternal age 40 years- 1:100 and maternal age 45 years- 1:50 and greater. Source: Gray, J.A.M. & Ward, P. (2004) National Down's Syndrome Screening Programme for England: A Handbook for Staff. UK National Screening Committee Programmes Directorate.

pregnancy outcome, and pregnancy loss or infertility. Women with a confirmed diagnosis of epilepsy were the focus of the study. In the majority of cases this implied their experience of more than a single seizure, and the recommendation to commence AEDs. The purposive selection criteria proposed eligibility commencing a minimum of three months after diagnosis, with no limiting factors for epilepsy duration. The inclusion criteria were established to reflect epilepsy as a chronic condition, taking into account its influence upon the quality of life trajectory proposed by Jacoby and Baker (2008), framed by the time from seizure onset/diagnosis and response to treatment, and shaped by a wider range of personal and social factors.

4.3.2.2 Exclusion criteria

Women were excluded from recruitment if they met any of the following exclusion criteria:

- A diagnosis of non-epileptic attack disorder, psychogenic or dissociative disorders, and / or chronic depression or psychiatric disorder.
- Significant learning disabilities.
- Deteriorating neurological or terminal illness.
- Additional chronic disease requiring preconception care and treatment through a future pregnancy, e.g. diabetes, asthma, hypertension.
- Women who had received direct care from the author in the preceding 12 months to study commencement. This reflected ethical concern for the need to distinguish between clinical and research role (see also Section 4.2.4 ethical considerations).

4.3.2.3 Participant recruitment

Participants were selected from two Northwest of England Regional Epilepsy clinics held in Manchester (Salford Royal Hospitals NHS Trust) and in Liverpool (The Walton Centre NHS Foundation Trust), the monthly Joint Neurology Obstetric clinic held in The Liverpool Women's Hospital NHS Foundation Trust, and from two additional monthly satellite clinics held in Manchester and Wigan. Recruitment began in September 2006¹⁷ supported by Multi-Centre Regional Ethics and NHS Research and Development approval.

¹⁷ Recruitment at Wrightington, Wigan and Leigh NHS Trust began in November 2006 and was prematurely ended with the departure of the clinician responsible for the clinic leaving the Trust in June 2007. Recruitment for the GP with Specialist Clinic was delayed until NHS R&D approval was granted in February 2007.

Women were recruited by the neurologists and epilepsy nurse specialists reviewing their weekly clinic lists, and by midwives and obstetricians recruiting women from the monthly Joint Neurology Obstetric clinic. Women meeting the inclusion criteria were identified as potential recruits, and offered study documentation¹⁸ by outpatient clinic staff on their arrival into the department on their scheduled clinic visit. Restriction of direct contact with potential recruits was stipulated within Ethics Committee approval (see section 4.2.4.1 Informed consent). This prevented my awareness of any differences between women motivated to participate in the study and those who were not. However, women were advised that the study author was present in clinic to answer questions and supplement study information. The decision for the author to attend clinic during recruitment was to provide early contact with women showing interest in participating in the study. Attendance was also felt to reduce the burden of additional workload upon the outpatient clinic staff and clinicians, with study documentation prepared in advance. All available opportunity to discuss the study with the recruiting clinicians was afforded to maintain momentum during recruitment.

The majority of women had contact with the study author during initial recruitment, and this provided early insight into how women described themselves as planning pregnancy and descriptions of their stage of planning. This informed my communication with women showing interest in the study. There was sustained contact with all participants showing interest in the study, and for focus group recruits, continued contact was required to arrange a suitable date for focus group attendance and transport arrangements. For recruitment into the observed clinic visit, contact was maintained to capture any changes regarding observed appointment dates, and following the consultation to arrange a suitable date for interview. Both the process and progress of recruitment was closely monitored and participant selection was purposively and theoretically driven. Theoretical sampling directed recruitment of participants to confirm emerging themes and ensure adequate analysis of the study question. Staged recruitment first identified women eligible for focus group attendance and second, women who had informed their clinician of their plans for pregnancy.

¹⁸ See Appendix 1 Study Documentation (personalised letter of invitation signed by their clinician, study information sheet and consent form).

4.3.2.4 Stage 1 Recruitment (focus group)

Women who returned the reply slip were contacted and offered dates of planned focus group meetings. Initial contact offered women the opportunity to ask questions, clarifying information, and allowed me to begin to ‘get to know’ the focus group population. Group composition was structured by age and prior reproductive experience, in order to support group cohesion, and facilitate discussion of potentially sensitive topics (Finch and Lewis, 2003).

The first focus group was held in January 2007 with five women attending (women were aged between 21-27 years and all considering future pregnancy). Appreciation of the commitment to maintain contact with women throughout the process of arranging and holding the focus groups was reinforced by experience in the third group as only one participant attended, with two other women giving notice of non-attendance on the date of the group meeting. A decision was made on that day to conduct a personal interview using an adapted focus group topic guide (the decision was based on the participant’s commitment to attend, and her inability to attend a future focus group date). This experience was reflected upon, considering factors for poor attendance, acknowledging the need to over-invite the number of participants to allow for ‘drop-outs’, and the importance of confirming transport arrangements and venue information in advance. Reflecting upon the difficulties recruiting teenagers and mature women, changes were made to the recruitment process, which involved direct approach by the author in addition to postal invitation¹⁹. The last focus group (11th October 2008) invited mature women who had made reproductive decisions to limit their family size. Two women invited to attend this group, and who had been unable to attend any of the earlier groups, were interviewed individually using a modified focus group topic guide (discussed in more detail in Chapter 5 Introduction to the study population)²⁰.

¹⁹ Ethics and NHS Research and Development approval was obtained for substantial amendments to the study protocol version 4 14-07-08. The amendments addressed problems identifying teenagers, and retention of women who had previously shown interest in focus group attendance but due to logistic problems had been unable to attend, were invited into study stage two.

²⁰ The decision to include these women within the study population was based on theoretically sampling decisions searching for deviant cases. The decision to amend the focus group topic guide and conduct individual interviews was discussed with my academic supervisors.

4.3.2.5 Stage 2 Recruitment (clinic observation and follow-up interview)

Women who returned the reply slip were contacted and arrangements for observation of their next planned clinic visit were made. Participants wishing to attend their next clinic appointment accompanied by a partner, friend or relative were acknowledged. At the end of the clinic visit, arrangements were made for the follow-up interview. Interviews were planned to take place in the participants own home for their convenience, if inappropriate arrangements were made to use the focus group venue, as a central location, with suitable facilities to conduct an interview. The potential for a partner, relative or friend to be present during the interview was acknowledged, highlighting the likely content of the interview to allow the participant to make informed decisions as to whether they interviewed alone or with a partner or other person present.

The total number of women provided study information was not recorded, as clinic staff did not consistently return unused study documentation, and any patient invitation letters were either taken by women and not returned, or were returned blank to the clinician or clinic staff (this action resulted in confidential disposal of study documentation preventing tracking non-responders).

4.3.2.6 Recruitment of Clinicians

Clinicians working with WWE at each recruitment site were initially approached during protocol development. This was in line with the local NHS Research and Development approval processes, as clinicians were familiar with their local committees. Clinicians were provided with study documentation, and requested to sign participant invitation letters to facilitate recruitment of eligible patients attending their outpatient epilepsy clinics. Clinicians provided consent for observation of their future consultations (See Appendix 1 Study documentation).

3.3.3 Methods of data collection

The data collected and analysed represents the verbal/written accounts shared by women during focus group discussion, within clinic observation and at follow-up interview.

4.3.3.1 Field Notes

Field notes relating to focus groups included descriptions of group process and the seating order to facilitate transcription. Notes concerning the clinic observations reflected descriptions of the clinical environment and additional non-verbal communication/behaviour. Field notes were used to support analysis through questioning and memo writing, rather than being analysed within the corpus of data.

4.3.3.2 Participant questionnaires

Questionnaires were completed by all participants to gather background demographic and reproductive data (Appendix 2 Data collection tools). Questionnaire data were used to display simple descriptive statistics in the form of means and averages (see Chapter 5 Introduction to the study population).

4.3.3.3 Methods of transcription

All data were digitally recorded and transcribed verbatim. I typed most transcripts; however, taking account of the volume of data collected (especially from the focus groups) additional support was enlisted from two medical secretaries. The transcription methods were informed by interpretative phenomenological analysis and the role of the transcript was to produce written text of the research encounter to support analysis (table 4.4). Formal transcription methods advocated by conversational analysis were not required, and therefore prosodic aspects of the recording such as length of pauses and non-verbal utterances were not noted. The goal of transcription was to present all spoken words, spelt conventionally, unless the words themselves were 'non-conventional'. Non-verbal utterances such as laughter were presented in square parenthesis (Smith et al., 2009).

4.3.3.4 Topic guides

Topic guides were developed assist data collection for the conduct of the focus groups, observations and interviews (Appendix 2 Data collection tools). The question wording was carefully considered during protocol development, amended following participant contact, and informed by experiences, for example, re-wording a line of questioning to prevent ambiguity. Key words (pregnancy planning, planned, unplanned, risk and malformation) were avoided in the opening stages of the focus groups and interviews to reduce influence from my prior knowledge, and also to reflect the literature

concerning women not spontaneously using the terms of planned, unplanned, intended, unintended, wanted or unwanted, despite talking at length about the circumstances of their pregnancies (Barrett and Wellings, 2002).

Transcription symbols displayed in results chapters
C: Clinician P: Participant Line number refer to the consultation transcript [...] unrelated text. [Laughter] non-verbal communication or description of participant behaviours. [Hospital] used to indicate edited text removing names, locations to preserve anonymity. / interrupted speech, participants talking at same time. To avoid breaking the text and aid readability, { } indicate the insertion of speech from the non-dominant speaker, while the main speakers is acknowledge. <i>Italic</i> emphasis by speaker.

Table 4.4 Transcription symbols

4.3.3.5 Focus group methods

I assumed the role of moderator following completion of formal training in focus group moderation²¹. Training in qualitative research methodology was achieved by my involvement in supervised training of the running of focus groups and having feedback on my development of moderator skills. My role as moderator was to support the individual participants form as a group; being aware of the different stages of group process, and supporting the participants feel comfortable discussing their experience of being a woman with epilepsy. In practice, as women arrived at the focus group venue, signed consent was obtained, including consent for the use of audiotapes to record group discussion. The focus group topic guide (Appendix 2 Data collection tools) was used to focus discussion into three phases, supporting group process:

1. **The opening stage** of the focus groups was structured by an opening statement which included general ground rules (Appendix 2 Focus Group introductory script). The introductory script and statements of ground rules was important to set the scene for group interactions and to indicate the expected role of the participants in discussing the research topic. Therefore, a key aspect of the ground rules was to emphasis that there are no right or wrong answers, and that everyone's views are important, and that participants

²¹ Training was accessed from NatCen (The National Centre for Social Research, London). The 1st and 4th focus groups were observed by my academic supervisor Professor Ann Jacoby who provided feedback on my moderation skills to support my postgraduate research skill training.

should feel free to either agree or disagree respecting individual perspectives. Information about the venue such as fire exits, location of toilets, and the timing of a coffee break were included. The participants were reminded of the digital recording and general group behaviour and conduct, including maintaining the reciprocal confidences of their focus group peers. The focus group began by participant introductions. This was followed by an open ended question about their experience of epilepsy as a woman to prompt the start of discussion.

2. **The content stage** was structured using open questions to gain an understanding of perceptions, beliefs, values and behaviours surrounding contraception, conception and pregnancy. The topic guide provided a list of potential prompt questions which were used to clarify points, or redirect discussion. The aim was to allow the participants as much relevant discussion as possible, probing for fuller responses to ensure issues are covered in depth. My role as moderator at this stage of the group discussion was to create a balance between individual contributions, by encouraging each participant to have a chance to contribute, and addressing dominant participants by inviting others to speak, such as ‘lets hear some other opinion’. A flip chart allowed participants to write statements, and to identify key issues for further discussion. A structured exercise was conducted in the second half of the group discussion – after the coffee break, and was used to direct group discussion on definitions and meanings of three risk framed statements. The exercise involved three different risk statements, read out, and both placed on the table and on the flip chart for women to read. Each statement was viewed in turn to generate comments and stimulate discussion (Appendix 2 Data collection tools).
3. **The closing stage** drew the discussions to a natural conclusion. It is recognised as good practice to warn participants of the end of the session, to allow statements of clarity, and to allow the topics of discussion to be concluded.

4.3.3.6 Procedures of non-participant observation

The goal of observation was to capture for analysis the processes experienced by women during clinic attendance. It also served as a back up to audio-recording,

providing a record of who was present during the clinic observation, such as a partner, with discreet notes made if words were whispered or the participant became distressed. My position within the clinic room was to allow observation of both the participant and clinician; and, out of direct gaze, to avoid any distraction to either the participant or clinician. It was not my intention to become involved in the consultation. However, the chance of participants asking questions was anticipated and managed by redirection of any question, repeating the question back to the clinician. The management of researcher-focused questions was discussed with the clinician prior to the onset of clinic observations, reminding the clinician of the purpose of the observation and my role as researcher, rather than as an epilepsy nurse specialist (my employment status).

4.3.3.7 In-depth interview methods

I assumed the role of interviewer following completion of formal training in in-depth interview techniques²². My role within the interview was introduced to the participant to clarify the non-interventional nature of the meeting, and the use of the topic guide to maintain focus on the key topics and issues reflecting the content of the participant's consultation (see Appendix 2 in-depth interview topic guide). The interview was linked to the consultation, and provided the opportunity for the participants to reflect on their experience of risk information and decision-making as topics from within the consultation. The interviews were held between one and three months following the consultation. The interview started by asking women to reflect upon the content of the consultation and the significance of the information they recalled relating to their pregnancy plans. Open questions were asked, for the participants to consider their perception of decisions made about treatment and future pregnancy planning. Anticipating participant questions concerning aspects of their epilepsy management, patient literature was made available at the conclusion of the interview.

4.3.4 Methods of analysis

The purpose of analysis was to learn something about the participants and about their personal histories of life with epilepsy as reproductive aged women. The analysis was informed by the analytic style of interpretative phenomenological analysis and

²² Training was accessed from NatCen (The National Centre for Social Research, London).

followed an iterative process of non-linear stages creating descriptive and interpretative accounts (Smith et al., 2009). The staged approach to analysis created a structure for initial analysis of focus group data. Stages 1-4 were repeated for subsequent focus groups prior to commencing analysis of clinic observation and interview data (table 4.5).

Stage	Analytic method (Adapted from Smith et al., 2009)
1.	Line by line analysis (reading and re-reading)
2.	Initial noting
3.	Developing emergent themes
4.	Searching for connections across emergent themes
5.	Moving to the next case (participant/focus group)
6.	Looking for patterns across cases
7.	Taking it deeper: Levels of interpretation ²³
8.	Organisation of transcribed data and thematic framework
9.	Group analysis
10.	Development of the written account

Table 4.5 Stages of analysis (Appendix 3)

- 1) **Line by line analysis** - The process of transcription assisted analysis by repeatedly replaying the participant's speech, supporting immersion within the participant's account. This stage was vital in creating an accurate written account of the participant's case as a form of data management²⁴. My involvement typing the majority of transcripts and verifying the accuracy of secretary typed transcripts required immersion in the recorded data, at the same time as reading the transcripts. Repeat listening to the recorded data supported review of my research relationship, reflecting upon the data collection processes, and informed the recruitment process. All transcripts were read repeatedly 'line by line' to highlight 'significant statements' and establish an overall chronological account of the data. Field notes further supported data management.
- 2) **Initial noting** - Initial notes were written as annotations to represent ideas and comments concerning the meaning within the participant account relating to

²³ The analytic process developed by Smith and co-authors (2009) involved six levels, however was extended to look for deeper meanings, reflecting the larger sample, managing data to create an audit trail and group analysis. Stage 10 – writing-up is generally acknowledged as a creative and interpretative stage of the analytic process, rarely included as a formal stage of analysis (Smith, J.A., Flowers, P. & Larkin, M. (2009) *Interpretative Phenomenological Analysis: Theory, Method and Research*, London, Sage Publications.)

²⁴ Data management was supported by NVivo 7.

key objects of concern (Smith et al., 2009). Comments were ‘exploratory’, concerning descriptions of experiences, practices or events of significance, or about the use of language, such as the use of metaphors. This supported interrogation of the transcript with questions such as ‘what had the participant meant by this?’ This involved reflexivity regarding the process of data collection, listening to how questions might have been asked to prompt the participant response, trying to ‘get closer to what the participant was actually saying’ (Smith et al., 2009). (See Appendix 3, Table A3.1)

- 3) **Developing emergent themes** - The coded transcripts were reviewed to develop themes which offered both descriptive and interpretative contexts for the participant’s responses to risk and decision-making. The interpretative context of the accounts concerned statements of behaviour or actions, which were interpreted alongside conceptual theories of social cognition; together with empirical work on risk perception and decision-making. Returning to the participants’ verbal and written accounts, interpretations were checked both for convergence and divergence, commonality and nuance (Smith et al., 2009). This stage was important in reducing the volume of data into more manageable themes which represented sections of transcript text.
- 4) **Searching for connections across emergent themes** - This stage involved creating a framework to organise the emerging themes, illustrating the relationship between the transcript text and the theme it represented. As an iterative process, this stage resulted in returning to the individual transcripts representing unique idiosyncratic instances and searching for other participant experiences that shared similar or presented alternate accounts. This stage was supported by focusing upon the differences rather than similarities in the participants accounts (Appendix 3: Table A3.3 and Figure A3.1).
- 5) **Moving to the next case** - Stages 1-4 were repeated with individual and group transcripts to build and test themes. Focus group data required modification of the staged approach to analysis to take account of the individual perspective and the group dynamic (Smith et al., 2009) (see Appendix 3 table A3.4). The importance of considering group processes is recognised as attending to the ways in which individuals make experiential claims and how these are responded to within the group and by the moderator, implying a cyclical analysis of how relationships formed within the group, their influence upon the

participants use of stories and language, and how this in turn influences emergent themes (Palmer et al., 2010). It has been recognised the process of analysis starts from the personal perceptions and understandings of the phenomena before moving to shared meanings (Smith et al., 1999). In practice, once data collection was complete, the corpus of data required re-review, recognising that early (interim) analysis had served a dual purpose: firstly, informing theoretical sampling and secondly, to create an overall structure of the range of participant experience. Formal analysis started by reviewing patterns both within and across the cases.

- 6) **Looking for patterns across cases** - Patterns within themes began to emerge through familiarity with the coded transcript extracts, and repetition of the emergent themes across the cases was taken as an indication of their status as recurrent themes representing the shared understandings that I was attempting to capture. (See Appendix 3, table A3.5)
- 7) **Taking it deeper: Levels of interpretation** - The final stages of analysis involved interpretations of the individual case and entire study population as a process of within-case and across-case analyses (Ayres et al., 2003). The purpose of looking for patterns was to ‘find commonalities and variations’ of the experiences of reproductive aged WWE, and to develop a representative account to support generalisations through reference to the existing literature (Smith et al., 2009). The results of the Cochrane Systematic Review (section 2.4) were central to making inference concerning the implications of the qualitative study results, to direct further research and influence healthcare practice within the wider community of reproductive age WWE.
- 8) **Organisation of transcribed data and thematic framework** - NVivo 7 supported data management by recording dates of all changes to emergent themes, such as changes made by merging codes or re-naming codes to reflecting new interpretations of participant accounts. The value of NVivo 7 was to create an audit trail of all analytic changes and modifications, allowing additional comments relating to participant observation to be linked via memos to coded text and the research journal.
- 9) **Group analysis** - The University of Liverpool MRES (633) Qualitative Data Analysis group provided the opportunity to present my transcripts for group analysis/discussion. Each bi-monthly meeting involved fellow PhD students

reviewing each other's analytic work, and developed interrogation to help test themes and challenge and question analytic assumptions. Four transcripts (one focus group transcript and three observation/interview transcripts) were also read and coded independently by my academic supervisors (Professor Gus Baker and Professor Ann Jacoby). During supervision sessions the code text were compared for coherence and the plausibility of the interpretations.

10) Development of the written account - The process of writing annual reports for the funding organisation, ethics committee and the University progress reports developed an expanding narrative account of the study methods and analysis from the point of project development, through early reflections on data collection, and finally detailing an interpretive account of participant experience.

4.4 Summary

There were two phases to this interpretative phenomenological analysis of the influence of risk perception and communication upon decision-making throughout the reproductive careers of WWE preparing for pregnancy: firstly, informing experience through focus group discussion and secondly, through observation of the participants clinic visit and linked in-depth interview. Women and clinicians were purposively recruited from two regional epilepsy clinics and a regional obstetric hospital in the Northwest of England. Analysis was informed by interpretative phenomenological analysis and was practically managed through the computer-assisted qualitative data analysis software NVivo 7. Appraisal of the methodology and methods will be used to assess the quality of study findings within the discussion chapter.

The results of this interpretative analysis are displayed in the following results chapters.

Chapter 5 Results –An introduction

Introduction

This chapter presents the format of the following four results chapters:

Chapter 5 Results - Introduction – the current chapter will introduce the total study population of 85 WWE and will illustrate their demographic and reproductive histories.

Chapter 6 Pregnancy Planning – describes the experience of WWE preparing for pregnancy, highlighting the factors that contributed towards an unplanned or accidental pregnancy.

Chapter 7 Communicating risk and uncertainty – examines the provision of risk information to women preparing for pregnancy, and the different risk management strategies adopted by women and clinicians in response to this information.

Chapter 8 Decision-making in preparation for pregnancy – explores the experience of decision-making from the perspective of women preparing for pregnancy, and the influence of risk communication to inform and support their participation in both pregnancy planning and risk management.

Chapter 9 A model of preconception counselling – describes a model of preconception care and illustrate its development from the three substantive themes presented in Chapters 6-8: pregnancy planning, the communication of risk and uncertainty, and decision-making in preparation for pregnancy.

5.1 Introduction to the study population

Women who were deemed eligible²⁵ to participate in the study were provided with study documentation and contact made on return of the reply slip. The total number of women provided with study documentation was not recorded. However, 107 reply

²⁵ See Chapter 4.3.2.1 Study Methods - Inclusion Criteria, in summary: women aged 16-45 year with a confirmed diagnosis of epilepsy, and section 4.3.2.3 Recruitment. See also Appendix 1 Study documentation.

slips were returned by women showing interest in taking part in this study. Eighty-five women and twelve clinicians provided consent and were involved in producing the data for analysis.

The majority of women showing initial interest in taking part in the study remained interested and provided consent to participate in the study (79%). Six women were excluded from the study²⁶: four women had received care from myself in the preceding 12 months, one women experienced her 46th birthday in the time between recruitment and her focus group invite, and one woman disclosed a diagnosis of severe depression when contacted to arrange focus group attendance (Table 5.1). There were 101 women indicating interest in the study and who were eligible to participate in the study. The reasons for women not participating in the study fell into two main categories: could not be contacted by the researcher (62%), or unable to take time off work (25%).

	No.		No.
Reply slips indicating interest:	107		
Women meeting inclusion criteria	101		
Women meeting exclusion criteria	6		
Reasons for exclusion:		Reasons for non-participation:	
Aged 46 year	1	Emigrated	1
Severe depression	1	Child care difficulties	1
Contact with researcher	4	Work commitments	4
		Could not be contacted	10
Women consented for participation: 85 (79%)			

Table 5.1 Reasons for non-participation in the study

5.1.1 Communication with study participants

Study participants were contacted to confirm arrangements for participation in the study, and to initially answer questions regarding the study format. The purpose of my communication with participants was threefold; firstly to maintain interest in the study and by answering questions to begin to ‘get to know’ the participants, and respond to changing circumstance such as offering an alternate focus group date, or changing the time of interview. Secondly, stage-two participants were provided with a copy of the clinic transcript and summary of the observed consultation; this was posted to the participants prior to their follow-up interview. The clinic transcript and summary were

²⁶ See Chapter 4.3 Study Methods; section 4.3.2.2 Exclusion Criteria, in summary: women with a diagnosis of chronic depression or psychiatric disorder, women whom had received care (<12 months) as part of my NHS employment, women under the age of 16 years or over the age of 45 years.

provided to assist the participant reflect upon the consultation, and served as an aid memoir. Thirdly, participants were requested to provide consent to the disclosure of information to their GP concerning safeguarding issues of 'best interests'. No circumstances arose that required disclosure of information to the participant's GPs.

5.1.2 Background demographics of the study population

The mean age of the study participants was 27.8 years (table 5.2). The recruitment process was amended to target teenagers²⁷ and women over 35 years (see also section 4.3.2.4 Stage 1 recruitment). The amendments reflected the results of interim analysis, highlighting the need to explore the experiences of young women at the start of their reproductive career and women over 35 years, both of whom may have experienced adverse pregnancy outcome.

The socio-demographic characteristics reflected mainly white British women. Three Asian women were recruited and contributed their reproductive experiences into study stage two. This represented fewer than might be expected, representing 4% of the study population, in contrast with the National Statistics in the NW of England 8.9% non-white population (Large and Ghosh, 2006). The research objectives required a breadth of reproductive experience and in the event, captured 43% of women whom had experience of pregnancy and 24% of women with live children. A further 14% of women were pregnant at the time of participation in the study, and 24 women (28%) identified themselves as planning a pregnancy. Twelve women were pregnant during study participation, of whom one was experiencing a twin pregnancy, and another conceived in the time between her observed consultation and follow-up interview (table 5.3). Fifty-five percent of women were reliant on contraception in the preceding six months before study participation. Marital and living arrangement status represented 55% of the participants as either married or cohabiting, a lower rate than that of the background population of women without epilepsy within the US and Denmark (Konda et al., 2009; Jennum et al., 2011). 51% were employed either full or part-time, comparable to other published results for populations of WWE and people with epilepsy; employment rates were comparable to the regional labour market statistics published for the NW of England (Office for National Statistics, 2011).

²⁷ Recruitment from the specialist epilepsy transition clinics, found many teenagers did not meet the inclusion criteria due to learning disability.

The total study population is the result of the staged recruitment:

1. Stage one – focus group (n=61)
2. Stage two – observed consultation and linked in-depth interview (n=24)

Study population n=85	% (Number)
Mean age - years (standard deviation, SD)	27.8588 yrs SD± 7.34061
16-20	17.6 % (15)
21-25	20% (17)
26-30	29.4% (25)
31-35	18.8% (16)
36-40	7.1% (6)
41-45	7.1% (6)

Table 5.2 Age characteristics of the total study participants

Study participants (n=85)	No. (%)
Contraception use in previous six months	47 (55%)
Nulliparous ²⁸	54 (57%)
Experience of pregnancy	32 (43%)
Miscarriage	5
Pregnancy loss	1 twin pregnancy
Termination of pregnancy	6 (7%)
Women delivering live children	20 (24%)
Pregnant at time of study participation:	12* (14%)
Preconception commencement of folic acid	8 (73%)
Folic acid commenced in pregnancy	3
Pregnancy taking polytherapy (2 AEDs)	3
Pregnant taking sodium valproate	1
* 1 twin pregnancy	

Table 5.3 Preconception demographics of the study population

5.1.3 Introduction to stage one participants

Sixty-one women provided consent to participate in a focus group. Of these, 58 were involved in one of 11 focus groups. Three women were interviewed using the focus group topic guide²⁹. The average age of focus group participation was 27.77 years (range 16 years – 45 years) and 21 % were young women under the age of twenty. Forty-six percent of women were single, and 34% were living at home with their parents. Fifty-two percent of women were married or cohabiting and 54% were living

²⁸ Nulliparous refers to a woman who has never given birth to a viable, or live, infant.

²⁹ One participant was interviewed at the focus group venue, and had been the only attendee of a planned focus group. The decision to interview the participant was made in response to her commitment to attend, and inability to return on a future focus group date. The participant agreed to an individual interview. Two participants interviewed in their own home due to their inability to attend any of the invited focus group dates due to family and work commitments. Both participants were purposively recruited to tests emerging themes of mature WWE modifying their reproductive plans (see Chapter 4 Methodology and Methods section 4.3.2.4).

with their spouse or partner (either alone or with children), of whom eight saw themselves as housewives. Forty-seven percent of the focus group participants were employed (either part-time or full-time), while eight were students. Twenty-two percent of women were unemployed or claiming sickness/incapacity benefit (table 5.4). A quarter of the study population held a valid UK driving licence, and a third of the participants reported no seizures in the six months preceding the date of focus group participation (31%). The majority of women rated their seizures as either very well or well controlled (Table 5.5).

Demographics	% (No.)
Mean age of focus group participants	27.7705 yrs SD± 8.34744
Marital status: (n=59)	
Married/cohabiting	52% (31)
Single	46% (27)
Divorced/separated	2% (1)
Living situation: (n=59)	
Alone	9% (5)
Living with spouse/partner	25% (15)
Living with spouse/partner and children	29% (17)
Living with parents	34% (20)
Living with others	3% (2)
Employment status: (n=59)	
Employed full-time	32% (17)
Employed part-time	19% (11)
Student	13.5% (8)
Unemployed/incapacity/sickness benefit	22% (13)
Housewife	13.5% (8)
Driving status: (n=59)	
Driving	25% (15)

Table 5.4 Demographic characteristics of the focus group participants

Forty-four percent of women were medicated with a monotherapy AED regimen. Lamotrigine was the most common monotherapy, followed by carbamazepine, sodium valproate, and levetiracetam. Forty-six percent of participants were taking a polytherapy AED regimen, while three women were not taking treatment to manage their epilepsy. Four women were taking sodium valproate as part of a polytherapy regimen³⁰, of whom one was taking sodium valproate, lamotrigine, levetiracetam and clobazam. Two women were taking sodium valproate as part of a three AED regimen. Three participants had surgical treatment for their epilepsy (table 5.5). Fewer focus

³⁰ The significance of women of childbearing age taking sodium valproate is discussed in greater detail in Chapter 2 Literature review, highlighting the increased congenital malformation risks associated with in utero exposure to sodium valproate polytherapy regimens, and including additional risks of neuro-cognitive delay and conditions such as fetal valproate syndrome.

group participants were on monotherapy when compared to stage two participants (Table 5.7). The lower proportion of monotherapy within the focus group population may be associated with the group composition including women whom had completed their families and perhaps accepted more aggressive treatment to improve seizure control, however, the finding was alarming given the focus group participants also included teenagers and women considering future pregnancy. The focus group findings are, however, similar to those found by Pack's et al (2009) cross-sectional survey of US reproductive aged women identifying 60% medicated with monotherapy.

Epilepsy management characteristics	% (No.)
Seizure control: (n=59³¹)	
None in last 6 months	31% (18)
Less than one per month	27% (16)
One or more per month	41% (24)
Not stated	(1)
Self-rated seizure control: (n=59)	
Very well controlled	39% (23)
Fairly well controlled	37% (22)
Not very well controlled	10% (6)
Not at all well controlled	5% (3)
Not stated	(5)
Treatment status: (n=52³²)	
Monotherapy AEDs	44% (23)
Polytherapy AEDs	50% (26)
No treatment	6% (3)
Monotherapy	
Lamotrigine	30% (7)
Carbamazepine	26% (6)
Sodium Valproate	17% (4)
Levetiracetam	17% (4)
Topiramate	1
Phenytoin	1
Polytherapy	
Polytherapy including Sodium Valproate	15% (4)
Polytherapy 2 AEDs	77% (20)
Polytherapy 3 AEDs	15% (4)
Polytherapy 4 AEDs	8% (2)
Epilepsy surgery:	(3)

Table 5.5 Epilepsy management characteristics of the focus group participants

Twenty-six women had experience of pregnancy: 19 had delivered live children, four women experienced a termination of pregnancy, and one woman experienced two miscarriages (table 5.6). Eleven women were pregnant at the time of focus group participation, of whom six women were experiencing their first pregnancy. One was

³¹ Number of questionnaires returned.

³² Of the 59 returned questionnaires, seven women did not answer the treatment question.

taking sodium valproate, and three were medicated with a polytherapy regimen with two antiepileptic drugs. Seven women had commenced folic acid 5mgs daily prior to conception, while three women started taking folic acid after discovery of pregnancy. One woman, not taking folic acid at conception, experienced pregnancy while taking both phenytoin and the oral contraception pill. Five women referred to their pregnancies as planned (45%), of whom three were experiencing their first pregnancy (see also, Chapter 6).

Forty-seven percent of women reported using contraception in the preceding six months. Nine women were using the contraceptive pill, and 7 were using condoms. A further 6 women were using the coil, 3 were using the contraceptive implant; and 2 women were using contraceptive injection. Two women reported using two forms of contraception: contraceptive pill and condoms; and contraceptive injection and contraceptive pill. Five women did not respond to this question, and one who reported not using contraception on the questionnaire disclosed during focus group discussion her use of the ‘withdrawal method’.

Focus participants (n=61)	% (No.)
Contraception use in previous six months	47% (29)
Nulliparous	57% (35)
Experience of pregnancy	43% (26)
Miscarriage	(2)
Pregnancy loss	(1 twin pregnancy)
Termination of pregnancy	6% (4)
Women delivering live children	31% (19)
One child	15% (9)
Two children	15% (9)
Three children	(1)
Twins	(1)
Adoption	(1) (2 children)
Pregnant at time of focus group participation	18% (11) (1 twin pregnancy)
Preconception folic acid	64% (7)
Folic acid commenced in pregnancy	27% (3)
Pregnancy taking polytherapy (2 AEDs)	27% (3)
Pregnant taking sodium valproate	9% (1)

Table 5.6 Reproductive history of the focus group population

5.1.4 Introduction to stage two participants

Twenty-four women provided consent to allow observation of their hospital consultation and all women were followed up with linked in-depth interview (study stage two). One woman who had been recruited during her second hospital

consultation to discuss pregnancy planning was interviewed without observation, as it was not possible to arrange clinic observation within the time allocated for data collection. All clinic observations took place in the out-patient clinic setting with pre-arranged NHS hospital appointments. All women had a definite diagnosis of epilepsy and were taking antiepileptic drugs at the stage of recruitment (one woman disclosed her treatment withdrawal during her index clinic visit) (table 5.7). Eight of the observed clinic appointments were new patient visits and 15 were follow-up visits, illustrating the varied clinical histories captured within the observed clinic visits (see table 5.10).

The mean age of women at the time of the observed consultation was 28 years with a range of between 20 and 35 years of age. The majority of women were single at the time of clinic attendance (n=17). Of these, twelve identified living with a long-term partner or co-habiting, two women identified themselves as engaged, one as living alone, and one living with her parents. Six women were married. The median age of seizure onset was 12 years (range 1-22 years). Thirteen women had been seizure free during the six months before their observed consultation, of whom six had achieved over 12 month seizure freedom and were driving. Of those continuing to experience seizures, six women were experiencing more than one seizure per month. Seventy-one percent of women were taking a single antiepileptic drug (monotherapy), while six were reliant on polytherapy, and one woman had withdrawn treatment. The majority of women rated their seizures as very well controlled (n=19), while one woman rated her seizures as not very well controlled.

One woman left school without qualification, while eleven women held GCSE, A level or vocational qualifications, and 12 women achieved professional or graduate level education (table 5.7). Seventeen women were employed either part time or full time, whilst one of these women identified herself as off-sick from her full-time position at the time of observation (this was attributed to a recent experience of seizure and the rationale for her referral for epilepsy review). One woman was an undergraduate student. Six women were not working - of whom one referred to herself as a housewife, four women were either claiming sickness or unemployment benefit, and one woman, who had been 'in between' jobs at the time of consultation, was about to commence a new job within a month of her follow-up interview.

Patient ID number (OI)	Age (Mean age 28.04 yr)	Marital status: Single(S) Engaged (E) Long-term Relationship cohabiting- LtR)	Age of epilepsy onset	Educational level	Employment	Driving status	Treatment status	Seizure freedom	Seizure frequency	Self-rated control
01	29	S/LtR	11	A level	Ft	N	M	N	<1 /m	VW
02	22	Engaged	13	GCSE	Unemployed	N	M	N	>1 /m	FW
03	23	S/LtR	12	Vocational	Ft	N	M	Y	0 /6m	VW
04	27	Single	16	Professional	Pt	N	P	Y	0 /6m	VW
05	29	Single	16	A/Vocat	Pt	N	M	N	<1 /m	FW
06	20	S/LtR	14	GCSE	Unemployed	N	M	N	>1 /m	FW
07	32	Engaged	17	GCSE	Ft	N	M	Y	<1 /m	VW
08	27	S/LtR	10	A/Vocat	Student	N	M	Y	0 /6m	VW
09	29	N	12	Graduate	Ft	N	P	N	<1 /m	FW
10	30	Married	15	Professional	Ft	Y	M	Y	0 /6m	VW
11	24	S/LtR	15	Vocational	Ft	N	M	Y	0 /6m	VW
12	30	S/LtR	14	Graduate	Ft	Y	P	Y	0 /6m	VW
13	28	Married	4	Vocational	Ft	N	M	Y	0 /6m	VW
14	27	Married	10	GCSE	Housewife	N	P	N	<1 /m	VW
15	31	E/LtR	21	Graduate	Ft	Y	M	Y	0 /6m	VW
16	29	Divorced	12	None	Unemployed	N	M	N	>1 /m	VW
17	33	Single	11	Graduate	s/l	N	M	N	>1 /m	VW
18	21	E/LtR	2	Professional	Unemployed	N	P	N	>1 /m	VW
19	24	E/LtR	7	Professional	Ft	Y	-	Y	0 /6m	VW
20	30	S/LtR	1	Vocational	Pt	N	M	N	>1 /m	NVW
21	35	Single	9	Graduate	Ft	N	M	N	<1 /m	VW
22	32	Married	13	Graduate	Ft	Y	M	Y	0 /6m	VW
23	30	Married	22	Graduate	Unemployed	Y	M	Y	0 /6m	VW
24*	31	Married	12	Graduate	Ft	N \diamond	P	Y	0 /6m	VW

IO24* participant was interviewed only.
Educational level: Participants OI05, OI08 reported A level & Vocat (vocational qualification)
Employment: Ft (full time); Pt (part time); s/l (yes, sick leave); Stu (student); Unemployed (claiming unemployment benefit, Incapacity benefit or other benefits)
Driving status: \diamond Participant IO24 ticked Yes to her driving status, she was not driving at time of study participation due to 12 month medical suspension, adjusted record.
Treatment status: M monotherapy, P polytherapy
Seizure frequency: measured in seizures per month (m).
Self-rated seizure control: (V) Very well, (W) well, (F) fairly well, (NVW) not very well controlled.

Table 5.7 Demographic and background details of study stage two participants

The preconception characteristics of study stage two participants are presented to contrast antiepileptic drug use compared to selection of contraceptive method, self-related pregnancy planning intention and decisions to action clinical recommendations to change AEDs or commence folic acid (table 5.8)(See also Chapter 6, Section 6.2.3). Five women were taking sodium valproate based on the clinician's reference to the patient hospital records and/or referral letters, one of whom was found during the

course of her consultation to have withdrawn sodium valproate of her own volition. Six women were taking two AEDs, one in combination with sodium valproate, and one woman was taking a third AED, clobazam, intermittently to manage clusters of seizures. Seven women took action to change their AEDs, while one participant had collected her prescription for lamotrigine but had delayed switching from sodium valproate.

Six women were not using contraception in the six months prior to participating in the study, of whom only one identified that she was not in a sexual relationship, whilst three identified themselves as trying to conceive and were also taking folic acid. From this group, one woman reported changing the immediacy of her pregnancy intentions during the clinic visit, without changes to contraceptive or folic acid use.

Eight women were reliant on condoms for contraception, of whom four reported taking folic acid³³. The majority of women were not taking folic acid (n=17). Of these, one was taking sodium valproate and another was reliant on a polytherapy regimen (both participants commenced folic acid following the clinician's recommendation). Nine women reported their pregnancy intentions as immediate and five were not using contraception at the time of observed consultation, and therefore at risk of pregnancy prior to receiving preconception review. Of the four women with immediate pregnancy intentions remaining on contraception, two women were using condoms and two women were taking the contraceptive pill. Six women had prior pregnancy experience; however, only one had a child. Three women had experienced miscarriage; two women had experienced a medical termination, of which one was due to pre-natal diagnosis of major congenital malformation; the other participant defined her termination as an abortion. One woman discovered herself pregnant and stopped treatment in the time between clinic observation and follow-up interview.

³³ High dose folic acid is recommended within NICE Guidelines for all women with epilepsy who are either planning pregnancy or felt to be at risk of accidental pregnancy (NICE, 2012).

Patient ID number (OI)	Antiepileptic Drug use (AED)	AED changes following consultation	Contraceptive in use in last six months	Pregnancy intention ‡	Folic acid use	Folic acid commencement following consultation	Experience of Pregnancy	Number of pregnancies	Pregnancy outcome
01	CBZ	None	Coil	F	N	R/Y	N	0	-
02	VPA	Switch to LTG◊	Condoms	F	N	R/Y	Y	1	M
03	CBZ	None	Coil	F	N	-	Y	1	M
04	VPA LEV	None	Pill	F	N	R/N	N	0	-
05	LTG	None	Pill	X	N	-	N	0	-
06	LTG	Switch to CBZ	None	I**	N	R/N	N	0	-
07	VPA	None	Condoms	F	Y	-	N	0	-
08	LTG	None	Depo Provera	F	N	R/N	N	0	-
09	LTG CBZ	Reduce LTG	Condoms	F	N	R/Y	N	0	-
10	CBZ	CBZ withdrawal	Pill	I	N	-	N	0	-
11	LTG	None	Pill	F	N	R/N	N	0	-
12	LTG TPM	None	Coil	F	N	-	N	0	-
13	LEV	None	Condoms	F	Y	-	N	0	-
14	LTG TPM•	None	None	I	Y	-	N	0	-
15	CBZ	None	Condoms	F	N	R/N	N	0	-
16	VPA	Increase dose	None	⊕	N	-	Y	2	1/M
17	LTG	None	Condoms	F	N	R/N	Y	0	T
18	LEV COZ	None	Condoms	I	Y	-	N	0	-
19	None§	None	Pill	I	N	R/N	N	0	-
20	LEV	Reduce dose *	None	I	Y	-	Y*	1	P
21	VPA	None	Pill	F	Y	-	Y	1	T
22	LTG	None	None	I	Y	-	N	0	-
23	CBZ	CBZ withdrawal	Condoms	I	N	R/Y	N	0	-
24	CBZ AZM	AZM withdrawal	None	I	N	-	N	0	-

Antiepileptic drug use: AZM Acetazolamide, CBZ carbamazepine, LTG lamotrigine, VPA sodium valproate, LEV levetiracetam, TPM topiramate, COZ clobazam • OI14 intermittent use of clobazam § OI19 withdrew AEDs

AED changes after consultation: * OI20 reduced treatment dose following observation, and stopped treatment on discovery of pregnancy. ◊ OI02 collected prescription but not started recommended treatment switch (see Chapter 6.2.3)

‡ Pregnancy intention: reported desire to conceive, immediate (I), future (F) not stated/not clear (X). **OI06 changed pregnancy intentions. ⊕ OI16 was not in a sexual relationship.

Folic acid use: Yes (Y) No (N); commencement after consultation refers to participant action taken to clinician recommendation (R) no change in folic acid status (-).

Experience of pregnancy: total number of pregnancy experiences independent of outcome, OI20 conceived shortly after the index consultation and stopped treatment on discovery of pregnancy.

Pregnancy outcome: M (miscarriage), T (termination), P (pregnant), number of live born children

Table 5.8 Preconception demographics of study stage two participants

5.2 Introduction to the Clinicians

Twelve clinicians consented to observation of their consultations with study participants. The majority of observed consultations were held with consultant Neurologists, and three with Registrar grade Neurologists. The gender of clinician

observations was evenly split, although all Epilepsy Nurse Specialist observed consultations were with female nurses (table 5.9).

Professional title/grade (n=12)	Gender		No. of observations (n=23)
	Male	Female	
Neurologist	4	2	14
Obstetrician	-	1	1
Neurology Registrar	1	2	3
Epilepsy Nurse Specialist (ENS)	-	2	5

Table 5.9 Clinician characteristics

5.3 Observed consultations

The typical (median) consultation duration was 18 minutes 52 seconds, and consultations ranged in duration from 6 minutes 31 seconds to 67 minutes 50 seconds. The duration of clinic visit did not vary greatly between new and follow-up patient consultation, with the shortest new patient consultation 9 minutes 32 seconds and the shortest follow-up consultation 6 minutes 31 seconds. The majority of women attended their consultation unaccompanied (61%). Attendance with an accompanying adult, interruptions to the consultation, or the gender of the clinician did not alter the mean duration of consultations (table 5.10). There were few interruptions causing distractions with one exception; the clinician leaving the consultation room (OI06).

The consultations were all held in NHS hospitals. The clinic settings were similarly structured in each location, with patients having contact with outpatient department clinic staff, waiting in an outpatient waiting room, before being called into the consultation room. The clinic room environment was typically formal with a desk separating the clinician and patient. The nature of communication between the patient and clinician was verbal; few clinicians provided written literature (although patient information was available within the waiting room). The outcome of the clinic appointment was dependent upon hospital policy regarding the provision of patient copy letters. This was observed practice in one hospital, where patients indicated a preference to receive copies of correspondence as they booked into the outpatient department; the topic was not routinely discussed by clinicians, observed in one consultation (OI19).

Patient ID number (OI)	Visit type	Accompanied	Clinician	Clinician gender	Clinic Duration (hrs:mins:sec)	Clinic interruption	Clinic outcome
01	FU	-	ENS	F	00:38:36	-	-
02	FU	Partner	ENS	F	01:02:41	-	D
03	FU	-	Neurologist	M	00:13:25	-	-
04	FU	-	ENS	F	00:39:02	-	S
05	FU	-	Neurologist	F	00:06:31	-	H
06	NP	Carer	Neurology Registrar	F	01:07:50	Dr left room twice	D
07	NP	-	Neurologist	M	00:37:47	-	-
08	FU	Family x2	Neurologist	M	00:15:21	-	-
09	FU	-	Neurologist	F	00:17:27	Clinic door open	H
10	NP	-	Neurologist	M	00:12:48	-	-
11	FU	-	Neurologist	M	00:09:32	-	-
12	FU	Partner	Neurologist	M	00:25:43	-	-
13	FU	-	Neurologist	M	00:16:45	Clinic door open	H
14	NP	Spouse	Obstetrician	F	00:14:55	-	-
15	NP	-	Neurologist	M	00:24:37	-	-
16	NP	Friend	Neurology Registrar	F	00:17:33	-	D
17	FU	-	Neurologist	F	00:16:54	-	-
18	FU	-	ENS	F	00:24:57	-	-
19	NP	Partner	Neurologist	F	00:18:52	-	C
20	FU	-	Neurologist	M	00:23:53	-	S
21	FU	-	Neurology Registrar	M	00:17:14	Clinician bleep	-
22	FU	Spouse	ENS	F	00:37:30	-	-
23	NP	Spouse	Neurologist	M	00:59:02	Clinic door open	-
24*	-	-	Not observed	-	-	-	H

Visit type: NP New patient appointment; FU Follow-up appointment
Clinic outcome: (S) letter of support regarding benefits; (C) copy letter; (D) drug change schedule
(H) Hospital policy to provide copy letter, not confirmed if participants had taken up this offer.

Table 5.10 Observed consultations

5.4 In-depth interviews

The majority of women were interviewed in their own home; four women requested an alternate venue for their interview. Fifteen women were interviewed alone. Of the nine accompanied interviews, a partner / spouse were present in eight interviews, and one participant was interviewed with her sister and children present (OI16). Interviews in the presence of a partners / spouse did not substantially vary compared to unaccompanied interviews, and the majority of women maintained dominance in their role as interviewee. The structure of the interview format (see Appendix 2 In-depth interview topic guide) was similar in all interviews, women openly discussing their experiences. One participant interviewed with her husband, was an exception (OI14). I

needed to use my interview skills to encourage the participant to speak, using open questions directed towards the participant and giving positive reinforcement and maintaining eye contact with the participant, whilst acknowledging her husbands contributions.

