Public Health England

Protecting and improving the nation's health

# Preconception interventions and resources for women with serious mental illness

## A Rapid Evidence Review

# Contents

# Abbreviations

| | |
|---|---|
| APP | Action on Postpartum Psychosis (UK) |
| AUDIT | Alcohol Use Disorders Identification Test |
| BAP | British Association of Psychopharmacology |
| BMI | Body Mass Index |
| BUMPS | Best Use of Medicines in Pregnancy (UK) |
| CBT | Cognitive Behavioural Therapy |
| CMHT | Community Mental Health Team (UK) |
| COPE | Centre of Perinatal Excellence (Australia) |
| CPMHT | Community Perinatal Mental Health Team (UK) |
| CI | Confidence Interval (95%) |
| ED | Eating Disorder |
| GP | General Practitioner |
| IPV | Intimate Partner Violence |
| MD | Mean Difference |
| NHS | National Health Service (UK) |
| NHSE/I | NHS England and NHS Improvement |
| NICE | National Institute of Clinical Excellence (UK) |
| OCD | Obsessive-Compulsive Disorder |
| OR | Odds Ratio |
| PANSS | Positive and Negative Syndrome Scale (for schizophrenia symptoms) |
| PHE | Public Health England |
| PND | Postnatal Depression |
| PTSD | Post Traumatic Stress Disorder |
| RCP | Royal College of Psychiatrists (UK) |
| RCT | Randomised Controlled Trial |
| SIGN | Scottish Intercollegiate Guidelines Network |
| SMI | Serious Mental Illness |
| STI | Sexually Transmitted Infection |
| UKTIS | UK Teratology Information Service |
| WHO | World Health Organization |

# Executive summary

## Background

Preconception care is defined by the World Health Organization (WHO) as ‘the provision of biomedical, behavioural and social health interventions to women and couples before conception occurs, aimed at improving their health status, and reducing behaviours and individual and environmental factors that could contribute to poor maternal and child health outcomes’. Women with serious mental illness (SMI) often have interrelated social, physical, and mental health needs, and experience stigmatising attitudes about their desire for motherhood. As such, there is a need to better understand the provision and effectiveness of preconception interventions for women with SMI, to ensure that care is tailored to meet their needs.

This report details the findings of 2 rapid evidence reviews of peer-reviewed academic literature, grey literature and clinical guidelines supplemented by expert stakeholder consultation and a survey of healthcare professionals, to identify interventions and resources of relevance and to assess their effectiveness for women with SMI. The findings from this review were used to inform the design of a digital tool for preconception planning to be used by women with SMI (available as part of the ‘Are You Ready Tool’ on the Tommy’s the Baby Charity website), and a resource entitled Delivering preconception care to women of childbearing age with serious mental illness published by Public Health England for universal and secondary care health professionals to be utilised both opportunistically and in regular reviews.

## Aims

### Rapid Review 1

What is the effectiveness of preconception interventions for women with SMI?

### Rapid Review 2

What is the effectiveness of interventions for modifiable factors impacting on pregnancy outcomes in women with SMI such as smoking and diet?

### Health professional survey

How are preconception interventions currently used and perceived within adult mental health services including specialist perinatal community mental health services?

# Main findings

## Rapid Evidence Review 1: What is the effectiveness of preconception interventions for women with SMI?

25 peer-reviewed articles were identified repoting on preconception interventions for women with SMI. No Randomised Controlled Trials (RCTs) of preconception interventions for women with SMI were found. Of the included studies, 8 used quantitative study designs, 5 qualitative methods and 12 described preconception recommendations from previous reviews of the evidence.

Researchers reported good adherence to medication and psychosocial recommendations among women with SMI receiving preconception interventions.

Women with SMI described barriers to accessing family planning, including discriminatory attitudes, stigma and fear about the heritability of disorders, potential custody loss, risk of relapse and medication teratogenicity.

Women wanted early preconception care and for their health provider to be sympathetic, informative, supportive, asking, understanding, and non-judgmental.