5.5 Summary

The study population was the result of recruitment and continued engagement with both the participants and the clinicians. Eighty-five women and twelve clinicians contributed to the data for analysis, with the findings from analysis representing three broad substantive themes. This chapter has introduced the study population, using data generated from participant questionnaires to present to the participants' background demographic and reproductive histories.

The following four results chapters will present the study findings.

Chapter 6 Pregnancy planning

Introduction

‘Pregnancy planning’ describes the experiences of WWE as they contemplate their desires for family, their experience of preparing for pregnancy and the barriers they identify throughout their reproductive lives. These experiential findings have been used to structure this chapter as follows:

1. Intentions to have a baby – describes the experience of desire for family formation in the context of changing life circumstance.
2. The experience of planning pregnancy – describes the activities and priorities as defined by women through their interaction with clinicians; and
3. The breakdown of pregnancy planning – illustrates the experience of unplanned or accidental pregnancy, and provides explanations and interpretations of the barriers to achievement of a planned pregnancy.

6.1 Intentions to have a baby

WWE acted on their desires for family formation, influenced by life events contemplating the appropriate timing for a future pregnancy.

6.1.1 Desire for family

The desire to have a family or wanting to have a child were described as natural and as being the same as for any woman in the general population, a taken for granted stage in the life of every woman.

OI09: My dream was always, I’ve wanted 3 children [...] I’ve always had that mentality of, I want children... (29 year old, future pregnancy intentions)

OI17: I do want children of course I do, that’s just nature...
(33 year old, future pregnancy intentions)

For some women the desire to have a baby was first recognised in childhood and developed with perceived maturity. Maturity was used to measure the degree of intentionality to act on desires for family, such as feeling responsible enough to have children. Desires to have a family were described as a natural life progression, illustrated by a 39 year old woman describing her experience of meeting “Mr Right”, getting married and then thinking of starting a family (FG123). Women tended to

construct a traditional or idealised social model of becoming a mother in the context of getting engaged, married and settling down in a house as prerequisite to starting a family. This construct shaped how women managed the disclosure of their plans to settle down and to start a family within the consultation, establishing a home with a partner first, before making the decision to discuss pregnancy intentions with their clinician.

Women described their expectations of wanting to become a mother as an inevitable move into a stage in life when having children would become significant in response to their desires for family. For some women this view was rejected, proposing that the desire for children was not instinctive, but developed in response to life experience and opportunity. For these women, acknowledgement of not always having wanted children was important, placing emphasis on going to University, starting a career, or more practically getting settled in a relationship, marriage or house. Changes in the desire for children were central within these descriptions of family life, illustrated by a mother of a 12 year old child:

O116: Well at first I used to always want a lot of kids. But as I've gotten older and think, like nowadays like, I haven't really, I've thought about having kids even if I meet someone, I've thought maybe I could just have one more, if I do meet someone... (29 year old)

For some women intentions for family formation were presented as emotional statements such as having one's "heart on it [family]", with the women expressing anxiety concerning their future ability to conceive and their intention to try for a family remaining tentative. Other women struggled to imagine not being able to have a baby, with one woman commenting on her desire for the "experience of a baby growing and feeling the baby kick" (OI04, 27 year old). The instinct to have children or extend their family was presented by some women as them feeling "blessed" by having a baby or family. Future pregnancy desires were described by women in response to their life experiences and relationships, and whilst the majority identifying future pregnancy intentions spoke of their perceived future achievement in meeting this goal; for some women, desires were dampened by life events such as troubled relationships or more active seizures (expanded further in Section 6.1.3).

6.1.2 The timing of intentions for pregnancy

Statements about future intentions to conceive often specified a time frame. Within the consultation, changing circumstance such as moving in with a partner, or changes in relationship status were made with reference to an expected timescale, such as the date for a wedding: or in relation to estimating future intentions for pregnancy “I’d say next year two years, I’ve got to get married first” (OI09). The intentional status of women observed in clinic and followed up with interview (presented in Chapter 5, Table 5.8) categorises pregnancy intentions by the time frame of ‘immediate’ or ‘future’ reflecting descriptive terms used by women. Clinicians had a tendency to request more precise estimations of pregnancy plans and, whilst not always clearly stated, implied that consideration was needed of the time required to make treatment changes ahead of pregnancy. In contrast, women revealed tentative time scales around life events such as marriage, often influencing decisions to ask questions concerning the timing of conception:

FG-I-02: when you sort of get to an age when you think, well this is the time I want to be having a family. I think when, you know yourself when you’ve reached a point in your career, that you think now’s the right time, I’ve met the right person, I’ve done this, and this and this at the right time. Yes, you think well this is the avenue that I want to be taking. The consultant is not going to know that, but he will know the timescale of your life where you are, so whether or not that’s the time you should be asking ...
(36 year old, adopted two children)

Clinicians were observed to place significance on estimations of future pregnancy intentions, revealing a tendency to judge intentional status as static:

193. C: [...] Because years ago you
194. weren’t thinking about it, and we’ve certainly kind of, written that
195. down in our notes that it is not on the agenda ...
(OI01, 29 year old, future pregnancy intentions)

The changeable nature of pregnancy intentions was also susceptible to women changing their mind and responding to their biological clock. Some women made reference to a perceived time scale, such as, “I better get a move on” and “I don’t want to be trying for a baby to a timetable”. For several, the practicality of successful conception, the logistics of pregnancy spacing, achieving their desired family size in the context of their age and the pressures of comparison with other women evolved into a sense of urgency. For one 30 year old woman, with immediate pregnancy

intentions, the change in her desire for pregnancy had moved towards an “urge”, which at the time of follow up interview had resulted in emotional distress:

OI23: ... I haven't always had like an urge, to want a baby. But I've always known that in the future I would want one. But now I have got the urge, definitely, and [husband] has always wanted children ever since I've met him. He's crazy you know, he treats our dog as a little baby, he bought a paddling pool for him yesterday [laughs] a huge thing and I find it quite upsetting actually. [Starts crying]

The following participant defended her need to conceive as soon as possible in response to the clinician's request to delay conception (illustrated later in relation to prioritising improvements in seizure control ahead of conception, page 108):

327. P: [...] it takes ages for some people to get pregnant.
328. C: How old are you now [participant]?
329. P: 20
330. C: Oh, you've got loads of time haven't you?
331. P: No, it'll, my time will go fast [clicked fingers]
(OI06, 20 year old, immediate pregnancy intentions)

Judgements about the right time for pregnancy were not always the same as desires for children, resulting from the interplay between life events and an idealised future family life, as opposed to the reality of undertaking a pregnancy and having a baby. This point is exemplified by participant OI21; as she made reference to her feelings of missing out earlier on in life as a result of termination of pregnancy, following prenatal diagnosis of major congenital malformation when she was 16 years old (not illustrated). She reflected on her changing perspective about wanting a child; from her teenage experience to more recent consideration of artificial insemination while not in a relationship, through to the present day analysis of her desire for a child in the context of her current relationship.

OI21: ... I always thought all I wanted was a baby or all I want to do is be a mum and have a big family... But now I have [a partner], it's not something I really want, right now... But now I know I can, it's not a big rush ... I'm not ready yet to have a baby but, I'm just saying it because of my age, and I'm thinking if sort of looking at reducing it [the drug] now, in a couple of years I'll be off it, and then I might be ready then, I'm just sort of planning ahead...

Interviewer: So looking into the future

OI21: I wasn't picturing having a baby I was picturing having a child. Yes, or like teenagers... I think because my friends had their babies young, my friends got three teenage girls now, and I could, I'd be picturing that sort of life rather than a little baby (35 year old, future pregnancy intentions)

The ability to time a future conception was described by women frequently in relation to the challenges in establishing effective contraception. Some women described the potential for AEDs to interfere with seizure control, while for others, the interaction between AEDs and hormonal contraception led to frustrations, as illustrated by a 33 year old mother of a 6 year old child, and her perceived fight to locate an effective reversible contraceptive. Her desire to avoid sterilisation was an expression of concern for her perceived limited options to preserve her fertility.

FG42: Because like in later in life, in a couple of years, you might decide to have them. Because I never wanted children and then, we both didn't want children. I never wanted another one until a few months ago, and then I thought, oh hang on, I might do. But you don't know what's around the corner.

Clinicians were observed to recommend contraception to delay pregnancy until the 'right time' was achieved such as completion of a treatment change. The following extract displays the typical guidance provided by clinicians in response to the questions about contraception:

399. P: ... I was thinking about the pill, but I'm scared in case it
400. affects me epilepsy tablets, and I take a fit ...
[...]
456. C: Taking the pill, yes it would affect the epilepsy tablets, and it's a
457. case then trying to adjust the tablet doses and things like that. But if
458. you are planning to fall pregnant, I suspect then the best thing to do
459. is use barrier methods things like either condoms, or just
460. barrier methods like that. Just so we can get the doses up and the
461. tablets right, but it is important for you not to fall pregnant when we
462. are trying to get things right.
(OI06, 20 year old, immediate pregnancy intentions)

Women revealed a struggle to cope with any delay in conception once the decision to start a family had been made, with a potential conflict emerging between the patient's and clinician's time-scale. For one 23 year old participant (OI03), her personal efforts to manage feelings of wanting a baby led to conflict with her partner's intentions and her own desires, resulting in a two year trial without contraception and eventual pregnancy. Her earlier experience of pregnancy unfortunately resulted in a miscarriage which initially intensified her desire for a baby and subsequently led to a sense of urgency to conceive. On reflection, OI03 acknowledged her changing decisions concerning priorities in life, supporting a revised and perceived realistic timescale for

future pregnancy, with a recent change in focus to plan her wedding signalling relief from the pressure to conceive.

OI03: ... now I've got my wedding on my mind I don't mind waiting for kids but beforehand, when I had no plans for anything, it was like I want a baby and I want it now, my body was telling me I want a baby and it was like too much pressure on [partner]

6.1.3 Influences on pregnancy decisions

Decisions made by women to act on pregnancy desires were often influenced by changing circumstance and relationship status, and referred to as a joint venture between them and a partner. The importance of family support in pregnancy decisions was identified by the majority of women, and reflected their belief that pregnancy and future motherhood required additional support, implying recognition of the greater risk for things not going according to plan. In contrast, clinician's advice on the staging of future conception drew attention to the development of a pregnancy plan:

384. C: We're not in a rush anyway because you are not/ immediately
385. P: /No, not yet, no
386. C: for pregnancy so we can again have a further discussion
(OI07, 32 year old, future pregnancy intentions)

For a small subset of women, epilepsy was used to explain a lack of confidence in becoming a mother, or a fear of losing seizure control leading to hesitation in taking action to pursue their desire for children. For one 30 year old woman, her earlier experience of a difficult to control epilepsy, her undertaking of epilepsy surgery, and outcome of near seizure freedom, had resulted in her concerns about a relapse to more significant seizures needing to be balanced against her husband's desires for family:

FG72: I'd probably like a child in the future, at the moment, I'm on the pill [...] But the only thing I'm frightened of is, because my fits are now controlled through the operation, and I still get the auras. I'm frightened if I get pregnant [laugh], that I might be back to square one, having fits again, that's the only bit that's quite off putting for myself. I don't want to be, back in out of them seizures again, if possible [...] I know my husband would love to have a child, but I'm not ready for one at the moment.

Concerns regarding the potential risks associated with pregnancy were expressed in relation to a number of concerns including inheritance, fertility and future abilities to cope or bond with the desired baby. The latter point was exemplified by a 32 year old woman disclosing her earlier work to become seizure-free as requiring several

switches of AEDs and frequent hospital attendance until control had been achieved on lamotrigine 600mgs per day. Questions centred upon concerns about a seizure relapse and the potential for lamotrigine levels to drop in pregnancy, which had led to concerns about the possibility of resentment to a future child if these events occurred:

145. P: Because, I don't know how I'd feel about, I just wonder how, I
146. don't know how it feels to be pregnant but I just wonder how
147. attached I'll be to the baby if, oh I couldn't be, I don't know [breath
148. exhalation sounds]
149. C: In what terms, are you thinking of the baby sort of when you are
150. actually pregnant
151. P: If, I'd, if, if having this child was making my life awful it makes me
152. worry that how would I feel about it, but probably a really silly
153. thing to think, but these are the kind of things you do think...
(OI22, 32 year old, immediate pregnancy intentions)

For other women, the diagnosis of epilepsy in childhood had influenced their perceived future ability to become a mother and led to changes in their childhood ambitions for family, due to assumptions being made about the impossibility of pregnancy either with epilepsy or while taking AEDs. The influence of prior assumptions led some women to delay motherhood, leaving one 44 year old woman concerned about her age revealing regret at not providing her parents with grandchildren, reflecting that her fertility was coming to its end and her desire not to be the oldest parent at the school gate (FG-I-01). Age was seen to influence pregnancy decisions, emphasised by one participant recommending women with epilepsy consider having their pregnancy earlier in life. This participant revealed a preference for experiencing pregnancy within the age of "twenties to mid-thirties" which she associated as being "your best health wise" (FG21, 41 year old). In contrast, other women approached their thirties feeling tentative about future pregnancy and motherhood, and their opportunity to enter a suitable relationship or act on their desires; exemplified by a 29 year old participant stating "it's something I would think about, just don't know when" (OI05).

6. 2 The experience of planning pregnancy

Both women and clinicians were involved in making sense of and interpreting the life stage of pregnancy planning; and while the majority of women referred in ambivalent terms to planning for something to happen; for clinicians, 'planning' was more closely linked to definitions of preconception health care involving assessment, health education and interventions to improve epilepsy care.

6.2.1 What planning means to women with epilepsy

There was a near consensus among the women as to what planning meant, with the majority simply describing planning pregnancy as intentionally wanting or trying to become pregnant. For example, one teenager saw pregnancy planning characterised by the US sitcom *Friends* (FG106):

FG106: it really reminds me of Chandler and Monica off *Friends*, doesn't it, like they are trying for a baby and stuff that's what normally planning a pregnancy means. (18 year old)

Others defined the meaning of planning pregnancy as making the decision to have children and the majority of women included deliberation, suggesting planning involved thinking about what might be involved in preparing for pregnancy, as well as accessing information to support coping and caring for a future baby. For women who considered planning as a structured activity this involved getting to know everything that could happen including 'the worst case scenario'. For these women, planning was a series of stages, and involved review of treatment and epilepsy stability. This was extended further by one teenager (FG103, 18 year old) who saw planning as being guided through the process, by talking about and doing everything advised to "minimise absolutely every single risk". This point was illustrated by another participant as she retold her experience of termination of her second pregnancy following prenatal diagnosis of spina bifida (FG23). The 43 year old participant described her experience of planning her third pregnancy as involving getting her medication "sorted" and being taken off certain drugs to lessen the risk:

FG23: I think I had it planned more or less before I went with [neurologist] and he did this plan, and he said, we'll take you off so much then, and we'll withdraw you off them, and I was given a written plan of what to do, in a book. So, that was to me, was more sensible, and I had more. More comfort in the fact that. Well at least, I'm being sensible here. Before I go ahead with this pregnancy this time...

FG23 emphasises two important defining features of pregnancy planning: the first, the potential to plan before commencing the formal process of planning with a clinician; and the second, requiring agreement between parties, the patient, her partner and clinician, with all parties committing to take action to complete the agreed plan. Commitment to planning also focused on women stabilizing their financial position and relationships, implying a need to be careful until planning was complete. Descriptions of planning also made reference to the benefit of planning as opposed to

reckless unplanned pregnancy, with a critique made by some women of an unplanned pregnancy as losing the opportunity to review AEDs, commence folic acid or establish a good diet. The evidence of FG23's commitment to planning was exemplified by her commencement of preconception folic acid and adherence to the plan, both of which were described as providing reassurance that everything was being done, with the goal of improving the outcome of her next pregnancy:

FG23: And it was good, because [neurologist] said we'll put you on a course of folic acid, keep taking folic acid right the way through ... took me off the Epilim, weaned me off so much at a time so everything was sorted... I had to make sure I stuck rigidly to everything that was on this book...

The outcome of her third planned pregnancy was referred to as having the sense of everything having gone according to plan, the visible proof of which was when her baby was born with his spine intact, all fingers and toes counted and with a "good birth" (FG23).

The ability to plan ahead of a 'planned pregnancy' was identified by several participants to distinguish additional activities which lay outside of the formality of the clinician defined plan, and involved preparatory deliberations. For some this extended to more in-depth searches for information, and review of epilepsy management – getting the drugs sorted before starting to plan pregnancy. This defined the duration of planning as unique to WWE, in comparison with women without epilepsy. The significance of time was illustrative of commitment to "having planned everything" or the allocation of time such as committing "a year and a half, before I even tried to conceive" (FG86, 30 year old). In the case of FG-I-03, she defined planning in terms of the time required to achieve her desired objectives:

FG-I-03: I think I'd definitely want to plan like every single, cover every single aspect I could of pregnancy, to make sure it all went right ... I think I would probably plan 2 years ahead of when I wanted to get pregnant, when I wanted to start getting pregnant. (23 year old)

Women focused upon the intentionality of planning, implying that to plan required preparatory activity; whether to simply withdraw contraception or, more of a challenge, to improve epilepsy management, illustrated by a 29 year old:

OI09: But I wanted a plan as in, in two years that is what I want, either one or two drugs, but something there that I know is working. With the pregnancy side as well [clinician] is thinking about the folic acid...

Within clinic, planning was frequently defined by clinicians in terms of a series of stages, making treatment changes to stabilise seizure control, before embarking into pregnancy:

853. C: [...] first
 854. basically we get the seizures better, second once the seizures are
 855. better, we can plan for the pregnancy/
 [...]
 859. C: The fifth thing is the folic acid just in case, if in case you fall
 860. pregnant, OK (OI06; 20 year old, immediate pregnancy intentions)

In the case of OI06, she defined her role in planning pregnancy in terms of “trying to become pregnant” once she had completed the switch of treatment (not shown). This view was supported by others, defining planning pregnancy as involving activities to improve seizure control and adherence to clinical advice as being “well on the way to planning” (OI07). To plan pregnancy for some women involved acting on health promotion activities such as commencing folic acid prior to decisions to start trying to conceive.

- OI08: ... it’s a process ... isn’t it, so far as I’m concerned it would be a case of right okay, there’s engagement, marriage and there’s folic acid ...
 (27 year old, future pregnancy intention)

The above participant exemplified a sub-group of women who defined planned pregnancy in terms of commencement of folic acid.

6.2.2 Priorities in planning

The main motivation for women to plan pregnancy was to reduce perceived risks by becoming healthy and thereby increasing the chances of a positive pregnancy outcome.

- FG74: as a woman, you’re, you know you are this vessel, aren’t you. And you’re supposed to be as healthy as possible when you get pregnant (36 year old)

Clinician priorities related to two main objectives, the first involving activities to improve epilepsy management, including attention to improving seizure control by review of AED selection. The second objective involved the delivery of information to support patient informed decision-making, and assist women in adhering to the clinical recommendations. Women interpreted medical interventions as implying the need to become seizure free before pregnancy could be considered; and to be taking the least number of AEDs, and ideally no treatment. For some, support from their clinician was

interpreted as providing assistance to structure a timetable for treatment change, allowing the charting of progress towards their goal.

FG101: my medication is the big thing with this planning pregnancy it's just the, it comes back to the medication all the time (18 year old)

The setting of priorities in order to identify which activities required most attention within the planning process appeared inconsistent. Women frequently ranked talking to the doctor as the first planning activity to determine “what had to be done”, and to establish the main priorities for provision of information essential for decision-making in their approach and preparation for pregnancy:

FG82: the biggest thing is being properly counselled beforehand (37 year old)

Counselling was judged essential by women who anticipated increased anxiety surrounding their preparation for pregnancy; and who identified the benefits of “getting things into perspective” or dealing with “things” to relieve future worries in preparation for future pregnancy.

6.2.3 The meaning of planning activities as preparation for pregnancy

Women were able to identify pre-pregnancy preparatory activities. However, the majority did not locate these activities consistently within their definitions of a ‘planned pregnancy’, suggesting a planned pregnancy was defined by making the decision to become pregnant. Table 6.1 illustrates the self-reported preparatory activities contributing to the experience of 12 women who were pregnant at the time of study participation.

The majority of women highlighted the importance of getting their AEDs ‘sorted’ ahead of conception as preparation for future motherhood and essential for their ability to cope with and care for their children. The inclusion of improving seizure control as a preparatory activity was important, especially given the time required to complete this activity, a point illustrated by participants in their description of preparations for a future pregnancy.

Participant ID	Age	Parity	Gestation (weeks)	Self-reported planning status	Participant accounts of activities they associated with preparing / planning pregnancy
FG81	28	0	24	'Planned' ³⁴	Introduced self as having planned pregnancy before discussing experience of epilepsy. Preconception epilepsy review, dose reduction, & folic acid.
FG82	37	2	29	Unplanned "surprise"	Planned second pregnancy following diagnosis of fetal valproate syndrome in 1 st child. No changes to AEDs between 2 nd and 3 rd pregnancy.
FG84	23	0	20	Unplanned "big massive shock"	Pregnancy taking contraceptive pill (not taken protective measure during antibiotic use). Folic acid commenced at 17 years, recommended as part of epilepsy review of risks associated with remaining on sodium valproate.
FG85	23	0	29	Unplanned "unexpected"	Pregnancy unexpected reported in relation to partner break-up. Had discussed plans to try and conceive with partner.
FG86	30	0	17	"Planned" stated during introductions.	Epilepsy review with risks and benefits of remaining on low dose sodium valproate commenced folic acid and withdrew contraception before study participation.
FG91	29	1	16	Not stated "not well planned"	Withdrew contraception two years earlier. Experienced preconception review for 1 st pregnancy, reviewed risks and benefits and switched from sodium valproate to lamotrigine, remained on folic acid "just in case".
FG92	32	3	18	"Planned" ³⁵	Pregnancy discovery reported as a shock as it had taken longer than expected. Weight loss and stopped smoking before epilepsy diagnosis, delayed starting AED.
FG93	27	0	12	Planned "shock"	Started fertility treatment to stimulate ovulation as attempting to conceive >18m. Reduced smoking as part of fertility recommendations, preconception folic acid.
FG95	25	0	11	"Definitely" unplanned pregnancy	Pregnancy taking contraceptive pill, no preconception review, unaware of AED risks, not taking folic acid prior to current pregnancy.
FG96	34	1	17	Not stated	Spoke to GP before 1 st pregnancy, prior switch from sodium valproate to lamotrigine and withdrawal of AEDs before 1 st pregnancy.
FG124	32	1	8	"Planned" "worried"	Preconception epilepsy review before 1 st pregnancy. Restarted folic acid 8 months before conception, modified diet and 'healthy lifestyle'.
OI20	30	0	5	Not stated "shocked discovery"	Preconception epilepsy review, AED dose reduction and commencement of folic acid. Fertility assessment as attempting to conceive, withdrew contraception >12m ago. Believed infertile due to prior use of Epilim.

Table 6.1 Pregnancy planning experience for women pregnant at time of study participation

³⁴FG81's self-report of a 'planned' pregnancy may have influenced subsequent participant introductions.

³⁵ Focus group 9 participants did not refer to pregnancy planning until prompted by the moderator in the latter stages of group discussion. This finding is in keeping with other researcher (Barrett and Wellings (2002)) (See Chapter 2 Literature review). The rate of planned pregnancy within this study based on participant self-reports is 42% and is similar to the reports of planned pregnancy reported by Fairgrieve et al (2000) and Pashley & O'Donoghue (2009).

The reality for one participant was that she had yet to achieve her planned objective of taking only one AED, implying future revision of her pregnancy plan or further attempts with alternate AEDs:

FG55: I'm planning. I'm planning two years in advance [laugh]; I've already started messing with my drugs, so you know that's quite a long... I wanted to cut down to just one drug to reduce the risk. I couldn't do it in the end, because as I reduced one of them, I started having fits again. But, that was one way I wanted to try and reduce the risks. I'm still on two [AEDs]... (28 year old)

Targeted clinical advice promoting the benefit of preparatory activities directed attention to the dangers of making abrupt changes to AEDs on discovery of an unplanned pregnancy. The following extract illustrates how the clinician responded to the patient's hypothetical question regarding her requirement to stop treatment if she were to experience an unplanned pregnancy:

376. P: [...] if in like the future. I mean I am definitely
377. not in the near future planning a baby. Because I haven't
378. met anyone and I would need to be with them a few years
379. before I go there ...
[...]
381. P: If say like I found out I was couple of months pregnant but didn't
382. realise, or something like that. Or as soon as I do find out I'm
283. pregnant, would I be best to literally stop or just cut straight
284. back {Well}the Valproate more than the Keppra
285. maybe, if I'm still on it, if that happens?
386. C: Right, well usually we, as a rule of thumb, we do not make any
387. changes in pregnancy.
(OI04, 27 year old; future pregnancy intentions)

An important component of preparatory activities defined by women related to being guided "in the right direction", finding "a way around" perceived problems, and being able to "give that worry over" to whoever was helping plan the pregnancy. In a similar way, the provision of risk information was seen as "filling the gaps" in knowledge to support involvement in the planning process, while the opportunity to ask questions was also vital in supporting becoming "more prepared" for future pregnancy. The provision of information on topics such as pregnancy care and childcare was judged an essential preparatory resource to alleviate worry concerning abilities to cope with the demands of childcare, given the unpredictability of life with epilepsy. Reassurance was provided through the application of commonsense knowledge gained from preparatory

discussions with the epilepsy specialist on child safety topics – making the house safe, along with simple measures of risk avoidance such as not bathing the baby alone.

Clinicians utilized the clinic visit as an opportunity to highlight preparatory activities for women to follow on their discovery of pregnancy, most commonly emphasising AED adherence during pregnancy, and informing of the potential requirement for future drug dose changes, such as the requirement for drug level monitoring and adjustment of dose during pregnancy. In a minority of observations, clinicians recommended early booking into antenatal care, and monitoring prenatal health by women making early contact with their midwife during pregnancy (the latter point made in a single clinic observation, participant case OI13).

6.3 The breakdown of pregnancy planning

Women described their ideas of what a planned pregnancy entailed and its influence upon their engagement in planning activities. For some, planning was influenced by past experience of pregnancy, with reference to the responsibilities involved, and the struggle to control fertility. Multiple factors influenced pregnancy planning, and for some this led to an eventual breakdown in planning.

6.3.1 The influence of predetermined ideas on pregnancy planning

One of the main barriers to planning pregnancy identified by the women was their perception of what planning involved, such as it not being natural, being hard work or an uphill mountain, an ordeal, awkward or regimented, and complicated so that they did not know where to start. Women used these statements often in defence of their experience of struggling to achieve a planned pregnancy, invoking worries about their plans not working out due to epilepsy related concerns such as poor memory and the need for additional support. The latter points are illustrated by the following 22 year old participant:

FG57: ... if I was to plan to get pregnant, I think I would be focussing on all the bad things that could happen. And I'd just be trying to go about it ways where it wouldn't affect me as much. That's what, you just don't know. I think, I don't think I could possibly plan actually, because, I just wouldn't know where to start. [...] Like with my epilepsy, as well, it affects one part of my brain. Were I can't, in day to day things like. I can't, I'm not an organised person, I'm very forgetful. I can remember things like ten, fifteen minutes again. [...] I'd need someone to come out of there way to, to help

me, and to guide me through it, I just wouldn't be able to sit down on my own and plan. (22 year old)

Women reflected on their frustration and longing for the ability to conceive “naturally”, with the ambivalent perspective of “if it happens, it happens”. In addition, frequent mention was made of the widespread lack of planned pregnancy in the general population, of women who were able to live each day as it comes, leaving pregnancy to chance and conception to nature, in contrast to the difficulties experienced by women with epilepsy struggling to live a planned life.

OI23: Do you know what I find a horrible thing like other people get pregnant and my friends “oh” unexpected, and then I was thinking well, it's really awful, I feel I have had to be so regimented and to plan it. And often I think I probably would have, if it hadn't been for the epilepsy, I probably would have fallen pregnant sooner. Because like I used to say to my friends, I don't think it's ever necessarily the right time to have a baby is it?
(30 year old, immediate pregnancy intentions)

Clinicians also acknowledged failures to plan pregnancy as not being limited to WWE, but widespread across the general population. For example, one clinician noted:

119. C: /Yes planning ahead. But not
120. everybody/
121. Patient's relative 1: /Gets the opportunity to plan ahead do they
122. [laugh]
123. C: Most women, in fact most women don't really plan that much
124. Patient's relative 1: No, no
125. C: But we like the planning aspect of it.
(OI08; 27 year old, future pregnancy intentions)

The impact of the terminology used upon the potential breakdown in pregnancy planning was also apparent. Clinicians often used ‘planning’ referring to a series of interventions completed before conception. Women, in contrast, used the term ‘planning’ as synonymous with trying to conceive, as illustrated by the partner of a 27 year woman with immediate pregnancy intentions:

Partner: We tend to say planning in the loose sense of the term you know, it's like we say yes we want children and we'll go through this. But it's very loose, we've not said like by April... (OI14)

While the above quote implies this couple's attempts to strive for a less regimented approach, there was nevertheless acknowledgement of a process of activities that needed to be worked through to finally achieve the planned pregnancy. Several women

made reference to their anticipation of engaging in preparatory activities ahead of a future pregnancy and motherhood, as illustrated by the following participant:

OI01: To be honest with you it's just to do with giving myself the best chance, I think. Anything I can start doing, and start doing as earlier, I'll start doing it really [...] obviously you want your child to be fit and healthy and you'll do everything you can to make sure that comes through...
(29 year old, future pregnancy intentions)

However, despite OI01's intention to give her future child the best chance, when questioned at interview about her intentions to quit smoking, she implied smoking would be the last thing she would give up – and that she would only do so within pregnancy, rather than prior to conception:

OI01: if I've got to do it [stop smoking], I will do it. And I would have to do it if I was pregnant, that would be something I'd be pretty hot on, I think, I'd be a nightmare to be around I reckon but I would do it...

One 20 year old participant accepted the recommendations from her clinician to switch AEDs, her statements during interview implying agreement with the aim of improving seizure control in preparation for pregnancy (not illustrated). However, when asked her views regarding quitting smoking prior to conception, the participant suggested general health improvements as only requiring attention if she failed to conceive:

OI06: ... if they said to me yes you can have children but at the moment you are not conceiving because you are smoking and you are not eating properly then I would change all that. I would stop smoking and I would eat properly to make my baby, to try and get pregnant. So that is what I would do, yes. (Immediate pregnancy intentions)

The lack of attention to preparatory activities, such as stopping smoking, reducing alcohol consumption, healthy eating, dieting and weight management, were significant especially within the observed consultations as the status of preparing for pregnancy defined the participants' recruitment. From this group, weight loss had been mentioned by participants OI07 and OI18 as an intervention recommended by their GP and fertility specialist respectively, while participant OI13's case was notable for the inclusion by the clinician of life style advice, including questions concerning smoking and diet. The following extract from this participant's case illustrates the confusion between the terminology of 'planning' and the interpretation of preparatory health promotion activities. The clinician's question was asked at the closing stages of the consultation to elicit any remaining issues requiring discussion. The patient's reply illustrates the

failure to identify as components of her planned pregnancy her involvement in activities to improve seizure control and establish a healthy lifestyle:

238. C: Is there anything else you want to ask?
239. P: Not really the only thing I was wondering really does it have
240. to be a planned pregnancy, with having epilepsy. What if
241. when
242. C: Well, it is very important; well you have planned it really. So yes,
243. I mean, you need to know the risks in advance which are very
244. low, you need to be on the folic acid, you need to make sure that
245. you are healthy otherwise, which you are. So, I mean, you don't
246. have to actually plan when you are going to conceive but, if you
247. are going to stop using the contraception after you get married,
248. then just wait and see what happens.
249. P: Right (OI13; 28 year old, future pregnancy intentions)

Confusion surrounding the implementation of planning activities resulted in the following teenage participant's comparison between the meaning of planned and unplanned pregnancy:

- FG45: not unexpected I suppose. Not sort of waking up and going oh I think I might be pregnant sort of a thing and sort of intentionally wanting a child sort of a thing and planning ahead for it as opposed to finding out you are pregnant and then planning sort of thing. (19 year old)

The above quote highlights a frequent error made by the women in defining planning as an activity which could also take place following the discovery of pregnancy.

6.3.2 Control and management of fertility

Fertility problems and the perception of a future struggle to conceive resulted in a sub-group of women taking a more relaxed and ambivalent approach to pregnancy. This point was illustrated by several participants' failure to use any contraception, and for those women using the combined oral contraceptive pill, failing to take the necessary action during illness or antibiotic use to prevent accidental pregnancy, defended by their belief that they were unable to conceive due to infertility:

- FG84: I've been on the pill constantly and then I was on it was in the May, I was on antibiotics, and I just took my pill as normal and all that, and then obviously when, when they say you're on antibiotics it can stop the pill working. But then I thought that's not going to bother me, because I can't get pregnant anyway. At that time, I was having a period every three months so it was, it was normal for me to have a late period and it was only collapsing in work [...] I'd done a test, and my Mum was going just, and I was like Mum, I'm not pregnant, I can't get pregnant, (23 years old; 1st pregnancy)

Women interpreted their bodies as unpredictable in response to the perceived interaction between epilepsy or AEDs and their reproductive cycle. In the case of OI03 a 23 year old with future pregnancy intentions, she expressed frustrations in her ability to conceive when desired. She described her approach to a second pregnancy after an earlier experience of pregnancy resulting in miscarriage (not shown):

OI03: I assumed because it took so long last time, it could have been to do with the medication. So, because I was saying [to partner], well it took two years last time, maybe we should start trying now, because in two years time I will be wanting a baby and then I couldn't have one.

Fertility problems linked to the experience of menstrual disturbance were frequently attributed to polycystic ovaries, and a joint diagnosis in teenage years left some women uncertain of their current fertility status, despite the passage of time or changes to AEDs. The most commonly implicated AED 'causing' polycystic ovaries was sodium valproate. Women who had previously taken sodium valproate required additional work by the clinician to both reassure them that drug withdrawal would result in the return to full fertility and to suggest a lack of consensus between epilepsy specialists concerning the link between sodium valproate and polycystic ovaries. Other women perceived non-specific risks from epilepsy, questioning whether epilepsy per se could have influence upon the likelihood of experiencing fertility problems.

OI06: Yes because I have always wanted babies but with me I have always thought because people get pregnant quick I have always thought that there is something inside me that feels like I can't have kids.
(20 year old, immediate pregnancy intentions)

Age-specific fertility risks were included by clinicians in their advice concerning delaying conception, especially as women approached their late thirties. For one participant, the competing risks of conditions such as Down's Syndrome were highlighted:

- 63. C: As you get older the risk, the risk in pregnancy,
- 64. malformations in pregnancy increases in its own right,
- 65. P: Yes it does
- 66. C: Whether you have epilepsy, whether you're on medication or
- 67. not
- 68. P: Yes I know (OI21; 35 year old, future pregnancy intentions)

Some women perceived their fertility as problematic, due to the difficulty achieving effective contraception, leaving them critical of achieving a planned pregnancy as an

unattainable luxury. One teenager identified her belief in being unable to prevent pregnancy despite utilizing available contraceptive methods as defence for her inability to plan a future pregnancy (FG102, 16 year old). In contrast, participant OI18, a 21 year old young woman with immediate pregnancy intentions revealed her struggle to regain fertility following prior reliance on three methods of contraception:

103. P: ... they're that up the wall my periods, it's so hard to judge
 104. what my cycle is/
 105. C: /Yes, and has that been since you came off your
 106. contraception, they've/ been very erratic
 107. P: /All three forms of it, yes
 108. C: Yes, right. I know because I noticed that you were using belt braces
 109. and a few buttons as well/ weren't you [laugh]?
 110. P: /Yes (OI18)

Participant OI18 reflected on her earlier choices of contraception method in the face of uncertainties over achieving her desired pregnancy:

- OI18: [...] I stopped taking the pill and the jab but they said just to be on the safe side with me weaning off topiramate, use condoms at the time because they said technically it is still in your system but it's always best to be safe than sorry [...] I said to my mum if I knew I would have this problem to try and have a family I wouldn't have gone through all that precaution...

Several women identified barriers to utilizing mainstream family planning clinics due to the limitations of health professional knowledge about the potential interactions between AEDs and hormonal contraception. A point made by one participant following receipt of new information concerning the 'pill' interactions with her current AED, leading the 24 year old to reflect upon her potential to have experienced accidental pregnancy:

- FG54: I'm actually coming off a drug now, but apparently that drug interacts with the pill I'm on. So the pill and the prick³⁶ don't work. But I only found out about two weeks ago.

The lack of confidence in contraceptive advice reinforced several women selecting less effective barrier methods including, for one woman, reliance on the unorthodox technique of the 'withdrawal method'. The general lack of confidence in controlling fertility led this sub-group of women to discuss attempts to conceive as a test of their fertility, exemplified by one participant's attempts to conceive despite her clinician advising delaying conception during an AED switchover (not illustrated):

³⁶ FG54's use of the term 'prick' refers to the contraceptive Depo Provera, progesterone injection.

OI06: ...sometimes I do try for a baby but I'm not conceiving yet ...
(20 year old, immediate pregnancy intentions)

Women revealed distress when discussing the uncertainties of their fertility status and how this might influence their future ability to conceive, progress through pregnancy and deliver a future baby.

OI23: also there's going to be the issue now of, am I going to fall pregnant [...] it's something that I've worried about since I was really little, would I or would I not be able to have a baby
(30 year old, immediate pregnancy intentions)

Women dealt with questions concerning their plans for a family by hiding their failed attempts to conceive and making use of statements such as "not being bothered" with having a family, "not being ready", or "not at the moment". The perceived public awareness of their pregnancy intentions, such as "everyone knows", was managed by one woman by pretending she "didn't want" a baby, thus protecting herself from providing explanations about her perceived infertility (OI06).

6.3.3 Responsibilities for pregnancy planning

Women referred to their responsibility to plan pregnancy, requiring their commitment to return to see a specialist before conception, and to allocate sufficient time and take the required action on recommended interventions. Their responsibilities to recognise a right time to start discussing preparations for pregnancy were interpreted by women, in response to the clinician asking questions about their desires for family, as meaning they had reached an appropriate stage in their epilepsy control when pregnancy could be considered appropriate. This type of interpretation was illustrated by the following participant:

OI08: Because I mean if he didn't think that I was at a level where I could perhaps think about it [pregnancy], then I don't suppose it would come up in conversation really would it or that I would be eligible.
(27 year old, future pregnancy intentions)

For other women the importance of preventing an unplanned pregnancy was seen as avoiding the possibility of receiving punishment for failing to have taken adequate precautions in preventing a pregnancy:

FG53: I've been told if I was to find out that I was pregnant, I'd have to go and see my consultant straight away. Which makes me feel a like, I'll have to go and get told off. And that I'd get in a lot of trouble. (23 year old)

Considering the activities involved in preparing for pregnancy as being hard work, resulted in some women perceiving their return for review as an obstacle to be endured:

OI22: I think it is responsible going to see [the clinician], I think it is, finding out [information]. Then actually braving yourself to go, but, that's the responsibility I have. I don't like going to hospital, I don't like talking about all this, but I just have to. And if I don't, and I just sort of risk it [get pregnant], it may have dire consequences so, I feel that is responsible... (32 year old, immediate pregnancy intentions)

For other participants, their perceptions of what it meant to have epilepsy and the chance of their future child inheriting epilepsy required targeted preparatory activities focused on the potential for becoming a mother and child with epilepsy:

FG101: I think epileptics have got to be more prepared than any other person to be honest. Because if they [the child] get it, you know what to do, because you've got it [epilepsy]. But if it, it can be a big problem to be honest and in the future like, because if you are not prepared ... (18 year old)

6.3.4 The influence of past experience to improve pregnancy planning

Receiving information concerning the potential risk of adverse events for the woman and her future offspring influenced some women's experiences of planning pregnancy. For others, the experience of an earlier pregnancy with an adverse outcome caused worry and influenced future pregnancy decisions. The experience of OI17 exemplified the dilemma faced by such women, when discovering an accidental pregnancy exposed in utero to sodium valproate. The participant described her prior communication with clinicians and her awareness of the need to prepare for pregnancy, including her knowledge of the risks associated with in utero valproate exposure (not illustrated). Despite prior knowledge, OI17 described herself as being ill-prepared to progress with the pregnancy:

OI17: I think one of the things that does hurt me more than anything is I did make the decision to sort of like abort one child because I was worried about the fact that I hadn't done the things that I was supposed to do, hadn't planned it. The medics say plan it, take the folic acid but sometimes it just doesn't happen like that. But then I was seeing somebody that was saying well you have probably put your child at risk, well no I've not put the child at risk I've just been me, but it's dead easy for people to say plan it, you can't always plan it. (33 year old, future pregnancy intentions)

The significance of unplanned pregnancy was interpreted by women with experience of delivering a baby affected by in utero AED exposure as a missed opportunity to manage

preparations for pregnancy, thereby failing to support pregnancy decisions. A 23 year old participant who was pregnant at the time of focus group participation (FG84), described her shocked discovery of an unplanned pregnancy secondary to her failure to maintain adequate contraception during antibiotic use (illustrated earlier in Section 6.3.2, page 115). FG84 contributed further to the understanding of how “just in case” health promotion activities such as commencing folic acid may fail to influence future awareness of the importance of planned pregnancy.

FG84: ... when I was seventeen and I was thinking why is she giving me folic acid because I was seventeen then, and now I think, thank God [...] if I decide to have another one, I'd like to prepare for it, go and speak to [clinician] and everything. Because with the, I got it all, I found out I was pregnant, and then it was like, you've got to get to hospital, and have a scan and find out exactly how far you've gone, because obviously because when the baby gets to the 90 days is it? Then it's fully formed, so I got all the risks and everything after I'd been told I was pregnant.

For a small minority of women the experience of an accidental or unplanned pregnancy had resulted in prenatal diagnosis of major congenital malformation and decision-making concerning termination of pregnancy. These women made reference to the perceived missed opportunity to plan pregnancy either through a prior lack of awareness of the importance of preparation for pregnancy or information deficits concerning the risks associated with in utero AED exposure.

In contrast, for one participant, her experience of miscarriage resulted in her reflecting upon a missed opportunity to have stopped smoking and to have avoided drinking alcohol prior to conception:

OI02: I think that's why I lost my other baby, through drinking and smoking. Well I feel like it was, it's stupid there's no other explanation, why it died. But like, the night before I found out, I did have a little drink with my mates and then I found out that I'd lost it [...] it has like crossed my mind, whether because I've got epilepsy, why I lost it, (22 year old, future pregnancy intentions)

This woman interpreted her experience of miscarriage by constructing an explanatory link to her behaviours of smoking and consuming alcohol, and in doing so excluded any potential causal link to her epilepsy or its treatment. During the observed clinic visit OI02 presented her first unplanned pregnancy occurring while she was taking sodium

valproate, a point clarified by the clinician who questioned whether OI02 had concerns surrounding future preparation for pregnancy:

183. P: [...] Well I have had a miscarriage ...
[...]
186. C: Was that an unplanned pregnancy?
187. P: Yes it was unplanned.
188. C: Do you know how far on you where when you miscarried?
189. P: Two and half months.
190. C: And presumably at that point, were you on Epilim then?
191. P: Yes
[...]
196. C: [...] have you got any concerns
197. about becoming pregnant, having epilepsy and your treatment is
198. there anything that's especially worrying you?
199. P: Not really is there
200. Partner: Just what they told us about the tablets, and about each
201. tablet to go moving them, have you?
202. P: [Clinician] had mentioned to me about my medication.
203. C: How do you feel about that?
204. P: Well at first I was not happy about it because I am happy with the
205. medication that I am on now. But obviously if I've got to change
206. then I'm going to have to aren't I, so.
(22 year old, future pregnancy intentions)

The failure to associate the earlier experience of miscarriage to AED-related risk resulted in reinforcing OI02's resistance to changing her AED and her preference for the status quo as opposed to the opportunity for an alternative future pregnancy outcome taking an alternative AED.

The process of preconception counselling for some women is complex, involving treatment review and careful monitoring of seizure management, leading up to the patient's attempts to conceive and, finally, support through the planned pregnancy. For other women the process of preparation is more straightforward with preconception review signalling the go-ahead of attempts to conceive. The significance of women receiving preconception information and epilepsy review was the opportunity to improve the outcome of pregnancy if the information was acted on prior to conception. Some women reflected on information deficits at a stage in their lives when they were trying to conceive, as illustrated by the following quote from a 34 year old woman who has had two children both affected by in utero exposure to sodium valproate:

FG125: I fell pregnant accidentally with the kids I didn't plan it, I was 21 with my son so I did no planning involved in it, and I did tell the hospital and stuff

like that, and I was told it was okay to take my medication. And then the same with my daughter, and it was only after my daughter then all, I discovered all the problems that the Epilim had caused in my kids. So from then, that's when I decided I'll not have anymore.

The majority of women accepted the opportunistic delivery of preconception and health promotion information, whether concerning contraception, folic acid status or focused information concerning the risks associated with in utero AED exposure and/or seizure related risks. The timely delivery of information was most frequently highlighted as an important component of any preconception review, whether pregnancy was imminent or not:

FG-I-02: But I think the Consultant has that ability to just say, have you, are you, thinking about this now or shall we revisit this another time in another appointment. And then he can write that on the notes, you know, not wanting to consider family at this time, (36 year old)

The above participant had, in fact, struggled with her experience of opportunistic delivery of preconception information, and while her opinion was not shared with the majority, a sub-group of women had struggled either with risk information increasing anxiety and worries or the mistiming of information (these issues are discussed further in Chapter 7).

6.4 Summary Results: Pregnancy planning

- Preparing for a planned pregnancy requires actions from both the patient and clinician in preparation for the future event of conception. The process requires review of patient-perceived anxieties, worries and fears which have been shown to influence women's engagement in pregnancy planning activities.
- 'Planning' as a descriptive term, relates to a woman giving forethought to the way she might achieve her desired future pregnancy outcome, and in this sense the activities of pregnancy planning were deliberative, rather than a set of observable behaviours.
- The most significant finding from the analysis was the inconsistent use of the term 'planning' both by women and their clinicians. Women frequently defined planning as the intention to conceive, implying that activities to improve epilepsy management were something that occurred prior to the formality of 'planning' with their clinician.

- For women who defined planning as involving more complex activities this required commitment to following the ‘plan’ and acceptance of delays in conception. Improving preconception health was acknowledged as improving their future pregnancy outcome. However, many of these women also reported longings for a more natural approach to achieving pregnancy, which could act as a potential barrier to adherence to preconception activities.
- The influence of significant others upon the experience of women preparing for pregnancy, factors around timing preparatory activities, and the experience of difficulties in establishing reliable contraception all contributed to the potential breakdown in pregnancy planning.
- Women had competing interests and worries concerning their ability to conceive and their fertility status, both combining to influence the use of contraception and the approach by women to avoid conception when advised by their clinician.
- The influence of past pregnancy experiences, including the experience of miscarriage, pregnancy termination or abortion, had a significant impact upon how women approached future pregnancy, including the likelihood of engaging in preconception interventions ahead of a future pregnancy.

The following chapter will focus upon the communication of risk and uncertainty.

Chapter 7 Communicating risk and uncertainty

Introduction

‘Communicating risk and uncertainty’ describes the perceptions of epilepsy and pregnancy related risks held by WWE, and their experiences interacting with their clinician. This theme is illustrated by three interconnected sub-themes which have been used to structure the presentation of findings:

1. The presentation of information on risk and uncertainty – outlines the experience of being provided with information concerning the potential occurrence of adverse pregnancy outcomes.
2. Focus on the health of the unborn child prior to conception – describes the perception of risks concerning the future health of the unborn baby following in utero exposure to antiepileptic drugs and seizures, and
3. Risk management – illustrates the strategies used by women and clinicians to reduce, avoid, prevent and manage future pregnancy related risks.

7.1 The presentation of information on risk and uncertainty

The communication of risk information within the epilepsy clinic served to help women make sense of their prior perceptions of potential adverse pregnancy outcomes, and manage their fears of the uncertain outcome of pregnancy. Women anticipated the communication of risk concerning adverse pregnancy outcomes, and the recall of statistics had influence on how women perceived risk management.

FG74: I was given statistics of something like 14%, possible risk with that [Epilem], and then two other drugs greatly reduced in the risks. 14% seemed like quite a lot to me, and then I think one of them was mentioned, 7%, and then Tegretol Retard was two, and that kind of figure, compared to fourteen, sticks in your mind. (36 years old)

Narrative descriptions of risk were used to illustrate specific malformations and present the uncertain risks associated with newer AEDs or the long-term risks of neurodevelopmental delay.

7.1.1 Presentation of risk

Within the epilepsy clinic, risk information was presented as estimations of the potential risk of an adverse pregnancy outcome. Data from the UK Epilepsy and

Pregnancy Register was quoted to support numeric comparison of the risks between established AEDs and the associated drug-specific MCM risks. These strategies are exemplified by the clinician's presentation of risks to a 22 year old participant who attended clinic with her fiancé:

273. C: [...] right now, just say you wanted to start
274. trying for a child and you kept your dose, you stayed on Epilim.
275. On a dose of 1500mgs a day [...] your
276. risk would be higher than 9% chance of having a child with a major
277. malformation, OK [...] in comparison with for instance
278. lamotrigine on a lower dose under 200 mg a day, the risk would be
279. around about 3% so there is quite a difference really [...] the
280. other thing about Epilim is, we are talking about major
281. malformations such as spina bifida, you might of heard of that,
282. problems with the growth of bones, cleft palate, heart defects these
283. are what we call major malformations ...
(OI02; 22 year old, future pregnancy intentions)

The clinician utilized percentage estimations of the size of risk and the naming of specific malformations as strategies to reinforce or frame the objective nature of risks to the unborn baby, positioning Epilim (sodium valproate) as more risky than the proposed alternative, lamotrigine. The quantification of drug risk supports the opportunity to reduce risk by lowering drug dose (discussed further in Section 7.3 Risk Management).

328. C: [...] If you're on a lower dose of Epilim then that risk falls.
329. And if you were on less than 1000mgs your risk would in the region
330. of, just over 5% chance. So being on a reduced dose does
331. reduce the risk... (OI02)

When proposing AED changes, the clinician included warnings against accidental pregnancy resulting in additional fetal drug exposure (two AEDs during the switch-over compared to one AED before and after the switch-over). In the case of OI02, the importance of preventing pregnancy while making changes was highlighted through provision of the evidence of increased risk:

337. C: [...] What we do know is the combination of
338. Epilim if it is with other treatments the risks then become really
339. very high indeed. It would be past 10% upwards if you fell
340. pregnant on Epilim and lamotrigine together.

From the perspective of the clinician, the purpose of presenting risk information was to support consideration of what was involved in the proposed treatment changes, such as

the risk of developing a hypersensitivity reaction to the proposed new drug, lamotrigine.

598. C: [...] there is also a risk of a rash, a risk
 599. of an allergic reaction. It can happen in something between 3 to 5%
 600. of people. (OI02; 22 year old, future pregnancy intentions)

The presentation of patient-specific risk information concerning adverse reactions to AEDs was variable, and extended to include the drug-specific risks such as liver failure and death (OI07). The risks of seizures were common examples of patient-specific risk information, utilized to communicate seizure relapse risk for patients having entered remission while taking AEDs, and to communicate the potential risks of seizures during pregnancy and delivery. Epidemiological data from the Medical Research Council (MRC) Antiepileptic Drug Withdrawal Study (Chadwick et al., 1996; Anonymous, 1993b) was quoted to support numeric comparison of the seizure relapse risks between alternative treatment strategies, remaining on AEDs, or gradual AED withdrawal. Seizure relapse risk information assisted OI23 consider the opportunity to withdraw her treatment following an 8 year remission from seizures:

404. C: [...] a big study has shown that the risk of seizure
 405. recurrence is very high like between 20 and 40% or something
 406. like that
 407. P: Yes
 [...]
 410. C: [...] But there is, there was a fairly high
 411. risk and because of that, people say maybe we should give
 412. people a five year course, but there are no rules written in tablets of
 413. stone.
 414. P: Right
 415. C: The risks are probably lower now, than at five years
 (OI23; 30 year old, immediate pregnancy plans)

The risks of seizures in pregnancy were discussed in 20 out of the 23 observed consultations. Clinician's presented warnings against stopping AEDs as a cause of status epilepticus or death and the likelihood of worsening seizures in approximately a third of women. This approach is illustrated by the following two participant cases:

1. 390. C: don't make any changes, don't suddenly stop taking your
 391. medication, because if you suddenly did that, you could go on and
 392. go into status epilepticus which is continual tonic-clonic seizures
 393. and that is extremely dangerous. You know people have been
 394. known to die through status
 (OI04, 27 year old, future pregnancy intentions)

2. 173. C: we particularly don't want you having convulsions ...
 [...]

 176. tonic-clonic seizures it can increase the risk of having a miscarriage
 (OI18, 21 year old, immediate pregnancy intentions)

The value of presenting risk information was to highlight alternative and unexpected future outcomes. For example, the unpredictable course of pregnancy where things could go wrong for both mother and baby was a perspective several women preferred - knowing the 'worst case' scenario. From the perspective of the clinician, the purpose of presenting risk information was to advise and support informed patient decision-making to fulfil their ethical duty of care. The presentations of risk information supported women to consider the differing outcomes from decisions made, and the potential for seizure relapse was an unwanted outcome for many women, and required alternative treatment options to be considered. The utility of risk information to clarify the choices available was exemplified by participant OI20 as she considered her options which include: remaining on the current AED with proven effectiveness (7-8 year seizure remission), weighted against a "5% chance of any physical malformations"; or, switching to an alternative AED:

386. C: ... if you are switching over from one treatment to another,
 387. you know it can destabilize your condition, and
 388. you could go on to having seizures.
 [...]

 390. C: [...] you might start a different medication, and you feel
 391. well on it, and have the same control, and it have a slightly,
 392. say have the 2%, risk of the physical abnormalities
 393. but, you might still have, you might go on to have
 394. seizures, we don't know.
 (OI22; 32 year old, immediate plans for pregnancy)

7.1.2 Response to risk information

Women interpreted risk information mainly as helpful and informative, in line with perceptions of the clinician's duty of care. There were exceptions, and for one participant (OI06) the purpose was interpreted to scare and deter her pregnancy plans:

229. P: They said because like with the tablets the baby could become
 230. disabled so I was a bit scared about that,
 [...]

 239. P: [...] that's what my doctor [GP] said I
 240. don't know if she was trying to scare me...
 [...]

 247. C: [...] you are taking these tablets, which would put the unborn
 248. child at risk of having problems. But the risk is about 4%, that we

249. say, in terms of pregnancies. And some women would then
250. say oh then would I need to take the tablets. But in
251. someone like yourself you are having lots of fits. We, there is
252. a risk to the unborn child if you're having fits that its not /controlled
253. P: /But if I
254. had a baby like about me, could I die or something?
255. C: Usually when patients have epilepsy and if it is controlled, a
256. lot of women with epilepsy have children with no problems and
257. they go through their pregnancy and the delivery with no problems.
(OI06; 20 year old, immediate pregnancy intentions)

The above quote highlights the important relationship between using risk information to inform and its use to direct the patient's attention to their role in adhering to treatment recommendations (lines 249-51). By challenging the patient's fears about the risk information provided by her GP, the clinician focuses attention on the opportunity for the patient to reduce the risks to herself and her future baby. The importance of seizure control and the role of AEDs in achieving it are highlighted, rather than simply focusing on the drug-related risk. This supports warnings to the patient considering stopping her tablets, and allows the patient to re-consider her own prior judgements of pregnancy risk. The clinician adopts the role of advisor, focusing the patient's attention on her continued need for treatment, the inevitable risk she faces from frequent seizures and, at the same time, offering the outcome of healthy children when seizure control has been achieved. OI06 reflected upon the receipt of risk information comparing the 'high risk' she understood from her GP's message and the optimistic 'lower' risk as reassuring:

- OI06: With the 4% it made me feel a little bit better because it's not really, to me that's not a high risk, that's like, kind of a low risk...but the way the (GP) was speaking, it to me, she just said oh it's a high risk and like it made me feel like she was putting me off...

Preconception risk information was judged by some women as focusing their attention upon future pregnancy, projecting worry concerning the outcome of pregnancy, illustrated by the following extracts:

- OI22: I don't think I will enjoy being pregnant [...] I really don't think I will, I think I'll just, be wanting it to end...
(32 year old, immediate pregnancy intentions)

- Partner: ...We've spoke about it a hell of a lot really because we want, the first is find out how bad it is, because I'd rather she'd be healthy than have something happen wrong, you know instead of having two, have nothing...
(OI14; 27 year old, immediate pregnancy intentions)

Questions raised during preparation for pregnancy revealed the extent of worry concerning the risk of seizures at the time of delivery as an added source of anxiety. From the patient perspective, there was a need for reassurance regarding the risks of uncontrolled seizures. This was managed by a minority of clinicians playing down the chance of seizures influencing pregnancy outcome, and emphasising the risks as only becoming significant if the woman required admission into an intensive care unit. For many women, this type of reassurance was counter-intuitive, illustrated by the following 39 year old participant reflecting on her experience of seizures in pregnancy and her concern for her unborn baby:

FG123: I started fitting ... and then I was coming round and just wanted to curl up and die ... I felt so awful yet the fear set in and this little baby inside me is it going survive, am I killing this baby off. I couldn't control it and I just didn't know what was going on. I was in and out, in and out and then as I say she arrived and I had this little girl and I couldn't believe it

For one participant (OI23), the potential for worsening seizures during pregnancy raised additional concerns. The clinician (who had neurology training) played down the risks associated by maternal anxiety upon pregnancy outcome – although obstetric opinion is sometimes in opposition to this view:

596. Partner: ... from my perspective, it was if you're going to have a
597. baby it needs to be worry free, and if you're going to worry more
598. doing, going one path, that's probably going to have a greater effect
599. on how the pregnancy goes, I would have, from my point of view,
600. but
601. C: Yes, well if, you would still be fine
602. P: Yes
603. C: Even if you worry a little bit, your baby will still be fine (OI23)

OI23: ... how I feel now is I'm worried about having the seizures in pregnancy, but I suppose the reason I am getting upset and crying, is because I'm scared of the actual seizure itself. (30 years, immediate pregnancy plans)

Clinicians addressed these concerns by reinforcing the importance of optimising epilepsy management prior to pregnancy, and recommendations for booking early into obstetric care on discovery of pregnancy.

Describing a future child, as 'being at high risk' either due to seizures or in utero AED exposure, required women to compare their desires for pregnancy against the needs of the unborn child. Blame was the most commonly expressed emotion identified by

women across the entire study population, while for some this emotion was interpreted as selfishness (see also, Chapter 9, section 9.2 The Selfish Decision), as illustrated by the following participant:

OI08: [...] I suppose some people would say that I was selfish, if I knew there was a 10% possibility of a child being disabled. Because I still want to have a baby, then perhaps I shouldn't do it? But, why shouldn't I, there's people taking heroin and they're still doing it.
(27 year old, future pregnancy intentions)

The presentation of risk information in percentage terms was objected to by a small group of women as failing to support their informed decision-making, which required more detailed narrative description. From this group, one participant who had experience of delivering two children affected by in utero exposure to sodium valproate, expressed her response to being presented with the percentage chance that something could happen if she were to consider further pregnancy:

FG21: [...] but the thing is, if you're that one percent you know it's hard. If you're that one person, (41 year old)

The perceived risk could be zero if reviewed retrospectively when the outcome of pregnancy is known, whereas if the adverse event occurred you would reflect that your risk had been 100%. Avoiding a focus upon numeric risk was managed by some women by reliance on luck. Illustrated by the following participant as taking the chance that the desired healthy outcome of her pregnancy would occur:

FG121: [...] I suppose I was just a bit naive in thinking that everything would be okay... we both decided to just sort of take the chance and see what happens. Luckily you know she is fine now... I've not been too bad through the pregnancy, so it is something that we maybe looking to do again some time in the future. So I do think I am fairly lucky as in how, how it affected my pregnancy ... (32 year old)

Reference to luck, in terms of relief that a potential risky outcome did not occur, implied a perceived lack of influence upon the management of risk. It also detracted from the work of the clinician in supporting pregnancy planning and future decision-making, implying the participant's good outcome was the result of fate.

7.1.3 Presentation of uncertainty

The context of uncertainties surrounding the newer AEDs required women to make decisions concerning treatment recommendations based on limited or no knowledge of

the teratogenic risks. Two main sources of uncertainty were discussed by women, relating to: the uncertainty of AED effectiveness; and the uncertainties in predicting pregnancy risk as a consequence of in utero exposure to AEDs and/or seizures. The following participant exemplifies the former concept, as she describes her approach to locating evidence as part of her preparations for pregnancy:

FG57: There's no one in this world that actually knows the answers to everything about epilepsy. There are still people researching it, studying it. We will never know I don't think. All we can do is just trial and error with medication. (22 year old)

During consultation, discussions of pregnancy risk often highlighted ongoing research emphasising the delays associated with gathering information on adverse events, a point emphasised by one clinician:

127. C: We don't really know, because the drugs are relatively new and
128. there are not many women who have been exposed to these drugs
129. during pregnancy, because they are relatively new.
[...]
180. C: ... it takes decades to find out properly... (OI12; 30 year old).

The lack of research to provide meaningful evidence to direct epilepsy management was illustrated by the following clinician:

296. C: [...] we haven't actually carried
297. out a study where we are looking specifically at the dose. But we do
298. have this gut feeling, or this, I think we feel that it's dose dependant.
(OI07; 32 year old)

The nature of medical research was also called into question, both in relation to the length of time required to detect rare adverse events, and the ethical limitations on the type of research designs possible:

956. C: [...] we can't really do randomised controlled trials
957. in humans in this subject. And also we need a long time to
958. follow the children (OI23; 30 year old)

The clinician extrapolates the limited evidence on newer AEDs such as levetiracetam (Keppra):

265. C: [...] Keppra we don't know so much about in animal
266. studies; we know that it doesn't cause problems in the babies of rats
267. and mice, but that does not necessarily mean that it's going to be a
268. safe drug in adults. (OI02; 22 year old)

Utilizing the UK Epilepsy and Pregnancy Register as a source of reference the clinician extends the account of uncertainty in human testing, and the ever-changing numbers of in utero AED exposures. The clinician provides reassurance about drug safety (by making reference to the human children born to mothers) resulting in the presentation of a kind of ‘pseudo-certainty’ (lines 173 & 180-1), which is used to defend the lack of certainty that problems could still occur:

149. C: [...] And the difficulty we’ve got is these other tablets, these newer
150. tablets. We don’t really know for certain where they lie between the
151. tablets that might be very safe and the tablets that are very
152. dangerous. But, what we know so far is that the Keppra tablet seems
153. to be a pretty safe one.
154. P: Right
[...]
168. C: ... These numbers are always changing,
169. but I think there’s about a hundred women so far, who have children
170. only taking Keppra, [...]
[...]
173. C: ... And so far, none of them, have had any problems...
[...]
180. C: ... it seems to be as far we can tell, a reasonably
181. safe drug, we can’t give you a hundred per cent guarantee...
(OI13; 28 year old)

The difficulty applying population data to predict individual patient risks emphasizes the uncertain outcome of changing treatments:

- 112: C: [...] we could reduce topiramate a bit and
113. see what happens. Or put you on an entirely new drug which is
114. something we wouldn’t do in pregnancy, but you could try and do it
115. now, but, then it is totally unknown territory, you have never used
116. anything other than these two drugs before, and we don’t
117. know if your seizures would be worse or better.
(OI14; 27 year old)

The following extract illustrates the uncertainty when extrapolating individual patient risks from epidemiological modelling from trial data on the risk of seizure relapse:

215. C: [...] What’s more difficult to
216. predict is whether you fit into that 20% who maybe have an
217. increased risk or not. The fact that you haven’t had any seizures
218. after being on medication, is a potentially good sign, it’s
219. obviously been easy to control and so it’s well controlled.
220. But again, nobody could guarantee that you wouldn’t have a seizure,
OI15 (NP, 33 year old)

A further example of uncertainty was raised by women questioning the potential to ‘pass on’ epilepsy. The risk of a child inheriting epilepsy was a subject of discussion for 40 participants, and women raised questions in seven of the observed consultations. The inheritance risk was presented as complex and dependent on a number of factors including, whether one or both parents had epilepsy and the type of epilepsy. Risks were presented by clinicians as uncertain and therefore an unquantifiable risk. However, one woman constructed her personal risk:

FG122: It is a risk that people take, isn’t it. Fifty percent of one parent is epileptic and more so if you have got two parents that are epileptic that the child will be... that’s just like a risk, you know a risk factor that they could be (43 year old, two children)

In the case of participant OI20, she reflected on earlier meetings with clinicians where the provision of information about the life-time prevalence of epilepsy provided reassurance:

OI20: I was talking to the [clinician] and she said everybody has got a 5% chance of getting epilepsy, so I really wouldn’t worry about it. Because I was thinking, oh is my baby going to be born with what I’ve got and she said don’t worry, she said everybody has their risks, so don’t be panicking about this, that and the other, and I was thinking when you put it like that it makes sense though doesn’t it? (30 year old)

The above quote emphasises the search for meaningful risk information – which this patient felt enabled her to interpret the risk as small, and manage her personal worries concerning her future child’s genetic inheritance. Similarly, in the case of FG122, although she had calculated a higher personal inheritance risk, she also drew comfort on the probability that it might not occur suggesting her estimate represented “a risk factor” rather than statement of fact. In contrast, OI13 expressed worries about her ability to cope in response to the clinician emphasising the concept of genetic endowment, implicating the patient as the sole contributor to the risk of her child inheriting epilepsy:

49. C: So, and so there is nobody else in the family with epilepsy?
50. P: No
51. C: And your husband to be does he have epilepsy?
52. P: No
53. C: So it’s just really you, isn’t it?
[...]
254. C: There might be a slightly increased risk of the baby having epilepsy,
255. but you’ve gone through life pretty well without, with
256. the seizures, and it’s not a reason obviously not to have a baby, and

257. the risks are pretty small, if there is only one of the parents has
258. epilepsy. (OI13)

OI13: Because there's nobody else in my family at all, that's got it. So I mean mine must have just been a fluke kind of thing. But that was one of the things when I first started [planning pregnancy]...if there is a child that I will need to give care to, I would just panic ... would I be able to give that care or would it affect my health as well kind of thing.
(OI13; 28 year old, future pregnancy intentions)

Women interpreted uncertainties on the part of their clinician as frustrating, highlighting the unpredictable nature of their condition and its management. For individual women, clinicians' reliance on gut feelings to direct decision-making emphasised the degree of uncertainty, while for other women, interactions with their clinician left them feeling they had no certainties in life, since the clinician was unable to provide the necessary precision, exemplified by the following participant:

OI20: no one has given me a percentage yet ... they haven't got enough information to say it could cause this, this, this, so how do I know?
[...]

OI20: it just makes me feel like a bad mother ...you are just pumping your body full of drugs, which no one can give you a clear answer what its doing.
(30 year old, pregnant at time of interview)

The uncertainty surrounding the long-term effects of in utero AED exposure on infant neurodevelopment was also a source of anxiety, sufficient to influence the acceptance of drug withdrawal in preparation for pregnancy. The following participant illustrates an extreme response to the unfolding picture of limited information, in which she considered an uncertain future with potential for "repercussions" such as the discovery of the risk of "learning difficulties" leading to make comparisons with thalidomide:

OI10: ... you start thinking oh, and all these things go into your mind and spinning round a bit, and you think oh, do people know enough about these drugs because obviously they didn't about that [Thalidomide]. ... When I went to see [clinician] and he said about the learning difficulties. I thought ooh... because last year no one knew about that, and then suddenly this year and then you think, in another years time will they be finding more things ... you start worrying about all these things that start stacking up a bit, don't you, and all these possible that don't show their face now, but in years to come ... they could say oh well see all these problems it's because of that. (30 year old)

The experience of OI10 illustrates an important aspect of clinic communication; where the content of risk information is mainly selected by clinician's. For some women, the

later discovery of information concerning risks or the extent of uncertainty had influence on their reflections both on their earlier informed decision-making and their doctor-patient relationship, as illustrated by the following discussion of two pregnant women:

FG82: I was really annoyed, because my neurologist, [...] I changed medications for my second baby, and he was saying oh, this it's superb, it's great, an, I'm sure it is. But then, when I had my 20 week scan, the lady said, "oh, it's only been out for 7 years", and for me, that was a step back, because I thought, hang-on a minute, like, he's pretty confident in it {Yes} but 7 years isn't a long time {No} To tell if there's cognitive, you know it's not a long time, {Yes} an even then, I kind of felt, I've been?

FG83: Tricked?

FG82: Because, number one I felt I hadn't been told everything, until I met [epilepsy nurse specialist] [laugh] and that was really annoying. Because I just, you need to know. (FG82, 37 year old; FG83, 34 year old)

7.1.4 Stories of risk from practice

The usefulness of the clinician sharing past patient experience about in utero drug risk, emphasising the majority of pregnancies being successful despite exposure to combinations of drugs, and the value of experience and personal opinion assisted women to make comparisons with other women with positive experience and reinforced the perception of a small risk of adverse pregnancy outcome.

IO24: giving me examples of people who've been on a multitude of tablets and had 11 children and they've been okay ... just by knowing things like that, makes you think oh well actually ... just giving me some facts and figures about people, and the numbers and it's really small isn't it (31 year old)

For other women, seizure risks were contextualised by stories of patients having healthy babies notwithstanding experience of tonic clonic seizures, as illustrated by the following extract:

189. C: [...] We don't really know how bad the epilepsy has
190. to be in order to damage the fetus, but we know that we have lots of
191. women who have lots of grand mals during pregnancy and the baby
192. has been entirely normal. (OIO8; 27 year old)

Stories from practice were used to provide both positive and negative illustration of potential future pregnancy outcomes for women: in the former, to encourage patients to consider the proposed intervention as achievable; in the latter, to bring the patient's attention to potential negative outcomes:

527. C: Sometimes people are OK to reduce it down to the last tablet and

528. when they drop that one, the auras recur, and having said that
529. I'm optimistic that if you would get your auras or your seizures
530. back, that you would have the auras first, and then you would know
531. that you had reached a critical level
532. P: Yes
[...]
839. C: Most women are OK that I've seen, but I've seen patients, mothers
840. who then have to look after the spina bifida as well...
[...]
929. C: [...] I see all my patients
930. making a happy and quick recovery from them [seizures].
(OI23; 30 year old)

The power to direct attention to the negative outcomes was illustrated by one participant's request for assistance evaluating the risk of adverse pregnancy outcome, both in relation to her plans to delay conception and making changes to her AED regimen until she had successfully emigrated and become settled:

225. P: Yes, so what do you suggest that I do? [Laugh]
[...]
278. C: And I don't think I can make that decision for you? But if I was a
279. woman, I wouldn't want to stay on two drugs while I was pregnant,
[...]
281. C: [...] But, looking after a
282. disabled child that would be a great tragedy for anybody {yes} in
283. what ever country. (OI12; 30 year old)

7.2 Focus on the health of the unborn baby prior to conception

The expression of concern for the unborn baby was an important finding in the context of women receiving preconception risk information. The importance related to the timing of these statements within women's reproductive career, often highlighting a projection of worry ahead of planning pregnancy and conception.

7.2.1 Perceived risks to the baby from in utero exposure to drugs and seizures

Risks were perceived as dangers and potential harms to the unborn baby. Women were observed to weigh up the balance between seizure and drug-related risks to the unborn baby, revealing a tendency to value the health of the baby above their own, and in doing so, placing greater emphasis on AED-related risks while minimising personal seizure risks. Focusing attention on the risks of in utero drug exposure led some women to question the benefit of medication in relation to their baby's health. The

majority of women viewed their treatment as risky, exposing the baby to the dangerous properties of the drug, emphasising the risk of delivering an AED-affected baby.

FG105: If people our age get pregnant now it is probably not planned ... but isn't it more likely that the child would be disabled like spina bifida or something quite severely wrong with them because of our medication. (19 year old)

Women discussed the tension between public health messages about drug use in pregnancy and their requirement for continued medication:

FG74 ...you get bombarded with press messages about, don't drink that, and don't eat that and so knowing that internally that, the baby's getting a medication, for which it's got no need, you need it's very impure. It's a very impure feeling for me...
[...]

FG75 ...your baby doesn't need it. It's you that needs it, and it's going into your baby unnecessarily... (FG74 36 year old, FG75 26 year old)

Patient questions illustrated the powerful imagery of their future baby's vulnerability to in utero drug exposure, while emphasising their requirement for protection. The following extract exemplifies the typical response from clinician's:

267. P: So what can Epilim do to the baby?
268. C: Well Epilim in particular it can induce certain malformations, OK
269. [...] There is a range of possibilities and it can
270. cause significant disability to the child but there is different degrees.
271. OK from the studies carried out so far [...]
272. We haven't actually looked into the specific dosages, OK, that can
273. potentially harm the baby but on a large population of people who
274. take or women who take Epilim and have had a child
275. [...] In the majority of cases we see some
276. minor neuropsychological impairment and so if.
277. P: Right, so it is more with the brain
278. C: Yes it can cause certain,
279. P: Not disabilities with their limbs.
280. C: If you will, retardation or learning difficulties if you will, and
281. the development of the brain would be some what slowed
282. down.
283. P: Alright, OK (OI07 32yr old; planning first pregnancy)

The perceived unnecessary exposure of the baby to medication was inevitable when women were advised of their own continued need for treatment throughout pregnancy. An equally difficult scenario faced women who were in remission from seizures and offered the choice to withdraw medication. In either situation women were required to make judgements, in the former to agree with recommendations to continue treatment, in the latter to consider AED withdrawal, albeit a proposal not entirely risk-free.

Expressions of fear by women concerning the implications of in utero AED exposure for their baby had the effect of emphasising the vulnerability of the baby over the woman. Her own potential vulnerability to seizures and the consequences this might have, in extremis, maternal mortality, was down-played. Clinicians' warnings to avoid introducing instability in seizure control by impromptu changes to medication were supplemented by statements of their prior experience, of women struggling to regain seizure control, the risk of seizure relapse, and of seizure control being harder to achieve. For some women the impact of receiving such warnings was to increase their anxieties concerning the chances of achieving seizure control either prior to or during pregnancy. In the following extract, the participant reveals her concern that she will be unable to have nine months free from seizures, and so will be limited in her ability to influence the outcome of a future pregnancy:

FG-I-03: Because I just probably feel a bit guilty. If something bad were to happen. I don't think I would feel too terrible, because its something you can't help ... I mean it's 9 months, it's a long time too ... Especially for myself at the minute, I don't think, for 9 months, yes I'd definitely have more than one or two fits. I couldn't see a pregnancy going right, I really couldn't ... I think that would probably cause a lot of grief actually. In fact I reckon. But my health, would definitely come second, the most important thing would be the baby. (23 year old)

Women appeared to project their concerns regarding seizure risks towards their baby, rather than themselves, exemplified by the following case (OI07):

OI07: ...the only thing that frightens me is if I put that child at risk. So, me having a seizure would put that child at risk. So that is the only thing that frightens me. If there was nothing wrong with me ... I wouldn't even think about it at all. It wouldn't bother me. (32 year old)

The projection of concerns to the unborn baby is reinforced in this graphic quote from a 19 year old participant:

FG45 ...you have got the whole thing of when you're having a fit that your brain is starved of oxygen so of course you are starving the baby of oxygen and that could have just as much risk as the medication does as well...

Seizure risks were almost constantly referred to by clinicians in terms of risks associated with maternal tonic clonic seizures, while reassurance was offered concerning the likely risks from non-convulsive seizures:

149. C: [...] and I think the risk
150. of your seizures to the baby would be quite small...

153. C: [...] Because you
 154. have only these petit mal type attacks {that's it}
 155. there's the risk to you, isn't it, you might be doing something in
 156. your petit mal like, ironing and burning yourself {yes}...
 (OI10; 30 year old, future pregnancy intentions)

Several women articulated the struggle to make judgements about pregnancy outcomes, and the tension between their personal fears of seizures versus their desperation to avoid harm to their unborn baby. This is illustrated by the following quote by a 30 year old woman with immediate pregnancy intentions:

- OI23: [...] the reason I keep saying selfish is because I'm thinking about my own feelings, and being scared of having seizures. Whereas I am not just thinking about the risks to a baby, but it's not that I am not worried about those things, because I am desperately...

7.2.2 The perceived risk of delivering an AED-affected baby

Women made frequent reference concerning the visibility of major malformations and the long-term risks to child development and learning. Risks to the unborn baby accounted for the majority of the distress experienced by women when weighing up their need for continued treatment versus their abilities to cope if they had an AED-affected child. Worries centred on the potential for disability, the uncertainty of discovering a deformity at birth, or concerns about the hidden nature of neuro-cognitive delay as a future as yet undiscovered:

- FG42: I was also worried about what, like what had the medication, what it done to [name of child] as is, spina bifida in her body, but also the effects if it had on her, mentally if you like, if it would slow her down or.
 [...]
 FG42: If I thought it would do anything like that to her. I mean up to now it hasn't she is bright as a little button but I worried about that as well. (33 year old)

Clinician's advice to women taking sodium valproate focused on future risks to the child in relation to minor malformations and to neurodevelopmental delay, illustrated by the case of OI02, a 22 year old with future pregnancy intentions:

288. C: [...] those minor malformations could be a
 289. form of, almost a form of a learning disability we are seeing in some
 290. children as they are growing up, starting school, they might have
 291. problems with their speech, delayed speech, they might have
 292. behavioural problems, they might have minor malformations in their
 293. faces that most people would not notice but people who are in the
 294. know might notice. High foreheads, just a certain look called the

295. fetal valproate syndrome, so it is something that we are watching
296. and research continues looking at these minor malformation rates...

In the case of OI02, she is positioned as reliant on experts, who would be able to identify the future baby as looking different and showing signs of ‘fetal valproate syndrome’. The graphic description of the AED-affected child and the need for continuing research reinforced an uncertain outcome. Difficulties knowing whether a child had been affected by AED exposure were emphasised by comparisons between the apparent ease of seeing physical malformations at birth and the difficulties in detecting neuro-cognitive delay until a child had reached school age:

134. C: And there is a possibility that the drugs can even cause more subtle
135. damage to the baby, {Oh} which is not visible at birth, but only
136. within the, five years we see them, perhaps not as clever as
137. they should be. {Are right, oh} Or, they have delayed speech or
138. developmental things like that
139. P: Oh, I never knew that.
140. C: But that is far less certain,
141. P: Yes
142. C: Because it’s quite difficult to measure.
143. P: Yes
144. C: Whereas the malformations at birth, that’s an the easy thing,
145. everybody can see
(OI10; 30 year old, immediate pregnancy intentions)

The visibility of major malformations at birth was a source of guilt for one pregnant participant:

- OI20: But it’s the fact that it could have really bad deformities, that’s what worries me the most. It’s like facial deformities, and I don’t know whether I can cope with that. And with me being on meds, and like just pumping my body I’d feel responsible for that. (30 year old)

Women appeared to struggle with the uncertainty of predicting the health of their future baby leading to increased worry, as illustrated by a 24 year old participant planning pregnancy in the future:

- OI11: Just the risks of being pregnant and worrying at the back of your mind while you’re pregnant, is it going to be born with heart defects, a disability. I don’t know, I guess I wanted a worry free pregnancy, as much as you could.

Women expressed concern about their ability to cope with having a disabled child. For some, this intensified during pregnancy, focusing on a sense of uncertain future, such as how they would know if something had gone wrong:

FG42: [...] when she came out I, the first thing I said ... is her mouth alright. [Laughing] That was the first thing is her mouth alright ... but that was, the thing they couldn't say but it, that is all the time, that is, the whole 9 months because I still didn't know she was alright [...] Because of the my medication the problems she could have had, it was 9 months of worry, of the medication, she could have had spina bifida, water on the brain, there was a list of problems and it was just 9 months of worry. (33 year old)

While the risk of specific malformations such as spina bifida were rarely the focus of the drug-specific risk information within observed consultations³⁷, for the above participant the certainty of risk became a statement of future fact, rather than a probability. Therefore, following delivery of her baby, she needed reassurance that her baby had not been affected. In contrast, participant FG82, who was pregnant with twins in her third pregnancy, was reassured by being informed of the treatment risks as a guide to what to expect:

FG82: ...because I've changed medications, for my second, because as you know, an I was panicking, and [clinician] just told me the worst case scenario which was fine. I knew what to look for. (37 year old)

7.2.3 Fears of harming the baby or child

The perception of risks concerning becoming a mother and caring for a baby were mixed, with most women optimistic about their ability to cope. Others focused on the potential for accidents, and even the death of their infant, as a source of increased anxiety. Expressions of worry concerning childcare risks were not restricted to women with experience of pregnancy or childcare, but also had the power to influence the judgements of women preparing for pregnancy. The following 16 year old participant exemplifies the concerns expressed by young women anticipating their ability to care for a baby while managing their own seizure risks:

FG113: When I'm asleep and I take my fits everything just blanks out and I can't hear anything, so if I have a baby and the baby is screaming I wouldn't be able to hear it so there is that chance of things like a baby maybe wanting its milk and all that and I might not hear it [...] the baby could have a chance of dying and all that so like that has really put me off and everything.

³⁷ The risk of spina bifida as an AED-related risk was raised in 6 of the 23 observed consultations.

Worries concerning the inadvertent killing of a baby/child during or secondary to the experience of a seizure were vividly displayed across the entire study population. The majority of women managed their worries concerning child safety through engagement with their clinician and actions, such as adhering to their AEDs as a means of preventing future accidents. Some women were unable to provide themselves with the desired sense of reassurance, becoming distressed during their preparations for pregnancy:

610. P: ... what also worries me, is the future OK. I have a, I come off
 611. my medication, successfully, fall pregnant, have a baby everything's
 612. fine then what if I've got a little kid and I'm crossing the road...
 [Patient became distressed, comforted by her partner]
 614. P: Oh I'm sorry, I know you can say that about anything couldn't you,
 615. anybody could have like a heart attack at any /time but it's not,
 616. C: /Well that's very fair
 617. P: /and it's not, but /or
 618. C: /comment isn't it, /Yes, your risk of causing harm to your baby or
 619. suffer an injury is really low, do you know/
 620. P: /It's not just that though,
 621. it's selfish as well, it's because I'm so terrified of having another
 622. seizure... (OI23; 30 year old, immediate pregnancy plans)

OI23 projects her perceived future responsibility to her child, and through her disclosure of an imagined 'worst case' scenario is offered support. The clinician provided advice about the need for common sense surrounding activities, such as sitting on the floor when feeding the baby to avoid the risk of dropping baby if a seizure were to occur. Participants made reference to their responsibilities of caring for a baby/child as a mother with epilepsy which resulted in restrictions, and required additional vigilance or adaptations, such as, not being left alone with a baby in case of holding a baby at the onset of a seizure and dropping or squeezing a baby, or requiring ground floor accommodation or shower facilities.

- FG73: ... it's looking after the baby... like I'll be looking after it, I'd be on my own ... I can like daydream, and now I like, I'm dribbling, and the next thing, lately I've been falling asleep. If I'm looking after my child ... giving it a bath, if I have a seizure and dribbling, next thing falling asleep ... next, I wake up in the next 15 minutes, and bathing a baby, it could be dead. It would be floating, it's like [gasp], "*oh my God, what have I done*". And it's like, it takes me a few/
 FG71: /But that's were the planning comes in, isn't it, because what you would do then, is not/
 FG73: /But, I've just killed my own
baby (FG71, 45 year old; FG73, 31 year old)

Childcare risks were considered during preparation for pregnancy and resulted in concerns surrounding future abilities to cope, requiring risks to be managed:

- IO24: So I think, well I need to make sure that I'm okay, because if I'm not okay then you shouldn't risk looking after a child or whatever...
(31 year old; immediate pregnancy intentions)

7.3 Risk Management

Risk management involved the processes of assessing risks and benefits, and was reliant on women making judgements concerning which risks were perceived to be acceptable and which required management. The selection of risk management strategy was often the result of discussion with the clinician and significant others (partner, friends or relatives), and involved decisions concerning the preferred approach to be taken during pregnancy preparation – whether to avoid risk, reduce or prevent risks.

7.3.1 Risk benefit assessment

Risk assessment was reliant on women receiving risk information and being able to make comparisons between perceived risks:

226. C: Are you aware of the potential side effects of the Epilim?
227. P: [...] the only thing I think is that
228. I can either come off my Epilim and risk a seizure whilst I am
229. pregnant which is quite dangerous or stay on my Epilim which is
230. also quite dangerous to the baby and that's all I know...
(OI07; future pregnancy intentions)

Women were involved in making a complex set of judgements. These judgements were not restricted to women with immediate pregnancy intentions but, rather, changed in response to experience and life circumstance, as illustrated here by two participants. The first woman drew on her experience of work with and knowledge of individuals with disabilities; the second on her prior experience of an adverse pregnancy outcome:

1. OI12: Some people will be willing to risk it wouldn't they of having a child but it's like he said the disability, but I work with people with disabilities and I wouldn't want one. (OI12; 30 year old, future pregnancy intentions)
2. OI21: If I found out I'd had an accident now and I was pregnant, I would be mortified ... I don't think I'd be able to cope with it, because I'm on Epilim. It's not the fact of having a baby it's the fact that I'm on Epilim, I couldn't cope with the thought of being pregnant on that... I know there's a

risk with everything, with any operation, any drug, anything that you do in life. The thing isn't the, if it had never happened to me, I'd say, I wouldn't even think about coming off it because it's such a small risk, there's risks with everything, and that's how I normally look at things. But because it's happened to me I'm looking at it completely different...
(OI21; 35 year old, future pregnancy intentions)

There were differences between women and clinicians in their approach to risk assessment, with the women frequently placing seizure-related risk and treatment-related risk in opposition, while clinicians were observed to advice a balanced approach. The following quotes from two teenage participants illustrate the difficulty in reaching an acceptable compromise:

FG106: ...you take the tablets your baby could be disabled or don't take the tablets you have a fit you fall over and the baby might be disabled. So there are disadvantages either side... (18 year old)

FG111: [...] when you are pregnant because on the tablets ... It's the first 3 months of pregnancy that really get affected. So I am going to have to be taken off the tablets for the first 3 months of pregnancy, and then I could have a seizure. And I could end up losing the baby so it is like it is all a big vicious circle really and it is scary... (16 year old)

Both women and clinicians acknowledged that poorly controlled epilepsy would influence general quality of life, work, driving and home life, as well as future relationships and family plans. The process of assessing risks required women to balance perceived risks of continued seizures with a relapse of seizures or in utero AED exposure to the unborn baby, as well as the perceived threat to their quality of life as a result of adverse pregnancy outcomes. Risk assessment required women to make judgements often in the form of gambling odds:

FG43: ... what is the best thing to do, for yourself and for your baby? You know there is implication on both sides isn't there really. If you come off you could have more fits and that would have implications on your child and vice versa... (35 year old)

The clinician's approach to risk assessment tended to focus on an assessment of objective evidence of risks:

99. C: [...] Obviously, we have to weigh the risks and benefits
100. and in the past going through your notes earlier on, I noticed every
101. time we've tried cutting things down you've had more seizures. And
102. looks like you do need what you are on at the moment ...
(OI14; 27 year old, immediate pregnancy intentions)

An alternate approach during the consultation was for clinicians to present the ideal of optimal pregnancy care, emphasising the target of the least amount of treatment required to maintain best possible seizure control prior to conception:

350. C: [...] what we want to do is to
351. try and optimise what you are taking, so that we don't need to
352. change it during pregnancy ideally
[...]
380. C: [...] we want to get that balance between the seizure
381. control and any potential adverse effects and so, I think the dose,
382. /as low-ish
383. P: /as low as possible
[...]
388. P: It gains me good stead if I do become pregnant then obviously.
389. I'm on a bit more, lower dose {yes} than I am, {yes} than
390. what I was on.
(OI20; 30 year old, immediate pregnancy intentions)

Risk assessment was most commonly introduced by the clinician. However there were exceptions, illustrated by the following extract:

165. Patient relative: ... if you balance out like you
166. are saying like reducing the dosage to sort of about 200mg instead
167. of 500mg a day what is the risk of, to the baby if she has fits
168. because if she is not having enough medication.
169. C: I know
170. Patient relative: So is that risk higher than the risk of taking the higher
171. dose of the drug do you know what I mean is it
172. P: Is it more harmful to the baby?
173. Patient relative: Do you, what I mean is it more harmful to risk a fit and
174. then deprivation of oxygen to the baby is that more of a risk than
175. taking the higher dosage of the drug.
176. C: Both risks are pretty low.
(OI08; 27 year old, future pregnancy intentions)

The process of assessing risks and benefits frequently presented the potential for gains and losses or pros and cons³⁸. Gains were cited by women as achieved through establishing an acceptable balance between seizure control and the selection of AEDs guided by risk information, with the intention of increasing the chances of having a healthy baby, a concept expanded upon by the following 33 year old participant considering future pregnancy intentions:

- OI17: I think in terms of the Epilim and this sounds really, I don't know it sounds really selfish I suppose, I think any parent ... or any person who wants to have a baby, they want to give that child every opportunity ... I don't want

³⁸ See also, Chapter 9 The model of preconception counselling.

to add to the risk factors so I would like to be able to do everything I can to ensure that any child I conceive has the best chance ... I would be scared that if I stopped taking the medication full stop that they would never stop [seizures] ... even though I would want my child to be healthy and happy to, I mean how good a parent would I be then if I was having seizures every single day because then you've got into a new sphere of can you actually be the primary carer for a child. So to me that would be the risk. (33 year old)

Making comparisons between drug and seizure risks reveals the struggle to find the right balance between the risk of increasingly frequent seizures during pregnancy and concerns for continuing to adhere to medication to reduce seizure risk. The following extracts illustrate the struggle to achievement of a successful balance between the risks and benefits of epilepsy management prior to and during pregnancy:

356. C. ... we'd want to optimise it before pregnancy and then ideally keep
357. it stable because poorly controlled epilepsy is potentially more
358. harmful than the medication
(OI20, 30 year old, immediate pregnancy intentions)

FG123: ...trying to find that right balance with the medicine ... and I'm looking at the tablets I am actually resenting taking them... (39 year old)

When opportunities to reduce or avoid risks were perceived to be limited, acceptance of the inevitability of risk allowed some women to accept their limitations of being able to avoid all risks:

- OI15: But like I say, you'd never have a baby would you if they thought about all the potential problems before doing it. So, I guess you just have to be willing to accept that risk [carbamazepine]... And I am willing to accept a slightly higher level of risk, for the benefit of trying to remain seizure free really... (31 year old, future pregnancy intentions)

7.3.2 Risk reduction

Efforts to reduce risk most commonly required women to consider one or other of the following: reducing the number of AEDs taken; switching to an alternative AED with lower malformation risk; or, consider withdrawal of AEDs. Reducing the total number of AEDs was presented by clinicians utilizing evidence from the UK Epilepsy and Pregnancy Register. For other women drug withdrawal was proposed to reduce risk:

440. C: [...] The
441. question is whether you could like to try coming off all together
442. P: /Well I do
443. C: /While you are trying for the baby. It would reduce the risk
444. further a little bit wouldn't it? Because there are children who

445. are born with spina bifida on carbamazepine. It's a low-ish risk
446. but it's a risk, and it's high, slightly higher than background risks
447. its fair to say. (OI23; 30 years immediate pregnancy intentions)

Outside of the consultation, women revealed a tendency to consider the prevention of delivering a disabled baby as priority and judged the opportunity to stop treatment as a method of reducing or minimising perceived AED-related risk and thereby reduce the likelihood of the unwanted outcome.

FG104: But, but I know how hard it is to bring up a disabled child so I don't think I would want an unplanned pregnancy, I won't want to get pregnant right when I'm taking my medication.

FG106: You would want to minimise the risks wouldn't you?

FG104: Exactly, so I would stop my medication
(FG104, 17 year old; FG106, 18 year old)

Women described their attempts to reduce all potential risks as much as possible; a point illustrated by a 31 year old with immediate pregnancy intentions:

IO24: nobody wants a poorly child, and you try and eliminate it ... you just think well it's, everything is going to be okay, and it's just a case of doing what you need to do, to make sure everything is going to be okay ... So by coming off the acetazolamide, and reducing my carbamazepine, and doing everything I can do, I feel that should be okay

There was no consensus in the preferences between the reduction of seizures or treatment-related risks. For some the priority was to reduce seizure-related risk rather than reduce AED-related risks. In the case of pregnant participant FG84 she evaluated her baby as dependent upon her maintaining her own health.

FG84: I'm not just looking after myself, and I can't be selfish. I've got, I'll have someone else to look after, so I need to protect myself to protect them. So if I'm seizure free, then I'm constantly able to look after the baby...
(23 year old)

One participant, who was diagnosed with epilepsy and started AEDs shortly before she discovered herself pregnant, expressed anger as she reflected on the missed opportunities:

FG22: Nobody ever said to me [...] do you think you should take him out on your own, and bearing in mind I'd only just been diagnosed [...] all they knew is this person has never had a fit in her life, she's suddenly had one, she's got pregnant [...] she's been on drugs she doesn't know it hasn't worked, she's on this other one which was Epilim which is dangerous for people who are pregnant, she's had a baby and that was it. I was just left, nobody came near me. Now I was dead lucky because I didn't have anymore for a while.

But I could have gone out with [son] and thrown him under bus or all of us gone under a bus. (45 year old, one 8 year old son)

The failure to highlight risk at the appropriate time (both during pregnancy, concerning treatment-related risk, and following delivery, concerning child safety) resulted in the participant evaluating her successful progress through early motherhood as ‘lucky’, as she had been able to engage in risk reduction or avoidance strategies during her pregnancy and after caring for her child.

7.3.3 Risk prevention and avoidance

Risk prevention and avoidance strategies were presented during clinical consultations as opportunities to avoid in utero AED exposure, and were managed using similar strategies to those discussed in the previous section. Risk reduction strategies were accepted by many women as a compromise between the perceived ideal of a risk-free pregnancy and the balance between seizure and treatment-related risks. For other women, risk avoidance was the preferred option and resulted in more extreme views. From the clinician’s perspective, risk avoidance was presented as the opportunity to consider switching from high risk AEDs, most notably sodium valproate:

404. C: [...] ideally we would have wanted to have
405. tried you without the Epilim before you fall pregnant. So if you do
406. {yes} have a lot of seizures then we want to obviously
407. avoid that because of the risk to you, but you know you
408. are not risking your pregnancy as well. So we do like to try the
409. changes before there is a chance that you may
410. become pregnant {yes}.
(OI04; 27 year old, future pregnancy intentions)

From the patient perspective, selection of the least risky alternative was required; and in this context, women had preference for avoiding risks towards their future baby, and accepting their own higher risks such as worsening seizures. This approach is illustrated by a 34 year old participant who had delivered her 2nd baby seven weeks before focus group attendance:

FG83: All the time, what damage can those tablets do, what damage, and if [epilepsy nurse specialist] said well that’s got a 3% chance and this has got a 10, I would always, whether that was more effective, I would still go on the 3% one [...] Because that to me, I know how the epilepsy had impacted on my life. And I’d do anything to try and prevent any kind of damage or, even if it meant me having, a few more seizure, to prevent any ... I would take that risk

Drug withdrawal was a preferred option both for women and clinicians and, for the following 30 year old participant; it offered the opportunity to eliminate all her perceived risks in advance of pregnancy:

116. C: And, and that the carbamazepine is still better than other
117. drugs {Yes} but it's not entirely risk free/
118. P: /Yes,
119. C: It is probably better to come off the medication isn't it? Than
120. /putting up with anything, well
121. P: /Well yes I thought, because even a 2% risk I suppose it's just a
122. woman thing, isn't it. You don't want to I'd hate to
123. think there's any kind of risk really if I can help it (OI10)

The idea of risk avoidance achieved through drug withdrawal is further emphasised by the following 28 year old:

- FG61: Thinking about risk, even, that, I would definitely come off all my medications, I've said it before. I would want to come off all my medications to make sure there was no harm to the child what so ever. You know, full stop. And then get back up support [...] No drug is safe, that's the reality...