Findings from previous literature reviews and commentaries recommended that preconception interventions should include mental health considerations (for example, risk of relapse), medication, physical health, and reproductive and sexual health, social support including support with relationships, domestic abuse and violence.

Searches of grey literature identified 8 online preconception resources for women with SMI or clinicians, and 5 clinical guidelines. No published information on the effectiveness of these resources was found.

## Rapid Evidence Review 2: What is the effectiveness of interventions for modifiable factors impacting on pregnancy outcomes in women with SMI such as smoking and diet?

10 papers (Cochrane reviews and RCTs) describing the effectiveness of interventions delivered to individuals with SMI which targeted modifiable factors which could contribute to healthy pregnancy were identified (these studies did not always target women only).

### Alcohol interventions

No significant treatment effect of the intervention was found (1 RCT).

### Diet, weight and exercise

There was no evidence of effectiveness of dietary advice interventions for individuals with SMI. Provision of free fruit and vegetable to individuals diagnosed with schizophrenia improved the amount consumed, and exercise interventions demonstrated a positive impact on psychological

wellbeing, but there was no evidence of an effect on BMI or physical health outcomes (2 Cochrane reviews; including 3 RCTs)

### Intimate partner violence

No Cochrane reviews or RCTs identified.

### Nutritional supplementation

There was some evidence that nutritional supplementation in individuals diagnosed with SMI led to improved Erythrocyte fatty acid composition (1 RCT).

### Sexually transmitted infections

No interventions were identified in the review. (1 Cochrane review).

### Smoking

Interventions to reduce smoking in individuals diagnosed with SMI were associated with a positive benefit at 6 months post-intervention, though not sustained at primary outcome of 12 months post-intervention (1 Cochrane review; 1 RCT).

### Substance misuse

Studies of interventions to reduce substance misuse in individuals with SMI did not demonstrate effectiveness and were noted to be of poor-quality study designs (1 Cochrane Review including 41 RCTs).

Overall, the evidence for these interventions was of low quality and did not disaggregate findings for men and women.

## Survey

235 health professionals responded to survey questions on preconception care practices, 22% reported that they used existing preconception materials in their practice through interventions such as counselling, contraceptive care, and resource provision. Health professionals desired clear and easily accessible resources as well as training to provide effective care.

## Conclusions

There is a lack of research on the effectiveness of preconception care interventions for women of childbearing age with SMI. The evidence for interventions targeting potentially modifiable factors relevant to preconception care is limited but there is some evidence of the effectiveness of smoking interventions on cessation rates among individuals with SMI, and psychological benefits of exercise interventions.

There is a clear potential for preconception care to impact on the physical and mental health of women with SMI before pregnancy but women with SMI want more sensitive and comprehensive provision of preconception care. Mental health professionals are similarly keen to provide this care and would like more online resources to guide this.

# Summary of recommendations

1. Preconception care should be provided to all women with SMI of childbearing age, whether or not they are currently planning a pregnancy. Care should start early in a woman's mental health treatment plan, including at the point of diagnosis, and the principle of 'making every clinical contact count' should be applied to preconception health.
2. Mental health professionals should provide the opportunity for women to consider their family planning options, including her right to start a family. Sensitive, non-judgemental and non- stigmatising preconception conversations can help engage women with SMI and empower them to make informed decisions.
3. Women should be provided with information about how their illness may affect pregnancy and motherhood, and include discussions about their physical, mental health and social circumstances. Creating a preconception care plan may help women prepare for pregnancy should they conceive.
4. Women may need support to improve their physical health or lifestyle to reduce the risk of adverse pregnancy outcomes and to optimise their current health. This may include weight management support and nutritional advice, smoking cessation and substance misuse interventions, support with relationships including information about domestic violence and abuse, sexual health and family planning. Holistic care should be provided and tailored to women's individual circumstances.
5. Healthcare professionals involved in the care of women of childbearing age with SMI should have access to preconception care training. Evidence-based information on preconception health and family planning should be widely available to healthcare professionals and accessible to women with SMI.
6. Further research is required to assess the effectiveness of different models of preconception care for women with SMI. This should include high-quality RCTs of interventions targeted at potentially modifiable risk factors for adverse pregnancy outcomes. RCTs of interventions for individuals diagnosed with SMI should present disaggregated data for men and women receiving the intervention.