A number of alternate avoidance strategies were considered, including delaying conception, presented by a 24 year old participant as the opportunity to test whether she had "grow-out" of her epilepsy:

- FG62: ...first before I even think about getting pregnant. To see how, leave it for a few years first, and then hopefully I will have grown out of it, and until I've grown out of it, not while I'm. Not while I'm still having them, it's too dangerous; you could be holding them, or anything. Don't want to put the child's life at risk...

While for one participant her attempts to reduce weight prior to conception revealed her strategies to avoid the added risks of obesity influencing the health of her future child:

- OI13: to be honest with you, I'm trying to lose weight at the moment ... I don't want me being an obese mother because that puts your child at risk as well (OI13; 28 year old, future pregnancy intentions)

For other women, prior experience of pregnancy motivated their attempts to eliminate future risk and, for one woman, her experience of a medical termination following diagnosis of a major malformation led her to plan drug withdrawal prior to a future pregnancy (OI21). For this woman the option of switching to alternative AED was insufficient to relieve her concern:

Interviewer: ...would you consider an alternative treatment to Epilim?

OI21: I just think I'd put it off completely the plan of being pregnant. Because another drug would be another, would be an unknown wouldn't it. I'm quite happy to have the unknown risks of my own age and natural things that happen, but not the unknown risks of a drug...
(35 year old, future pregnancy intentions)

The uncertainty concerning drug-related risks was judged to be unacceptable when related to the uncertain future of a child's development and learning. This is illustrated by the following participant as she struggled to manage remaining on treatment and the potential for guilt and self-blame if she delivered an AED-affected baby:

OI10: ... with this learning difficulty thing I thought, oh god ...when you balance that with a baby, and all the things that could go wrong, I'd rather be off my tablets and risk having an attack then, have a baby have it, have something wrong with it, and then, I'd feel like that's my fault then, because I've, you know... (30 year old, immediate pregnancy intentions)

For participant OI20, the discovery of her first pregnancy during the time between the observed consultation and follow-up interview offered a unique insight into the application of risk management strategies. OI20 had questioned the clinician concerning her actions in the event of discovering the pregnancy and later during interview revealed the dilemmas she faced making decisions regarding the continuation of treatment:

346. P: [...] you know when I do actually become
347. pregnant will I have to come off my medication
348. C: No
349. P: Altogether or would you just
350. C: No, no we would want you to stay on ...

OI20: ... because I am pregnant I am a bit overprotective ... paranoid a bit and I think that's why it probably clicked into my head, what am I doing here, why am I putting these drugs into my body. Because obviously if I'm taking it, the baby's going to be taking it as well. And I think I just thought it's just not fair, how could you, I just couldn't live with myself if anything happened to the baby ... (30 year old)

The experience of being presented with risk information and its influence on perceived risks shaped the experience of women in their preparation for pregnancy, and supported their subsequent decisions with regard to accepting, reducing, preventing or avoiding risk. In the final quote, perceived risks were managed by avoidance, as the

participant chose adoption in preference to her perceived risk of having a “deformed” child:

FG-I-02: ...there was a high risk of us having a child with deformities ... they could be very minor from something like having a cleft palate, to cardiac deformities to, it was quite, it went right across the broad spectrum, but did emphasise that it could be quite marked, and could reduce the life expectancy of the child ... he [consultant] reckoned it was something like 20-25%, chance of having these problems [...] just before I got married, he actually brought up the subject of children, and discouraged us from having children due to the epilepsy ... and the Consultant did say, when I said about the medication and the family ... that it would have no effect if I was to come off medication however, the child would still have a deformity, if I was to have no medication at all. So it was very cut and dried, from his point of view ... We felt that it was a sign for ourselves, that maybe adoption is the best way for us. So we have adopted ...
(36 year old; 2 adopted children)

7.4 Summary Results: Communicating risk and uncertainty

- The communication of risks and uncertainties within the reproductive lives of women served to both inform and guide pregnancy planning and preparation.
- The main functions of risk communication were to highlight the significance of AED-related risk alongside seizure-related risk information to encourage discussions of the potential opportunities to manage risk in a timely manner, and to support informed decision-making, crucial to maintain the safety of the future mother and baby.
- The communication of risk which focused on the health of the unborn baby/child had a persuasive element, defining the nature of risk in terms of the vulnerability of unborn baby to in utero AED exposure and maternal seizures, and extended to include concerns for the child’s vulnerability to heredity risks.
- The presentation of risks concerning pregnancy and motherhood were influential for women preparing for pregnancy, and resulted in perceptions of high risk pregnancy and perceptions of increased risks for child safety.
- Women engaged in making judgements concerning which risks were perceived acceptable, and which required management through strategies of risk prevention, reduction or avoidance. The choice, application and adherence of risk management decisions reflected individual preferences and, in extremis, resulted in decisions to avoid or restrict having a family.

- The significance of risk messages that over-inflated the risks to the future child following in utero AED exposure or exposure to maternal seizure risk was the resistance to new more favourable information, suggesting the irreversible hazard resulting in the shadow of doubt difficult to erase.

In the next chapter, the interpretation of risk and uncertain information upon decision-making in preparation for pregnancy will be explored.

Chapter 8 Decision-making in preparation for pregnancy

Introduction

This chapter presents findings about women's involvement in decision-making concerning preparation for pregnancy, illustrating their experience of making multiple decisions throughout their childbearing years, and the importance placed upon information to support participation in decision-making to achieve their preferred reproductive outcomes. These findings have been used to structure this chapter as follows:

1. The decision to prepare for pregnancy – outlines the experience of women preparing for clinic attendance and their access to information.
2. Factors influencing decision-making – illustrates the emotive context in which decisions are made during preparations for pregnancy; and
3. Negotiated outcomes – describes the mutual agreements, discussion and compromise between women and their clinicians, and highlights preferences regarding the reproductive outcome of decisions made by women.

8.1 Decisions to prepare for pregnancy

Women were required to identify their future pregnancy intentions and take the necessary action, such as recognising the importance of allocating sufficient time to complete preparatory interventions before attempting to conceive. This required women to identify pregnancy planning as both a reason to consult with health care professionals and as an item for clinic discussion.

8.1.1 Decisions to attend the epilepsy clinic

Decisions to discuss planning pregnancy were motivated by the need for additional information, advice and reassurance. There was an expectation that women who had been discharged from clinic during seizure remission would return to review their epilepsy management prior to attempting to conceive. The recall of recommendations made in childhood was a challenge. One 24 year old (OI19), who had last attended hospital aged 14 years, had no memory of statements reinforcing the importance of returning for specialist review either to reconsider future drug withdrawal or for preconception review. The GP referral letter made reference to OI19's continued use

of Epilim, a treatment she had withdrawn on her own volition approximately two years earlier.

OI19: I came off the tablets, but I went to see my GP and asked my GP if they had any advice on like, not so much getting pregnant, but about being an epileptic and being pregnant. And they basically said well you will definitely have to come off the tablets, because it can effect if you have a baby, it can effect the growth of the baby whilst inside you. But we can't give you the ins and outs whether you still need the tablets or not.
(Immediate pregnancy intentions)

OI19's actions had been prompted by several competing agendas - frequently missing treatment, becoming more independent with plans to move in with her partner, and contemplating pregnancy. The potential negative consequences of drug withdrawal, such as a potential relapse of seizures or her need to withhold from driving during drug withdrawal, had not been considered, although OI19 admitted that not telling her mother was to avoid causing worry.

For other women, their experience was reliant on friends and family. Participants OI10 and IO24 illustrated this route back into epilepsy care. In the case of OI10, a 30 year old with immediate pregnancy intentions, she revised her prior judgements concerning the inability of WWE to have successful pregnancies following a chance meeting with a friend with epilepsy who had had a positive experience. In the case of IO24, her mother's experience of epilepsy had reinforced the importance of preconception review. This had inadvertently reinforced her belief in the safety of her treatment, a point which was challenged by the GP practice nurse. Whilst IO24 had decided to disclose her pregnancy intentions to the practice nurse, this had been to initiate appropriate preparation which she felt involved monitoring her epilepsy. The practice nurse warning, "I will refer you to the hospital to come off your tablets", raised concern of the potential for drug-related risks.

Referrals for epilepsy review required discussions with the GP, and additional work by women to bring about a new patient referral, both bringing pertinent information to their GP's attention and negotiating referral to their preferred health professional/service. The experience of previous consultations with hospital clinicians was often associated with the experience of seizures and/or changes with AEDs. For one woman this resulted in a wariness of returning to the epilepsy clinic:

OI22: when I was put on lamotrigine the Consultant in [location] said look I've put you on this, because you will probably have children. She said it to me when I was 21 and I thought it was quite funny [...] But when you are so young you just sort of go yeah! Okay! But equally you do look on the internet and you do read things [...] I knew that I would have to go through a process of again going to the hospital, this time through my own choice [...] any messing about with my tablets I'm a little bit nervous of. First of all, it takes such a long time to be weaned off one and on to the other, but there is always that element, of we might be back to square one...
(32 year old, immediate pregnancy intentions)

The above participant's anxiety about the outcome of clinic attendance and her investment of time in internet searches revealed the extent of her concern about the potential to destabilise her epilepsy. For other women, there was less evidence of any expectation for preconception epilepsy review³⁹, as exemplified by participant OI06 who had attended her GP for pregnancy testing. The GP's referral only came about due to a negative pregnancy test result. This case demonstrates the experience of a subgroup of women, in which making decisions to conceive did not take into account the significance of preconception care:

170. C: [...] Your GP sent you back also, in the letter there
171. was a mention about pregnancy and your worries about that.
172. P: Oh yes. I asked for the test, because I thought I was pregnant,
173. because I was late on my period.
[...]
176. P: ... They said because if you have a baby now, with the tablets that
177. you are on, your baby could be disabled, there could be
178. something wrong with its lip or could have spina bifida or something
179. like that she said. So really I wouldn't try yet while you are on those
180. tablets. I would speak to your specialist first and let them give you
181. advice and tell you what they think of it.
182. C: Are you planning to be pregnant?
183. P: Well I do want to have a baby, but, I just wouldn't want to have
184. a baby now and it was disabled. (OI06; 20 year old)

This case highlights the role played by GP's to identify and refer women at risk of unplanned pregnancy. The significance of the GP's warning to delay attempts to conceive while continuing the current treatment was that it highlighted the risks of having a disabled baby and revealed knowledge deficits. From the clinician's perspective, opportunistic questions about pregnancy intentions were an attempt to

³⁹ There was a tendency for women who had infrequent epilepsy clinic attendance to experience a lack of awareness of the importance of preconception epilepsy review; in the case of OI06 she had stopped attending clinic despite continuing to experience frequent seizures.

manage knowledge deficits concerning the importance of preconception review. Some women appreciated opportunistic questioning since it relieved them of the potential embarrassment of broaching the subject of their intentions to conceive:

OI22: ...it was quite good that my doctor [GP] actually brought the subject up, because it prompted to me to sort of start talking about it ...
(32 year old, immediate pregnancy intentions)

8.1.2 Experiences of directing the clinic agenda

The ability to influence the clinic agenda was questioned by some women, referring to 'being in the dark' and having limited information concerning pregnancy related issues. The search for information was presented as a request for advice, and included questions concerning aspects of epilepsy management and updates on research:

IO24: I just wanted to know why, why a) you need to come off the tablets, why, and I felt that I'd not had any, he'd not really give me any information, because he was just saying there's risks for this and risks for that. And I was saying where's, how do you know there's risks. Because people have always said to me, they can't test pregnant women, so then if you can't test pregnant women, and when they're on their medication when they're pregnant, how do you know what the risks are... (31 year old)

For the majority of women, the agenda also included the search for reassurance and peace of mind concerning their ability to have a successful pregnancy. In the case of IO24, she had questioned the accuracy of previously provided information, requiring additional information to offer reassurance. The approach taken by women to direct the clinic agenda was variable, from simply answering questions asked by the clinician through to asking their own questions and making comments concerning their AED regimen and future pregnancy intentions. In the case of OI17 the GP referral letter had requested review of seizure management; however, during OI17's initial hospital visit, the 33 year old had informed the clinician of her additional requirements to review her pregnancy intentions:

OI17: when I first saw [clinician] and felt that she was, I mean I didn't walk into the clinic with the intention of going yes I want kids because I had my mum sat with me. But after listening to her and her understanding of my condition, I felt at that point I could say well actually I have been thinking about this for months, what do you think about it and felt that her advice was really supportive. (Future pregnancy intentions)

The transfer of information between patient and clinician required both parties to identify gaps in knowledge and to share new information updating changes in personal

circumstance. Participant OI13 exemplified this point through her contact with the clinician's secretary to inform of her wedding date and request a consultation. The disclosure of information was judged as her responsibility:

- OI13: Basically it's whatever is going on with you, at the time. If you've not expressed that you're into that, they obviously don't know that you're thinking of having a family or anything, so they don't know what best advice. So it is up to you to a point, to tell, if like when they're asking what is going on with you at the moment, it's not. But then I think it should be good to give like the information.
(28 year old, future pregnancy intentions)

The role played by women in directing the clinic agenda was implied by women asking questions or making statements which required the clinician to respond. The clinician made explicit enquiries concerning pregnancy intentions in 19 of the 23 observed cases; of which 7 involved new patient appointments. In the case of participant OI23, a 30 year old with immediate pregnancy intentions, she confirmed her pregnancy intentions as both the reason for the consultation and for her specific requests about risk information and clinical opinion:

251. P: ... well my ultimate goal is that, we would like to try for a
252. baby,
253. C: I think that's a very good idea
254. P: I saw [name] in [city] about a year ago because we were
255. discussing it and, we came to the conclusion that I was going to
256. come off my medication after we got married in August. But then I
257. had these funny, this vertigo thing, and it knocked me for six...
[...]
275. P: But I don't know, I wanted to know what the risks are of
276. what, what your thoughts are really (OI23)

The clinician's role in initiating discussion concerning pregnancy was reliant on knowledge of the patient's stage in life, relationship status, work and home circumstance. The approach adopted by the clinician focused attention on the range of issues needing to be discussed, and the value of the patient's involvement in providing detail to support the clinician's work:

107. C: [...] your doctor's sort of, put all the relevant things in the
108. letter {yes} really the issues about potentially thinking about
109. pregnancy. {Yes} Also mentioned about what job, what
110. kind of job you do {yes}, and the fact that you rely on driving for
111. that as well.
112. P: Yes, I mean, I don't, I could not drive if it was absolutely
113. necessary {yes}. But I mean I do at the moment drive
114. C: Yes, OK

115. P: Both commute to work and then drive
116. occasionally /for work, so.
117. C: /right OK. I mean the issues kind of
118. linked in a way. And I'll explain {yes} what I mean by that. In that,
119. if you're in the situation that you are in, which is
120. essentially, being 10 years without any seizures? Then, I
121. think essentially we've got three options. We, you could consider
122. drug withdrawal completely and we need to discuss the pros
123. and cons of that. You could stay completely as you are, or
124. we either consider reducing the dose or switching to another drug.
125. P: Right (OI15; 31 year old, future pregnancy intentions)

The above extract highlights the provision of treatment choices from which the patient needed to consider her preference before reaching a decision. The implications of her treatment decision extended beyond her plans for pregnancy, and directed the patient to also consider driving and employment.

8.1.3 Having information to inform decision-making

The experience of attending the epilepsy clinic was interpreted as providing an available resource of specialist advice and information, which could be easily accessed when the perceived need arose:

FG74: Well I really do go about my business on information, it's crucial to me. Whether or not, the pregnancy was planned. As soon as it was, I wanted to know everything I could possibly know. Especially to counter the things that are said that don't help ... I want to be armed, with as much information as I've got. Knowing that, no two people are the same. Knowing that, no two births are the same. Doesn't matter, I just want to know, just tell me *everything* tell me everything, and I will base it on that, and I read everything. Information is crucial to me. Really is.
(36 year old with one child)

The information offered at diagnosis and during follow-up visits was interpreted as beneficial. One participant described her relationship with her GP as reinforcing her search for information which she felt had prevented her from experiencing an accidental pregnancy. For many women their search for information involved:

1. Joining voluntary organisations such as Epilepsy Action⁴⁰
2. Links to experiences of WWE via internet chat rooms
3. Attending local libraries - searching the general health and self-help manuals

⁴⁰ Epilepsy Action is one of two national voluntary organisations in the UK (the second, the National Society for Epilepsy).

4. Reading the problem pages of women's magazines/mother and baby magazines

The internet was judged by one 19 year old participant as a convenient resource and "more convenient than booking an appointment" with her doctor (FG45). The accessibility of appropriate information was a challenge for some women, especially in relation to the time pressures within the clinic environment, where guidance in locating trusted information was important for the majority of women. This point was emphasised by several participants who had benefited from the support of being offered several visits to discuss pregnancy-related topics and receive information in stages, in preferences to 'a whole load of information' being given at once and the associated pressure of needing to 'try and take it all in'. Frustrations were expressed relating to the desired content of clinical advice compared to the perceived reality, resulting in searching for reassurance and the request for honesty and openness from the clinician:

FG-I-02: I just felt they were keeping themselves on the wall, on the fence. Not giving an answer because they were scared of the consequences if they give you incorrect advice sort of thing ... he just said well there is an increased risk. It's the unknown at the moment or something, but very, very vague [...] he just said if you do decide to go, despite the risks [laugh], then we'd want you to register with this pregnancy thing but that was it. It was very much like if you go against my advice, this was the first Consultant; if you go against my advice then you join that register, so it's just [laughs]. So it was very, it did feel very, very negative, and that I was just glad that my husband was there, and he could try and take some of it on board as well, because I felt very bewildered. (36 year old)

8.2 Factors influencing decision-making

The perception of additional risk and responsibility towards the unborn child resulted in expressions of guilt, worry, blame and fear concerning the outcome of decisions made during preparation for pregnancy.

8.2.1 The influence of anxieties, worries and fears upon decision-making

Women experienced both positive and negative emotions in response to risk information and, for some; risk information was seen as relieving anxiety by providing reassurance about the likelihood of successful pregnancy:

OI09: The information from past hospitals I've had I think has hindered my opinions and everything on having children, I always wanted it, I've had

that mindset about I always wanted children but I think I had too many worries on my mind of what was going to happen [...] it's helped [observed consultation] a lot just putting my mind at rest about simple things, maybe it's just even talking out loud, I don't know. I don't like talking sometimes to my family because they just worry.
(29 year old, future pregnancy intentions)

The recall of previous presentations of risk information was an important factor for both patient and clinician, and the poor recall of both pregnancy and epilepsy-specific risk information had the potential to influence or bias the outcome of decisions made by women. The provision of new risk information required that it be sufficiently credible to alter prior beliefs, a concept illustrated in relation to two women challenging each other's prior beliefs during group discussion:

FG45: [...] for the ones I'm on and sodium valproate there is more chance; I think there's a 40% increased chance of abnormalities which is quite a lot. And that, if I was to intentionally want to get pregnant, I would have to come off my medication which worries me.

[Brief change of subject by a participant discussing the experience of seizures ...]

FG45: Well I think that's what [clinician] said, I might be wrong. I mean that to me is a significant amount. If they'd said to me 5% or 10% I would probably be less worried. But when they give such a significant percentage that/

FG44: /You see I was given a different percentage than that when I was on sodium valproate.

FG45: Well I might of got it wrong, that's what I remembered.

FG44: Yes, I know in your mind it seems a lot doesn't it.

(FG44, 29 year old; FG45, 19 year old)

The involvement of women in reviewing their epilepsy management and considering possible treatment options rested on being able to make judgements concerning preferred outcomes, all of which had a strong emotional association. The following extract illustrates the clinician checking the patient's recall of pregnancy related issues:

244. C: [...] So do you want to tell me what you remember because
245. that's quite helpful for me to remember what you need to, [laugh] to
246. know what your knowledge is, because people go, yeh yeh, and then
247. they are so stressed it all goes out of their heads [laugh]
248. P: What was my understanding from last time was they lower
249. the effectiveness of the lamotrigine
250. C: But what about the, what I was saying, what your understanding is
251. of the effect of lamotrigine on the pregnancy? You know because
252. you were worried about there being problems in pregnancy, and any
253. problems with the baby?
254. P: I can't recall

255. C: You can't recall
256. P: Sorry (OI17, 33 year old, future pregnancy intentions)

The above participant had completed a switch of treatment (sodium valproate to lamotrigine) following her last clinic visit, and the observed consultation was to review her progress, and presented an opportunity to confirm her knowledge and understanding. Within this context the significance of OI17's poor recall was her inability to remember the information which had informed her decision. This case illustrates a common problem cited by women, concerning their ability to remember the content of clinic discussion from one visit to the next, a problem intensified by the emotionally charged decisions surrounding pregnancy.

Information concerning drug-specific risks was frequently presented in the context of clinical recommendations, resulting in emotional responses with the potential to influence the preferences for drug selection or action to be taken. For other women, decisions to make changes with treatment raised their fears of possible changes to seizure control, tied into responsibilities towards the future child. Women considered the opposing risks of seizures versus AEDs harming the unborn baby in their attempt to manage the dilemma raised by clinical recommendations to switch treatment, exemplified by a 22 year considering pregnancy within the next 12-18 months:

OI02: ... the last big fit I had scared me, really did scare me... it is more risky isn't it to have kids without being on this special medication. But, it's nerve racking to get on to it, but I know I've got to do it, because I know that there could be something wrong with my baby if I don't take it... It's got to be the lamotrigine hasn't it because she [clinician] did turn round and say to me, that that's the only one that's more than likely not to be risky for anything to be wrong with the baby. The Epilim it's more risky to be something wrong with the baby, and that's why I don't want to, I do want to start the lamotrigine. It's like of a night when I can go to take my tablets, I do get them out to take them. And I just look at them, and just, it's just dead scary, I think, am I going to wake up in the morning in a hospital...

The clinical implications of eliciting fear in response to risk information were that for many women, uncertainties surrounding pregnancy or personal uncertainties around starting new treatment were heightened. Individual responses to risk information included the influence of personal blame and claims of selfishness:

FG-I-02: It was more to do with the things like the cardiac problems I think that had more of an impact on us. That it was going to change that child's life in

such a dramatic way, their quality of life would be poor. So it was those things that were keyed into us. (36 year old)

For other women, the potential for changes in seizure control influenced pregnancy planning decisions by increasing uncertainties concerning the experience of pregnancy on a new drug. The fear of seizure relapse had become an obstacle to the decision-making for one participant (OI23), influencing her approach to pregnancy planning (see also page 113). However, it was the uncertainty of developmental delay that influenced her final decision to withdraw from treatment:

OI23: The thing that I suppose that hit a nerve, I think really changed mine and [husband's] decision, was when he was talking about the developmental problems that we don't know about [...] I was thinking well if you're born with a child, whose struggling at school, whatever, you'd just be wondering well is it my fault, is it because I didn't do that. Or, but you don't know, it might have nothing to do with it, but there's so many variables. (30 year old, immediate pregnancy intentions)

Uncertainties, both surrounding drug-specific risk and the patient's response to a new drug, were the most common source of worry, resulting in more tentative decisions concerning the likelihood of future pregnancy:

OI12: ...we do want children but I don't think there is any point in saying we definitely, I don't think there is any point in getting your hopes up that you are going to have them. Because it might not happen, I've not changed my medication, I don't know whether the medication is going to work, and I don't think I'd want to risk being on this medication and having them [children] (30 year old, future pregnancy intentions)

For several teenagers, drug-specific uncertainties influenced their anticipated future judgements concerning both drug selection and pregnancy decisions, illustrated by the following 16 year old:

FG111: Personally if you gave me, if you said you can go on this drug or this one which we're uncertain of, I'd go on the one where I know what the risks are [...] I couldn't have pregnancy where I was uncertain, when like the baby came out, whether it would have 6 fingers stuff like that.

The influence of uncertainty upon treatment choice was expressed as feeling uncomfortable and confused about 'the unknown'. For participant FG111, her response to uncertainty implied selection of a drug with known risk as providing 'peace of mind'. The influence of emotions upon decision-making was exemplified by participant FG92, who was diagnosed with epilepsy three months prior to discovering

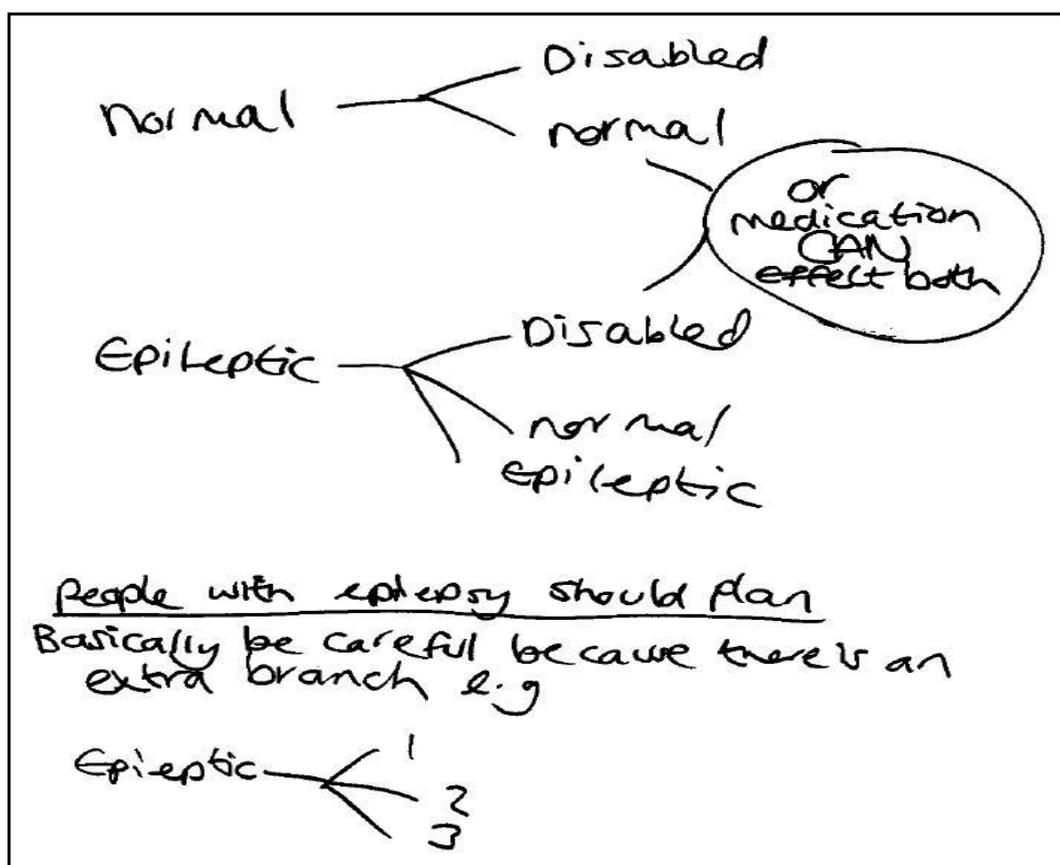
she was pregnant. She faced decisions concerning the progression of her pregnancy alongside clinical recommendations to start treatment:

FG92: To me, I think it was just more the protecting the baby, than anything. I know it was probably, if I did have a fit, and then if something did happen to the baby, then it would be my own fault for not taking the tablets. But then, it's just like you've got all these things flying through your head, and you just don't know what to do for the best, but I've started to take them yesterday anyway, so, hopefully, everything will be alright now (32 year old, 4th pregnancy)

Risk information was provided as reassurance and support for the revision of prior negative beliefs, and for some women influenced both treatment and pregnancy-related decisions. For others, decisions either to have children, or to revise plans for a larger family, revealed a tension between prior expectations and the reality of their experience of life with epilepsy:

FG123: it just wasn't through selfishness or anything, epilepsy was the main reason why we decided cut off no more [children] ... the epilepsy it just totally flipped it over and it did and that was what our decision was. I would have had about four, I'd gone like my mum and had about four, I always wanted four deep down. (39 year old)

Decisions to restrict family size (two children) were influenced by fears concerning the safety of her future baby and her own safety during pregnancy, as well as by her responsibility to care for her family which would not be possible if her seizures restarted. Decisions concerning risk management required women to reconcile their emotional responses of blame and guilt. Women articulated a struggle to 'live with themselves' in coping with the perceived inevitable worry of remaining on treatment during pregnancy versus delivering a disabled child. One 18 year old expressed her motives for planning pregnancy as a method of coping with the need to be 'careful', as she considered the options set out in front of her (see figure 8.1).



(Flip chart diagram drawn by FG101 (18 years old) Teenager focus group 1)

Figure 8.1 The influence of epilepsy upon decision-making

8.2.2 Assistance in making informed decisions

The support needs of women planning pregnancy were commonly met by being offered sufficient time and opportunity to ask questions and having access to expert knowledge and opinion. Clinicians skilled enough to communicate in a reassuring way, and their ability to pre-empt patients' informational needs, were also considered helpful qualities, and used to justify reliance on the clinician to guide decision-making:

FG96: Because you're going to the likes of [hospital] and the clinics for sort of medical advice, and reassurance from specialists and expertise. And so therefore you want to hear something, definite and concrete, and the research says this and this, and this is your, it's 96% and the 4% could be this, and this is what the sorts of things we could be talking about, and that differs from the general population, by x,y,z so, And, you can make your own decision [...] based on the facts... (34 year old, 2nd pregnancy)

The importance of up-to-date information was also to offer reassurance, exemplified by participant OI22:

OI22: ... you spend a lot of time worrying about what's going to happen, and I think perhaps I'd put off having a baby because, I know it's going to be a

big deal. But you do worry and you spend a lot of time before you are even planning, and you read all the negatives, so you already know all the negatives. It's just a good thing to go to somebody and them say it, actually it's a really good idea, and it's going to be alright. This might happen, but this is what will happen at the end, it's probably going to be a good outcome x amount. We've got all these women who have babies in [location] and they're all very happy, and you need that, as opposed to putting the fear of god into people. It's just, because, you already go there expecting to hear bad things. (32 year old, immediate pregnancy intentions)

Support in managing risk information was considered by one participant OI01, who considered herself a 'planner', as helping her manage the negative aspect of 'thinking about things too much':

OI01: [...] I mean, I could sit there and think oh no, but you'll be getting pregnant and you'll be worrying about the baby, and then you'll get yourself all stressed out, and then that will just lead to a fit [...] but I think knowing the stuff that I know now [...] when the time came I think I would be able to make a decision, yes, yes far better than I would have been able to do a few months back (29 year old, future pregnancy intentions)

Women highlighted the importance of having access to information alongside their need for support, as illustrated by OI01's reliance on the clinician to deliver timely information updates. The expert knowledge of the clinician was seen as a resource to be accessed by women involved in making their own decisions concerning pregnancy. However, the responsibility for making decisions rested with the participant alone, and implied an appreciation of the responsibility to consider clinical recommendations:

OI13: once you are given that information, you do need to think about it and make some decisions. Whether you want to even think about changing your drugs and things like that ... (28 year old, future pregnancy intentions)

The above participant positioned decision-making as happening outside of the clinic environment, whereas other women valued the chance to be offered a follow-up visits and the opportunity for 'talking things over again'. Several participants were critical of the lack of accessibility of support when needed, and the availability of appointments. The criticism was extended by one participant (FG-I-02)⁴¹ who considered the organisational constraints on the epilepsy clinic to respond to individual patient need, resulting in her feeling isolated and 'let down' by her consultant who she saw as not wanting to see her again for 'six or twelve months'. Deficits in service provision and

⁴¹ See also participant extract page 159.

professional knowledge were raised as practical constraints to informed decision-making:

FG75: It's just a whole minefield, and you say, well you can get Epilepsy Action⁴² to give you leaflets about having children when you have epilepsy, and you can get different information from your GP and your midwife [...] If there was some kind of package that was put all together, especially for people with epilepsy in pregnancy, that would be amazing. I mean you read and you say well you get preconception counselling, I mean what's that? I've never been offered that, sounds amazing but I've never had it, I have 15minute slots with my consultant and he's usually running an hour and half behind, and he hasn't got time. [...] when you're *about* to embark on something, it's seems scary, because it's the not knowing, and it's the what ifs [...] if someone could sit you down and say, this is our service provision (FG75; 26 year old)

For the majority of women, assistance in making informed decisions required up-to-date information and two additional elements: the provision of support, and the provision of reassurance. For one participant, her decision to withdraw sodium valproate required the approval of her clinician:

OI21: I know I've made my decision, but I still think it's the doctor that's made it for me. Well, helped me make it, agreed to it, say.
(35 year old, future pregnancy intentions)

Reassurance served as support for decisions made especially surrounding pregnancy decisions. The assistance provided by family members was seen as being a form of psychological support, both as the emotional support to reconcile the perceived difficult decisions needing to be made, and also practical support in dealing with the outcomes of the decisions made, such as practically coping with caring for a disabled child. Information about the availability of support (whether practical support in the form of maternity services and Local Authority provision for childcare, or emotional support in the form of reassurance from discussion with other WWE) were identified as helpful in reducing the perceived obstacles to planning a successful pregnancy, and thereby assist decision-making during preparation for pregnancy.

8.3 Negotiated outcomes

The decisions made by women involved a complex process of appraising information concerning pregnancy related risks, assessing its significance in relation to their

⁴² Epilepsy Action produce a wide range of written literature, internet services, and membership for patients, carers and professionals.

personal circumstance, and pregnancy intentions weighted against the available epilepsy management options and perceived risk management strategies. This involved negotiation and compromise between the differing views held by women, their clinicians and significant others, and resulted in a perceived challenge for women making decisions concerning pregnancy.

8.3.1 Decisions concerning risk management

The decision to become pregnant was seen as ‘massive’ and ‘potentially life changing’, requiring women to consider the ‘extra worries’ associated with the role taken by women in making decisions concerning risk:

FG22: It’s your risk, and it’s for you to make the decision whether to take the risk. But you need to have advice on what the risk is. And there’s the medical risk, and it got to be explained in ways that you can understand. There’s the psychological risk which is, are you going to be able to cope with the stress of having a baby and looking after it, and your family and all the rest of it. So it’s having the information to make the choices... (45 year old)

The ability for women to make judgements concerning AED selection during preconception review relied on them feeling sufficiently informed and having trust in the evidence presented by their clinician, a point illustrated by the following participant’s frustrations:

FG53: They keep changing, every time they change my drugs, they always say, oh, yes, actually I know we changed the drugs last time, and said these drugs are better for having babies on, but the, now the drug company have said they’re not actually better for having babies on [laugh] (23 year old)

The nature of the decisions facing women preparing for pregnancy reflected the need to make choices, and resulted in women’s tentative approach to make decisions to review treatment, often associated with anxiety concerning the outcome of the review such as recommendations to switch or withdrawing treatment. Preconception review of AEDs is an opportunity to switch to alternative less risky AEDs, especially in the case of women taking sodium valproate.

FG45: I think I would be more inclined to swap if I found one that was sort of like a low risk one; I think I’d be more inclined to swap than come off (19 year old)

The approach taken by FG45 reflects the desire to switch to lower risk AEDs. The significance of this extract is to illustrate the competing rationales (importance of

seizure control versus low risks to fetus) informing her preference, especially as FG45 was taking sodium valproate:

FG45: I got told to take the full dose of 1000 milligrams and I'm actually only taking 600 milligrams because I don't need the full dose in my opinion ... So I felt I was in control of that, but I think that was because I didn't want to go on them at first because my epilepsy isn't that severe

FG45 rationalised her treatment decisions on the grounds of seizure severity and her initial response to treatment, rather than considering the immediate needs of a future child. However, in her earlier statement, she makes reference to an awareness of drug risk. For women who decided to remain on sodium valproate, they justified their decision as a necessary evil, and used risk information to counter the criticism of having made a 'selfish decision' (see also Chapter 9.2), illustrated by a 30 year old pregnant participant:

FG86: Am I doing damage to it? Is it right to do this? Even though it's what you know, is it the right thing to do, is it a selfish act or sort of thing, and as I say after speaking to [epilepsy nurse specialist] and [consultant] at [hospital]. [...] I think the percentages that [epilepsy nurse specialist] gave me it was something like 5% and if you look at percentages for anything, new time Mum for anything... I think with me, it was that selfishness {Yes} Am I doing the right thing, and the planning? {Yes} That I feel, that I've put into it ... And looked and weighed everything up and spoke to [clinician], the same sort of chance, went on the folic acid all that [...]

Participant FG86 decided to remain on a low dose of sodium valproate (600mgs daily). However, reflecting on her pre-pregnancy decision during her current pregnancy, she revealed a tension between her earlier rationale for deciding to remain on the 'worst drug' and her current anxieties:

FG86: ... my pregnancy was planned, I'm 16-17 weeks pregnant and just living on my nerves really [laughter] but other than that [laughter] excited and looking forward to the future. (30 year old)

FG86's decision to commence folic acid was used to reduce her perceived risks while remaining on sodium valproate. Folic acid was a common recommendation by clinician's justifying the 'just in case' rationale. Whilst there was frequent reference to 'just in case' recommendations for folic acid, there were instances of misunderstandings illustrated by the case of one 16 year old, believing she was at increased risk of accidental pregnancy:

FG111: it scared me when they went you have got to go on folic acid just in case, and my mum was like what, just in case what. And they were like, just in case she gets pregnant. And she wasn't very pleased with that, but erm my dad said it was like she is preparing for a pregnancy which it scared me as well because I was like there must be a chance then. (16 year old)

For other women, their experience was of clinicians highlighting the importance of preconception commencement of folic acid through descriptions of early fetal development, and the limited benefit if commenced only on discovery of pregnancy:

413. C: [...] the folic acid as well to reduce the risk
414. of things like spina bifida {yes}. It's ideal for you to be
415. taking that before you become pregnant. Because most of the
416. time, by the time ladies have actually have found out that they're
417. pregnant the bony spinal column has actually been formed. So
418. {yes} those sort of defects have taken place already so it
419. is best that you take the folic acid. Usually they say about three
420. months before you become pregnant, so it is well in your system
421. {yes} and it is going to have its positive effect for you...
(OI04; 27 year old, future pregnancy intentions)

Eleven participants observed in consultation received a recommendation to start folic acid, of whom four had commenced folic acid by the time of interview. A further seven women were already taking folic acid prior to their observed clinic appointment (see Chapter 5, Table 5.8). The availability of information about the benefit of folic acid was inconsistent. Informant OI03, who had spoken to her pharmacist before attending the observed consultation, had required further reassurance from her epilepsy clinician about the best time to commence and her perceived risk of 'getting caught out'. The clinician's reassurance was not prescriptive about when to start folic acid, but implied that there was wisdom in starting folic acid in advance of conception, a point not picked up by this 23 year old participant with future pregnancy intentions:

OI03: the fact that I know now to take the folic acid just when you get pregnant really so, because I thought I would have to take it for a while, while I'm planning, and I was panicking in case I got caught pregnant and I had not took it. I thought that could cause problems but it's quite a good thing that it's just when you find out you're pregnant. (OI13)

Delays in taking action to commence folic acid were attributed by OI17 to her failure to appreciate the significance of not taking folic acid before pregnancy:

OI17: when I was 21, I saw a Consultant ... the only thing I remember when I was leaving he said just remember if you want to have a baby you've got to take folic acid ...and then when I saw the Consultant in [location] again

and was pregnant that's what he talked about [folic acid] and talked about you know worst case scenario was when a woman was taking sodium valproate you can have a child born without a limb and I was like Whoa! But it was stuff that nobody had ever sat down and said this is the truth (33 year old, future pregnancy intentions)

Accidental pregnancy resulted in women needing to decide whether to progress with the pregnancy and revealed an increased level of worry which was not entirely relieved by the availability of ultrasound scanning. These issues were illustrated by FG95, who had conceived while taking both the contraceptive pill and phenytoin:

FG95: when I became pregnant ... we just wanted to make sure that, everything was OK with the baby because I was on medication, I was on my medication from the start of the pregnancy, I wasn't taking any folic acid ... I had fits, so it's like the stuff that you hear, like from the internet, and when you read the leaflets, and things like that just panic's you a little bit more, like you've got this much percentages of normal, abnormalities you've got this much percentage of this, this, this and this. For me and [partner] it was like, right, we are pregnant, but, we're not going to get too over excited ... get as many tests and screens done as we possibly can, to know that everything's OK, and that's when you can get excited... (25 year old, 1st pregnancy)

The utility of prenatal diagnosis when used to manage anxieties concerning preconception decisions to remain on AEDs relied on women's awareness of the routine use of ultra-sound scanning to detect abnormality. Clinicians referred to this technology as a means of reducing risk through the early detection of something having gone wrong:

282. C: [...] with the lamotrigine you don't tend to get
283. abnormalities of the formation of the spinal cord, OK. But, but there
284. could be a whole range of different abnormalities, and they're often
285. picked up on scans. And what we do say to people when they do get
286. pregnant, we plug them into the obstetric hospital
(OI17; 33 year old, future pregnancy intentions)

For some women reliance on ultrasound scanning was problematic, identifying the limitations both of time to access scanning and take action on the results, and the ability to detect 'all' abnormalities. For one woman, this was crucial in her preparations for pregnancy, supporting her treatment decisions as whether to remain on lamotrigine and topiramate or switch to either monotherapy with topiramate or levetiracetam (the clinician had recommended the latter option as preferable, to reduce as much risk as possible):

OI12: I would like to know now that this can be detected before it gets past that stage where I could have an abortion. And I think I need to know all them figures as well ... if it had spina bifida we could tell before it got past that point and we could obviously give you the options and the same with the other defects, if it could be detected [...] if it was a 95% chance, or 98% chance that all birth defects, major ones, were detectable then yes [...] it being detectable, be given that choice, then I would be quite happy staying on this medication (30 year old, future pregnancy intentions)

The potential to detect ‘all’ abnormalities by ultrasound scanning was an unrealistic expectation. However, discussions about ultrasound scanning during preconception review consultations resulted in many women judging prenatal diagnosis as a backup resource to detect adverse outcomes should they occur as a result of AED treatment decisions. The role of prenatal diagnosis during pregnancy was to assist women assess risks and benefits and served as decision support. Discussions about prenatal diagnosis during preconception counselling also served to assist women feel able to manage the uncertainties of pregnancy-related risks (from AEDs) and was especially important for women who felt they had limited options to switch from their least preferred treatment.

8.3.2 The experience of making decisions

Decisions were made by women as part of their daily life with epilepsy, and concerned adherence to treatment, continuation of contraception, and whether to take action on pregnancy intentions. Within the consultation, women appeared comfortable about making decisions, and the majority used ‘I’ to indicate their central role and ownership of decisions.

OI21: I feel like I made a decision to come off it [Epilim] eventually, because if I do decide to have a family I don’t want to be on it at all, and for me there’s more of a risk being on it than there is being off it. Because I’ve been off it for so many years, and I’ve been fine, and even if I did have a seizure while I was off it, there’s less chance of a problem occurring with an unborn baby than there is of me taking it. So I’ve took all that into account, and that’s the decision I’ve made. (OI21; 35 year old, future pregnancy intentions)

Patient decision-making was influenced by clinical recommendations. For example, ‘we should do *this* first’ before considering pregnancy, and set the boundaries for decisions by proposing what options were available and requesting the patient consider her preferences concerning the available options before embarking on pregnancy. The experience of involvement in decisions was variable, and while many referred to their

responsibility, the reality of involvement in treatment decisions appeared limited, exemplified by the following participants:

FG53: They keep changing, every time they change my drugs, they always say, oh, yes, actually I know we changed the drugs last time, and said, these drugs are better for having babies on, but the, now the drug company have said, they're not actually better for having babies on [laugh], well now you know.

FG55: You do feel like guinea pigs.

FG53: Yes (FG53, 23 year old; FG55, 28 year old)

One woman felt her involvement in decision-making had changed both with maturity and personal experience of previous consultant-led decisions:

FG61: ...it does feel quite equal. But, I think it's because I've had that many consultants in the past that have told me, and medications that turn out to be the wrong one. I am now, more keen to take control of my side of the medication. (28 year old)

In contrast, FG-I-02 was unable to recall participation in decisions to withdraw folic acid:

FG-I-02: it was done [folic acid] as, in case an accident happened, so someone must have then deemed that an accident wasn't going to happen because I'm not on it now. (36 year old)

From the perspective of the clinician, they were involved in making the patient aware of potential risks, commonly the risk of unplanned pregnancy and hitherto unforeseen consequences from the patient perspective:

517. C: you have got a lot at stake here if you do end
518. up falling pregnant when you are not planning it.

[...]

757. C: But I am just anxious I just don't want you to be on 2 drugs and end
758. up getting pregnant, alright.

(OI02; 22 year old, future pregnancy intentions)

The expression of urgency reflected the priority of concern perceived by the clinician. The opportunity to action these decisions changed outside of clinic, with differing priorities from the patient's perspective, for example, worry about seizures and her plans for a worry free wedding resulting in the patient's decision to delay acting on clinical recommendations:

OI02: I think when the wedding is out the way, then I would really start it [lamotrigine] but, hopefully I do want to start it now. Just for in case, it's just, I don't know it's just that it's hard like [...] yes, I think it would be

just start the lamotrigine like to come off the epilim and then, plan for a family like (22 year old, future pregnancy intentions)

The time required to make treatment changes often resulted in women feeling a sense of urgency to achieve the recommended treatment plan. This point was illustrated by a 26 year old participant who was taking topiramate, carbamazepine and levetiracetam:

FG75: I'm concerned with only having two different kinds left, because obviously I'm being on three different medications, because obviously wanting to have children and I know you've got to be on, only a few medications to have them, ideally ...

The window of opportunity to decide to switch treatment or take action on clinical recommendations was frequently missed, and resulted in women experiencing pregnancy on their least preferred treatment option. In the case of participant OI21, she reflected on her experience of termination of pregnancy at 16 years of age following diagnosis of spina bifida which was attributed to in utero sodium valproate exposure:

OI21: I think the pregnancy probably would have still happened, because I was, young. But, with you saying earlier, teenagers miss medication and they don't take it regularly, I remember now, I didn't take it regularly. But when I found out I was pregnant, I took it more because I thought oh something might happen if I don't take it. Yes, so that would have changed, I wouldn't have took it.

Interviewer: So knowing more about medication

OI21: Yes, because I'm thinking I need to take it more than I normally do, to prevent any problems, whereas if I'd have just, not touched it things would have been different... (35 year old, future pregnancy intentions)

The significance of this extract is to illustrate the differing approaches to decision-making:

1. The laissez-faire approach to teenage pregnancy, in contrast to
2. The decisiveness to improve adherence on discovery of pregnancy

OI21 was critical of her lack of drug-specific information and how it had contributed (in her view) to ill-informed treatment taking decisions at the time of pregnancy discovery. Faced with a similar dilemma of taking sodium valproate, one woman recognised her impatience and intended to switch treatment to avoid missing her opportunity:

OI04: I want to do it now, when I've got no plans what so ever of having a baby and do it safely. So it's the Keppra just in my system for a couple of years, on its own. And as I say, even if I did get caught pregnant by accident,

either I'd be doing the folic acid long term by then anyway, and so I wouldn't have to worry about that, and I wouldn't have to worry about the quick come off the Epilim, because I'd be already off it and I'd have been off it for a few years, hopefully [...] I'm thinking if it does come to a point where I want to have a baby, so, I'm thinking I won't be able to wait three months for the folic acid and, I'm not soft, it's a very serious thing, so I would, but I'd find it very hard and that's where I'm thinking I might find it really, really stressful because I'm too over excited, and I'm annoyed because I want to get it over and done with.
(27 year old, future pregnancy intentions)

The opportunity to take early action implied a responsibility on both the woman and on their clinicians to make appropriate recommendations and provide the necessary reassurance about the benefits of early intervention. In the case of participant OI10, the practical barriers to deciding to act are illustrated. She had visited a neurologist twelve months before the observed appointment and delayed taking action:

91. P: ... and at the time we weren't thinking of having a family or
92. anything, so I just thought, because he said to me you'd
93. have to come off the tablets, and, well he said it was up to me. But,
94. he said, I could come off my tablets, but that means I'd
95. have to stop driving and all the rest of it. And because we weren't
96. planning a pregnancy then, I just said well I'll stay as I am
97. then because I want to carry on driving. But since then we
98. have started/ talking about it.
99. C: /Changed your mind, and you are 29 now,
100. anyway now aren't you/
101. P: /I'm 30 now, yes
(OI10; 30 year old, immediate pregnancy intentions)

The outcome of OI10's consultation had been to commence drug withdrawal, a recommendation which had been made a year earlier. The delay in implementation had resulted from OI10's assessment of her readiness to consider family. The timing of decisions to make changes was frequently referenced by women as presenting missed opportunities. Attempting to salvage a missed opportunity, several participants considered the ability to benefit from drug changes after discovery of pregnancy:

- OI05: But obviously if you just, if you get pregnant and then you say, well what do I do now? Then it's kind of you've, it's like you're rushing things really. If you kind of maybe, do it earlier, then you have to do, like change medicine that you need to do, than that I think is a lot better.
(29 year old, pregnancy intentions not stated)

8.3.3 Negotiating the preferred outcomes of pregnancy planning

Negotiation was a feature of decision-making, and questions were asked by both clinicians and women to challenge each other's beliefs. For some women, a failure to receive a clinical opinion resulted in seeking a second or third opinion. For others, managing disagreements and conflict also required acceptance of compromise in preferred pregnancy outcomes, including acceptance of the least preferred treatments or considering delays in conception until alternative treatment options had been fully explored. The development of shared treatment plans focused upon the preference for best treatment and/or seizure control. Participant OI09 presented her preference to the clinician in response to enquiry about pregnancy plans:

41. P: ... thinking about it [pregnancy] within the next year, but, it's to
42. do with the medicine because as I said last time, I think my
43. neurologist from the other hospital said this is not a safe
44. combination.
45. C: Well, lamotrigine or Tegretol itself is {safe}, fine, or safe,
46. reasonably safe. I mean nothing is safe even though you don't take
47. the medication there's no 100% chance that you will have a healthy
48. baby {No} [...]
[...]
54. C: /If you are on only one
55. P: That's what I was thinking. And I was thinking if I had to be
56. on one/
57. C: /Which one?/
58. P: /I have had carbamazepine, I know its
59. worse, not worse but stronger, but I know that has worked before
60. and I've never had lamotrigine by itself so I don't
61. want to try and mess with something that I've never had [...]
(OI09; 29 year old, future pregnancy intentions)

The dilemma of competing interests between self and baby were countered by the effectiveness of AEDs to stop seizures versus the immediate priorities in life and the need to maintain the status quo, resulting in women searching for the ideal safe option. In the case of OI04, her preference to remain on polytherapy with sodium valproate was judged a short-term measure, grounded in her unstable home circumstances. OI04 agreed with the clinical recommendation to withdraw sodium valproate at a future date before pregnancy, and to avoid accidental pregnancy in the interim:

436. C: Ultimately any treatment choices are yours, we aren't telling you
437. what to do it's just suggestions and you are weighing up the risks
438. and benefits of any medication change for yourself. So if you are
439. happy to leave things as they are at the moment then that is fair
440. enough. Just make sure that you don't get pregnant, if you can.

441. P: I know, God you know, that is the last thing on my...
(OI04; 27 year old, future pregnancy intentions)

Non-adherence to recommendations implied women's preferences not matching those of the clinician, exemplified by participant OI02; who had received recommendations to switch from sodium valproate during previous clinic visits, but preferred to defer decisions. Clinical recommendations which emphasised the dangers of actions taken, whether highlighting the dangers of accidental pregnancy on sodium valproate or suddenly stopping treatment, were cited as an influence by several women. The influence, however, was not always to direct acceptance of clinical recommendations as illustrated by OI02s response:

- OI02: The risks scared me but I've had that before, exactly like the first time I went into see the nurse, even more scary then [...] I know that there can be something wrong with my baby if I got caught pregnant now. Obviously no one wants anything wrong with the baby, surely try the best for anything, to make sure that nothing like that happens. But it's just the lamotrigine I'm just scared of getting on to it really, and fitting. I'm just nervous [...] it's just risk in everything that I do, it's just. It's horrible.

It was typical for the clinician to ask the patient's opinion concerning seizure control and treatment as a means of reviewing consensus about the treatment plan. This type of questioning supported the patient revealing concerns or changes of opinion which might have occurred. From the clinician's perspective, these questions assisted their appreciation of the patient's overall preferences and opinions relating to their desired approach to seizure management. OI20 had questioned the action to stop treatment if she became pregnant, resulting in the clinician's recommendation to reduce her dose down to the lowest to maintain acceptable seizure control and warning against abrupt withdrawal. Despite her initial action in adhering to the clinician's advice, in the time between observation and interview OI20 found out she was pregnant and stopped her treatment:

- OI20: you just feel like a bad mother, don't you, just filling your body full of drugs, and I just, I don't know. Because obviously you want to give your kid the best start in life, don't you and I just feel like I'm not, with the drugs, putting the drugs in? [...] I'm still taking the folic acid ... but I just feel bad in myself pumping my body full of drugs. I just feel like just a bit selfish looking after myself like, when you should be looking after two really isn't it. (30 year old)

OI20's decision to stop treatment revealed her preference to value the health of her baby in preference to valuing her own health and seeing herself as 'a bad mother'. The opportunity to consider drug withdrawal prior to pregnancy was a treatment option offered mainly for women in remission. The need to amend prior assumptions about treatment preferences included revision of intentions to withdraw treatment. For OI23, her initial agenda had revealed her concerns about seizure relapse, which were later revised as she decided to begin drug withdrawal:

OI23: Yes I have just changed everything around, decided to start reducing my medication [...] well I have actually dropped down my first 100mg two weeks ago, and that night I didn't sleep at all, I was absolutely petrified. But then after that, I've been really positive, and I think because the decision has now been made. I feel it's out of my control, and to what will be will be sort of thing [...] But my goal is now just to try and get it as low as possible. Because I thought well anything has got to be positive hasn't it. So I am not thinking about if I do have a baby, what it's going to be born like. I'm kind of accepting, I'm just doing what I can
(OI23; 30 year old, immediate pregnancy intentions)

Patient preferences for seizure control were variable. Many women struggled with needing to weigh preferences for their own health or social needs against those of a future child. Participant OI22 illustrated the value of preserving seizure control:

OI22: women do want to maintain their lifestyle, and it's not through being selfish for the child, you almost have to have a lifestyle to look after it.
(32 year old, immediate pregnancy intentions)

Other participants expressed a preference to avoid changes to seizure control, such as experiencing seizure during the daytime:

OI04: One thing that worried me [...] if I was to just suddenly have a fit in the day, and I hadn't been asleep, would anything like that? I think I'd actually have a heart attack; because to think oh my god my world's turned upside down now. (27 year old, future pregnancy intentions)

Several participants stressed the importance of the clinician's role as a guide to advocate on behalf of their best interests. Their comments implied the clinician's role as mediator, to guide patients away from 'risky decisions', and to highlight the potential unforeseen consequences. This was exemplified by OI07, whose motivation and eagerness to proceed with switching drugs from sodium valproate to lamotrigine after a brief description of drug risks was deferred by the clinician, advising the importance of additional information and discussion:

224. P: Yes I mean recently I got engaged so we both want children and
225. I'm 32 now so I think I better get a move on.
[...]
247. C: It is not an incredibly high dose of Epilim {yes} it's a fairly
248. standard dose. But at that dose we have found significant problems
249. already, OK {right}, and lamotrigine would be essentially a safer
250. drug. I think instead of going ahead and you know through the
251. change over straight away, erm because you are not in a sort of a
252. rush to become pregnant are you.
253. P: No we do want to get married first anyway so I guess
254. C: So we have time to go through further discussions and we have
255. an excellent epilepsy team here and you can have further
256. discussions with the [title of clinician].
257. P: Right OK (OI07, 32 year old, future pregnancy intentions)

For OI07 the clinic outcome had been a second visit to receive further information concerning the alternative treatment options. However in the time between observation and interview, OI07 experienced a prolonged seizure resulting in admission to intensive care. The experience of seizure resulted in OI07 reflecting on her opportunities to change treatment, the added motive had been her loss of confidence on her current treatment, and the loss of driving (not illustrated):

- OI07: ... once you are given that information, you do need to think about it and make some decisions. Whether you want to even think about changing your drugs and things like that, so I think it was better the way its been done

The role of the clinician in mediating the patient's involvement in decision-making was exemplified by informant OI17's case who had attended her initial appointment with her mother. The mediation of the clinician enabled the OI17 to challenge her mother's aversion to treatment change:

- OI17: ... basically I've had treatment for nearly 20 years I mean my family have been dead set against it because they thought I am going to have fits because I've changed my medication. But at the end of the day I was already having those bloody fits, wasn't driving, I can't work at the minute so why not change and I think [clinician] was really, really good because my mum is kind of over protective over my epilepsy and she sort of said if your daughter has made her mind up, she's made her mind up.
(OI17, 33 year old, future pregnancy intentions)

The opportunity for participants OI07 and OI17 to consider alternative treatment options were further motivated by their loss of driving licence, meaning they had less to lose even if the AED switch did not proceed according to plan. Further, in the case

of OI17, her knowledge of fetal valproate syndrome had influence upon her treatment decision:

OI17: I think maybe that's why I decided, I mean I hadn't heard of anything called lamotrigine syndrome...

The majority of women felt challenged by the unpredictability of their condition and, for some, this extended to the uncertainty of the risks of inheritance. This presented new challenges as interventions were not available to influence the outcome of inheritance. The preferred outcome of pregnancy was a healthy non-disabled baby, and women preferred their baby not to have inherited epilepsy – a point exemplified by a 21 year old who had questioned her ability to cope with the outcome:

FG12: I know it sounds pathetic but one of these days if I was to have a child, and if the child was to be born with epilepsy, I would, I couldn't help but feel that would be my fault and I couldn't help but, I'd be constantly waiting for that day when that child would turn around and say to me "mum, how would I, how did I get my epilepsy?" what would you say back to that child "erm, well I passed it on to you. By the way, I passed it on to you"? I know it's not your fault but it'd be one of them things that you have to live with every day of your life

The selection of preferred pregnancy outcomes was reliant on receipt of risk information to support consideration of the positive and negative outcomes of decisions made to change treatment, whether the outcomes affected their own health or that of a future baby, and whether the positive or negative outcomes were acceptable. Participant FG71 reflected on her experience of agreeing to take AEDs during pregnancy:

FG71: To get all the facts, to know everything it's really important I think, because nine months is a long time, to wait, you're carrying that little baby around. I mean when we were waiting for [name of eldest child] to be born, to see whether he's going to have a deformed lip. That was like the worst ever. But, it was my choice. Even though, I was still on edge and worried. It was *my* choice. And if he was born with a, hare lip, then there was, they told us there was operations, and. So there are positives all the time. There's always, a way out of things. (45 year old)

Participant FG71 highlights the comfort she had taken from her receipt of information about the management of cleft lip abnormalities, while she had remained hopeful for the best outcome of her pregnancy.

Pregnancy related decisions were made in response to information, and through the processes of risk communication women responded to treatment recommendations and interventions to negotiate their preferred approach to their first and subsequent pregnancies. The case of participant OI16, who had a 12 year son, revealed her ambivalence towards a future pregnancy and preference to increase her dose of sodium valproate to improve seizure control and improve her own quality of life. OI16 accepted the clinician's warning of potential future risks if she were to plan pregnancy, revealing her decision to restrict family size had been influenced by the unpredictable risks of seizures:

OI16: I think a lot especially if I am going to have kids in the future... I think about it that much that I'm thinking I might not have any more kids because of my epilepsy. Because especially at night, I find it very difficult, if I'm up too long, I don't get enough sleep and things like that, how am I supposed to do it, if I am going to have another, a baby? Because when I had my boy, I dropped him a couple of times because I had a little jerk and that's kind of like put me off as well, having any more kids.
(29 year old, pregnancy intentions not stated)

The discovery of pregnancy in women who judged their pregnancy as planned also resulted in a struggle to feel comfortable with the possible outcome of their preconception decisions:

FG124: I mean, you know read up as much, I mean probably excessively but as I said I still decided to go ahead but I mean I was happy with the lamotrigine [...] I didn't really enjoy my pregnancy as I wanted to because I was just a nervous wreck for 9 months [...] so I'm 8 weeks now and I haven't told anybody {Group offers congratulations} [...] I mean it is planned and this is what I want but it is just going to be a whole 9 months now of fear but obviously it has been okay the first time round I just hope it is the same again. (32 year old)

Negotiation was central throughout the process of preconception decision-making, and women relied on the provision of information and clinical opinion before making decisions, needing to be aware of the available options to support advanced planning.

8.4 Summary Results: Decision-making in preparation for pregnancy

- Decisions to review pregnancy plans were motivated by the need for additional information, advice and reassurance. Decisions to avoid or delay the approach for review were influenced by assumptions about the anticipated content of advice and information, and by the prior experience.

- Decisions concerning life-style changes were interpreted as a natural part of life (e.g. moving in with a partner, getting married, starting or stopping contraception and deciding to try to conceive) and were not seen as being part of the epilepsy clinic agenda. Updates on preconception information were an opportunity to introduce these topics into routine epilepsy review.
- Judgements concerning the preference for, and acceptability of, decisions made concerning future pregnancy plans were not static and were subject to change. This point emphasises the potential influence of new information on prior beliefs and the need to update preferences.
- Negotiation of pregnancy decisions refers to the sharing of treatment preferences. The preferences of both clinicians and women were not static and were influenced by changing opinions, changing trends in prescribing and the influence of new information.
- Decisions concerning preferences for pregnancy were emotive and influenced by the content of the risk message and the situation of its delivery. These were influenced by the presentation of available options and the emphasis of responsibilities towards the health of the future baby.
- Informed decision-making was dependent on having a trusting relationship with a consistent health care provider able to provide the 'best advice', which included: sufficient time for women to consider the information provided, supported questioning and provided direction to trusted sources of additional information.
- Women were found to require practical and emotional support when making changes with treatment due to the fears of the impact of changes both upon seizure control and life-style.
- Fearing the consequences of decisions made about treatment (whether to remain on treatment, switch to an alternative or withdraw treatment) did not always result in adherence with clinical recommendations due to the uncertainties of predicting individual response, and the uncertainties surrounding the impact of AEDs on the health of the unborn child.
- Risk benefit assessments supported decision-making and women anticipated a proposed treatment plan, which was agreed without compromise, amended or rejected. Negotiation of treatment changes needed to address women's anticipation of time commitment.

Chapter 9 A model of preconception counselling

Introduction

The preconception counselling model draws together the study findings of the three inter-related substantive themes of ‘pregnancy planning’, ‘communicating risk and uncertainty’ and ‘decision making in preparation for pregnancy’. This chapter describes the development of a model of preconception counselling (see Figure 9.1). It illustrates the ‘pregnancy contemplation ladder’ with supporting evidence, before testing the model’s explanatory function through analysis of women’s interpretations of making ‘selfish decisions’ in relation to preparation for pregnancy.

9.1 Description of the model of preconception counselling

The aim of developing a model for preconception counselling (the model) is to help target the delivery of interventional activities that mirror the reproductive life-cycle of women, while recognising the inconsistencies seen in clinical practice in relation to decision-making both from a clinician and patient perspective. The model targets promotion of shared decision-making as an approach to elicit patient preferences and practically support decision-making within the context of uncertainty, when the ‘right’ decision depends on the patient’s own needs and outcome goals (Coulter and Collins, 2011, p.11-12).

9.1.1 The pregnancy contemplation ladder

The model has been developed as a bi-directional continuum to reflect the interventional stages required to accommodate the changing life circumstance, motivations for pregnancy, and preferences for risk management experienced by WWE. The model builds upon existing social cognition theories including self-efficacy, risk perception, planning behaviours, and outcome expectations as active at differing stages of behaviour change (Whitelaw et al., 2000) - a point emphasised in Biener and Abrams’ (1991) Contemplation Ladder, which was originally developed to identify an individual’s motivational stage to consider smoking cessation. The ‘contemplation ladder’ and other stage theories have been applied to predict reproductive health behaviour change, including folic acid consumption and condom use (Prochaska et al., 1994; Milan and White, 2010).

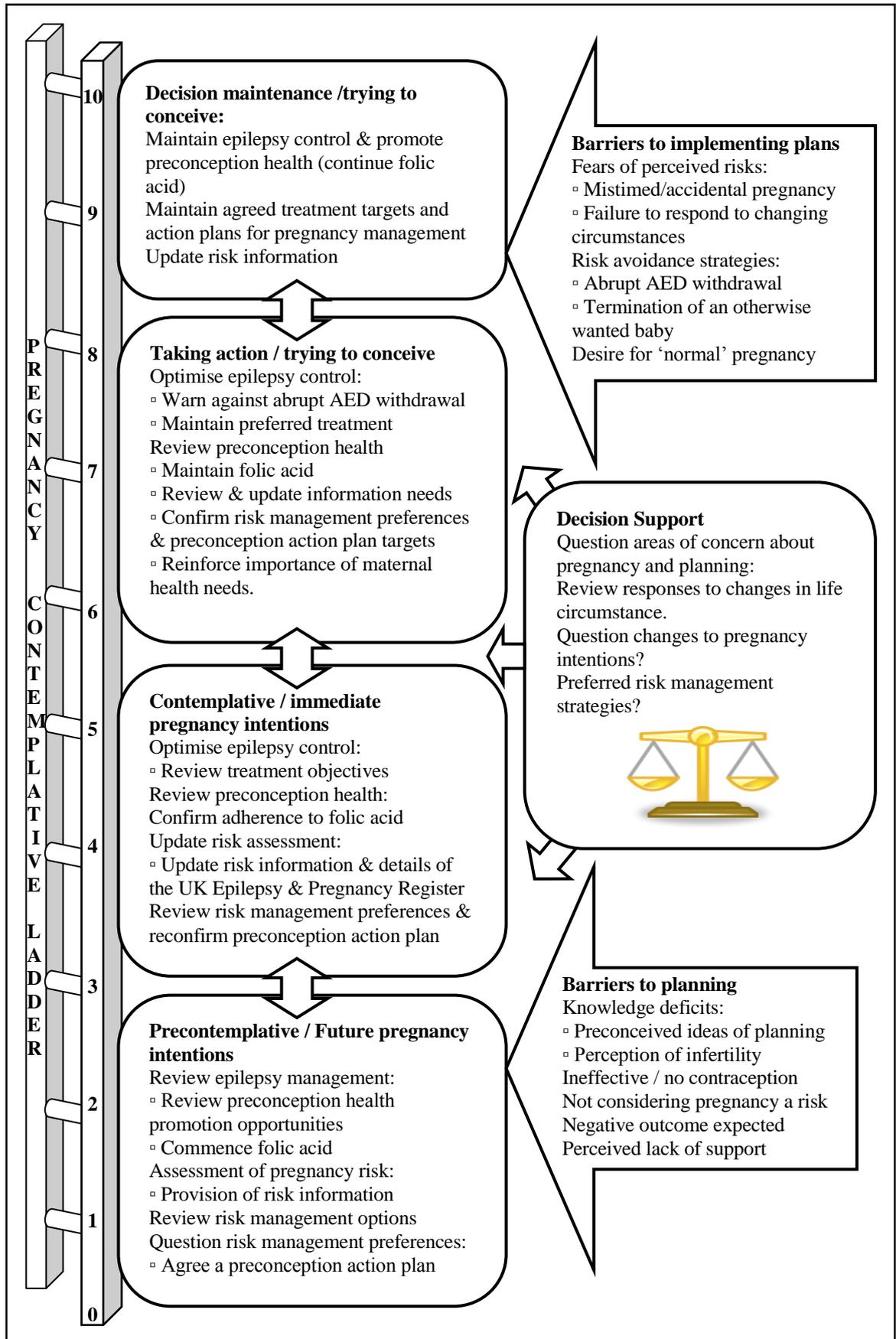


Figure 9.1 A model of preconception counselling

The model (Figure 9.1) presents a 'pregnancy contemplation ladder', which was adapted as an indicator of readiness to prepare for pregnancy. Each rung of the ladder represents the position an individual is at in their stage of thinking about the health behaviour, such as in Biener and Abrams' (1991) 'contemplation ladder' where the first rung indicated 'no thoughts of quitting smoking'. Within the model each rung indicates a stage of pregnancy intention. The stages of change are ranked in order of level of pregnancy intention, from: no thoughts of pregnancy (precontemplation), beginning to think about pregnancy in the future (contemplation), through to deciding to try and conceive (taking action) and maintenance of preconception behavioural change during the interval between trying to conceive and conception (maintenance). The relevance of adapting the 'contemplation ladder' to predict pregnancy intentions and readiness to action preconception health recommendations relied upon making an association between Biener and Adrams' (1991) validation study developing a single-item self-report measure of an individuals motivational stage, and the psychological concept of motivation. Motivation is influenced by risk perceptions and perceived threat (such as, considering the risks of treatment in relation to the risk of experiencing accidental pregnancy, as motivation to use contraception), which help to stimulate outcome expectancies (such as, considering the use of contraception to prevent accidental pregnancy and reduce the risk of experiencing pregnancy on a least preferred treatment), which further stimulates self-efficacy (such as, confidence in preventing pregnancy until completion of a treatment change) (Schwarzer and Fuchs, 1995).

The contribution of the 'contemplation ladder' to the present study findings was the potential to assess a woman's pregnancy intentional stage and thereby target preconception interventions likely to motivate positive changes in reproductive health behaviour. The contemplation ladder has wider application within the present study, and figure 9.2 illustrates my own adaptation of the ladder for WWE considering commencing folic acid, a stage which represents women at the precontemplative stage of pregnancy intentions within the model.

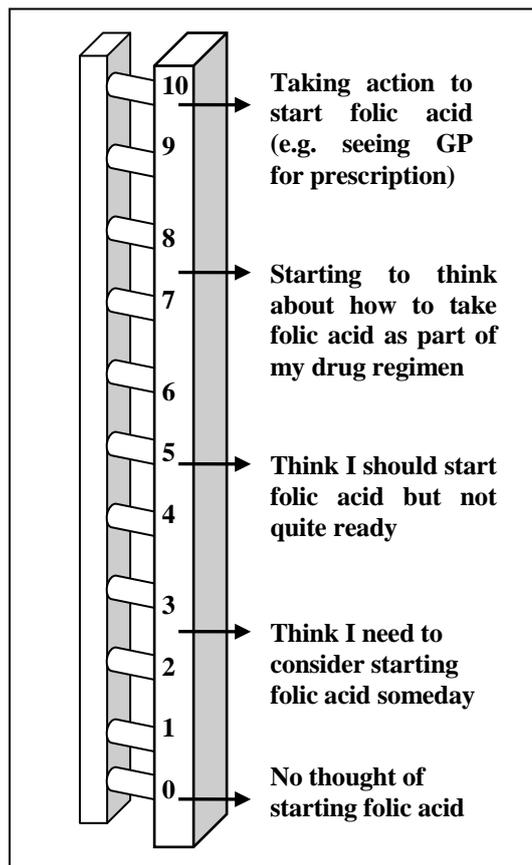


Figure 9.2 Contemplation ladder

(Adapted from: Biener and Abrams, 1991)⁴³

The contemplation ladder addresses the motivations expressed by women as they consider approaching their GP to access referral for preconception counselling; representing the contemplation stage (steps 3-6). This stage involves women reviewing AEDs, continuing contraception, commencing folic acid and seeking information such as internet searches or contact with voluntary organisations.

FG-I-03: ... you plan to get pregnant, you can plan that yourself sometimes, can't you, or it just happens and it's a happy accident or whatever. But I think planning it while you're epileptic is a lot to plan, I think. (23 year old)

The model recognises the bi-directional staging of pregnancy planning reflecting the experiences of WWE; which requires interventions to focus on both optimisation of seizure control and pregnancy intentionality, while remaining sensitive to the communication of risk messages as motivation for women to adhere to clinical recommendations, and their completion ahead of decisions to try to conceive (Schwarzer and Fuchs, 1995, p.163-4).

⁴³ Reproduction of the contemplation ladder with permission from Professor Lois Biener (02-07-12)

9.1.2 Contemplating pregnancy

Awareness of the importance of planned pregnancy was critical if women were to make timely access to epilepsy review, and was a pre-requisite to supporting informed decision-making, illustrated by a 34 year old pregnant participant reflecting on her experience preparing for her first pregnancy:

FG96: I know I went, before I thought of becoming pregnant the first time, I just went to the GP, because of the sort of conversations I'd had with the epilepsy nurses over the years about getting pregnant, and having to think about it with this history... He [GP] referred me to the, is it the preconception clinic, or something like that, but also said, there's no particular concerns just carry on... by the time I got the appointment for this preconception clinic at the hospital, I was actually pregnant, so anyway, that was sort of superseded by events. But, it was quite reassuring, it was the sort of medical advice really, I think. By the time we'd made a decision to start trying, we didn't do anything until we went to see the doctor [GP], and then, he said, that no particular issues, but had he, had that advice been slightly different, then that would have influenced me

The reassurance she reported from her GP had inadvertently reinforced her attempts to conceive, rather than delay pregnancy until she had attended preconception review. This action had acted as a barrier to opportunities to improve pregnancy outcome by reducing preventable adverse risks before conception. The experience of FG96 reflects a common experience of women presenting pregnant at the time of preconception review as a consequence of making separate decisions: initially deciding the stage of immediate pregnancy intention; secondly, deciding to stop contraception; and thirdly deciding to attend clinic. The significance of this finding is its ability to shed light on the failure to associate consequences of separate/isolated decisions (involving behavioural actions), all of which have influence upon the effectiveness of preconception counselling to reduce adverse pregnancy outcomes.

9.1.3 Stages of pregnancy intentions

Women made changes to their pregnancy intentions in response to personal circumstances (changing relationship status) including, motivational influences (for example, changes in job or career influencing timing to commit to family plans), changes in epilepsy control (the relapse of seizures, or changes with AEDs), and in response to new information. Participant OI01 exemplifies changes in pregnancy intentions:

186. P: [...] if you'd of asked me 3 years ago, I'd

187. of said no children ever. But I don't know, once you are happy with
188. somebody you kind of change your perspectives doesn't it. So,
189. yes, I mean, if an accident happened, then, you know, I would be
190. quite happy with that, but I mean, I'd be looking within maybe the
191. next 2, 2 or 3 years. (OI01; 29 year old, future pregnancy intentions)

An important barrier to implementing preconception interventions was perceived infertility, exemplified by a sub-group of women who interpreted their failure to experience accidental pregnancy as proof of their infertility. Not using contraception was a barrier to accessing preconception review and resulted in mistimed and 'accidental' pregnancy:

OI16: I just thought yes I'm getting married now, and in the future I'll have kids, you have all these thoughts when you are a young girl, you're going to get married, have kids. I just thought OK I'll get married, and we'll see what happens and then I got pregnant.

Interviewer: Yes, so a bit sooner than you anticipated?

OI16: Oh yes. Definitely (29 year old, 12 year old child)

The experience of surprise for OI16 upon discovery of pregnancy despite not using contraception reveals knowledge deficits concerning fertility, and implies not being adequately prepared for pregnancy. Women were receptive to opportunistic reminders of pregnancy planning activities and updates of their information needs. Women taking action on the provision of information and requesting preconception epilepsy review (contemplators) were receptive to recommendations to alter AEDs and commence folic acid. For some, this extended to accepting health promotion activities such as stopping smoking and abstinence from alcohol, especially when reinforced by information about the health benefits. In contrast, precontemplators were defensive about recommendations to make changes to their epilepsy control, as they lacked the motivation for change, and the potential outcome of destabilizing epilepsy control for some was judged as a higher risk than a future pregnancy.

9.1.4 Acting-on pregnancy intentions

Pregnancy intentions, expressed as a woman's desire to try to conceive represent the decision to engage in behaviours likely to result in the desired outcome (pregnancy), such as withdrawing contraception. Eleven focus group participants were pregnant at the time of participation. Five of these referred to their pregnancy as planned, defined by some level of intentional behaviour change prior to conception (stopping or

reducing smoking, discussion with epilepsy specialist, maintenance or commencement of folic acid and/or stopping contraception). Of the women experiencing unplanned pregnancy, two, were in their second pregnancies, had received preconception counselling prior to their first pregnancy and had not returned for preconception update. Another woman experiencing her third pregnancy had attended preconception review in preparation for her second pregnancy, while her current twin pregnancy (7 months gestation) was reported as a surprise (both in relation to her experience of pregnancy despite reporting use of condoms, and in relation to her discovery of twin pregnancy). One 23 year old participant (FG84) admitted to thinking about pregnancy in response to several of her friends becoming pregnant and, whilst her own pregnancy was unplanned and complicated at conception taking high dose sodium valproate⁴⁴, FG84 reported her response to pregnancy discovery as being ‘absolutely made-up’ tempered by ‘finding it hard to come to terms with’:

FG84: I started to read up on everything I can about pregnancy and epilepsy and all these websites I went on I just broke down because it showed you all these pictures of deformed babies with cleft palates (1st pregnancy)

In contrast, women were able to be supported to plan pregnancy and benefit from engaging in preconception health promotion, for example, commencing folic acid ahead of withdrawal of contraception:

FG124: I think you just try to because of the risks, the high risks that you have with your medication, causes high risks and things. I think I just try to compensate thinking if I can eat healthier and just daft things like. So that was part of my planning I tried to be healthier. (32 year old, 2nd pregnancy)

9.1.5 Preconception counselling interventions

The model challenges women’s preconception health beliefs by raising awareness of the benefits of taking action in advance of pregnancy intentions, thereby increasing preconception folic acid consumption and improving overall preconception health. By challenging beliefs of pregnancy risk and fertility status, targeted preconception interventions will support informed decision-making regarding contraceptive use and practice, thereby assisting women better time conception. Knowledge deficits about folic acid use and its value in preconception risk reduction were barriers to making an informed decision-making about commencing supplementation prior to attempting to

⁴⁴ The significance of women of childbearing age taking sodium valproate is discussed in greater detail in Chapter 2, highlighting the dose-related congenital malformation risks and dose-related risks of neuro-cognitive delay and conditions such as fetal valproate syndrome.

conceive. Recommendations from the clinician and supply of a prescription for folic acid improved women's adherence despite having knowledge deficits:

FG111: [Clinician] told me about this the other day. It decreases if you are on more than a 1000mgs with Epilim this is just what I know, then you have got a 10% chance if you give birth to your child is going to have 6 fingers or spina bifida. I have only got like a 5% chance of it but if I take folic acid it would like cut in half. So I'm not sure what they do but it must be good [...] I was just told that because I have been with my boyfriend for, so it is like a long-term relationship, that the doctors put me on it [folic acid] just in case. And that was it really that was all they told me. (16 year old)

9.1.6 Risk communication

Risk communication is required at all stages of pregnancy contemplation. The differing needs for increasing women's awareness of potential risk, and their needs for risk information in response to their stage of readiness to plan and take action to try and conceive must be taken into account. In contrast, the barriers to implementing planning activities included women's emotional responses to risk information, and their preference for information which emphasised the certainties of drug-specific risks rather than uncertainty. The emotive responses to risk information were also shown to result in women making decisions based on the powerful imagery of risks to the future unborn baby.

The discovery of pregnancy has been described by several women as arousing their fears concerning the risks associated with continued AEDs use and/or their experience of seizures and the consequences upon the health of the unborn baby - a response suggested as 'the fear setting in'. The implications of fear arousal were to heighten the perceived threat of adverse outcomes:

FG75: finding out you're pregnant, and you've got epilepsy. It's amazing, but there's also that element of fear of the implications. And then, when you've had the baby, how the isolation. But also the, if I have a seizure, and I'm looking after my baby, bathing my baby, blardy, blardy blar, am I going to be me more prone to postnatal depression? (26 year old)

The model focuses upon interventions that develop personal coping strategies, by assisting women develop preconception action plans and supporting their involvement in appraising the available options to manage future pregnancy risks. Women will be supported to question their risk management preferences within preconception and epilepsy review visits.

9.1.7 Barriers to planning and implementation

The model focuses on addressing knowledge deficits, for example, prior assumptions and misinterpretations of pregnancy risk as significant barriers to women engaging with epilepsy services prior to pregnancy. The conflicting definitions held by some women and clinicians of what preconception counselling is, along with predetermined ideas of what pregnancy planning might entail, resulted in women failing to recognise the significance of health warnings to complete changes of treatment prior to trying to conceive, or to commence folic acid and securing effective contraception during preconception review.

9.1.8 Decision Support

The purpose of decision support is to prompt consideration of the ‘pros and cons’ of pregnancy planning at all stages of pregnancy contemplation. The questions focus on preferences for pregnancy preparation, in which the ‘pros’ are seen as the strength of motivation to action preconception recommendations, while the ‘cons’ are the disadvantages and perceived negative outcomes of the proposed preconception interventions.

Successful preconception review requires women to make judgements concerning their intentions for pregnancy and to establish goals for achievement of a planned pregnancy. This requires changes in behaviours and attitudes concerning pregnancy and perceptions of pregnancy-related risk. The support is intended to reflect women’s requests for assistance in engaging in preparatory discussions concerning future pregnancy intentions, by opportunistic questions about changes to intentional status, and review of their likely responses to changing circumstance so that appropriate interventions can be targeted.

9.2 The ‘selfish decision’

The sub-theme ‘selfish decision’ emerged as an extremely emotive response to describe decisions to have a baby and as a rationale for risk management, which I felt required further investigation in the context of the model.

9.2.1 Participant cases constructing the ‘selfish decision’

The majority of women referred to managing their emotions surrounding the decisions they made during preparation for pregnancy as a necessary stage they had to endure, seeking to defend themselves against any potential criticisms by defining their decisions as, one, being justified, and two, what any woman would have chosen under similar circumstances. Emotional responses influencing women’s decision-making have been shown to include blame and guilt and to result in anxieties, worries and fears, and for a sub-group extended to include concerns about being identified as ‘selfish’. Table 9.1 illustrates the word frequency of the terms selfish and selfishness in comparison to more common terms such as risk, pregnancy and planning, 43 instances were found of the term selfish/selfishness in relation to reproductive decisions made within 16 participant accounts (19% of the total population)⁴⁵. The term ‘selfish decision’ in the context of reproductive decision-making implied women had a free and open choice of a range of differing options. However, the reality for many women was of epilepsy management presenting a polarized choice between trying for a baby and accepting the pregnancy-related risks or accepting not having a child. Seizure freedom as the goal of epilepsy management resulted in women being presented with choices either to withdraw treatment or to manage self regret if a future child were to have a disability.

Word frequency			
	Study stage 1 Focus Group	Study stage 2 Clinic observation/Interview	Total
Self	51	38	89
Selfish	5	57	62
Selfishness	4	7	11
‘Selfish decision’	6	37	43
Risk, risky	549	1383	1932
Pregnant, pregnancy	905	1455	2360
Plan, planned, planning	532	615	1147

Table 9.1 Analysis of transcript word frequency

9.2.2 Placing personal interests ahead of the needs of the future child

Table 9.2 summarises the interpretation of ‘selfish decisions’ as those decisions made by women placing their own personal interests ahead of the health of a future child.

⁴⁵ Nineteen percent of the total study population referring to a ‘selfish-decision’ appears high, however, many women made a single references (6 participants), whereas one participant (OI23) refers to her selfish-decision in eleven instances.

Whilst the majority of women found an acceptable balance between meeting their own needs and those of the unborn baby prior to conception (Chapter 7, Section 7.2), exploration of the process of assessing risk information by women who interpreted their pregnancy decisions as selfish implied a defence against perceived future criticism of their responsibility to meet the interests of the unborn baby prior to conception.

Stacey et al (2011) has shown the value of decision support in promoting shared decision-making in her Cochrane Systematic Review evaluating the support needs of people facing treatment and screening decisions. Decision aids were defined by Stacey et al (2011) as evidence-based tools designed to prepare a patient to participate in decision-making. Decision aids should ‘provide detailed, specific and personalized information’ about a health condition and the ‘benefits, harms, probabilities, and scientific uncertainty’ concerning the treatment decision. The goal of using decision aids is to increase the patient’s awareness of the ‘value-sensitive nature of the decision’, and ‘provide structured guidance’ in the steps they need to consider when making a treatment decision’ (Stacey et al., 2011, p.3). These authors identified the need to improve informed values-based choices when patients are presented with differing treatment options, where ‘choices’ between treatments are offered, and where each option has benefits and harms which may be valued differently (Stacey et al., 2011). Stacey and colleagues (2011) found decision aids were found to be ‘more effective than usual care to improve patient’s knowledge of their treatment options’ (p. 19). Interventions using decision aids were found to improve the accuracy of patient perceptions of their outcome probabilities and reduce decisional conflict. Stacey et al (2011) felt these findings were clinically important, concluding ‘usual care may not be good enough when informing patients about complex, value-sensitive decisions’ (Stacey et al., 2011, p.19).

The context of making of a ‘selfish decision’ which resulted in bring a disabled child into the world was interpreted as being selfish as a consequence of placing of one’s own desires or interests above those of the baby, or deciding to have a baby despite the presence of additional risks and uncertainty. Expanding on the latter point, several women struggled to cope with their pregnancy-related decisions and defined themselves as selfish because they had not felt able to imagine a future in which they

could cope with, care for or love a disabled baby. The finding that decision aids were not used within the observed epilepsy consultations, may have resulted in some women experiencing decisional conflict. These findings led to the development of the model of preconception counselling, as a means of supporting women as they considered pregnancy decisions; decisions that were felt to be both complex and highly sensitive.

Participant ID & pregnancy intentions	No. of quoted instances	Participant definition of ‘selfish decision’
OI23 Immediate	11	Preference to stay on AEDs to avoid seizures and blame for disabled child
FG-I-01 None	2	Preference to avoid deterioration in seizure control
FG84**Unplanned pregnancy	1	Mature approach to improve seizure control, sign of being a good Mum
FG86**Planned pregnancy	2	Preference for safety net of Epilim to maintain seizure control
OI17‡ Future	4	Duty of parent to protect baby from risk
OI13 Future	2	‘Fairness’ to desire a child and motive to plan pregnancy
FG123 None	1	Restriction of family size due to epilepsy
OI22 Immediate	4	Preserving lifestyle, selfish towards future child
OI12 Future	3	Focus on personal lifestyle preferences, avoidance of disability
OI01 Future	1	Prioritise personal healthcare and priority towards future child
OI20§ Immediate	5	Not wanting a child with disability, inability to cope with disability
OI10 Immediate	2	Justification for not wanting a child with disability
OI04 Future	2	Avoiding inheritance risk, dilemma of partner’s family history of epilepsy
OI05 Not stated	1	Avoid parenthood in relation to probability of child’s inheritance risk
OI21‡ Future	1	Avoidance of guilt associated with a 2 nd pregnancy taking Epilim
OI08 Future	1	Judgement of ‘others’ concerning acceptable risks
§ (OI20) conceived shortly after index consultation, intention was immediate at clinic observation with no prior experience of pregnancy. ‡ (OI17 & OI21) participants experienced termination of pregnancy, OI21 due to in utero diagnosis of spina bifida. ** (FG84 & FG86) participants in 1st pregnancy at recruitment and focus group participation.		

Table 9.2 Defining a ‘selfish decision’

The terms selfish and selfishness were also used in response to the perceived public moral judgement either directed to them as a woman with epilepsy allowed to have a baby, or towards their abilities to care for a disabled baby as a mother with epilepsy. This revealed the complex dual focus of identity transitions - from a woman contemplating her future pregnant and motherhood identity, while simultaneously constructing the identity of their future fetus (this stage is significant as only 3 participants in this analysis were pregnant at the time of study participation).

9.2.3 Decisions to conceive

Selfishness was used to defend decisions: either not to have children (FG-I-01), or have children and accept the status quo. In the case of FG-I-01, the decision not to have children shed light on her beliefs about unmanageable worsening seizure control if she acted on her pregnancy intentions. FG-I-01 reflected over the decisions she had made when she had contemplated pregnancy and the uncertain disruptions to her seizure control caused by changes to AEDs and commencement of folic acid, both of which were felt to cause unforeseen adverse reactions, and finally within pregnancy and future motherhood, the influence of added stress and sleep disturbance:

FG-I-01: I used to work with a girl ... she was epileptic and she had a family ... she had really bad seizures because she was coming off her medication, and having the folic acid ... But she'd gone through it, she carried on through it And I don't think I could. In a way really I suppose you could say I'm too selfish for it, because I didn't want the pain of sort of like, and the knocking of confidence if you like. To go through all that ... now my immediate thought with kids is, night feeds and this kind of thing ... So I think, like getting overtired, and the stress of having the babies, you sort of think well why? [...] the uncertainty of having to change your medication, the side effects of the medication and if it would affect the epilepsy side of it. [...] And like I say the selfishness of it, the tiredness, financial and just everything else sort of stems up from that [...] I think it is the consequences of what would happen if things sort of started to go pear-shaped [...] and I'm not particularly bothered about kids anyway, I just don't see the point. (44 year old)

The conclusion of FG-I-01's self-assessment had been her decision to reject any desire for pregnancy, as she was 'not bothered about kids'. The weighing of 'pros and cons' during contemplation of future pregnancy revealed FG-I-01's emphasis on the consequences of making changes to her epilepsy management, and the influence of uncertainty supporting her rejection of any personal benefits that might have resulted from her experience of pregnancy and motherhood.

Participant OI22 preferred to maintain the status quo, by deciding not to make changes to her AEDs. The following excerpt exemplifies the emotional struggle needing the clinician's approval that her decisions were justified:

47. P: Cause this sounds really selfish but I just don't want my life to
48. change. I don't want to go back to it, not
49. being able to drive or stuff like that
50. C: Yes, yes. I mean
51. P: It probably does sound selfish on my child, but I just

52. C: Well, I mean, if it's, everybody is different, everybody
53. has there own agenda in a sense, of what they want, and
54. it sounds to me like, your driving obviously is very
55. important to you. As you say, it sounds like your work
56. P: Yes
57. C: Sort of is very much dependent on your driving
58. P: Yes and I can't have disruptions at work, I just can't
[...]
665. C: Has that sort of covered what you think, and you are you alright?
666. P: I'm probably the worst I probably come across the most selfish
667. Partner: Yes
668. C: Listen, no not at all, I mean all your worries they are very valid,
669. and I don't think that at all, and I understand where
670. your anxieties are coming from, you are just like thinking, thinking
671. through everything aren't you and you're trying to cover all bases
672. P: Yes and you do think, yes and you do, well naturally, you think I
673. better prepare myself, because it is easier to do that than suddenly
674. have a shock (OI22; 32 year old, immediate pregnancy intentions)

The clinician accepts OI22's preference to retain the ability to drive as grounded in her need to maintain employment and her current lifestyle. OI22 reveals her motivations to eliminate the uncertain probability of losing seizure control during pregnancy alongside the dual motive of preserving her driving status. The result of OI22's presentation of her preferred risk management strategy is the clinician's reassurance about the normality of preserving seizure control, in both her desire to manage perceived risks and to prevent unexpected outcomes.

9.2.4 Moral dilemmas

The tendency for women to value the health of a future baby prior to conception highlights the competing interests between maintaining epilepsy control and the desires to reduce or eliminate the potential adverse risks for a future baby. For some, this dilemma revealed a struggle to reconcile beliefs about the value of life of all children, independent of disability, against a desire to avoid delivering a baby affected by disability, implying a woman's moral responsibility:

- OI10: Well like I say [Clinician] only said, about the skull malformation thing at first, so I thought, straight away, so I just thought, oh no that's terrible [laugh]. And then when I found out about the learning difficulties I mean I've got a [relative] who's got cerebral palsy ... I know it's probably a selfish way of looking at things. But like I see my [relative], he's 21 now and he's still in nappies, she's had so much hassle, and I think, oh my god. You worry about all these things, and I think well [breath exaltation sound] if in the planning if you like, before the baby ... If I had a baby and it had

learning difficulties or it had some kind of you know, due to me taking tablets, if, I'd feel terrible. Because they've got that for life, or what ever. So I think something as simple as coming off your tablets and just doing without driving for a few months if that could prevent anything like that, then that suits me. So I don't know if that's the right way to be, I don't know (30 year old, immediate pregnancy intentions)

OI10 rationalized her decision to withdraw from treatment as being to avoid having a disabled baby, as opposed to a selfish decision to have remained on treatment during pregnancy. The perceived selfish decision to want a pregnancy reveals a tendency to evaluate the pregnancy options as either having a pregnancy or not, and the pregnancy outcomes as either delivering a healthy non-disabled child or not, with the outcome of a having a child with disability as being a lifelong commitment.

In contrast OI05 considered the commitment to having a child as requiring her to provide a safe future for her baby and protect against the harms from exposure to seizures. This illustrates a process of weighing up to the 'pros and cons' of pregnancy. Treatment options are seen to offer the opportunities to reduce risk, whereas focusing on inheritance risk reinforced personal traits that could not be changed. In the case of OI05, her choice not to contemplate pregnancy was to prevent cruelty to a future baby and her moral duty by preventing passing her epilepsy on to the next generation:

OI05: if I did have a child, then if the child would inherit it. If it did, I couldn't do it, definitely, couldn't. But I think as, as time goes on, I'd know more. But at this stage, that is definitely my main concern ... even if it didn't inherit it, with what I've got, I'd be petrified if I had a weird feeling and then to that stage were I would have a full blown, and if say, I was holding my child, I dread to think, I actually don't, I do dread to think, no I couldn't, definitely at this point, if I was to have a child, I'd say no. I would say no if I was given, if I was given the chance to do it, definitely no. But, things can change can't they [...] But I think for me, it will, probably still be as strong in the future as it is now. Probably, because I couldn't be selfish and say oh I want a child, so I'll have a child [...] does that sound cruel?

Interviewer: What makes it feel cruel?

OI05: To the child, because what I've got, is what I've got. And I wouldn't want any, I wouldn't wish it on anyone, because it's not nice to have, but I definitely would not want to pass it on if I had a child, I would not want to pass it on. (29 year old, pregnancy intentions not stated)

OI05's case sheds light on the process of considering reproductive choices and attempts to predict future outcomes, such as, the experience of seizures (or likelihood of relapse), response to treatment (if changes were made), the outcome of pregnancy

and child neuro-cognitive development, or the future child's chance of inheriting epilepsy before it has occurred.