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# About this document

## Purpose

The purpose of this work was to collate evidence to inform a resource for healthcare professionals on preconception care for women with serious mental illness (SMI) and digital preconception resources for women themselves. Rapid evidence reviews of peer-reviewed literature, grey literature, and clinical guidelines were carried out along with a survey on preconception care practice by healthcare professionals.The results of the reviews and survey were discussed with an expert stakeholder group who provided feedback and additional steering.

## Audience

This document is written for policymakers, commissioners, academics and health workers directly involved in the care of women of reproductive age with SMI, including general practitioners (GPs), mental health professionals (particularly care coordinators, psychiatrists and psychologists) and health visitors.

# Chapter 1 Background

## 1.1 Preconception care

There is increasing recognition that women's health before and around the time of conception has a crucial influence on the long-term health of both mother and child (3 to 5). Modifiable risk factors for adverse pregnancy and birth outcomes are established before pregnancy (for example, maternal weight, smoking, and substance misuse), with limited potential for change after conception (6).

Preconception care is defined by the World Health Organization (WHO) as 'the provision of biomedical, behavioural and social health interventions to women and couples before conception occurs, aimed at improving their health status, and reducing behaviours and individual and environmental factors that could contribute to poor maternal and child health outcomes' (7). A conceptual framework has recently been articulated in a Lancet series which consists of 3 perspectives: biological (the months before conception), individual (the decision to have a baby) and life-course (critical periods for the adoption of health behaviours, such as adolescence) (4).

Although some aspects of pre-pregnancy planning such as adequate folic acid supplementation can be achieved within weeks, other important health indicators, such as a healthy body mass index (BMI), may take several months or years. Therefore, preconception care takes a variety of forms, including face-to-face counselling targeted at women planning a pregnancy or opportunistic care in primary or secondary care and digital or web-based resources (8). The potential for health benefits, at relatively low cost and risk of harm, particularly when strategies are combined across these approaches is clear (9).

## 1.2 Serious mental illness and preconception health

Mental health problems in the perinatal period are experienced by around 20% of new mothers (10) and are associated with an increased risk of adverse obstetric outcomes including low birth weight and prematurity (11). These outcomes are more likely in women with mental illness with more severe symptoms. Serious mental illnesses (SMI) can be defined in several ways but most definitions include schizophrenia, bipolar disorder and other mental disorders requiring treatment from secondary mental health services. These more serious presentations occur less frequently and are associated with higher rates of unplanned pregnancy, domestic and sexual violence or abuse and sexually transmitted infections as well as lower contraceptive usage compared to women without an SMI diagnosis (12, 13). Women with SMI are also more likely to have multiple pre-existing health problems also associated with adverse pregnancy outcomes, such as increased rates of smoking and substance misuse, high BMI and nutritional deficiencies, co-morbid physical problems such as diabetes and hypertension, poverty and homelessness (14, 15).

In addition, some psychotropic medications are associated with an increased risk of adverse foetal and infant outcomes yet stopping medication may lead to relapse and consequent higher foetal exposure to medication. Medication needs are therefore complex and must be considered in the context of risks and benefits for an individual woman and her mental health needs. Maternal suicides have been associated with a lack of prescribed medication despite contact with mental health services (16) and women with SMI are more likely to stop medication than women with epilepsy (also a potentially life-threatening illness in pregnancy) who are taking the same mood stabilisers with similar risks of relapse (17 to 19). Women with SMI, therefore, require preconception care tailored to their specific needs to optimise maternal and child health.