9.2.5 Identity and the transition to pregnancy and motherhood

The model developed from participant accounts, which highlighted the value placed on adopting an internal locus of control⁴⁶ over their own health as a means of optimising future pregnancy outcomes. Constructing the ideal of a 'good mother' required women to demonstrate their ability to achieve a planned pregnancy and their ability to cope with becoming a mother with epilepsy. This was socially constructed through interactions with other women (including family and friends), health professionals, and the wider social community including social media. The experience of women's interaction with other women, in the main, was through contact with women who did not have epilepsy. Only a minority of participants identified role models in a friend or relative with epilepsy. For other women, positive role models of women with epilepsy were not readily available, and the internet a ready source of frightening pictures of things that could go wrong. Attending the epilepsy clinic, in contrast, offered the majority of women the opportunity for information updates, and access to the clinician's experience of women having successful pregnancies and healthy babies:

O113: because you don't think about yourself when you think you are planning on a child. You think now I hope the child's fine, all this, so that is the main thing. Because again if the risks are high for the child then, and if they are extremely high then I wouldn't be happy about it but I would have to give up the thought of having a child, because that would just be my own selfishness, if I went ahead with it kind of thing. So that is the biggest thing for me, if the child would be safe or what the risks are for the child.
(28 year old, future pregnancy intentions)

The importance of helping women to be able to see themselves, as being able to be a good mother, was fundamental to the construction of decisional support to challenge the barriers to planning and implementations of pregnancy action plans. WWE have been shown to be vulnerable to unplanned pregnancy as a consequence of knowledge deficits, adding further to their support needs:

O121: I can't describe it, it's just because I had that termination I've lived with the guilt for so long. But at the same time I know I did that right thing, because since then I've [employment] with spina bifida and oh my god it would have been so awful to see that. But it's affected my whole life, I'm 35 now

⁴⁶ See also Chapter 3, Section 3.1.3 Health Locus of Control

and it's shaped my whole life that happening to me. It's not just something that happened and I got over it straight away, I know no one really gets over things like that, but, yes it's affected every single thing since that happening to me [...] maybe I am just being selfish, I don't know
(35 year old, future pregnancy intentions, experience of termination of pregnancy at 16 years of age, following diagnosis of major malformation)

Women with prior experience of termination of an unplanned pregnancy were able to reflect on the impact upon their contemplation of future transitions into pregnancy and motherhood. For one 33 year old, the decision to prepare for a future pregnancy was seen as identifying herself as responsible both for her own health and that of the future child by instigating preconception review and accepting recommendations to switch AEDs as preparatory action:

O117: ... if I was planning, but at the moment I couldn't even consider not taking my medication. Maybe that sounds selfish on my part or on any, it's a dilemma isn't it ... maybe if I was pregnant its something I'd go yes stop taking it but from my point of view and the support [required] I would never consider I don't think, I mean this is me in a position of not being pregnant, but I would never consider not taking my anticonvulsant medication [...] It's worth managing this risk ... something that can be to a degree could be managed. And that isn't being selfish. There are two sides to that [...] People could think that you are being selfish but I don't. There is part of me that thinks no actually not ... it's about the planning its about being aware and balancing the risk of me dying and dying with a child or me managing that risk being monitored ... you would rather that percentage than not give birth at all (future pregnancy intentions)

9.2.6 Conclusion

The analysis of women's 'selfish decision' has served to support the model's validity by deepening understandings of the processes in which women seek to defend their approaches preparing for pregnancy. The model is able to highlight women ambivalent towards their pregnancy intentions by focusing interventions to improve preconception health and encourage adherence to contraception especially in the precontemplative and contemplative stages of pregnancy intentions. The model is also able to accommodate women's 'selfish beliefs' concerning reproductive decisions through its focus on the emotional support required by women during stages of decision-making, and concerning recognition of changes in circumstance that influence motivations to take action on pregnancy intentions.

9.3 Summary Results: A model of preconception counselling

- The findings presented in this Chapter demonstrate pregnancy planning and intentions to conceive as multidimensional concepts, which extend beyond the presentation of risk information into aspects of decision support required by women as they navigate the emotionally charged stages in their reproductive lives.
- The model of preconception counselling presented targets both barriers to pregnancy planning and the barriers to implementation of pregnancy plans, by focusing interventions to improve self-efficacy in the areas of epilepsy self-management, and to increase awareness of the benefits of risk prevention through targeted health promotion interventions.
- The staging of interventions along a continuum of pregnancy contemplation was designed to enhance a woman's self-awareness of her pregnancy intentions, and support delivery of appropriate interventions to minimise fear arousal and promote preconception awareness and self-efficacy.
- Consideration of the 'selfish decision' sheds light on the processes of staging pregnancy preparation. This highlighted women's responses to pregnancy intentions and challenges current practice by recognising the complex roles adopted by women considering preconception interventions and the barrier to implementation. Elements of the model need clarification, suggesting further investigation of such issues as its predictive function, and extensions of decision support to assist women commence preparatory actions in collaboration across the wider multidisciplinary healthcare team.

In the next Chapter I will discuss the thesis findings presented in the five Results Chapters in the context of previous published work in this area. I will critically appraise the study methods and findings against the Quality Criterion described in Chapter 4 as well as in relation to previous research. The final Chapter will draw conclusions upon this thesis before directing future research and clinical practice in this area.

Chapter 10 Discussion

Introduction

This chapter provides a discussion of the thesis findings. The major outputs from this work are two-fold; first the completion of a Cochrane systematic review of preconception counselling to reduce adverse pregnancy outcomes for WWE, found no high quality evidence of the effectiveness of preconception counselling interventions. The Cochrane review recommends further investigation to prospectively evaluate the outcome of preconception counselling, delivered at different stages of a woman's reproductive life likely to influence pregnancy planning behaviour (Chapter 2); and secondly, the qualitative analysis of the experience of WWE preparing for pregnancy (Chapters 6 – 9). This qualitative study set out with the aim of exploring perceptions of risk and probability of adverse pregnancy outcome from the perspective of 85 WWE of reproductive age; identifying a complex set of responses to risk which presented challenges to women before, during and after clinic attendance and had a significant influence upon their responses to pregnancy planning, risk management and reproductive decision-making. The discussion will demonstrate the interconnectedness of these findings and their contribution to extending the extant knowledge in five important ways:

1. Pregnancy planning – Women define “planning” differently to health professionals.
2. Communicating risk and uncertainty – Women perceive risks as frightening and fearful. Not all women perceived or managed risks and uncertainties in the same way.
3. Decision-making in preparation for pregnancy – Decision-making is not easy; in practice decisions are complex, challenging, and spread over time.
4. Model of Preconception Counselling – Preconception Counselling can be integrated into a continuum of stages supporting women's pregnancy decision-making.
5. Methodology – Qualitative analysis has provided a sensitive approach to considering the context and processes of reproductive decision-making. This final section, will evaluate both the strengths and limitations of the approach taken throughout this thesis.

10.1 Pregnancy planning

This study's findings reaffirm the struggle experienced by WWE to plan pregnancy (Fairgrieve et al., 2000). Fairgrieve et al (2000) estimated less than half of all pregnancies in WWE are planned, and rates remain comparable to those quoted in the general population (Gipson and Santelli, 2011).

10.1.1 What planning means

The current study's findings present a possible explanation for the continued experience of unplanned pregnancy despite preconception interventions, suggesting differing meanings and interpretations are used to define pregnancy planning whereas women describe planning in terms of trying to conceive, clinicians describe planning as involving activities to change treatment, improve seizure control and improve general health. Women defined their plans to become pregnant as involving withdrawal of contraception. For some this was the only activity implemented prior to trying to conceive. A minority of women associated planning with starting folic acid. The result is that women are being asked by their clinician to plan (to conceive), with the result (becoming pregnant) counter to what the clinicians had meant for them to do.

Preparations for pregnancy were found to be reliant on a number of factors extending beyond the recognition of plans for pregnancy – including changes in circumstances, such as marriage and settling down in a home, and age influencing the perceived 'right time' to attempt to conceive. Women described their individual desires for a family as stages within their preparations for pregnancy, judged simultaneously as normal/natural and high risk, and motivating the search for additional information and/or request for preconception epilepsy review. Desire for a family represented a variable focus of attention, with some women describing plans for pregnancy as progressing towards an 'urge', while for others, changes in circumstance resulted in desires shifting focus. The US qualitative study by Stanford et al (2000) identified the importance of understanding a woman's lifetime goals for childbearing as relating to values and desires for family, motivating fertility behaviours, and influencing perceptions of the right time for pregnancy. Stanford et al's (2000) findings highlight the implications of WWE failing to account for changes in their fertility behaviour and the relevance of epilepsy review in relation to their experience of planning pregnancy.

The observed link between women's struggle to interpret pregnancy planning activities and their actions to optimise epilepsy management might be illustrated by Figure 10.1, a theoretical framework informed both by the study findings and the work of Fishbein (1972), Prochaska et al (1994) and Connor and Norman (1995) concerning social cognition. This presents a linear perception of pregnancy intentions and decisions to try to conceive, in which epilepsy review is seen as a delay or deviation as a consequence of misunderstanding what is meant by 'planning'. One implication for practice is the possibility that clinicians will need to take account of women's changing circumstances in the context of recommended treatment changes, and explicitly enquire about contraception use and pregnancy desires.

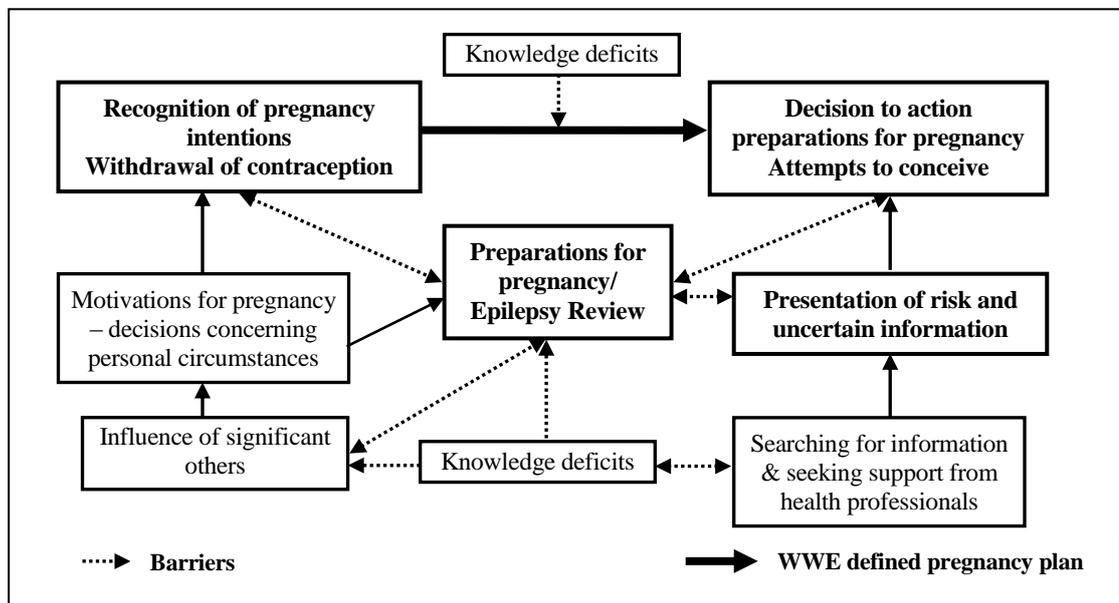


Figure 10.1 The process of preparing for a planned pregnancy

The term 'mistimed' pregnancy has been applied by Barrett and Wellings (2002) to describe women experiencing pregnancy before the perceived right time, highlighting that women define 'planning' as 'associated with producing a birth at a specific time'. A similar conclusion was drawn by Earle (2004) who proposed the term "laissez-faire" pregnancy to describe women who were less clear of their pregnancy plans, were not using contraception, and described their approach to pregnancy such as "if it happens it happens" (Earle, 2004). Earle's findings are similar to those in the present study of women's ambivalence about planning by the partner of a woman receiving fertility assessment, who suggested they used the term 'planning' 'loosely' as they no longer

felt able to conceive to a timetable. This point is further illustrated by Oakley (1979, 1981) in her sociological analysis of the transition to motherhood:

Few organise their lives according to some overall plan ... the subject of children provokes ambivalent feelings, so that 'planning' is an euphemism for allowing one particular feeling or pressure to gain an upper hand. An additional complication is that conceiving a child is not like buying a three-piece suite: demand and supply may not be easily equated (Oakley, 1979, p.32)

As implied by Oakley's quote, the term 'planning' can hold differing meanings for the same women at different times in their life and in relation to different life events. The notion of allowing one's desires to gain the upper hand was also found in the accounts of women in the current study, for example, the expressed desire for a 'natural' approach to becoming pregnant – interpreted as letting nature decide ("if it happens it happens"). These findings corroborate those of earlier UK qualitative analysis of the abilities of women in the general population to 'exercise agency with respect to conception', suggesting the concept of planning represents an 'illusion' of control (Earle and Letherby, 2002). The current study also highlights the difficulties experienced by WWE interpreting recommendations to plan pregnancy. The proposition that intentions to become pregnant are more accurately measured as a continuum between 'planned' and 'unplanned', with most pregnancies positioned between the two extremes (Bachrach and Newcomer, 1999), is strengthened by the findings of Barretts et al (2004) that women occupy a range of positions relating to pregnancy planning. Earle (2004) highlights the varied experience of planning in which some women's definitions of planned pregnancy most closely resembled contemporary health promotion, linking planning to consultation with health professionals and commencement of folic acid. In a UK study, Pashley and O'Donoghue (2009) identified 46% of their study population of WWE as experiencing planned pregnancy defined by the authors as 'steps a WWE should take before pregnancy to minimise harm to the infant', a definition they suggested 'avoids the complex and fluid notion of whether a pregnancy was intended'.

An integral part of the meaning applied to the term 'planned pregnancy' was translated into reproductive behaviours (stopping contraception) and 'preconception activities' (starting folic acid). Epilepsy management activities, such as changes to AEDs in teenage years or early adulthood, were not readily described as activities forming part

of a 'planned pregnancy'. The failure to define such preparatory activities as part of the process of 'pregnancy planning' requires attention, especially as Pashley and O'Donoghue (2009) and Meador, et al. (2011) have suggested causality between adherence to preconception activities and the outcomes of pregnancy. Within the recent epilepsy literature, there has been a tendency to compare pregnancy planning status with pregnancy outcome (Betts and Fox, 1999; Pashley and O'Donoghue, 2009). In particular, preconception folate use was found by Meador's group to be associated with higher verbal outcomes in children and was therefore proposed as a key preconception intervention (Meador et al., 2011). However, further research on this topic needs to be undertaken before the association between preconception folic acid supplementation and improved fetal outcomes is more clearly understood. Studies which take these preconception variables into account will need to be undertaken, consistent with recommendations by Nicolai et al (2008) for preconception recruitment of women in studies investigating neurodevelopmental delay in children exposed in utero to AEDs.

10.1.2 Barriers to planning

The majority of women accepted guidance on preparing for pregnancy from health professionals, a finding in keeping with others (Thompson et al., 2008; Griffiths et al., 2008). This was illustrated by women referring to receiving preconception information at an earlier stage in their life (when they had no thoughts of pregnancy) as raising their awareness of their future needs (precontemplative stage of pregnancy planning). Women welcomed their GP's opportunistic questioning of pregnancy intentions but, as shown by others (Fairgrieve et al., 2000), their ability to recall preconception recommendations and reliably action their return to the epilepsy clinic before pregnancy remains uncertain. Crucially, the timing of clinicians' questions concerning pregnancy plans was important. Some women preferred *to be asked* about their information needs, rather than being expected by the clinician to raise the topic. This is consistent with Prunty et al's (2008) analysis of motherhood choices by women with multiple sclerosis. The current study's findings are in support of opportunistic delivery of preconception information. They are consistent with a multidisciplinary approach involving GPs, raising preconception awareness during routine primary health care visits, and enquiring of pregnancy plans, and the offer of preconception counselling as part of their annual epilepsy review (NHS Employers and British Medical Association,

2011)⁴⁷. The importance of finding opportunities for GPs to initiate and extend the availability of preconception counselling has been reported previously in a randomised trial in a general population sample in the Netherlands, which found increased service uptake by women considering pregnancy in the next 1-2 years, without increased worry (de Jong-Potjer et al., 2006; Elsinga et al., 2006). Finding women reassured by the opportunistic provision of preconception information was important in the context of the current study, as it highlighted the potential unmet information needs in this group. The need for additional information led some women to search the internet, and whilst some women found the internet a convenient resource; others sought guidance from their clinician to direct them to trusted sources of additional information. This latter finding is supported by De Santis and colleagues warning of the ‘variable quality of online medical information’ which ‘cannot be considered a substitute for informed medical advice’ (p.157).

Receipt of uncanvassed pre-pregnancy risk information was problematic for some woman within the present study, who felt the clinician should first enquire about their requirements for such information. The exception to this rule was raised by women experiencing an accidental pregnancy, where knowledge deficiencies were felt instrumental. Acceptance of opportunistic questions concerning pregnancy plans was also supported by a subgroup of women who identified their preconception information needs as for ‘advanced planning’, including of what to expect during pregnancy in advance of when needed, and what their future pregnancy plans might entail. However, an important finding in the present study was that some women interpreted the clinician’s questions about their plans as indicating approval to ‘go ahead’ and consider pregnancy.

The finding that women felt embarrassed raising topics concerning pregnancy and contraception helps to explain failures sometimes to disclosure changes in personal circumstances, and highlights the importance of opportunistic reminders about preconception information and of adequate time to prepare for pregnancy. In keeping with this study’s findings, other qualitative research examining women’s decisions

⁴⁷ Epilepsy Indicator 9: “The percentage of women under the age of 55 years who are taking antiepileptic drugs who have a record of information and counselling about contraception, conception and pregnancy”.

about the timing of motherhood identified a number of individual, familial and societal factors influencing personal beliefs and values about the readiness for motherhood (Benzies et al., 2006). Furthermore, Benzies et al (2006) supported this study's finding that adolescent women were as likely as older women to express their life plans for motherhood and family. Supported by the work of Miller (1994) on the timing of pregnancy, desires for pregnancy were found to relate to perceptions about the 'right time' for pregnancy. Other studies have also shown that attitudes towards pregnancy are not static and develop in response to changing circumstance and over time (Miller, 1994; Oakley, 1979). This was illustrated by women reporting a sense of urgency to conceive at the perceived right time, and responding to the influence of their biological clock. As shown elsewhere (Stanford et al., 2000), some women were concerned about their ability to conceive when the right time had arrived.

A belief expressed by several women was that epilepsy or AEDs could influence their chances of becoming pregnant. This is in keeping with reports of higher rates of infertility and menstrual difficulties experienced by women with epilepsy (Davis et al., 2008), and concerns about fertility expressed by women considering pregnancy in the future (Crawford and Hudson, 2003). Previous pregnancy did not eliminate all these concerns, congruent with findings from the current study that women struggled to change prior beliefs and concerns despite clinicians' reassurance and provision of new information. This emphasises the requirement for preconception information to be both credible and trusted (Douglas, 1990, p.11-12). Further complexities around pregnancy planning behaviours are illustrated by the finding that women with experience of adverse pregnancy outcomes were no more inclined to plan future pregnancy or implement preconception recommendations. This is comparable to the findings from Holing and associates (1998) who, in their study of diabetic women's experience of pregnancy, were unable to demonstrate a link between preconception knowledge deficits and the likelihood of a planned pregnancy (Holing et al., 1998). The influence of preconception knowledge deficits on pregnancy planning and upon delays in accessing antenatal care have been documented by Mayer (1997) in their hospital-based survey of postpartum women without epilepsy. A similar pattern emerged in the present study among the sub-group of women pregnant during study participation, where the experience of an unplanned pregnancy was associated with perceived delays in the discovery of pregnancy. Fairgrieve and colleagues' (2000) UK prospective study

of the care of pregnant WWE is frequently cited in relation to the preconception knowledge deficits associated with unplanned pregnancy.

Analysis of the barriers to a planned pregnancy in the current study population identified a widespread belief that WWE were unable to plan pregnancy. This was further supported by the clinicians drawing attention to the general population of women being 'poor planners'. Further, the general view held by participants about the unpredictable consequences of 'life with epilepsy' was seen to inhibit planning opportunities and restrict options for health improvement prior to conception, a finding in support of others in the field (Thompson et al., 2008; Pashley and O'Donoghue, 2009; Crawford and Hudson, 2003; May et al., 2009). The current study revealed three distinct motives for non-attendance for preconception counselling: women's concerns about the 'public gaze' focused on them by openly stating their 'plans for pregnancy'; the issue of 'hiding failed attempts to conceive' and preventing unwelcome questions drawing attention to possible infertility; and perceptions of the likely chances of getting pregnant being improved by preconception interventions. These findings are supported by the work undertaken by Hosli and colleagues (2008) in a non-epilepsy population, which explored why Dutch women did not participate in preconception counselling and found that almost half of their participants associated preconception counselling with advice about (in)fertility. These authors concluded that the aims of preconception counselling should be made more explicit and that there is a need to challenge what is considered 'sufficient knowledge' both of the preventive role of preconception counselling and personal risk (Hosli et al., 2008).

In the present study, teenagers with epilepsy, who were in most cases at a 'precontemplative' stage in relation to pregnancy, were found to be receptive to the clinician proposing a time scale for initiating AED changes in relation to their future pregnancy plans, and willing to accept delays to conception until the AED changes were complete, especially when they perceived a low risk of adverse outcomes on the new AED. The timely delivery of preconception messages was crucial, and several teenage participants identified that they were in established relationships and had immediate desires for family, prompting their search for information and guidance. The findings from the Oregon Pregnancy Risk Assessment Monitoring System (Adams et al., 1993) survey raised concern about the unmet preconception health

needs of adolescents in their population sample, finding only 9.2% to be taking folic acid and that these adolescents more likely to report unintended pregnancy (62%) when compared to older women. This resulted in recommendations for focused interventions among young women who are not contemplating pregnancy (Rosenberg et al., 2003). These findings are extended by the current study, which highlights women's variable responses to preconception recommendations as associated with stage of pregnancy contemplation rather than age per se, with women preferring to delay taking action to change AEDs, or preferring to commence folic acid as affording some protection while remaining on 'higher risk' AEDs. The provision of risk information at the precontemplative stage was revealed as not always motivating women to implement recommendations and prepare for pregnancy, and the study highlighted an important finding around women's precontemplative attitudes towards pregnancy.

The current study adds to the literature in the field, revealing that while WWE share many of the same challenges as women in the general population over timing of pregnancy, and similar beliefs to women with other chronic illnesses about likely fertility difficulties, the low rates of planned pregnancy amongst WWE can be in part explained by confusion surrounding the terminology used to promote 'planned pregnancy', and requires clinicians to ask appropriate and timely questions to identify women at greatest need of preconception interventions. The implications for the design and conduct of future research evaluating the effectiveness of preconception counselling, is the need to specifically define the preconception interventions; including, clearly defining the role of both the health professionals and WWE, and the context of interventional delivery targeted at a woman's stage of pregnancy intention (See Reviewers' conclusions in JB Winterbottom et al., 2008, and also Chapter 2.4).

10.1.3 Summary

The importance of understanding pregnancy planning behaviour has been the focus of public health research, emphasising the significance placed upon preconception health improvements for maternal and infant health (Kost et al., 1998; Carson et al., 2011; Gipson and Santelli, 2011), and for reducing maternal mortality for WWE (Lewis, 2007; de Swiet et al., 2011). In the present study, the significance of women's perceptions of what pregnancy planning means, defined as attempts to conceive, may

explain the frequent withdrawal of contraception and resultant pregnancy before receiving preconception counselling. Deviation from the perceived natural process of pregnancy planning requires acknowledgement of the additional work entailed in advance of conception, especially as that may represent unwelcome delays to conception. This finding is supported by Thompson et al (2008) in their ‘moral guidelines of reproduction’, who reported the experience of receiving specialist advice in advance of planning pregnancy as variable, with a focus upon warnings against pregnancy on certain AEDs, failure to warn against avoiding pregnancy during recommended treatment changes and clinicians making recommendations judged as ‘counter intuitive’ to what women perceived as being a ‘good mother’.

10.2 Communicating risk and uncertainty

The majority of women had some awareness of the risks of pregnancy, perceiving AEDs as potential sources of disability for their future baby and seizures as potentially life threatening either to themselves, their baby, or both. The most significant findings were: 1) that not all women perceived risk in the same way, and 2) women’s responses to preconception information were often highly emotive. Both of these factors had influence upon women’s approach to risk management.

10.2.1 Risk perception

Women perceived risk as potential dangers and harms (e.g. “dangerous drugs”), and uncertainties surrounding, for example, the long-term affects of in utero AED exposure upon an infant’s neurodevelopment as sources of anxiety. Fear was a central concept within the analysis, representing an emotional reaction to risk communication influenced by the vividness of descriptive imagery around the anticipated outcome. Risk information was interpreted by study participants as both reassuring and threatening. The measure of reassurance or threat were found to be both person specific and topic specific, with similar risk information presented to different women resulting in differing responses. The differing perceptions of risks held by women were important findings, paralleling the study by Helbig et al (2010), who found individual perceptions of risk, and personal values and beliefs, were influential upon perceptions of the effects of epilepsy. A number of authors have reported over-estimations of risk with study participants quoting figures considerably higher than published data

(Marteau, 1989; Jasper et al., 2001). The same pattern emerged for the majority of women in the present study, though a small group of women denied awareness of any issues concerning pregnancy and epilepsy. A similar conclusion was reached by Pack and colleagues (2009) who assessed awareness of the teratogenicity of AEDs, and reported most women as not knowing whether AEDs affected fetal development, and some believing there was no teratogenic effect of category D AEDs⁴⁸. The latter is consistent with the present study finding. Several women identified their risks as related to epilepsy per se rather than AEDs or seizures, and utilized risk information to reassure themselves and see their risk as equivalent to women in the general population.

The pervasive character of pregnancy-related risks identified by Turner et al (2008) may help explain the responses to pregnancy-related risks of present study participants, where AED and seizure-related risks were most commonly referenced, and more limited reference was made to the AED-related risks upon neuro-cognitive development and risks of Autism Spectrum Disorder for children exposed to AEDs in utero. Santucci et al (2010) examined women's experience of being counselled about medication-induced birth defects, and reported that women preferred comprehensive information on all potential impacts, a finding consistent with those of the current study, where women questioned the content of risk information and the clinician's provision of the latest research or reference to the Epilepsy and Pregnancy Register.

10.2.2 Communication of risk

In the present study, clinicians' presentation of seizure-related risks included statements of the probability of experiencing a seizure during pregnancy as dependent upon pre-pregnancy seizure control and relative to adherence to AEDs during pregnancy. The possibility of changes in seizure control during pregnancy and the unpredictable nature of seizures were commonly cited by both women and clinicians as barriers to considering drug changes and reasons for maintaining the 'status quo'. Changes in seizure control were perceived as risking harm to the developing fetus and to the woman as a result of seizure-related injury and the possible social consequences, for example, driving eligibility. Risks were also framed by time, both specifically in

⁴⁸ US Food and Drug Administration's category D drugs includes AEDs with positive evidence of human fetal risk: carbamazepine, phenobarbitone, phenytoin, primidone and sodium valproate.

relation to pregnancy, and more loosely relating to the uncertain lengths of time of preparing for pregnancy and future-time concerns around motherhood and childcare safety. The temporal nature of definitions of pregnancy-related risks is consistent with Heyman's (2010) analysis of risk communication in clinical practice, suggesting personal time framing has the potential to create variance in perceptions of 'time horizons', leading to conflict and misunderstandings. Heyman (2010) characterises the influence of time framing surrounding pregnancy, suggesting the risk time horizon may focus on the length of pregnancy, whereas for others it may become 'embodied' in a future envisaged life with a disabled child (p.114-5). Applying Heyman's perspective in the context of the preconception epilepsy review would require clinicians to 'appreciate the variety of temporal perspectives adopted' by women 'and the implications of such differences for risk management' where presentation of risk information emphasising causation can inadvertently create worry about the future, which itself can become a risk factor (Heyman, 2010, p.115). The results are also consistent with those of other studies and suggest that perceptions of risk status vary in response to a women's reproductive status and plans for further children, as first highlighted by Lippman-Hand and Fraser (1979a) in their qualitative study of women's experiences of genetic counselling:

...recall of rate information depends on the relevance of this information to the family at the time they are asked to remember it. Those whose families are incomplete are likely to retain these facts: others are not. Thus, recall can be expected to change with time. (Lippman-Hand and Fraser, 1979a, p.55)

Research into communication of the risks concerning fetal alcohol spectrum disorder (FASD) identifies that health messages framed around loss (i.e. presenting the baby as suffering from FASD) were more effective in promoting preventive health behaviours and in promoting seeking information. It highlights the importance of targeting risk information to women's intentional stage, since women at the precontemplative stage viewed the threat of FASD as far distant from them (Yu et al., 2010). Extrapolation of such findings to the current study must, of necessity, be tentative. Further research is required into the impact of risk framing upon WWE preparing for pregnancy generally, and specifically upon women treated with sodium valproate who face the greater risk of having a baby affected by fetal valproate syndrome.

The work of May and colleagues (2009) examined the implications of heightened perceptions of risk for WVE, who experienced ‘great worry’ during pregnancy concerning malformation risks to their newborn child. Women’s heightened perceptions of having a disabled child both prior to and following consultation, and the potential barriers to engaging in preconception consultations following the initial arousal of fear, requires further investigation. Observations in the epilepsy clinic highlighted the use of communication strategies by the clinician emphasising the objective nature of risk (with frequent reference to the results of the UK Epilepsy and Pregnancy Register or MRC AED Withdrawal Study (Chadwick et al., 1996)). Implicit within clinician presentations of risk information was the suggestion of ‘high risk’ labels, constructing risks relative to exposures to AEDs or having seizures, or risks relative to clinician-supervised AED withdrawal versus the heightened risks of abrupt AED withdrawal. In contrast, the probabilistic status of risks to fertility (lowered), inheritance (increased), childcare safety (increased) were emphasised by the narrative presentation of risk. The communication of risk framed negatively was found to influence both risk perception and ‘informed’ decision-making, in keeping with conclusions made by Jasper et al (2001) about the influence of framing bias upon decision-making. Experimental research into risk perceptions has found that decisions were more likely influenced by interventions in which outcomes or the status quo were framed positively than when negatively framed (Marteau, 1989). This contrasts with the current study, where some participants were reassured by negatively framed risks. Extending earlier research by Gordon et al (1996), the present study also identified variability in what constituted acceptable risk of seizure recurrence. Some women, presented with percentages of up to 10% risk of delivering a child with major congenital malformation, interpreted the risk as lower than anticipated, in contrast to other women who judged *any* risk to the health of their child as unacceptable.

The experimental study by Choi and colleagues (2011), comparing numeracy among adults with epilepsy compared to normal controls, presents a possible alternative explanation of women’s variability in response to risk presentation. Choi et al (2011) found many patients had poorer numeracy skills and were more likely to exhibit framing bias, misunderstanding the risk information typically presented by clinicians and being at risk of making uninformed decisions. This difficulty may have been extended for women in the present study when clinicians combined numeric and

narrative risk information. A limitation of applying the findings by Choi and colleagues (2011) within the context of the current study is their failure to differentiate gender differences within framing bias. As shown elsewhere (Knapp et al., 2004), the tendency for clinicians to present narrative descriptions of the probability of adverse pregnancy outcome may lead to overestimations of the level of harm and may result in patients making inappropriate decisions about whether or not to take medications.

The use of narrative information about treatment risk or outcome probabilities is seen as established healthcare practice, using first or third person stories of experience to assist patients to make sense of their situation and support decisions concerning treatment options and illness management (AE Winterbottom et al., 2008). The persuasiveness of the clinician's use of 'stories from practice' have been linked to the 'vividness of information' and 'credibility of the speaker' (AE Winterbottom et al., 2008), with the most striking finding from the current study being how several participants changed their minds in response to descriptions of the risk to their future child affected by neuro-developmental delay secondary to in utero AED exposure.

The unpredictability of responses to the communication of risk among women interpreting the risks of adverse pregnancy outcome following in utero exposure to AEDs emphasises the findings of others. For example, Einarson, et al. (2001), researching women's abrupt discontinuation of antipsychotic drugs during pregnancy, reported reasons for discontinuation included fears of birth defects and harming the fetus, concerns extreme enough for one woman to elect termination, and others to remain off treatment despite experiencing adverse withdrawal effects. The authors found counselling did not reassure all women about the safety and benefits of resuming treatment, and whilst 61.1% restarted their medication, not all were sufficiently reassured to breastfeed (Einarson et al., 2001). In a systematic review of genetic risk perception and decision-making, clients' unpredictable responses to risk communication was emphasised (Sivell et al., 2008).

Despite the relative importance of women's judgements about their clinician as being a source of accurate and personal risk information, many were critical when reflecting upon the content of risk communication and critical of clinicians' expressions of uncertainty. Uncertainty was perceived as a source of worry, highlighting the unknown

risk of adverse pregnancy outcomes. For some women, this led them to be critical of clinicians' statements of uncertainty, seeing this as discrediting their expert status a finding consistent with the work of Douglas (1990). Douglas (1990) examined the cultural debate about risk, in which experts' reference to risk has been 'unequivocally used to mean danger from future damage' and where the degree of risk exposure can be taken for granted as ascertainable. Therefore, Douglas (1990) proposed that anyone insisting on the presence of a high level of uncertainty could leave themselves open to be judged as 'opting out of accountability' - for example, in the context of the current study, a clinician's insistence on the level of uncertainty around drug-related risks may heighten a woman's sense of responsibility for the outcome of pregnancy and increase the likelihood of her discontinuing drugs upon discovery of pregnancy (p.9). Understanding women's response to uncertainty has important practice implications, emphasising the value of developing strategies that promote self-efficacy. Whilst clinicians can not eliminate uncertainty as inherent in medicine, encouraging women to gain confidence in their ability to take positive action; to plan pregnancy, optimise seizure control and commence folic acid, has been demonstrated in the current study to help some women manage uncertainty.

10.2.3 Risk management

The presentation of risk information was seen as essential for women to be able to compare their available options and clinicians often requested women consider the risks and benefits of proposed treatments. Corbin's (1987) study of pregnant women with chronic illness identified women as 'balancing' perceived benefits of medical interventions against the risks of intervening, the women as being torn between competing interests. This finding is supported by the current study in which WWE managed their perceived pregnancy risks by acceptance of interventions judged as 'not adding to the risks' and tending to adhere to clinician recommendations, with some responding by 'doing everything possible to give their future child the best possible chances' a response termed by Corbin (1987) as 'protective governing'. In the context of the current study, some women were found to accept less favourable odds of their epilepsy remaining stable through pregnancy in preference to reducing or stopping treatment, whereas others justified maintaining seizure control as a way of avoiding additional seizure-related risks to their future child. The variable responses to risk by

WWE were in keeping with the earlier research by Gordon et al (1996) concerning parental responses to their child's seizure relapse risk.

Fear was an unexpected response to the clinician's risk message, and might be tentatively explained by Witte's (1997) research evaluating 'fear appeals'. Witte (1997) reported variable responses to fear, as either motivating behaviour change by promoting risk reduction opportunities, or representing a barrier through denial or defensive avoidance, and where failure to provide information about the preventive opportunities influenced 'fear control processes'. For example, Witte (1997) found teenagers who perceived the high threat of pregnancy, but had low efficacy to prevent the threat, responded by avoidance and 'not thinking about getting pregnant', suggesting the effectiveness of risk communication was reliant on clearly defining the threat and defining the strategies to intervene.

The similarities between attitudes towards risk expressed by women in the current study and those described by Witte (1997) support a link between clinician communication about pregnancy risks, and women's avoidance of thinking about AED risks. In the present study some women struggled to envisage a positive outcome for pregnancy due to their concerns about harming their baby, while other women were able to moderate these concerns as not requiring their attention until they were pregnant or had delivered their baby. Further, the sub-group of participants pregnant at the time of study participation described themselves as 'living on their nerves', and talked about worries as to whether they might deliver an AED-affected baby as a consequence of their AED adherence during pregnancy. At the same time, their worries were tempered by the increased need to know the 'worst case scenario'. It is possible, therefore, that some women's response to fear maybe to avoid seeking information or discussing pregnancy with their clinician. These findings are in contrast to others, such as Lupton's (1999) positioning of the pregnant woman as protecting the fragile fetus, wherein risk avoidance behaviours are considered a moral enterprise relating to a woman's need to adopt self-control and accept 'institutional and expert objectives' (p.90). Miller (2005) suggests women's interaction with the medical model during pregnancy provides reassurance by the 'authoritative knowledge' in which the use of screening technologies and compliance is judged as being safe and responsible (p.49-52). These differences in findings can help explain the varieties in responses to

risk by the women in the current study, where only limited reassurance was offered by ultrasound screening to detect the extent of AED-related risks.

The responsibilities expressed by women in terms of their guilt and self-blame concerning pregnancy decisions, focused upon risks as distinct categories of competing concern, for example, mother versus baby, or seizures versus AEDs. This resulted in decisions being interpreted as difficult and some women struggling to make them, while others saw themselves as selfish and subject to public scrutiny if they gave birth to a disabled baby as a consequence of decisions they had made. This finding corroborates the ideas of Lippman-Hand and Fraser (1979a) in relation to genetic counselling who suggested:

The difficulty of decision-making was brought on not only by the risk these women faced but by the fact that something could go wrong (either-or) and there would be social (and psychological) implications if they took a chance and lost (Lippman-Hand and Fraser, 1979a, p.61)

Women in the current study were found to perceive blame from their partner's family for anticipating making a bad decision, and the consequences of the results of selecting their needs above the unborn child. Perhaps the most striking finding from this thesis was the emotional response to risk and its influence upon decisions to plan pregnancy and decisions to act on intentions to conceive. Whilst other authors have reported emotional responses of blame, this has been limited to the study of pregnancy or retrospective accounts of experiencing pregnancy (Corbin, 1987; Lane, 1995; Miller, 2005; Berg and Honkasalo, 2000). Few have studied perceptions of risk during preparation for pregnancy. Supporting the current findings, Thomas (1997) in her study of disabled women considering pregnancy, reported women's self-blame for the consequences of their decisions:

[...] considerations of 'risk' were an important feature of the women's reproductive journeys [...] disabled women often share, albeit sometimes ambivalently, in the wider social and medical discourses about what constitutes reproductive 'risks'. Having a child with an impairment is seen as something to be avoided, and if it occurs, is experienced with feelings of 'guilt' which spring from the knowledge that their actions in having a child are widely seen as both irresponsible and 'unfair' to the child. (Thomas, 1997, p.631)

The finding that women's assessment of risk differed from the advice offered by their clinician has important implications for risk management decisions made by women in

the current study. Turner and colleagues (2008) investigated worries about childbirth in WWE compared to women without epilepsy, reporting that women with higher seizure frequency experienced significantly higher levels of fear about childbirth both during pregnancy and after delivery. Similarly, in the current study, women pre-conceptually reported anxieties about worsening seizures during childbirth. One participant reflected on her heightened fears concerning her own mortality and that of her unborn child, fearing she was killing her baby because of her inability to prevent her seizures worsening. Turner and colleagues (2008) openly questioned women's fears about pregnancy, identifying WWE were significantly more likely to fear delivering a baby with malformation when compared to non-epilepsy controls, who were more fearful of pain in childbirth. These findings are extended by the current study, which identifies women as expressing worries and fears concerning their likelihood of delivering a baby with malformation even before pregnancy.

The limited opportunities for WWE to know other women with epilepsy with positive experiences of planned pregnancy was highlighted by the present study, with huge value placed on positive role models and reliance on the clinician's use of 'stories from practice'. Prior studies into clinical consultation have noted the importance of the clinician's choice of exemplars as sources of bias outcomes being influenced by the case selected and nature of risk being emphasised (Charles et al., 1998). The type of exemplar case selected by clinicians within the current study was found to influence women's perceptions of the likelihood of AED-related harm to their future baby. The data from the present study confirms Charles et al's (1998) proposition, with examples of children affected by learning disability heightening women's awareness of their ability to care for a future affected baby, one participant making comparison to thalidomide.

Uncertainty information influenced risk avoidance behaviour, some women perceiving themselves as having limited options for achieving a successful outcome of pregnancy. The most extreme example of this was one participant preferring adoption as a means of avoiding unwanted outcomes if she became pregnant. The concept of choice and the limitations on choice has been reported elsewhere in relation to women facing the option of amniocentesis and their expressions as feelings of selfishness in relation to their own self-determination and desires to avoid fetal suffering (Rapp, 1999, p.90-92

& p.136-140). Greater understanding is required of women's responses to risk reduction strategies, with Corbin's analysis of risk management in pregnancy suggesting that women may feel they have fewer management choices when risks are perceived as high (Corbin, 1987, p.327). The diversity of risk information content and variable framing strategies selected by health professionals, including the use of 'stories from practice' may not meet the needs of all patients, especially when measured against individual preference and stage of readiness for changing reproductive health behaviour. Clinicians need to be sensitive to the information needs of WWE, the importance of directing women to trusted sources of additional information, and the support required by some women to interpret their pregnancy risk requiring the clinician to confirm the information presented has been understood as intended. In addition, finding the inconsistent provision of patient copy letters may represent a missed opportunity to assist women recall the content of risk information and action preconception recommendations. Women observed during their clinic appointment, described the benefits of receiving a summary of their consultation, provided as part of study participation. Other women highlighted the importance of receiving all possible information as a means of managing their perceived barriers to informed decision-making. This finding is applicable for practice, where provision of tailored clinic copy letters providing a summary of the content of the consultation may act as an aid memoir and reinforce clinician recommendations. Further investigation of the influence of different presentation formats of risk messages is required, as is work to extend the qualitative observations in the present study of preferences concerning the framing the risk and its influence upon reproductive decision-making.

The current study also found not all women felt confident about their abilities to cope with motherhood. Some participants revealed anxieties and fears about the risk of their future baby being killed as a consequence of their loss of awareness during a seizure. These findings parallel those of Thomas (1997), who found disabled participants vulnerable and insecure, questioning their ability to cope, and their need for additional assistance or surveillance. While the majority of the current study participants felt confident about their ability to care for their babies, the risks involved in childcare were frequent topics of discussion between women and their clinicians. These experiences of living 'at risk' and of guilt and blame have been investigated in relation to the increased likelihood of postpartum depression for WWE (Turner et al., 2009).

Further, the assessment of childrearing knowledge and practices by WWE was the focus of investigation by the Kerala Registry of Epilepsy and Pregnancy (Saramma et al., 2011), which found WWE had significantly poorer scores in childrearing practices.

10.2.4 Summary

The current study revealed a tendency for women and clinicians to focus upon seizure and AED-related risks during consultations and this may inadvertently have detracted from the promoting of routine antenatal preparations for childcare, with the potential to further disadvantage children born to mothers with epilepsy. The same conclusions have been reached by others (Bagshaw et al., 2008; Bromley et al., 2011). Bromley et al (2011) highlighted the need for further research, with potential confounders such as social class and economic status being adequately controlled. The current study further highlights the need to investigate the effectiveness of preconception risk information in influencing maternal awareness of child development and ways to reduce preventable child injury.

10.3 Decision-making in preparation for pregnancy

10.3.1 The nature of decision-making for WWE

This study confirms the complex and challenging nature of reproductive decision-making experienced by WWE. Such decision-making represents a range of both discrete and interconnected decisions, with women active in the process: accessing information to increase their preconception awareness; requesting referral for preconception epilepsy review; deciding to secure effective contraception until epilepsy management has been optimised; and, finally deciding to try and conceive. Throughout this process women are faced with a series of decisions, including about treatment, among which they are required to weigh up the possible outcomes or consequences of their actions. The term ‘decision problem’ has been applied by Tversky and Kahneman (1981) to the behaviours observed by the decision-makers considering the acts or options from which a choice must be made, the possible outcomes or consequences of those acts and the conditional probabilities relating to the outcomes following from those acts, all of which is framed by the person’s norms, habits and personal characteristics (p.453). The context of the ‘decisional problem’ facing WWE planning pregnancy was found to relate to two main concerns: the

potential for pregnancy to destabilise seizure control; and the requirements for AED use in pregnancy. The implications of epilepsy-related risks upon decision-making have been reported in the literature:

Most life decisions are governed by an assessment (conscious or unconscious) of the consequential risks and benefits, and treatment decisions in epilepsy care are no exception... assessment of the risk to benefit ratio is difficult. It has to be made on the basis of information which is often incomplete and it must account for disease [and] personal treatment factors which are themselves often neither quantified nor predictable (Perucca et al., 2000, p.180).

Prior studies in decision-making have noted the importance of affect, uncertainty and perceived risk status upon rational decision-making. They identify the strong relationship between outcome preferences (e.g. healthy baby, no change of seizure control) and the influence of risk information framing, such as the use of scenarios to guide choice, the preference sensitivity of the decision to be made (e.g. the value of retaining a driving licence), and the potential for decisional conflict and regret (Lippman-Hand and Fraser, 1979a; Tversky and Kahneman, 1981; Janis and Mann, 1977; O'Connor et al., 2007). The nature of pregnancy-related decisions facing WWE have been referred to as 'moral work' (Thompson et al., 2008), and in the context of the current study there was a tendency for clinicians to emphasize women's ownership of decisions both relating to acting on clinical recommendations, and to choices not to act on them or defer decisions to a later date. The experience of making decisions among WWE emphasised the temporal nature of their decision-making, for example, to complete a treatment change in advance of contemplating pregnancy. This finding about the timing of decisions is consistent with Corbin and Strauss's (1987) concept of the 'biographical work' involving in living with a chronic illness, in which 'the process is rarely complete and recurs each time there is a major trajectory or biographical change'. This is mirrored in the current study by women facing multiple decisions concerning the future whilst also attending to decisions in day to day life, such as adhering to a treatment regimen (Corbin and Strauss, 1987, p.266). The duration of the decision process was also highlighted by Lippman-Hand and Fraser's (1979a) study as not ending with the choice to reproduce or not, but as a process that continued to be questioned. In the current study, women were often found to revise earlier decisions in light of new information.

Women in the present study saw clinicians as having privileged information or understandings able to guide their decisions. This contrasts to other clinical settings such as genetic counselling, which is associated with nondirective counselling, a position which Sarangi and Clarke (2002, p.166) suggests results in the explicit handing of responsibility for decisions to the person being counselled (Sarangi and Clarke, 2002, p.166). The suggestion that women making childbearing decisions (described by Miller, 1994), are liable to experience 'post-decision regret' might help explain why some WWE made decisions to withdraw AEDs upon discovery of an unplanned pregnancy, which were counter to clinical recommendations and liable to expose the woman to significantly greater risks. This finding has practice implications, and emphasises the role of the clinician in the provision of preconception counselling for WWE. The significance of the variable nature of counselling provision observed in the current study requires further investigation, to evaluate the potential impact of clinicians receiving counselling training upon women's satisfaction of preconception decision-making, and motivation to engage with services.

Decisions to prepare for pregnancy and the fact that women in the current study attempted to exercise agency in relation to planning pregnancy and achieved some degree of capacity to control their outcomes is only partly consistent with the majority of published results. There was a difference in the present study, since some women experienced outcomes that failed to match their intended preferences. Women reflected on their failure to heed warnings about the risks of pregnancy, with several participants using the term 'roulette' in relation to considering the pros and cons of pregnancy especially when their final decision was to opt for chance rather than planning. The use of the term 'roulette' by women in the current study parallels the term 'reproductive roulette' described by Lippman-Hand and Fraser (1979c) in the context of genetic counselling, suggesting that a 'non-decision' (or 'fatalism' a term used by Pashley and O'Donoghue, 2009) was considered a 'valid alternative to a deliberate choice of reproduction or contraception':

A woman who knows she is taking a chance of getting pregnant and clearly chooses to take this chance is not behaving in an undecided fashion, but is selecting a course of action that for her may best neutralize the dilemma. (Lippman-Hand and Fraser, 1979c, p.81)

As noted earlier, Helbig et al (2010) have pointed to the influence of risk perception upon reproductive decision-making in WWE. The decision not to have a family was related to perceived restrictions on having a family successfully. These related mainly to the consequences of AED-related or seizure-related fears and concerns and, for a minority of women, the judgements of others including family and friends had influence, as did patient's desires for a family. These experiences are not unique, however, in relation to conditions in which positive outcomes can not be assumed. Luce (2005) has shown that in patients approaching a very different clinical condition, cancer, risk information provided to motivate patient involvement may actually increase the 'decision-related threat' and discourage the patient from considering all available options. These conclusions are in agreement with the current study, in which some women retained pregnancy as a future goal, while others revealed their decision not to pursue pregnancy, either restricting family size or deciding not to pursue pregnancy at all.

Consideration of pregnancy revealed women as balancing their responsibilities towards the unborn baby against their own preferences and values, resulting in 'conflicting interests', a concept described by García et al (2009) in the context of prenatal screening decisions. In support of the findings of García et al (2009), the majority of participants saw the use of antenatal scans and prenatal testing as a way of balancing conflicting interest during their deliberation of preconception decisions, with some women accepting prenatal diagnosis and others rejecting it. García et al (2009) examined women's motivation for using prenatal testing, identifying parental duties towards the unborn child and towards other children as countered by perceptions of responsibility to their own health. Women in García's study who declined prenatal diagnosis shared a similar rationale to those in the current study, opting to avoid the risks associated with screening. The routine offer of ultrasound screening was highlighted as challenging informed decision-making in Baillie's et al (2000) qualitative analysis of women's experience of receiving false positive screening results, confirming the need for health professionals to explicitly inform women of the purposes and potential outcomes of screening. Failure to do so has clear implications, given women's translation of perceived risks into binary form (either having an affected baby or not) and the increased anxiety waiting to confirm the outcome of pregnancy.

Several women in the present study questioned whether they had received sufficient information to make informed decisions and, for some critical of prior contact with their clinician, this resulted in seeking a second opinion. Consistent with the investigation by Viguera and colleagues (2002) of reproductive decision-making following pre-pregnancy psychiatric consultation, the current study identified women's actions as motivated by locating expert knowledge, and responding to prior recommendations to return to the epilepsy clinic when planning pregnancy. McCorry and colleagues (2008) have suggested that few patients with epilepsy hold treatment preferences prior to their routine epilepsy review appointment. In contrast, the current study found the majority of women anticipated the need to consider the suitability of their current treatment(s) and the possibility that pregnancy could destabilise seizure control, leading some women to request AED changes. Women had clear expectations and hopes for the outcome of the consultation. They made specific requests to switch from AEDs perceived as holding unacceptable risks or for which they had prior experience of adverse outcome, and they required reassurance for worries raised by their personal research. Pashley and O'Donoghue (2009) describe a similar pre-consultation agenda for WWE planning pregnancy.

10.3.2 Negotiation and preference in decision-making

Women's active involvement in shaping the consultation agenda is in line with UK government targets to promote shared decision-making throughout the NHS (Coulter and Collins, 2011, p.1). There is an increasing focus upon the epilepsy consultation and the need to move away from paternalistic decision-making (Toerien et al., 2011; McCorry et al., 2009). The epilepsy consultation as the site of patient decision-making concerning treatment was the focus of investigation by Toerien and colleagues (2011), confirming observations in the current study that women invest time in searching for information prior to the consultation, and then use such information to present alternate possibilities when negotiating with the clinician over his/her recommended course of action.

The current study identified the negotiation of preferred outcomes by WWE, revealing their perceived responsibility as an inherent aspect of the 'preference-sensitive' nature of the reproductive decisions they faced. The term 'preference-sensitive decisions' has been applied to a range of healthcare decisions, where

available treatment options are equally valid and the ‘best choice’ is dependent upon the patient’s view of the ‘advantages and disadvantages of the various treatment options’ (O’Connor et al., 2007; Wallace et al., 2010). The nature of ‘preference sensitive’ decisions facing WWE was emphasised by reference made by clinicians to there being ‘no right or wrong answer’, whether relating to seizure control or pregnancy. The differing choices identified by the current study participants illustrate the complex nature of epilepsy review and mirror the work of Corbin and Strauss (1987) relating the ‘temporal character’ of the illness trajectory among individuals with chronic illness, wherein management of their illness is only one of many of life events (p.264).

Where no treatment option is free from potential undesirable outcomes, individuals have been proposed to face a ‘choice dilemma’ characterised by ‘decisional conflict’ (O’Connor et al., 2002; Janis and Mann, 1977, p.85), a point well illustrated within the current study. In terms of Janis and Mann’s theory (1977, p.85), WWE are placed in a position of ‘relatively high decisional conflict resulting from two clashing types of threat that make it impossible to adopt any easy resolution’. The relative importance of choice about pregnancy outcomes in the current study is consistent with Amir et al’s (1999) conclusions about the impact of epilepsy upon quality of life, with lack of control and uncertainties identified as central to the subjective experience of living with epilepsy and managing seizures. Amir and colleagues (1999) emphasized opportunities to improve quality of life for patients with epilepsy through counselling and treatment interventions designed to reinforce the sense of perceived control and mastery and encourage ‘self-management’. This was also identified as key within the model of preconception counselling developed in the present study which encompasses the emotional context of decision-shaping preferences and the availability of support, both practical and psychological, from the woman’s clinician and significant others.

Research in the field of genetic counselling has highlighted the possible outcomes of decisions made in circumstances of uncertainty described as ‘a-rational’ and susceptible to regret (Lippman-Hand and Fraser, 1979b, p.330). In this context findings from the current study are in marked contrast to the paternalistic clinician-led decisions described by McCorry et al (2009). Whilst evidence of delegating decisions

was found, the majority of women acknowledged the importance of taking control of their reproductive decisions, in keeping with an informed decision-making model proposed by Wirtz et al (2006). The question of rational decision-making within this context requires attention, as labelling as irrational decisions at odds with the clinicians recommendations, has been cautioned against by Lippman-Hand and Fraser (1979b). The fact that the WWE searched for the 'worst case scenario' and placed value on the 'clinician's use of stories from practice' can be explained by Lippman-Hand and Fraser's (1979b, p.330) analysis of how parents processed the facts of their genetic risk situation to formulate their choices with those parents deciding to try for pregnancy relying on strategies to limit or neutralise uncertainty. Likewise, in the current study, the weighing-up by women of the potential outcomes of their decisions drew on the use of 'scenarios' around which deliberations could be focused, thereby allowing the importance of differing consequences to be considered (Lippman-Hand and Fraser, 1979a, p.63). The finding that women deliberated the potential outcomes of their decisions, describing their imagined worst case scenario or finding comfort in clinicians' reports of patients having healthy children despite taking AEDs can also be located in the work of Corbin and Strauss (1987) who describe an 'ideational process' in which decisions are rehearsed over time:

Reviews are the reflective parts of actions and involve the use of day-dreams and various types of imagery for recapturing the past, examining the present, and projecting the future – reviews often serve as a basis for future action. the person mentally rehearses or thinks through how he or she will handle a problematic situation (Corbin and Strauss, 1987, p.268)

A concerning finding in the present study was that WWE did not consistently decide to return for preconception review between pregnancies, nor did their experiences of adverse pregnancy outcome consistently motivate them to engage in preconception activities. One subgroup of women reported experience of adverse pregnancy outcome: among those with children with developmental problems, the delay in diagnosis was reported as influencing their decisions to have a second child. Observation of participant consultations offered further insight into the resistance of some women to action recommendations to switch or withdraw AEDs. For one participant, neither repeated clinical recommendations to switch from sodium valproate nor her experience of miscarriage were sufficient to counter her fears for her own safety, were she to experience a relapse of tonic-clonic seizures. For other

women, the experience of prenatal diagnosis of congenital malformation often resulted in the decision to terminate pregnancy. Interestingly, though the experience of a pregnancy whilst on sodium valproate was found to influence decisions to terminate pregnancy, it did not consistently result in immediate engagement with epilepsy services. Their perceptions of the risk of adverse pregnancy outcome, and of subjection to the public gaze once pregnancy intentions were announced, were the explanations given by a small number of women for their non-initiation of preconception review, with these women admitting to secretly trying to conceive and purposefully choosing not to discuss their intentions with health professionals. Lippman-Hand and Fraser (1979a) also examined this phenomenon, highlighting the difficulty for women making pregnancy decisions, both in relation to the risks and the chance something could go wrong which, if linked to a purposeful decision, could result in blame (p.61). For this reason, an accidental pregnancy was seen as a preferred outcome. That women in the present study also avoided initiating preconception interventions was also consistent with Fishbein's (1972, p.216) theory of behavioural intention in the area of family planning, which proposes an individual's appraisal of their risk status as determined by their 'beliefs and attitudes' towards the consequences of implementing a given intervention. The potential conflict between women's preferences and clinicians' recommendations were highlighted within the current study through the finding that the differing appraisals of risk were managed by a willingness to negotiate. This findings is in support of Corbin (1987) who identified pregnant women with chronic illness as taking action to minimise risks and negotiating differing opinions about the appropriateness of a particular interventions so that 'decisions could be mutually agreed' (p.334-336).

10.3.3 Summary

Perhaps the single most important finding from the present study is the women's use of negotiation and compromise as strategies to utilize the available support. A similar pattern emerged in the qualitative study by Lippman-Hand and Clarke Fraser (1979a) regarding the 'burden of decision-making'. The current study highlights women's struggle to make decisions about preconception care within the wider context of the trajectory leading to pregnancy. This is addressed by the development of a model of preconception counselling, discussed below.

10.4 A model of preconception counselling for women with epilepsy

The model was developed during analysis of women's experiences of preparing for pregnancy, as a theoretical underpinning to the application of preconception interventions in practice and support for further research into the conditions required for effective preconception counselling to reduce adverse pregnancy outcomes. The model reflects the longitudinal nature of investigation aimed at capturing both private actions and targeting socially acceptable decisions and the important links between responses to changes in personal circumstance. Few previous studies have attempted to address the limits of evidence of effectiveness of preconception counselling to reduce adverse pregnancy outcomes in a population of WWE.

10.4.1 Pregnancy contemplation ladder

Adaptation of the 'contemplation ladder' was seen helpful here. Appreciation of the stages of pregnancy intentional behaviour was supported by the constructs of self-efficacy (Bandura, 1997) and health locus of control (Wang et al., 2006; Spirito et al., 1990) as integral to motivating increased pregnancy planning and implementation of preconception interventions, in keeping with others (Charron-Prochownik et al., 2001; Bastani et al., 2010; Weisman et al., 2008). The current study highlights an association between women's information seeking behaviours and their experience of receiving risk information. The outcome, motivating women to take action on preconception interventions (high sense of self-efficacy) is in agreement with Bandura (1997), and helps explain why some women felt information alone was insufficient to motivate them to take action. This raises questions of 'what needs to be done' and what are the requirements of practical and psychological support (developing 'self regulatory skills', 'goal setting' and 'self-incentives for personal change') (p.302-3). Movement up or down the contemplation ladder appeared influenced by epilepsy-specific factors (i.e. changes in seizure control), AED-specific factors (i.e. high versus low risk AED, polytherapy versus monotherapy) and lifestyle factors such as changes in employment, driving status and relationships. Changes in women's pregnancy intentions may not be known or shared with their clinician, whereas the clinician may be aware of epilepsy or AED-related risks which may not be known to the women. Therefore, communication is found to be vital to support shared decision-making between women and their clinicians throughout the all stages of planning pregnancy.

10.4.2 Implementing preconception interventions

The model developed throughout this analysis highlights the process of decision-making as being made-up of incremental decisions, such as the decision to prepare for pregnancy, deciding to continue adhering to contraception, and decisions to implement interventions prior to attempting to conceive, before finally deciding to try to conceive. This finding is supported by O'Connor's et al (2002) concept of a 'cascade of decisions' requiring women to balance the potential benefits against losses from choices they face as they progress through the transition from pregnancy to motherhood. The finding that some women perceived themselves at low risk due to their endeavours to live a healthy lifestyle, considered themselves to have sufficient knowledge to assess their own risk status as low and similar to everyone else, and that they derived reassurance from their clinicians' questions about their pregnancy intentions as implying low risk status were in keeping with the research of others (Hosli et al., 2008; Parsons and Atkinson, 1992). Further, for a small sub-group the delivery of a 'healthy baby' despite AED exposure implied evidence of their low risk status, reinforcing ambivalence towards planning a future pregnancy, an approach interpreted as 'fatalistic' by Pashley and O'Donoghue (2009). The prospective study by Lum and colleagues (2011) of women without epilepsy planning pregnancy aimed to determine women's intentions to modify their behaviour during the preconception period. Despite women reporting intentions to change their alcohol and smoking behaviours prior to pregnancy, few women actually made changes. This highlights the disparity between reported intentions and enacted behaviours, and underlines the importance of gathering baseline data prior to implementation of preconception interventions, especially if relying on measures of behavioural intention as an outcome measure of the effectiveness of such interventions (Lum et al., 2011). Lum and colleagues (2011) identified two important findings replicated by the current study:

- 1) Women were likely to delay commencement of health protection behaviours, initially trying to conceive, and motivated to changing health behaviours only if they became concerned by perceived fertility problems;
- 2) Women attended preconception review already pregnant, having decided to try and conceive before requesting preconception consultation.

These findings highlight the significance of the timing of receipt of preconception information and the location of decision-making as frequently being away from the

consultation. Further barriers to the achievement of planned pregnancy were perceptions of the decision to plan as involving a regimentation of natural processes. Therefore, planning only became relevant if they had not managed to conceive naturally within their perceived time scale.

Miller (2005) reports that, among the wider population of pregnant women, acceptance of professional support is judged as an appropriate way to reduce risk and act responsibly (p.72). Miller (2005) suggests this perspective compels women to accept expert advice and avoid risk through appropriate behaviours and self-management (p.49). Miller's observation of perceptions of uncertainty leading to dependence on authoritative expert knowledge is supported by the behaviour of WWE in the present study, with many women seeing their epilepsy specialist as an expert, best suited to provide guidance regarding appropriate preparations for pregnancy.

Women's involvement in preconception decision-making was reliant upon being offered interventional and treatment choices. The majority of women anticipated taking part in decision-making and, whilst some referred to their clinician as taking the lead, all made reference to the final decision either to proceed with the recommended interventions and/or try to conceive as their own. These findings contrast with those of others researching involvement of adults with epilepsy in treatment decisions. For example, McCorry et al. (2009) identified few patients using the pronoun "I" to denote "decisional ownership" (p.213). In contrast, women in this study both deliberated proposed AED-related options and proposed their opinions concerning the preferred course of action. In addition, the current study contributes to understandings of how women interpret and utilize risk information when faced with reproductive decisions (Helbig et al., 2010), and is in agreement with the findings of others, highlighting decisions about whether and when to have a child, and the number of children, as among the most important decisions individuals and couples face during their reproductive years. However, the findings also suggest women struggle to maintain the role as decision-maker, as evidenced by their reported 'changes of mind' and their reported emotional responses to the requirement to make judgements concerning competing and equally valued outcomes (the personal ones relating to seizure control and those held on behalf of the unborn baby). Given the nature of decisions facing women, a model of shared decision-making would be advantageous in the provision of

support. Coulter and Collins (2011) describe the model of shared decision-making as based on the assumption that clinicians and patients bring differing, yet equally valid forms of expertise to the decision-making process thereby supporting negotiation and compromise within the consultation. This, however, is dependent on the clinician eliciting the patient's attitudes to risk and preferences concerning probable outcomes, informed by the clinician's expert knowledge of the available treatment/intervention options. The contribution of Stacey and colleagues' (2011) evaluation of the positive effects of decision aids to enhance patient active participation in informed decision-making are applicable to the development of a model of preconception counselling. The benefits of the use of decision aids within the preconception counselling consultation and specifically to support decision-making as part of the model of preconception counselling, may provide a useful format of presenting pregnancy and treatment-related risk information, supporting women explore the possible benefits and harms of the available options, and consider their values and preferences of the outcomes of their decisions thereby enhancing patient-clinician communication when used by WWE in preparation for the consultation, and by both the patient and clinician during the consultation.

The purpose of the model of preconception epilepsy review for WWE was three-fold: first, to gain additional information about treatment options, what needed to be done before pregnancy and what to expect during pregnancy and future motherhood; second, to seek advice concerning available options for improving epilepsy control; and third, to gain reassurance concerning treatment and seizure related risks, and more generally about their ability to cope with the outcomes of pregnancy. The importance placed on information seeking as a resource both supporting and influencing decision-making is in keeping with research focusing on reproductive decision-making by women with multiple sclerosis (Smeltzer, 2002). Seeking risk information was considered by Corbin (1987) as a prerequisite for balancing and controlling risks during pregnancies complicated by chronic illness, suggesting management involved women 'weighing the degree of benefit of a potential option versus the degree of risk it presented' (Corbin, 1987, p.331,333).

10.4.3 Summary

The implications of the study findings support conceptualisation of the model's staged approach in terms of theories of shared decision-making, the effects of applying decisional support alongside a pregnancy contemplation ladder, and social cognitive theories of predicting health behaviours. The potential benefit of developing the model for validation in current practice is improvements in women's recall of preconception options and outcomes, and more accurate perceptions of outcome probabilities. Further, the development and testing of a theoretically structured model and decision support for preconception counselling will both address the limitations of evidence of the effectiveness of preconception counselling, while developing practices to assist women comprehend their preconception options and make judgements about preference based on the benefits versus the harms of the probable outcomes.

10.5 Methodology

The research methods were designed to produce valid and trustworthy findings adhering to the quality criteria established by Seale and Silverman (1997) and Yardley (2000) (Chapter 4, Table 4.3). The importance of evaluating the conduct of the study is two-fold:

- 1) To confirm the quality of data produced for analysis and the quality of analysis to answer the research question, and
- 2) To meet the study objectives as a moral obligation to the participants, funding body and sponsors.

10.5.1 Appraisal of methodological quality (Table 10.1)

A qualitative methodology informed by an interpretative phenomenological analysis was chosen as appropriate to answer the research question, which required a sensitive approach to the subjective experiences of women preparing for pregnancy and a focus upon participants' perspectives of reproductive decision-making. A quantitative methodology was felt unsuitable, due to the assumptions such an approach would involve of how preconception counselling is understood by women, and the limitations for exploring potential explanations about women's experiences preparing for pregnancy. My study objectives were a response to the practical challenges I had professionally encountered working within the field. My first step was, therefore, a

systematic review of the evidence of the effectiveness of preconception counselling to reduce the risk of adverse pregnancy outcomes for WWE; leading to construction of the empirical research study questions:

- 1) How do women with epilepsy interpret risk information when presented within consultation?
- 2) What factors influence decision-making, do women use risk information when making decisions, and following consultation, are women prepared to make a risk-benefit assessment and potential modifications to their epilepsy management and or health behaviour?
- 3) What are women's perceptions of the influence of communication of risk upon decisions made?

The research context was informed by awareness of the needs of WWE, national and international guideline documents, copious review papers, and the dearth of high quality evidence to inform of the effectiveness of preconception counselling (JB Winterbottom et al., 2008). The results of a Cochrane Systematic Review (Chapter 2) identified the limitations of available evidence concerning the evaluation of preconception counselling interventions, and sets the research agenda with reference to the Medical Research Council's (2000) framework concerning development and evaluation of randomised control trials of complex interventions to improve health, establishing the need to develop a theoretical understanding of the processes of preconception decision-making. This framework raised the importance of understanding the differing organisational factors surrounding preconception counselling delivery, the "underlying assumptions in relation to the intervention", the need to "determine which groups of participants are most likely to respond positively to the intervention", the appropriateness of using qualitative research to identify the "active" components of preconception counselling, and the relationship between these components "which may act both independently and inter-dependently" to influence the outcomes (MRC, 2000, p.2,9; Craig et al., 2008, p.9, 19).

The aim of this qualitative analysis was to explore the 'uniquely embodied and situated' experience of preparing for pregnancy in the lives of WWE (Smith et al., 2009, p.29). The current study methods were not looking for a representative sample as defined by quantitative methodology, but rather an idiographic account which valued the individual richness and detailed interpretations made by WWE. The ability to generalise from the current findings was to produce a detailed account which

supported theoretical insights. This approach was felt to represent the differing meanings of planning pregnancy, and be able to reflect the emotive nature of risk information and the complexity of decision-making which could prove useful if transferred into other clinical contexts. The ability to transfer the findings into other groups of WWE, such as those from differing ethnic and religious backgrounds requires further research. By recognising that other groups of WWE may share some similarity with the current study sample; the differences would be the focus of future research.

Quality criteria	Application of criterion within the current study
Sensitivity to context	<p>Reflexivity to researcher-participant relationship was ensured by careful construction of study documentation, making explicit my employment as an Epilepsy Nurse Specialist, and my role as a researcher.</p> <p>Sampling and recruitment techniques ensured the study population was similar to the wider population of WWE, reflecting the consistency between AED use between study participants and registrants within the UK Epilepsy and Pregnancy Register. Reporting techniques were evidenced by the depth of descriptive data supporting theoretical generalisations. This was achieved by openly displaying the participant accounts, thereby supporting ‘the reader to evaluate the transferability to persons in contexts which are more or less similar’ (Smith et al., 2009, p.51).</p> <p>Details of the extreme case of ‘selfish decision’ were highlighted as an unexpected finding used to test the model, and reflected sensitivity within reporting style.</p>
Commitment to rigour	<p>The development of research skills was a practical measure of commitment to rigour, and was part of the expectation of PhD student research training. The author’s commitment to the progress of this study extends beyond the time of postgraduate study; as time was required to negotiate release from an NHS contract and to secure funding. Within the conduct of the study, rigour within data collection techniques focused on a thorough and systematic approach. Within data collection sufficient ‘probing’ through questioning, and a flexibly applied to follow up on participant cues, digging deeper for explanation and interpretation (Smith et al., 2009). Rigour in data management involved detailed transcription and electronic storage of the data.</p>
Transparency & coherence	<p>Opportunities to present the findings were availed within peer group analysis sessions as part of the post graduate qualitative analysis and reading group accessed as part of my research training at The University of Liverpool. The consistencies of applying themes were enhanced through supervision and peer group analysis sessions in addition to oral presentations and annual reporting. An audit trail was established with NVIVO7 qualitative analysis software and further supported reflexivity tracking the development of themes and changes coded text vital as the process of analysis was lengthy.</p>
Impact & importance	<p>The significance of the prolonged exposure to perceptions of blame, fear and guilt have been identified within the current study findings as requiring further investigation, considering the influence upon pregnancy planning for WWE, and the influence of framing AED and seizure-related risks prior to pregnancy. Further, the clinician’s use of exemplar cases and ‘stories for practice’ has impact upon the pervasiveness of risk perception for women at the start of their reproductive careers and as they moved towards pregnancy and progressed into motherhood.</p>

Table 10.1 Appraisal of the quality and validity of the current study

The value of the qualitative methods within this study is the production of rich data, able to extend existing evidence of the complex and challenging experiences of WWE preparing for pregnancy. This was illustrated through participants' openness in sharing their experiences both with each other during focus group participation, with their clinician during observed consultations, and with me during individual interviews. The study revealed women as welcoming questions from their clinician concerning future pregnancy intentions and the offer to review past experiences and factors influencing their reproductive decisions. The majority of women identified participation in the study as beneficial and an opportunity to reflect on their experiences, and for the focus group participants as providing the first opportunity to meet another WWE.

The triangulation of data collection methods provided an opportunity to explore women's experience from multiple perspectives, with each method contributing to the strength of the findings in three important ways:

- 1) Focus group data explored diverse and contrasting accounts of women's differing epilepsy trajectories, their influence upon perceived pregnancy-related risks, and perspectives concerning preconception decisions. The focus group participant is positioned to present their own views and experience while hearing those of others. It is through this reflective component that participants' own standpoint becomes clear.
- 2) Clinic observations proved valuable in illustrating the context for risk communication, allowing me to gain insights into the interactions between women and their clinician, observe discrepancies between the clinician's recommendations and actions taken by women in whom the influence of their relationship and the negotiation of decisions became apparent.
- 3) In-depth follow-up interviews were vital to uncover the range of emotional reactions underpinning the multiple and complex decisions faced by women as they began to consider pregnancy. The interviews presented women with an opportunity to explore their feeling about preparing for pregnancy, revealing them as moving between competing interests and priorities of interest as they approached decision-making. Within this context the extent of emotional investment became apparent, with responses of blame and guilt and questions about selfishness.

The benefits of focus group data have been emphasised by the ‘experiential discussions’ of Dunne and Quayle (2001) and by others, as bringing individuals together who share an experience and providing opportunities to discuss issues of personal meaning within a group setting, gaining access to accounts which may otherwise be inaccessible (Wilkinson, 2008). The development of the topic guide was designed to encourage in-depth accounts, in keeping with Finch and Lewis’s (2003) work utilizing focus group techniques. Focus group findings informed non-participant observations, offering the opportunity to explore and understand the processes of preconception counselling. Observations of the consultation as a naturally occurring event have successfully been applied within health research, for example, women’s decision-making regarding contraception (Lowe, 2005). The observational research by Lowe investigated the complex power relationships within the negotiation of contraceptive decisions and revealed the gendered roles within the consultation (Lowe, 2005), a point extended within the current study. The value of in-depth interviews is the opportunity they offer to enter the psychosocial world of the participant (JA Smith, 1995). The aim of the interview within the current study was to elicit detailed stories, thoughts and feelings from the participant in their own words, utilizing techniques described by Legard et al (2003) and Smith et al (2009), and with the use of probing techniques, to expand on initial statements to gain depth, nuance, clarity and further understanding.

Interpretative phenomenological analysis, informed from a psychological perspective, was felt to suit the overall research objectives: supporting detailed examination of the process of preparing for pregnancy, and analysis of risk perceptions and decision-making experienced by WWE. Smith et al (2009) considers interpretative analysis as contributing to making sense of the lived-experience of the research participant, furthering understandings of ‘beliefs’, ‘attitudes’ and ‘behaviours’, and supporting development of a model to interpret the main study findings (p.183).

10.5.2 Limitations of the research

There are three main limitations to this qualitative analysis of women’s experience preparing for pregnancy: first, the sample was limited to mainly white British women; second, the data were gathered at a single time point, with no attempt to gather prospective longitudinal data able to reflect the decision-making process in more

detail; and third, the sample size was over-large within the discipline of interpretative phenomenological analysis. The reason for the first limitation concerning the fact that only 4% of the total study population are Asian women reflected the struggle to recruit a multiethnic study population. The experiences of WWE from differing ethnicities requires further study to ensure services are sensitive to both ethnic and religious differences. Analysis revealed several focus group participants who referenced religious factors as influencing their use of contraception and views concerning termination of pregnancy. However, the study provides a detailed account of the study participant's experiences, and provides an opportunity to 'transfer the findings to other persons in context which are more or less similar' (Smith et al., 2009, p.51). The findings may not however, be directly transferable into other populations, such as non-white British WWE. The opportunity to conduct a follow-up study looking at multiple perspectives may help develop a more detailed account of the meanings of preconception care from the points of view of, for example, Asian women in the North West of England. For this reason the findings, discussion and implications of this thesis must be considered with caution, as the transferability to other populations of WWE maybe limited.

The second limitation resulted from the decisions being made at study design stage, to focus on the breadth rather than the depth of reproductive experience and on reporting a detailed account of a wide range of participant experience to provide illustration and support theoretical generalisation. The limitations of gathering data at a single time point were balanced by the opportunity to follow up women observed during consultation. This study is therefore the first observational study reported in the field of epilepsy to incorporate a prospective account of decision-making, albeit limited in duration of follow-up. The study has highlighted the tension women experienced between competing interests, finding decision-making as not easy and spun out over time. Further, the process of pregnancy planning reflected a staged model of behaviour change, supporting development of a 'pregnancy contemplation ladder'. The findings challenge assertions of paternalistic decision-making during routine epilepsy consultations, identifying a shared decision-making approach providing both practical and psychological support for WWE preparing for pregnancy.

The third limitation was that the level of analysis may not have done justice to the large sample size and corpus of data for interpretive analysis (Smith et al., 2009, p.52). An alternate approach would have been a case study design, recruiting a small group of women representing the different stages of pregnancy contemplation and producing a detailed examination of the processes of decision-making.

10.5.3 Strengths of the research

This research has a number of strengths that allow its results to be viewed as reliable and applicable to the wider group of reproductive-aged WWE. These strengths include:

- 1) Transparent recruitment processes, offering a description of the study population as representing a broad range of WWE of reproductive age from the North West of England, comparable to women with epilepsy recruited into published registries and cohort studies exploring pregnancy outcomes (Meador et al., 2008), and thereby supporting transferability of the study findings.
- 2) The recruitment of a population of WWE reflective of other reproductive-aged women's experiences of preparing for pregnancy highlights the opportunities to research this population. The current study supported a process of recruitment in which amendments to the study protocol helped establish contact with teenagers and maintain contact with women during changes in life circumstance while remaining flexible to support their participation. In keeping with Brown's et al (1997) descriptions of the tentative nature of women's pregnancy plans, caution was exercised during recruitment in order to be sensitive to life events such as separations, financial difficulties and other unfavourable events, as well as favourable events such as engagement and moving in with a partner.
- 3) The current study provided a description of the women's demographic and reproductive characteristics to support transferability of the results into the wider population of WWE.
- 4) Evidence of specific stages of planning was gained, confirming the possibility of both identifying women during the precontemplative and contemplative stages of pregnancy planning, and retaining their interest in participating in the study until completion. All women showing interest in taking part in the study remained happy with the researcher contact. There was no loss to follow-up

between observed consultation and interview completion, supporting analysis of a full range of experiences.

- 5) In keeping with Seale and Silverman's (1997) description of hypothesis testing, the current study looked for patterns across 'cases', identified recurring themes and served to test the representativeness of emerging themes, for example, it was possible to describe a variety of individual planning experiences. The analysis also identified outlying beliefs and opinions, locating women who had defined their approach to planning in terms consistent to clinicians and helping to draw attention to the 'outliers'. This work to identify similarities and differences in cases studied as described by White et al (2003), contributed to development of original explanations which form part of the overall conclusions.
- 6) Comprehensive and objective recording of data was maintained. Data collection was completed on the 22nd July 2009, with 85 women and 12 clinicians taking part in the study, generating 74 hours 14:45 minutes of recorded data all of which was transcribed verbatim, and entered into NVIVO 7 qualitative computerized software to ensure a systematic analysis of all the available data.
- 7) Attention to the closeness of "researcher-informant relationship" was acknowledged within study documentation, use of topic guide and introductory discussion with the participant prior to data collection. Further, in keeping with Hamberg's et al (1994) examination of qualitative rigour, I reflected upon the potential influence I might have had during data collection and throughout analysis, providing an account within my research journal, and utilizing opportunities for group analysis to check my interpretations of the data against those of fellow PhD students. In contrast to Hamberg et al (1994), I was cautious to avoid direct clinical work with research participants, in an attempt to support my observations as an 'outsider'. However, my position as researcher-clinician underpinned the development of rapport with the participants and contributed to the richness and quality of data.
- 8) The study provided original in-depth insight into the psychosocial aspects of preparations for pregnancy and reproductive decision-making, delineating a model of preconception counselling reflective of individual perceptions of risk

communication and the importance of defining meanings of the pregnancy planning process to support the needs of WWE.

- 9) Examination of both the processes and experiences of WWE preparing for pregnancy offered a fuller understanding of possible preconception counselling interventions, identifying barriers and facilitators. Often research in this area has focused on detailing pregnancy experience, with few studies including a process evaluation. As described by Craig et al (2008), there has therefore been a failure to explain the discrepancies between expected and observed outcomes, and continued high rate of unplanned pregnancy. The current findings of significant discrepancies between women's and clinicians' definitions of planning have helped reveal women's unmet support needs.

Based on the discussions drawn here from this study and previous published accounts, conclusions and future directions of research in this area are outlined in the final chapter.

Chapter 11 Conclusions and future directions

I will conclude by reviewing the contributions of my work to practice and the implications for future research. The findings reported in this thesis are the product of seven years of study, more than half of which was spent in the field, gathering data, transcribing individual and group accounts, and undertaking an interpretative phenomenological analysis with the purpose of answering the research question.

11.1 The contribution made by this research

The principles of preconception counselling of WWE are well documented within the epilepsy literature, with more than 87 guideline documents and narrative reviews examining the topic published between 1950 and February 2012 (see Chapter 2). This preoccupation with review and guidance is somewhat misleading, as the Cochrane Systematic Review I led identified no robust evidence of the effectiveness of preconception counselling to reduce adverse pregnancy outcome in WWE. In addition, current national guidance is based on level III or IV evidence, or ‘good practice points’ developed from the clinical experience of the NICE Guideline Development Group (NICE, 2012). In contrast, the numbers of publications documenting teratogenic effects of AEDs have gathered momentum, with recommendations pointing to preconception counselling to ‘convey reliably the full risk to the child’ associated with in utero AED exposure (Bromley, 2009, p.229). The findings here indicate attention is required to providing high level evidence of the effectiveness of preconception counselling to deliver on these recommendations. I now highlight a number of unique contributions made to achieve this goal:

1. The results of the systematic review of the effectiveness of preconception counselling to reduce adverse pregnancy outcome in WWE identified no high quality evidence, with only one study meeting the inclusion criteria. Due to methodological limitations and risk of bias, conclusions about effectiveness of preconception counselling remain unanswered. The current study has gone some way to underpin future research by identifying individual variance likely to influence the identification and recruitment of preconceptual WWE, and the requirements of risk communication strategies likely to influence women acting on preconception recommendations as intended. In practice, clinicians and WWE may benefit from the development of targeted communication

strategies that; a) support clinicians identify the appropriate information and/or intervention to best meet a woman's pregnancy intentional stage, and b) support women identify their pregnancy intentional stage, such as applying the contemplation ladder as a single-item self-reported measure of the stage of contemplating pregnancy.

2. The findings from this study contribute to the current literature by explaining the differing responses of WWE to recommendations to plan pregnancy. For many women planning simply meant trying to conceive, an implication of this being the possibility of women withdrawing contraception earlier than anticipated by their clinicians. This may explain why women continue to attend clinic pregnant before receiving preconception counselling. The timing of care delivery is essential if the objectives of preconception counselling are to be achieved, i.e. optimizing health prior to conception, management of teratogen exposure, and informed reproductive decision-making on the part of the WWE. The practical application of this finding will require changes in the nature of communication between women and clinicians, requiring changes in questioning style to open a dialogue concerning future pregnancy intentions, and opportunities to share definitions of what preparing for pregnancy means for each party.
3. The results of this study have highlighted the emotional implications of risk communication and the influences upon decision-making for WWE preparing for pregnancy. The key themes emerging from analysis highlight the importance of developing a shared meaning of the concept of pregnancy planning, which promotes the benefit of preconception epilepsy review. The implications of failing to account for the active role women assume during assessment and management of risk is likely to contribute to a sub-group of women taking action by risk reduction or avoidance strategies at a time when contraception techniques may not be adhered to, increasing in the risk of unplanned pregnancy.
4. This study has provided a unique opportunity to observe risk communication between women and their clinicians in action, during the epilepsy consultation and within the context of women making plans and preparations for pregnancy. This has revealed several interesting aspects of women's decision-making and the strategies adopted to manage decisions which could be simultaneously

viewed as 'selfish' and complex, requiring careful management of risk information. The implications of this finding for practice and future research highlights the opportunity to study risk communication in practice, and the ability to gain valuable insights into what influences women making decisions within the context of the epilepsy consultation. In clinical practice, increased awareness of the potential for women experiencing decisional regret emphasises the importance of clinicians understanding of how they might influence the outcome of decisions, and the potential benefits of clinicians receiving counselling training.

5. The findings offer the opportunity to direct an important public health message about the value of planned pregnancy, given the responsibilities faced by WWE to protect the health of their future child, whilst managing risks to themselves from seizures and treatment.
6. Risks are presented both numerically and as narrative, to provide reassurance by the reframing of prior over-estimations of risk, and the rationale to action health promotion advice. While communicating risk and uncertainty remains a challenge, the women's preconception counselling agenda is dependent on beliefs regarding the significance of pregnancy and seizure risk within a wider social context of health priorities, pregnancy intentions and general risk awareness. The recognition of the social context of a woman's plans for pregnancy is essential for interpreting poor treatment adherence on discovery of pregnancy.
7. Preparing for pregnancy was a complex issue. When interpreted against the health and social science literature, women's definitions of planning were revealed as not resembling those endorsed by the epilepsy professional community. Lay definitions were socially constructed and influenced by the experience of living with epilepsy, views of spouse, friends or family, and distrust of taking medication. This analysis reveals the importance of increasing understanding of how women define 'preparing' for pregnancy. It has high relevance for promoting uptake of preconception counselling through the development of targeted interventions focus on changing health beliefs, increasing self-efficacy and supporting women's awareness of the benefits of preconception interventions and increasing their confidence to take action.

8. The impact of preconception counselling upon the experience of decision-making has focused women's attention on a part of their lives many have tried hard to distance themselves from. For some, the focus of attention upon the risks about pregnancy heightened their fears associated with treatment and seizures, or with the uncertainties of life or pregnancy with epilepsy.
9. The experience of difficulties in making decisions was interpreted by women as due to the unpredictability of the outcome that was out of their control, and requiring their acceptance of a 'threatening' drug. This was found to place personal responsibility upon the woman, not only to make this "huge massive life changing decision", but ultimately to face the consequences of that decision, which were located outside of the clinic and, for some, resulted in avoidance strategies. Public perceptions of blame and responsibility for the outcome of decisions made resulted in a sub-group of women interpreting their decisions as selfish.
10. The most significant finding was that not all women perceived risks in the same way, responding differently to information concerning risks and uncertainties, with implications for clinical practice and the communication of preconception information as influencing women's risk management and decision-making.

11.2 Unexpected outcomes

This study provided a unique opportunity to observe prospectively WWE and their clinicians engaging in risk communication within the context of the epilepsy clinic, and to gain insight into the real life perspectives of women preparing for pregnancy. This opportunity enabled a 'fly-on-the-wall' account of decision-making and supported the interpretation by women of their role within the clinic consultation and subsequent decisions made and actions taken.

The most significant unexpected result has been the degree of difference between definitions of pregnancy planning held by clinicians and patients/participants in comparison to guideline definitions. This was first noticed during recruitment, and was explored through focus group discussion and interviews. The findings revealed that both women and clinicians have a tendency to judge planning as the activity of trying

to conceive, whereas planning is defined in epilepsy guidelines as the review and management of epilepsy treatment and seizure control prior to attempting to conceive, and as involving commencing folic acid and optimizing seizure control and treatment before withdrawal of contraception. While clinicians were observed to review and attempt to optimize treatment and seizure control, there was a tendency not to include this activity within their discussion of the importance of planning pregnancy. From the perspective of women there was also a tendency to separate improvements in epilepsy care from their activities of planning pregnancy. This finding has significance as women are frequently recruited or categorized for analysis within studies based on their statement of pregnancy planning intention, such as in recent questionnaire studies to assess the knowledge of women regarding preconception issues.

WWE preparing for pregnancy were found to be a vulnerable group, due to their reliance on health professionals identifying their pregnancy intentions within referral documentation, the resultant risk being either a failure to assign urgency to review or appropriate allocation of clinic or clinician. With the exception of women with recent relapse of seizures or active epilepsy, referrals failed to acknowledge the urgency of need for preconception review, resulting in potential delays in appointment allocation during a time when contraception had most likely been stopped as women were trying to conceive or ‘planning pregnancy’.

11.3 Implications for practice

This study’s findings have implications for clinical practice in relation to care and management of WWE during their childbearing years, and also regarding future service developments:

1. There is increasing pressure to communicate the results of the ongoing research into the potential adverse pregnancy outcomes associated with in utero exposure to AEDs. These studies report on the risks associated with in utero AED exposure and require both clinician and patient to interpret and discuss the results. There is also pressure for the communication of these results to take account of the continued uncertainties both in relation to the extrapolation of population data to individual patient care, and in predicting individual responses to changes to AED regimens and the emotional responses of

individual patients. The results of this project have immediate applicability for the development of clinical practice, supporting improvements to risk communication strategies and the delivery of preconception counselling.

2. The results highlight the important role of the clinician in communicating risk and acting in an important health promotion role, by supporting informed decision-making crucial to maintain the safety of the future mother and baby. Communication of risk which focuses on the health of the unborn baby/child has a persuasive element, given the vulnerability of the unborn baby to in utero AED exposure and maternal seizures. The patient's perspective was as recipient of risk information delivered by the clinician, and the study revealed a variability and individuality of the responses among women towards their perceived risks and uncertainties, with the power to influence their assessment and management of risk both prior to and during pregnancy.
3. The communication of risk was challenging for both women and clinicians, and no consensus was observed with regard to the content of risk information delivered by clinicians. This finding is significant for future practice development, as no clinical protocols currently exist to guide counselling practice, despite the increasing likelihood of more complex sets of risk information data requiring communication, such as the Epilepsy and Pregnancy Registers and prospective studies examining neurodevelopment outcome. The literature acknowledges the limitations of clinician communication skills in translating population estimates into individual susceptibility. This area requires urgent attention and the current study findings support recommendations to investigate development of communication support both for clinicians and patients, the use of decision aids and the application of prospective observational studies to extend findings longitudinally within a lifespan perspective.
4. The model of preconception counselling highlights opportunities to offer support to women when assessing their pregnancy intentional status, suggesting a need for interventions to improve self-efficacy for WWE to influence their engagement in epilepsy management and health promotion strategies to improve seizure control and overall health prior to conception. An implication of these findings is that pregnancy intentions were both independent of age and highly emotive, with the latter influencing engagement

in planning activities. The study identified a sub-group of teenagers with clearly stated intentions, reinforcing the need for delivery of targeted interventions to improve awareness of preconceptual issues from the earliest opportunity and repeated over time.

5. The implications for practice will require a shift in the perceptions of clinicians regarding the role played by women in assessing, interpreting and managing perceived risk and uncertainty relating to pregnancy planning. Clinicians will be required to make known their personal interpretations of what they mean by the terms 'planning pregnancy' and to develop a shared meaning of planning behaviours early within the clinical relationship. This requires an open dialogue, with the clinician reviewing the patient's perceived anxieties, worries and fears concerning pregnancy planning.
6. WWE have been found to take an active role both interpreting and negotiating the preferred outcomes of pregnancy. However, the results have revealed a disparity between what interventions WWE and clinicians expect and want to include within the preconception review. Communicating risk is a vital component of any preconception review and the results of this study have shown the powerful influence the content and methods of delivery can have upon risk management strategies accepted and acted upon by women.

11.4 Future Directions of Research

This research study has illustrated the acceptability of observations of clinical practice and the value of providing women with feedback in the form of follow-up interview. It is likely that this method of research would be applicable both in practice development and future research to analyse the differing methods of delivering risk information and the impact of risk communication strategies upon preconception decision-making. Further research in this field would be of great help in raising the profile of this clinical area, and the practical application of developing risk communication and preconception care interventions to improve future pregnancy outcomes. This highlights the importance of collaborative research, such as considering inclusion of preconception recruitment within the WWE national epilepsy and pregnancy registers, and prospective cohorts investigating in utero AED exposure and the risk of neurodevelopmental delay.

The current study has contributed to the design of future prospective studies, clearly defining the participant groups of interest, namely patients and clinicians, in which clinicians could be further defined as involving: 1) primary care clinicians including GPs, practice nurses and community pharmacists, and 2) secondary/tertiary care clinicians involving a multidisciplinary team of neurologists, specialist nurses, obstetricians, midwives and psychologists. The patient group for future studies requires a wider population sample, involving women with a confirmed diagnosis of epilepsy, identifying women at the time of diagnosis, or in the case of teenagers, identifying young women prior to first sexual encounter. These women could be prospectively monitored to answer questions such as “what clinical and behavioural interventions provided before pregnancy will improve pregnancy outcomes for WWE and their offspring”, and including satisfaction scales and economic evaluation as part of the research protocol (JB Winterbottom et al., 2008).

The Cochrane Systematic Review of the effectiveness of preconception counselling identified several topics requiring further investigation including the need to address the limits of methodological quality of the current evidence. It is proposed the development of prospective randomised-controlled studies, prospective cohorts and controlled before and after studies, powered to detect difference between interventions will be able to provide evidence effectiveness. These studies would need to collect sufficient data for analysis of significance, making comparisons at baseline and over several data entry stages during the study, with sufficient duration to collect long-term outcomes of pregnancy.

The methods of research have been acceptable to both women and clinicians. They have consented to the invitation for observation and digital audio recording of the epilepsy consultation, revealing a future opportunity to extend the application of these research methods into larger prospective studies which will evaluate the effectiveness of future developments in the presentation of risk information within the preconception counselling consultation.

The presentation of pregnancy-related risk information consists of multiple sources of data, requiring a clinician to have full awareness of the current literature and be skilled to translate risk data into meaningful messages that will help women make informed

reproductive decisions. It is also recognised women require suitable comparisons when facing risk decisions, for example, when making choices between teratogenic risks within a proposed treatment regimen (Nicolai et al., 2008). The development of a model to support the communication of risk information requires further refinement to allow for changes in risk framing and the content of risk information.

The model of preconception counselling requires further testing of the predictive function of the model components, including further investigation of the ability to predict an individual's pregnancy intentional stage and accurately tailor individual risk information to accommodate preferences. The model was based on social cognitive theories and, it is proposed, presents an opportunity for experimental studies to test the 'active components' of preconception counselling interventions, for example, which factors promote or inhibit pregnancy planning behaviours, the ability to identify stages of pregnancy contemplation, and the influence of risk communication strategies upon the stages of change to achieve the desired outcome. It is likely further mixed methods studies will best suit this type of investigation, with the application of further qualitative research to examine the social context of women's reproductive decision-making alongside quantitative studies to measure the variance of factors within the complex process of undertaking preconception counselling during preparation for pregnancy.

11.5 Final conclusions

The findings here reveal women with epilepsy contemplate pregnancy and make decisions to try and conceive within the context of their whole life with epilepsy. Planning for pregnancy has been shown to vary in meaning between women and clinicians and requires further defining to support women taking advantage of the opportunities afforded from a planned pregnancy. Experiencing prior adverse pregnancy outcome did not consistently motivate women to engage in preconception counselling, with women often requiring assistance to consider an alternative course through a future pregnancy. The research presented here finds communication of risk and uncertain information is an emotive topic associated with risk management strategies which may act as barriers to pregnancy planning and receipt of preconception counselling. Decisions made during preparations for pregnancy are

multiple and often complex, requiring women to achieve a balance between their preferred outcomes. For some, this emphasised responsibility towards the health of the unborn child, while for others decisions to place one's own health above the child (exemplified by decisions concerning treatment adherence during pregnancy) were judged as selfish. The findings reported here regarding decision-making during preparation for pregnancy highlight the importance of predicting the pregnancy 'contemplative stage' thereby supporting women with targeted interventions. Women experience additional worries both preparing for and during pregnancy concerning the uncertainties of pregnancy outcome, and the evidence suggests as Evans (1952) noted, pregnancy need not feel a 'grim problem', but rather the potential adverse effects of preconception counselling maybe mitigated by supportive counselling and positive framing of risk information.

Appendix 1 Study documentation

Study documentation includes:

1. Participant invitation letter
 - 1.1 Focus Group
 - 1.2 Clinic observation and follow-up interview
2. Participant information sheet
 - 2.1 Focus Group
 - 2.2 Clinic observation and follow-up interview
3. Participant consent form
4. Clinician information sheet
5. Clinician consent form

Study documentation Version 4 is illustrated here, reflecting changes made during the recruitment process. An example of the clinic observation & follow-up interview participant invitation letter and study information sheet is presented here; focus group documentation met ethical approval, and followed a similar format.

To be printed on hospital headed paper of the recruiting clinicians Trust.

Letter of invitation to participants (14.07.08 version 4)

Letter of invitation to participate in observation of clinic appointment and follow-up interview.

Dear Patient's name

Study Title: A research study of women with epilepsy preparing for pregnancy.

This study may be of interest to you, and I would like to offer you the opportunity to consider taking part in the study, which would involve the researcher observing a future clinic appointment, and interviewing you a few months later.

The study is designed to increase understanding of how women with epilepsy make decisions about pregnancy.

The aim of the study is to obtain a range of differing views and experiences, of women at different stages of their reproductive lives, in order to better understand how doctors and nurses can best provide advice and support.

The researcher (Janine Winterbottom) is a trained nurse, and a post-graduate research student at Liverpool University. This study is part of her research training.

Please take the opportunity to read through the study documentation enclosed.

If you would like to take part, and would be happy for the researcher to contact you, please return the reply slip below in the envelope provided, or you can approach the researcher by telephone, email, text, or in person when you attend for your hospital appointment.

Thank you for taking the time to read through the information provided.

Name of recruiting Clinician: - _____ (in capitals)

Signature.....

------(tear off slip)-----

Return to – Janine Winterbottom at The Walton Centre for Neurology and Neurosurgery NHS Trust in the stamped addressed envelope provided.

Study Title – An in-depth analysis of women with epilepsy preparing for pregnancy.

I would like to take part in the above study, and I am happy for the researcher to contact me.

My name and address (please print).....

.....
Telephone number..... Best time of contact -.....

To be printed on hospital headed paper of the recruiting clinicians Trust.

Patient information sheet- Observation of clinic visit and follow-up interview.
(14.07.08. Version 4)

An in-depth analysis of women with epilepsy preparing for pregnancy.

You have been invited to take part in a research study.

Before you decide whether or not to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 tells you how the study will be conducted.

Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1

What is the Purpose of the Study

The study aims to provide a greater understanding of the preparations women with epilepsy make when considering pregnancy.

At present, we do not know the best way to provide relevant information to women with epilepsy thinking about pregnancy. We also don't know how best to help women with epilepsy make decisions about pregnancy.

The study is part of my research training and education. I am a part-time student at the University of Liverpool, and an epilepsy nurse specialist working at The Walton Centre for Neurology and Neurosurgery NHS Trust in Liverpool.

Why have I been chosen?

You have been invited to take part in the observation and interview stage of a study concerning being a woman with epilepsy, and your past, present or future pregnancy plans. I am interested in talking to women with epilepsy with differing ages and experiences. To complete this stage of the research I need to involve approximately 20 women in the observation of their clinic appointment and follow-up interview.

Do I have to take part?

No, it is up to you to decide whether or not to take part.

If you agree to take part and sign the consent form, you remain free to withdraw from the study at any time, without giving a reason, and without affecting the standard of your care. (Further information is given in Part 2)

What will happen to me if I take part?

You have been invited to take part in a study to increase awareness of the range of issues concerning being a woman with epilepsy.

Your part in the research will involve meeting with me on two future occasions.

The first meeting will take part at your next planned clinic appointment in approximately 3-6 months time.

Observation of your clinic visit

I will be present with you in your clinic appointment with your epilepsy specialist. Your appointment will be audiotape recorded.

I will take no part in your appointment, and will simply be present to observe, and make occasional notes, about how the discussion within your appointment flows. The clinic visit will last as long as your usual appointment.

My role is to observe the process of the clinic appointment, with the audiotape recording the content of the discussion.

In the time between the first meeting and the follow-up interview, I will study the observations I make to develop my ideas and produce a summary. You will be sent a copy of the summary before our next meeting. The summary report is for your own use as an aid to your memory.

Just before our 2nd meeting, I will make contact to arrange a suitable date and time to meet in your own home, or if inconvenient, an alternative venue can be agreed.

The second meeting will take place approximately 3 months after your observed clinic appointment.

Follow-up interview

The interview will be audiotape recorded and last no longer than two hours.

It will involve me asking you some questions. These will cover several different topics I'd like to hear your opinions and feeling about.

The success of the research rests on you feeling able to share your experiences, beliefs and views within the interview, and I will wholeheartedly respect your involvement in the study and your confidence, by protecting your identity within any written reports or presentations.

Expenses

I do not anticipate that involvement in the study will cause any additional expenses. I appreciate that the interview will require you giving of your time. However, by being flexible I hope this will limit any inconvenience to you.

If meeting in your own home is inconvenient, I will arrange to reimburse any travel costs to an alternative venue on production of a receipt. Public transport or taxi travel costs will be reimbursed.

What are the possible disadvantages or risks of taking part?

There is no physical risk associated with taking part in the observation or interview, although because sensitive topics may be discussed you may feel upset or distress. Therefore, there will be an opportunity for de-briefing at the end of both the observed appointment, and interview, making available a range of literature. (De-briefing will offer the opportunity to ask questions, or clarify any issues raised)

If personal issues are revealed through taking part in any stage of study, facilities are available for referral to the Clinical Neuropsychology service at The Walton Centre for Neurology in Liverpool.

What are the possible benefits of taking part?

I cannot promise the study will help you personally. However, the information generated in discussion might help improve the future care of women with epilepsy.

This study is designed to update the recent epilepsy guidelines published by the National Institute of Clinical Excellence.

What happens if there are problems?

If you have any concerns or feel harmed by your participation in the research project, you are entitled to complain. (Further information is given in Part 2)

Will my taking part in the study be kept confidential?

Yes, all information that is collected about you during the course of the study will be kept strictly confidential. (Further information is given in Part 2)

Contact Details:

Researcher – Janine Winterbottom can be contacted both by phone and by email if you have any further questions or concerns at any stage in your participation.

Telephone number – 0151 529 8424

(Answer phone operating 24 hours, calls retrieved and returned during office hours, with limited weekend calls).

Email- janine.winterbottom@thewaltoncentre.nhs.uk

This completes Part 1 of the Information Sheet.

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

Part 2. Additional Information

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

If you don't want to carry on with the study, I will make no further contact.

Any basic information collected before leaving the study, for example, your age and type of epilepsy may be used in the final report. However, direct quotes will not be used in the study report or any publication, and your rights to confidentiality and anonymity will be maintained.

What if there is a problem or I want to complain?

If you feel harmed by taking part in the study, there are no special compensation arrangements, and if you wish to pursue a claim, you may need to pay for it.

Regardless of this, if you have a concern about any aspect of this study, I (Janine Winterbottom 0151 529 8424) will do my best to address your concerns. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your local hospital, which you attend for your epilepsy care.

Will my taking part in this study be kept confidential?

Any information about you collected during the course of the study will be kept strictly confidential. Your name and any other names mentioned within discussion will be removed, so that you cannot be recognised by anyone reading the final report. All procedures for handling, processing, storage and destruction of the data will be compliant with the Data Protection Act 1998.

As the lead researcher, I am responsible for restricting access to this information; however, through the course of the research project the records may need to be accessed to check that the study is being carried out correctly. Anyone being granted access to the study data will have a duty of confidentiality to you and nothing that could reveal your identity will be disclosed outside the research team.

Involvement of your General Practitioner (GP)

Your GP will be informed only of your recruitment into the study with your consent. No additional information will be passed to your GP without your written consent and agreement.

Your GP is informed for the following reasons: -

In case unanswered questions about your condition are revealed during the progress of the follow-up interview and you need to approach your doctor for assistance, treatment or referral.

The need for additional contact with your epilepsy specialist or your GP might arise, if in the course of the interview, you mention something that I (as an epilepsy nurse specialist) feel might jeopardise your health. I have a duty of care, and would need to discuss this with you should the event arise. No contact would be made without your written agreement.

What will happen to the results of the research study?

The results will be written up as part of the examination of my PhD studies. It is my intention to publish the research results in medical journals with the goal of improving awareness of the needs of women with epilepsy. I would like to reassure you that every effort will be made to prevent your identity from revealed within any written report or presentation.

On completion of the research, the findings will be shared with the national patient support groups e.g. Epilepsy Action; and, in two local public meetings, arranged in Liverpool and Manchester. You will receive an invite to attend these meetings along with local service providers.

Funding of the research

Funding has been secured through two research bursaries, from the HSA Charitable Trust and Epilepsy Action, and I have been awarded a fellowship grant from the Epilepsy Research Foundation to replace my clinical time as Epilepsy Nurse Specialist.

Who has reviewed the study?

My supervisors, Professor Gus Baker and Professor Ann Jacoby from Liverpool University, have reviewed the quality of the study, and will monitor its progress and any outputs.

The study *has* received favourable review from Newcastle & North Tyneside Local Research Ethics Committee, where it was submitted for approval as the lead Multi Centre Research Ethics Committee; and from the departments of Research Governance in all participating Hospital Trust.

Thank you for considering taking part and taking the time to read this information. I am happy to answer any remaining questions you might have by making contact by telephone or email.

You may wish to keep this information sheet and the copy of your signed consent form.

To be printed on hospital headed paper of the recruiting clinicians Trust.

Clinician information sheet (14.07.08. Version 4)

STUDY TITLE: Women with epilepsy preparing for pregnancy: A Qualitative analysis of the perception and communication of risk information.

The overall aim is to provide an in-depth exploration of women with epilepsy's perception of risk and the probability of adverse pregnancy outcomes, in the context of their involvement in shared decision-making. This will enable wider inference to be made regarding the role and potential outcomes from preconception counselling.

The rationale for study design reflects the need to understand women with epilepsy's experiences and feelings all of which might shape reproductive behaviour. Qualitative methods offer the opportunity to address the research objectives, which require explanation, and offer the opportunity to gain access into these areas of a woman's private life, which are rarely accessed by quantitative research methods.

The proposed study will be conducted in three phases (see table 1), with two stages of recruitment.

Group 1- recruitment for Focus group

Group 2- recruitment for observation of consultation & In-depth Interviews.

Within each study group, stratified purposeful sampling will be used to identify female patients that meet the following criteria:

- Women aged between 16 years and 45 years.
- Have a confirmed diagnosis of epilepsy by a neurologist with a specialist interest in epilepsy.
- History of epilepsy of at least 3 months.
- Prescribed anti-epileptic medication for treatment of epilepsy.
- Able to participate verbally in a group (phase 1 and 2 recruitment).
- Able to converse in English.
- Provide informed consent (copy filed in the patient case record).

The women will also represent a stage during their reproductive career:

- Teenager 16-19 years.
- Women actively seeking preconception advice.
- Pregnant women.
- Women who have experienced pregnancy whilst taking AED's.
- Women with a recent diagnosis of epilepsy, or commencing treatment for the first time.

Stage	Expected work for participating Doctors and their patients.	Expected time commitment.
<p><u>Phase 1</u> Focus Group discussion with women with epilepsy, to develop an understanding of their breadth of experience, views, beliefs and perceptions of being a woman with epilepsy.</p>	<p><u>Patient selection using inclusion criteria.</u> The researcher will be present during epilepsy clinics and will be available for patients to approach if they wish to discuss their involvement in the study. Pre-selected patients will only be approached as directed by the clinician, or if they request to speak the researcher at the end of their clinic appointment, or on return of the reply slip.</p>	<p>It is expected that any extra time generated through patient selection, will be minimised by the researcher being available during referral triage, and ahead of the clinic start time. Patients will attend one 2-hour focus group.</p>
<p><u>Phase 2</u> Observation of clinic appointment – to develop an understanding of women’s experience of decision-making during clinic appointments in which reproductive issues are discussed, and risk information provided.</p>	<p><u>Patient selection using inclusion criteria.</u> Identification of potential participants will occur during routine referral triage and review of clinic lists. Recruitment will also occur during routine review of WWE, and will involve the selection of suitable patients who are likely to be presented with risk information at their next clinic review. Agreement and consent will be negotiated. The researcher will write to the patient ahead of their observed appointment, provide answers to any remaining questions, detail consent and plan to meet the patient at the time of their appointment.</p>	<p>No extra time commitment is anticipated. The observation is of patient discussion and the clinician is asked to follow usual clinical practice. The researcher will not participate in the appointment, being present as an observer of the patients interaction with the clinician. The observation will include audiotape.</p>
<p><u>Phase 3</u> Follow-up interview three months after the observed clinic appointment. The interview will be guided to enable woman to share their experience of decision-making and perceptions of pregnancy planning in light of information provided within their clinic visit.</p>	<p>The patient will have contact with the researcher and will be advised of their ability to withdraw consent. A summary of themes discussed will be sent to the patient, and copied to the doctor; this will form part of the structure of the interview. The patient will meet for one interview lasting a maximum of 2 hours.</p>	<p>Interviews will take place in the patient’s own home; therefore, there is no time commitment for the clinician.</p>

Table 1 Study method

Ethical Considerations

The sensitive and emotional content of the study will be acknowledged in all communication between WWE and their clinician’s; providing detailed information about their role in the study, their ability to withdraw consent at any stage, the role of the interviewer in response to issues raised within interview, and setting ground rules for focus group participation.

Tapes and transcripts will be securely stored within a locked filing cabinet within the investigators employing trust premises, and computer documents password protected. Data collection will conform to the Data Collection Guidelines and Clinical Governance. Confidentiality and anonymity will be guaranteed throughout the study, and within report writing and publication of findings. Audiotapes from observation and interview will remain the property of the investigator to enable further analysis and an ability to return to the raw data.

It is intended the data will be retained for eight years reflecting the maximum duration of study for part-time PhD including time for write up 'pending submission'. The wishes of the participants for final disposal of tapes, whether to return to the individual or to destroy will be acknowledged.

Newcastle & North Tyneside Local Research Ethics Committee has awarded ethical approval, whilst NHS Research Governance approval has been sought from the research and development departments of The Walton Centre for Neurology and Neurosurgery NHS Trust, The Liverpool Women's Hospital NHS Trust and Salford Royal Hospitals NHS Trust.

Project Management

The research study has been developed to ensure compliance with standards for research governance, and has involved both patients and patient organisations in the development of the study aims and objectives, and agreement of acceptable methods of enquiry. The standard of work, scientific quality and timely submission of research reports will be maintained through academic supervision.

The Epilepsy Research Foundation has awarded a fellowship grant, and two small research bursaries have been secured from Epilepsy Action and HSA Charitable Trust.

Utilisation and dissemination

It is expected the study findings will have immediate applicability to clinical practice, with short-term goals influencing patient care by publication within peer review journals and presentation at epilepsy meetings. The medium term objective would be to act as a source of evidence for the update of the NICE guideline review panel, whilst long-term goals are to influence further study into the information needs of WWE. Thank you for your considering taking part in the research, without your involvement the project would not be possible. Thank you for taking the time to read this information sheet, and please direct questions to the chief investigator Janine Winterbottom Tel- 0151 529 8424 (answer phone) or via Email – janine.winterbottom@thewaltoncentre.nhs.uk

(Form to be printed on hospital letter headed paper)

Clinician Consent Form (14.07.08. Version 4)

Title of Project: Women with epilepsy preparing for pregnancy: a qualitative analysis of the perception and communication of risk information

Name of Researcher: Janine Winterbottom

1. I confirm that I have read and understand the information sheet dated **14th July 2008 (version 4)** for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time.

3. The use of supporting quotations in any report or publication will not reveal the identity of either myself, my patient or hospital site.

4. I agree to take part in the above study.

Name of Clinician Signature Date

Researcher Signature Date

When completed, 1 copy for researcher's file; 1 (original) to be retained by the participating clinician.

Appendix 2 Data collection tools

Data collection tools include:

1. Focus group sampling frame
2. Participant questionnaire
3. Focus group – introductory script
4. Focus group – risk prompt cards
5. Topic guides
 - a. Focus Group topic guide 08-10-07
 - b. Observation guide
 - c. In-depth interview topic guide

Topic guides were adapted during the process of focus group data collection to reflect the different group compositions (by age and reproductive experience). The topic guide illustrated here: a) was used for focus group 8 - participants who were pregnant at the time of attendance, b) Observation guides were used as additional reflective tool for recorded observation, c) example of interview guide used for interview 23. All topic guides met ethical approval, and followed a similar format of questions and prompts.

Focus Group sampling frame

Age:	Teenage group	Planning group	Pregnant group	Mature group
Target age distribution: Group size n= 6-8	16-19 year olds	19-45 year olds	19-45 year olds	35-45 year olds
Reproductive experience across groups:				
Planning	✓	✓	✓	✓
Pregnant			✓	
History of pregnancy		✓	✓	✓
AED use across groups:				
Sodium valproate	✓	✓	✓	✓
Lamotrigine	✓	✓	✓	✓
Carbamazepine	✓	✓	✓	✓
Phenytoin				✓
Levetiracetam	✓	✓	✓	✓
Topiramate	✓	✓	✓	✓

✓ Targeted recruitment – drug use applied as a guide to ensure women’s experience was similar to the wider population of reproductive age WWE.

Participant questionnaire

Thank you for agreeing to take part in the research, which I hope you have found enjoyable and *perhaps* informative.

To assist my analysis I would value some brief background information. **This information is anonymous and your name does not appear on the questionnaire.** Your answers will not be used in any way that could identify you personally. The information will be used by the researcher to demonstrate that a broad range of views and experience has been gathered, and will help support the final research conclusions and recommendations.

Most of the questions require either a brief written answer or a tick in a box next to the answer that best applies to you.

First some questions about your epileptic attacks. By epileptic attacks we mean any fits, seizures, convulsions or episodes of loss of consciousness.

About your epilepsy –

How old were you when you had your **first** epileptic attack?
years

How old were you when you had your **last** epileptic attack?
years

Apart from your epilepsy, do you have any long-term problems with your health?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

If yes, please specify

.....

If yes, are you taking any drugs for the condition(s)?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

How many epileptic attacks have you had **in the last six months**?

None	<input type="checkbox"/>
Less than one per month	<input type="checkbox"/>
One or more per month	<input type="checkbox"/>

Do your attacks happen?

Only when you are asleep	
Usually within two hours of waking	
At any time of the day or night	

Sometimes people injure themselves during an epileptic attack.

In the last six months have you suffered any type of injury as a result of having an epileptic seizure?

Yes (please write in details)	
No	

.....

In the last six months have you experienced an epileptic attack while bathing or swimming?

Yes	
No	

Are you currently taking any drugs to control your epileptic attacks?

Yes	
No	

If yes, please name the drugs you are currently taking?

.....

How well do you think your attacks are controlled by the drugs you are taking?

Very well controlled	
Fairly well controlled	
Not very well controlled	
Not at all well controlled	

Women's issues

Have you experienced a pregnancy?

Yes	
No	

If yes,

How many pregnancies?

How many children?

Was your experience of pregnancy planned?

Yes	
No	

In the last six months have you used contraception?

Yes	
No	

If yes,

What method do you rely on?

Have you taken folic acid?

Never	
Only during pregnancy	
During preparation for pregnancy and during pregnancy	

Finally, a few questions about you, yourself. Could you please tell us?

Are you:

Single	
Married or living as married	
Divorced or separated	
Widowed	
Other (please write in)	

Who do you live with?

With your husband / or steady partner	
With your children	
With your parents	
No-one – live alone	
Other (please write in)	

Which of the following **BEST** describes your level of education?

Left school at 16yrs, no qualifications	
Left school with GCSE's	
Left school with A levels	
Vocational qualifications	
Professional qualifications	
University degree or above	
Other (please write in)	

Which of the following **BEST** describes your position about paid work?

Employed full-time	
Employed part-time	
Unemployed	
Permanent sick leave	
Housewife	
Student	
Other (please write in)	

.....

What is your current job title or last main job title?

.....

Are you / were you

An employee	
Self employed	

Are / were you a manager or supervisor of any kind? (Please tick all that apply)

Yes, manager	
Yes supervisor	
No, neither	

If you have been working during the last six months, how many days have you been unable to work because of your epilepsy?

None	
Number of days (please write in)	

Are you currently receiving any allowances / benefits?

Yes (please write in)	
No	

.....

Do you hold a current driving licence?

Yes	
No	

Thank you for completing of the questionnaire.

Focus Group introductory script

Thank you for all attending today's group discussion. I am Janine, I'm a student researcher and this research is part of my research education. I am employed as an Epilepsy Nurse Specialist by The Walton Centre for Neurology and Neurosurgery NHS Trust.

This research is funded by the Epilepsy Research Foundation, a large charity responsible for supporting epilepsy research in the UK, with the aim of extending understanding about women's experience of epilepsy during their child-bearing years and how they consider future pregnancy. We are holding several focus groups across the North West, with the aim of extending our awareness of the range of opinion and experience of women during this stage of their lives. The research aims to explore the views of women with epilepsy at different ages to determine the best methods of communicating information about pregnancy.

I'll start by asking a couple of questions just to get us started, and I really want to hear from everyone. There are no right or wrong answers, as I wish to explore as wide a range of opinions as possible. You can see the session is recorded, so if we can avoid all talking at the same time, this will help the quality of the recording, especially when I come to type it up. As we begin talking, if you feel something important needs to be said, you can write it on the flip chart, so we can come back to it. You can write anything onto the flip chart, and don't worry about spelling. It's just to help us, as a reminder; to highlight something you think is really important. I've put the pens on the table, so feel free. If we keep questions or subjects that are away from the main topic, for the break or at the end? I'm happy to answer any questions at those times.

In a moment, I will switch on the recorders, and I'd like to reassure you that all your comments will be made anonymous, and your names will not be used in any written report. Your confidence will be maintained, and if you ask from each other that what is said in the session is not repeated outside.

Finally a range of epilepsy literature is available for you to take with you today.

Focus group – Pregnancy risk prompt cards

You have a 4% risk of having a child with major malformations.

You have a 96% chance of having a healthy child unaffected by your treatment.

We are uncertain of the risks from your treatment upon the outcome of your pregnancy.

Topic Guide – Focus Group (pregnant participant group 08-10-07)

Introduction – I want to start by getting to know you, and would like you to introduce yourself to the group, saying something about your self, maybe your age, whether you live alone or with someone, and something about your experience of pregnancy?

Prompt

Brief about nature of epilepsy, type / frequency?

Number of pregnancies / children?

1. Focusing on your experience of being a woman with epilepsy (before we turn to your experience of pregnancy)-

a. What has been your experience of having epilepsy at this time in your life?
During child-bearing age?

b. Has epilepsy changed any of your future plans at this stage in your life?
Relationships / Family / Independence

c. What are / have been your views about your need for treatment?
What influence has this had?

d. How did you see your future with epilepsy and pregnancy?
Positive / negative
What influenced these feelings?

2. Focusing on your experience of making decisions about life with epilepsy-

a. What experiences have you had about making decisions about your epilepsy?
What factors influenced decision-making?
During hospital / GP appointments?

b. What was your experience of making decisions about contraception?
What about interactions?
What choices did you have?

c. How did you make the decision to become pregnant / start family?
What factors influenced your decisions?
What were the pros and cons?
What has been the role of information? Good, bad?

3. Focusing on your experience of decisions about pregnancy?

- I'd like to explore the meanings of planning a pregnancy for you as a group of women with epilepsy.

a. Did you plan your current / recent (any) pregnancy?

b. What did you do to plan?
Delay conception?

Commence folic acid?

c. How have you experienced planning pregnancy?
What influence has epilepsy had?

What influence has your AEDs had?

What influence has your experience of information / uncertainty had?

d. What do you think planning should involve / what would be your ideal plan for pregnancy with an epilepsy?

e. What would you see as essential for any WWE to consider when planning?

f. Who was the key decision maker in your plans for pregnancy?

When in your appointments, who is key decision-maker / shared?

4. How has your epilepsy influenced thinking about family?

a. What has been your experience of pregnancy and what influence has epilepsy had?

b. How do / did you feel when you discovered you were pregnant?

Have those views changed on becoming/following pregnancy?

c. Do you feel your experience is different from women who don't have epilepsy?

d. What experiences have had the greatest influence when thinking about pregnancy / motherhood?

5. Focusing on epilepsy & pregnancy risks-

a. What risks have been important to you?

b. How did you understand the potential risk in epilepsy for WWE, relating to?

- future pregnancy
- planning of pregnancy, and
- medications taken in pregnancy

c. What factors were relevant / influenced you becoming pregnant when taking AED's?

d. What is your experience of getting information when planning pregnancy?

- about the risks of treatment
- about the benefits from treatment
- What has/had the greatest influence?

e. How would you describe the best methods of communicating risk information at this stage (before / during pregnancy)

- views and experiences of the role health care professionals play

f. How have you used risk information?

- influence decision-making
- what have you learnt from your experience about making decision
- ideas/ solutions/ strategies

2

g. Where do you go / have you got your information from?

- Internet? What sites?
- What are your views about the type of information provided / available sufficient/adequate/balanced?
- Who do you trust?

Topic Guide – Observed clinic appointment

- Before observation - Introduce the researcher, the study, and format of observation, role as an observer and my position as both a researcher and student at Liverpool University, and Epilepsy Nurse Specialist from The Walton Centre.
- Confirm consent – patient and clinician
- Introduce issues of confidentiality, and the use of a tape recorder.

The following observations will be made, and documented during the course of the clinic appointment

Room layout: position of patient and clinician e.g. desk in-between

Accompanying persons: student observers, patient friends/relatives etc

Interruptions: noise distractions, persons entering room, clinician leaving room etc

Q.1 How involved was the patient within the consultation?

- Evidence of questions and answering between women and their clinician
- Evidence of clinician attempts to involve the woman in discussion about future pregnancy intentions

Q.2 How was pregnancy risk information introduced into the consultation?

- Was risk information individualised to the woman, her treatment and seizure type?
- Response to the delivery of risk information
- Risk information presentation style?

Q.3 Was a risk benefit assessment made within the consultation?

- Was a balanced approach to risk and benefit presented?
- Were potential health promotion opportunities explained, and if so how?

Q.4 Was a pregnancy plan discussed?

- Were alternative treatment options explained (drug reduction, switch or withdrawal), and if so how?
- Who raised the proposed pregnancy plan/time scale?
- Were contraceptive measures discussed?

Additional comments-

- Emotions between patient and clinician, if event, how managed
- Use of distinctive language e.g. medical terms or pseudo-medical terms or jargon
 - Use of structure in conversation
 - ⇒ Questioning style
 - ⇒ Turn taking
 - ⇒ Dominance

Interview Topic Guide 23

Confirm OK with study and interview, remind about confidentiality, duration of interview, & use of a tape recorder. **Opening – being woman in reproductive years**

1. Having thought about your clinic visit (reading transcript and summary):

- What had been your journey to this recent appointment? What had you hoped to get out of your recent appointments? What did you want to know/discuss?
- Any issues arising from the consultation? Anything got you thinking? **Specify**

2. What decisions have you made (considering) following this clinic visit?

- **Changes to medication? Withdrawal? Folic acid? Contraception?**
- Decisions about future family? Has anything changed? (what & why)

3. What's the most significant piece of information you recall from clinic?

- **Why? Specify**
- **Risk of remaining on CBZ v risk of withdrawing CBZ? & % reduction?**
- How have you balanced these risks? “CBZ chemical attack unborn child” Harm
- **Switch over risk, risk of relapse, uncertainty on control/baby**
- **What are your feelings about the risks mentioned? 2% risk of major malformations + long term developmental uncertainty?**
- **What do you feel are your risks? Seizure relapse risk? Treatment risk?**
- What is your experience of preventing risks? CBZ preventing seizure?
- What can you do to reduce these risks? Before / during pregnancy

4. What were your feelings about the things discussed in clinic?

- **Focused on making the right decision? “Live normal life once made decision”**
- **Anything not discussed?**

5. Looking ahead to a future pregnancy, any worries? Medication? Seizure?

- Fear of seizure relapse, panic, fear leaving house
- Coping with worry? What is greatest worry?
- **What are your decisions about future pregnancy?**
- **When might the right time be?** (Planned, informed, medication rationalized, best seizure control) (Intervention / support in place, or balanced)
- **What might be done to make sure you have a healthy pregnancy and baby in the future?** Folic acid? Any preparations before / after conception
- How might epilepsy influence decisions? **Seizure relapse risk? Drug switch?**

6. What do you feel is or has influenced this stage in your life?

- **Significant others? Epilepsy control? Treatment? Past experience?**

7. What are your thoughts about becoming a mother? Having a family?

- “Ultimate goal to try for baby”
- Looking after the baby? Having seizure as mum?
- Being able to cope?
- Breastfeeding?

8. What do you think should be done when preparing for pregnancy?

- What's your role? Who else might have responsibility? What does it include?
- **What's important to you as you move into this stage of life?**

Appendix 3 Stages of analysis

The aim here is provide a transparent account of my analysis.

Stages 1 & 2 Line-by-line reading and initial noting

Table A3.1 illustrates an extract of interview transcript for participant OI01. The extract highlights interesting sections of text (underlined within original transcript), and the left hand column represents the initial noting made as exploratory comments. Within NVivo 7 the process of noting text can be considered as building knowledge about the data through the development of codes as abstract representations of the participants experience of the phenomenon (Bazeley, 2007). The process of coding is analogous to developing a network of storage containers for related concepts or categories, known as nodes. ‘Node’ refers to a collection of references about a specific theme, and can be described as either ‘tree’ or ‘free’. Tree nodes refer to a theme of coded extracts of transcript which have been linked with a hierarchical structure (tree) representing shared meaning. Free nodes have no presumed relationship or connection to the thematic tree structure, representing ideas and comments about the transcript text that I wanted to highlight for further consideration. Each free node was given a title or name relating directly to the content of the participant’s speech. There were three levels of exploratory comments:

1. Descriptive (normal text)
2. Linguistic (*italics*)
3. Conceptual (underlined)

Descriptive comments involved describing the content of what the participant was saying and the subject matter of the participant’s speech. Prompted to describe what OI01 recalled from the consultation, she repeats the phrase as if describing a priority of concern to avoid having an accident, describing her choice of contraception specific for its mechanical obstruction of an accident, requiring removing of the coil before a pregnancy could occur. OI01’s use of metaphor further highlights the importance of securing contraception to avoid an accidental pregnancy. OI01 implies through the use of the metaphors “fly by the seat of your pants sort of person” that this type of person was reckless, whereas she saw herself as ‘not that sort of person’, identifying herself as taking responsibility for controlling the timing of her future pregnancy. This text was

commented on further, as relating to identity, and how participant OI01 wished to present herself at interview. Within the context of the extract, OI01 defined planning as an activity that would result in being “better off” and “in control”; the term control was also seen to represent the importance she placed on controlling her epilepsy management before planning pregnancy. Conceptual comments relating to OI01’s account of contraception were reflected upon through my review of the literature, revealing empirical evidence of women using the oral contraceptive pill relaxing pill taking when ambivalent towards their experience of pregnancy (Barrett and Wellings, 2002; Zabin, 1999).

Exploratory comments (Annotations)	Original interview transcript
	Interviewer: In the consultation there was quite a bit of information given over, what are the things that jump to you mind?
<p>Priority of concern. <u>Accident as term of reference for unplanned pregnancy.</u></p> <p><u>Meaning of planning.</u> <u>Control of epilepsy.</u> Better drug for pregnancy. Future baby Having a baby on medication. <u>Size of potential disability</u> Comparison of risk to anyone else. Don’t stop birth control.</p>	<p>OI01: Hmm, <u>the things that jump to my mind</u> is hmm, <u>don’t have an accident</u>, that was one that came out, thinking don’t have an accident <u>because [name of clinician] will kill you</u> (laugh), but no, no it was don’t have an accident because you know, <u>if you can plan things then you are better off aren’t you. Get it under control</u>, hmm, I was on, <u>I was on one of the better medications that I could be on if I was going to get pregnant</u>, hmm, and you know <u>if I do have a baby on the medication with my epilepsy doesn’t necessarily mean it’s going to come out with any massive disabilities or anything.</u> You know, you’re only <u>facing slight higher risk than anyone else getting pregnant</u> so hmm, that was what I got from it really I think, but don’t have an accident (laugh). <u>Don’t suddenly stop taking your birth control or anything.</u></p>
	Interviewer: Is that something you’d thought about before or
<p><u>Not who she is – identity</u> <i>Metaphor – reckless person</i> Relying on coil rather than her remembering the pill. Contraception restricts her chance of an accident.</p> <p><u>The planned ‘unplanned’ pregnancy – a phrase for it in the literature?</u></p>	<p>OI01: The don’t have an accident thing, <u>I don’t think I would have an accident to be honest with you, I’m not really a kind of fly by the seat of your pants sort of person</u> hmm but, which is why this contraception is so good for me, I mean you know, I don’t, there’s no chance of me missing anything so, and I’ve got to go and physically get the coil taken out in-order for it not to work. So hmm, that’s, that’s why this contraception is the best contraception for me, and I don’t think, I mean, I think erm, <u>I think if I was to have an accident it wouldn’t be an accident I’d still be planning it somewhere</u> so hmm, that would never happen I don’t think.</p>

Table A3.1 Example of Analytic Stages 1 & 2 (Participant OI01)

I also linked comments to OI01’s reference to “having a baby on medication” and her focus on the positive likelihood of “facing only slightly higher risk than anyone else”. The potential for ‘massive disability’ led me to consider whether OI01 had anticipated being presented with higher risk during the consultation, reflecting her relief and

supporting her focus on priorities to avoid an accident until her epilepsy was better controlled.

Stage 3 Developing emergent themes

The task of looking for emergent themes involved reducing the volume of detail within the transcript text, whilst retaining the complexity within the exploratory nodes. These titles were descriptive and became progressively more conceptual as analysis progressed. Developing emergent themes involved working with ‘discrete chunks’ of transcript text with the associated with the labelled free node categories (Smith et al., 2009) (table A3.2). Themes were developed out of the patterns that emerged, forming categories of codes (nodes) reflecting both description and interpretation. The task of developing emergent themes relied heavily upon the reorganisation of free nodes into tree nodes representing the hierarchical structures, and placed in order of their strength to describe the essence of the experience or concept that they were linked to. For example, the emerging free node theme “safer drug for baby” was defined by its use in the transcript discussing safety of one drug over another.

Emergent themes	Exploratory comments (Annotations)
Priority of concern / Information and communication Influence on pregnancy plans	Priority of concern.
Preparing for pregnancy	<u>Accident as term of reference for unplanned pregnancy.</u>
Review of epilepsy management / Importance of seizure control	<u>Meaning of planning.</u> <u>Control of epilepsy</u>
Safer drug for baby	Better drug for pregnancy.
Future pregnancy and motherhood	Future baby
Pregnant taking antiepileptic drugs (AEDs)	Having a baby on medication.
Risks to unborn child	<u>Size of potential disability</u>
Comparison of risk	Comparison of risk to anyone else.
Pregnancy avoidance strategies	Don't stop birth control.
Parenting role	<u>Not who she is – identity</u>
Fear of implications	<i>Metaphor – reckless person</i>
Pregnancy avoidance strategies	Relying on coil rather than her remembering the pill. Contraception restricts her chance of an accident. <u>The planned ‘unplanned’ pregnancy – a phrase for it in the literature?</u>

Table A3.2 Developing emerging themes (Participant OI01)

Step 4 Searching for connections across emergent themes

Several strategies are available to identifying patterns between free nodes supporting the development of a hierarchical structure of ‘tree’ nodes with the goal of representing

the ‘super-ordinate’ or ‘substantive’ themes from the final theses results. The strategies I found helpful in my search for connections involved creating charts with the name of each node written onto post-it note. These were charted to link the relationships between the themes presenting a visual representation. The process of charting identified a cluster of free nodes relating to the fear of the implications of the decisions made in preparation for pregnancy; each individual free node represented a series of related participant references (table A3.3).

Sub-themes	Theme: Fear of implications
	Cautious
	Dangerous drug
	Extra worry for women with epilepsy
	Fear of changes in seizure control
	Not worried for self
	Worst case scenario
	Scared of medication
	Scary not knowing

Table A3.3 Development of theme ‘Fear of Implications’

Other strategies used for testing the development of the thematic structure included ‘numeration’. Numeration takes account of the frequency with which a theme is supported within the participant accounts. It is a helpful way of identifying the importance of an emergent theme, as the frequency of terms used by the participant can be an indication the relevance of the theme.

Figure A3.1 illustrates the coding coverage chart I prepared for my PhD upgrade report (26-09-08). It was the outcome of interim analysis for three focus group transcripts. Its value at this stage in analysis had been to highlight ‘preparing for pregnancy’ and its relative importance to the communication and provision of information. It also focused my attention to the importance of the emerging theme ‘fear of implications’, representing descriptions of emotional responses to the dilemmas faced by the focus group participants. The development of emergent themes involved making connections between participant accounts, representing similar and recurrent themes. Having established a thematic pattern using the techniques of numeration and charting I was also able to identify the highly emotive term ‘selfish’ applied by a sub-group of participant cases for further analysis and the development of alternate explanations (see Chapter 9, Section 9.2 The ‘selfish decision’).

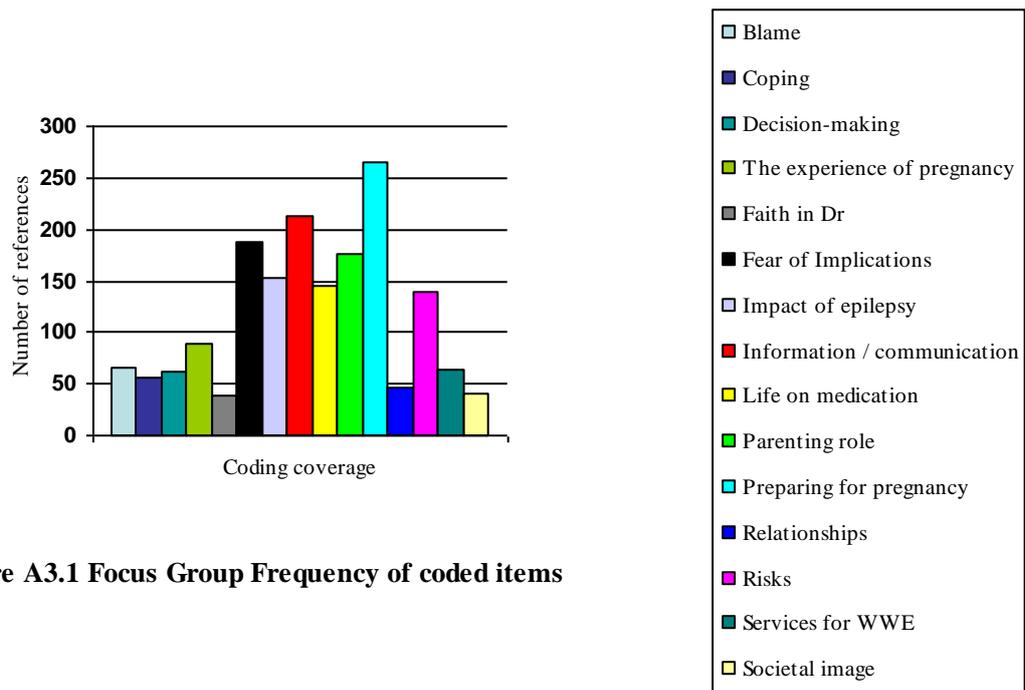


Figure A3.1 Focus Group Frequency of coded items

Step 5 Moving to the next cases

Repeating the analytic process for the next case involved balancing the demands of time required to recruit participants against the demands of time to focus on developing an understanding of their accounts. Although time consuming, transcribing helped stages 1 & 2 analysis as I became intimately engrossed in second by second accounts of the participant's speech. My involvement as moderator assisted my familiarity of the group; individual mannerisms and behaviours towards each other supported my comments regarding group process (supporting a double analysis). Participants were observed to support each presenting their experience, questioning each other for further details before commenting on their own contrasting experience or as reinforcement for a particular experience. Table A3.4 illustrates the comments concerning group processes alongside the individual participant comments concerning experiential claims. The transcript illustrates group support and the use of humour. Additional comments were added by my supervisors (Professor Gus Baker (GB) and Professor Ann Jacoby (AJ)) who independently commented on the transcripts to ensure consistent coding and logical application of the emerging thematic code. Field notes reflected my observations during the focus group session. Reflexive field note comments highlighted a significant event, such as the strong sense of despair I felt in response to the group's reaction, and FG71's reply implying her coping with the situation she had faced.

Group comments	Exploratory comments	Original interview transcript
Need to redirected discussion, moving off topic, wanted to get other comments		Facilitator: If I ask that we leave these issues until the end, I'm wondering if there was anything else about thinking about becoming pregnant.
FG74 introduced her experience of accidental pregnancy on Epilim prompting earlier group discussion of drug risk. Group support of FG74's focus on the harm of medication.	Experience of pregnancy <u>Having AED affected baby</u> Worried about medication Why was she worried immediately about medication? Had she prior information?	FG74: I think for me, <u>knowing that I was pregnant</u> . Was how the medication was going to affect, you know, the unborn baby initially? [Group: "Hmm", agreement]
FG73's use of dramatic comment as over emphasis of potential harm	Who are they? To blame? <u>GB coded as Blame</u> <i>Sick humour</i>	FG73: They're worried it'll come out with two heads do you, or something like that [laugh][Group laughter]
Need to re-direct	Focus on earlier comment	Facilitator: Worried about the treatment
Observation note: Group agreement	Media Being given risk information <u>Life on medication</u> Baby's drug exposure Biggest worry <u>Link to Risk society & overload of risk information?</u> Worst case scenario Uncertainty Luck	FG74: Yes, you know, so really that because, <u>you hear so much in the media, don't drink coffee, don't eat this, don't...</u> So then you're taking in, you know, we can't give blood, because the medication we're on, you know. So, obviously you know that <u>it's going to be going directly in their</u> , so that was the <u>biggest worry</u> for me. But, when I was given the appointment, erm, it was <u>just the case</u> that, well don't take it, and <u>you're in a worse sort of area</u> , really. Stop taking the medication and you <u>don't know what's going to happen</u> . And <u>I was really genuinely lucky</u> that my fits didn't interfere with me at that point,
	Seizures in pregnancy	FG73: Or are they going to get worse basically because you're pregnant?
Observation note: empathic sense of guilt/despair	Information <i>Emphasis-size of problem</i> <u>Futility of planning</u> <u>AJ coded as planning-effectiveness?</u> Focus on health of unborn baby	FG74: So in terms of planning then, you're just seeking information. But, it is very much case, of <u>that one large thing you can't change</u> . So as <u>much planning as might want to do, you can't change that, and it's always about the health of the unborn baby isn't it, so.</u>
Agrees with FG74 'it's true', absolving blame as she had not planned it.	Managing accidental pregnancy Coping	FG71: You can't, you're right. It's true that, I feel exactly the same. You know, I mean, and I think, like, because, I mean, you accidentally got pregnant, so you had to deal with it,

Table A3.4 Stage 5 – Focus Group Analysis

Stage 6 Looking for patterns across cases

Looking for patterns across cases was managed in a similar way to stage 4 analysis using NVivo summary reporting facilities. Table A3.5 illustrates the Code Summary report for the substantive theme 'Pregnancy Planning'. The sub-themes are nested within the substantive theme, with the linked participant quote referenced to its

location within the transcript. These were printed to map-out the structure of the overall thematic analysis. This visual representation allowed me to look both within and across participant cases, and within and across themes. The process served to highlight ways in which participants represent unique idiosyncratic instances while sharing higher order qualities (Smith et al., 2009).

Sub-theme- The experience of planning pregnancy	Examples of participant coded references	Reference location
What planning means to women with epilepsy	FG106: they're trying for a baby and stuff that's what normally planning a pregnancy means FG102: it means to me that I should make sure I'm stable before I get pregnant, FG23: it was more sensible, and I had more. You know, more comfort in the fact that. Well at least, I'm being sensible here. Before I go ahead with this pregnancy... OI07: I do like to be in control, and I do like to be organised, yes definitely like that, anyone will tell you that OI08: I know what sort of sub headings I would need to have within that bit of my plan, you know, folic acid, possible lowering the medication you know	FG10, line 1228. FG10, line 1440. FG2, line 614. Interview, line 793. Interview, line 874.
Priorities in planning	FG106: I don't mean stable like in not having fits, I mean stable as in money and a stable partner. FG101: my medication is the big thing with this planning pregnancy that's just the, it comes back to the medication all the time. FG82: That's the biggest thing, is being properly counselled, beforehand. FG61: I think you've got to build up the support mechanisms first, and then everything else can fall into place	FG10, line 1451. FG10, line 1507. FG8, line 1832. FG6, 632.

Table A3.5 Code summary report for substantive theme – Pregnancy planning

Stage 7 Taking it deeper: Levels of interpretation

Interpretation is an integral component of an interpretative phenomenological analysis and has been incorporated into all stages of analysis. However, at this final stage 'taking it deeper'; the stage of interpretation requires making inferences, providing meaning and giving explanations for the experiences of women with epilepsy preparing for pregnancy.

Working with my final study population (n=85), the importance of being able to make interpretive claims representing the group of participants from within the study population was made possible by group level themes being illustrated with particular

reference to the individual participant experience (Smith et al., 2009). The ability to support the claim of representativeness was established through charting the recurrence of emergent and substantive themes within the data. Figures A3.2 and A3.3 illustrates the representation of the sub-theme ‘Having an AED affected child’ within focus group and observation interview data.

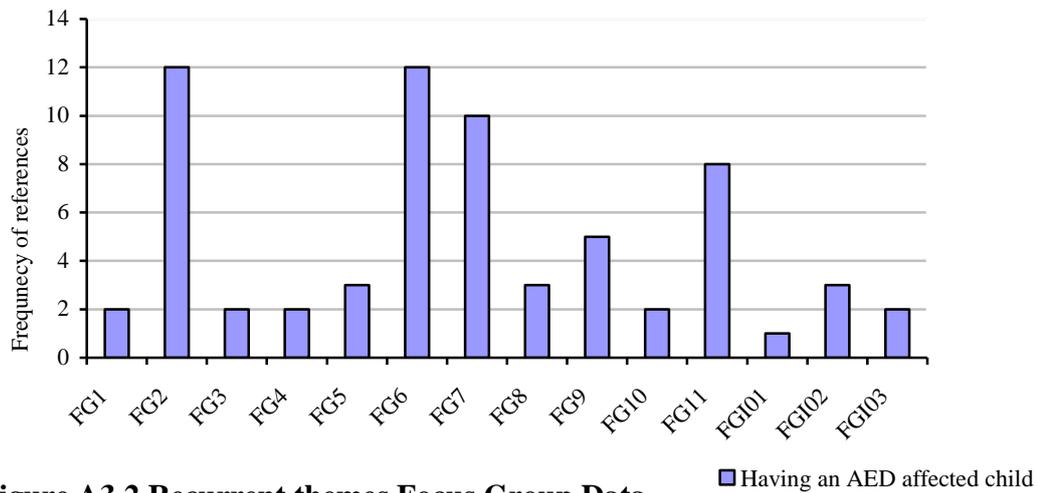


Figure A3.2 Recurrent themes Focus Group Data

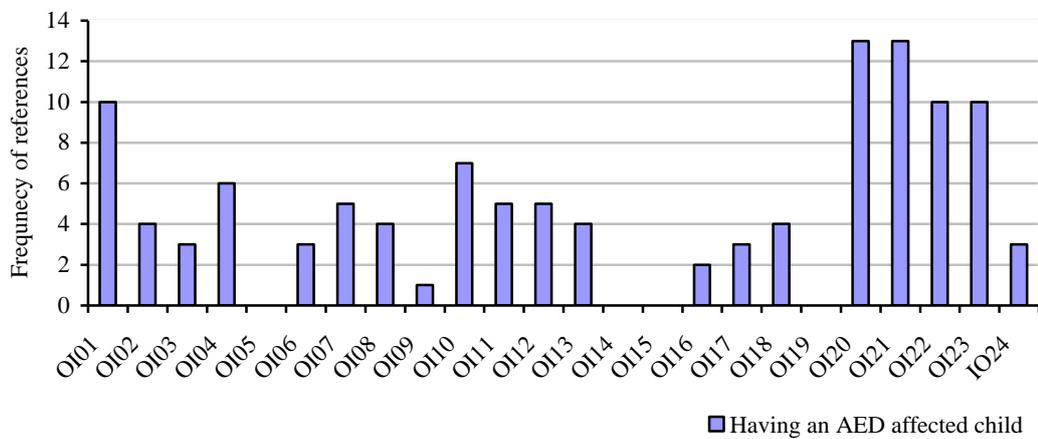


Figure A3.3 Recurrent themes Observation/Interview Data

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