## 1.3 Policy context

Public Health England (PHE) has recently published a series of general preconception care resources including 'Making the Case for Preconception Care' (6) aimed at supporting Local Authority and National Health Service (NHS) staff to work together to embed preconception care into services accessed by people of reproductive age. There is also an increasing focus on reducing perinatal health inequalities faced by women with SMI, including new care pathways and resources to improve access to specialist perinatal mental health services (20). Preconception counselling for women with SMI is now available in Mental Health Trusts via these newly expanded perinatal mental health services. The 'Pan-London Perinatal Mental Health Network's Pre-conception advice: Best Practice Toolkit for Perinatal Mental Health Services' (21) provides specific advice to specialist perinatal mental health services on how to deliver preconception care.

However, preconception counselling from specialist perinatal mental health services is not accessible for all women with SMI of childbearing age, and preconception counselling within specialist services is available (mainly) for women who are actively planning a pregnancy. Most women with SMI of childbearing age are, however, in regular contact with generic services, particularly care coordinators, general adult psychiatrists, and GPs who care for women across the life course, that is, preconception (in the broadest sense), the perinatal period and during motherhood. The healthcare practitioners in most regular contact with women with SMI are located in generic primary and secondary care services, but providing preconception care for women of childbearing age with SMI during their contact with these services has not usually been seen as part of their role (21). Regular contact with these generic services includes reviews of mental and physical health and are thus an ideal opportunity to start conversations about optimising health for a planned (or unplanned) pregnancy (22).

## 1.4 Background to this report

PHE commissioned Tommy's Baby Charity and researchers led by Professor Howard at the Section of Women's Mental Health at the Institute of Psychiatry, Psychology and Neuroscience, King's College London to develop 2 evidence-based preconception resources: one for health and social care providers and another for women with SMI themselves. The latter is an online

preconception resource for women with SMI, hosted through Tommy's existing preconception tool 'Are you Ready?' and supporting emails, to help women make informed decisions about their health and wellbeing before pregnancy.

The research team were therefore commissioned to review evidence for the effectiveness of preconception interventions to inform the development of these commissioned resources. The gold standard for evidence reviews and syntheses are systematic reviews using rigorous processes, such as Cochrane review methodology, and meta-analyses or meta-syntheses. However, these are time-consuming and expensive, and the WHO and others recommend the use of rapid evidence reviews to strengthen health policy where resources are limited, that is, conduct high-quality data synthesis through a streamlined use of the systematic review methodology (23). This typically involves reducing the number of researchers reviewing literature for inclusion, shortened timelines, and the searching of fewer databases. Furthermore, many preconception interventions have not been evaluated using randomised controlled trials (RCT) or published in academic literature, and it was, therefore, important to include a broader search of the grey literature and clinical guidelines.

This report details the findings of 2 rapid evidence reviews of peer-reviewed academic literature, grey literature and clinical guidelines supplemented by expert stakeholder consultation and a survey of mental health professionals to identify interventions and resources of relevance for the PHE commissioned new preconception resources for women with SMI.

## 1.5 Aims

### Rapid Review 1

What is the effectiveness of preconception interventions for women with SMI?

### Rapid Review 2

What is the effectiveness of interventions for modifiable factors impacting on pregnancy outcomes in women with SMI such as smoking and diet?

### Health professional survey

How are preconception interventions currently used and perceived within adult mental health services including specialist perinatal community mental health services?

# Chapter 2 Methodology

## 2.1 Rapid Evidence Review 1: What is the effectiveness of preconception interventions for women with SMI?

### Aim

To identify and describe studies evaluating preconception interventions for women of child-bearing age who have an existing SMI through searches of the peer-reviewed literature and grey literature, supplemented by expert consultation.

### Definitions

#### Preconception

The time before pregnancy in fertile women of child-bearing age. The WHO defines this age range as 15 to 49 years.

#### Serious mental illness (SMI)

Serious mental illness is also referred to as severe mental illness in the literature, and searches encompassed both terms. There is no single definition of SMI; commonly used definitions rely on either diagnosis, level of functional impairment, level of contact with services or use of medications to distinguish SMI from other mental illnesses (24). This review takes a broad definition encompassing all these definitions. With regards to diagnoses, schizophrenia and bipolar disorder are widely agreed upon as SMIs (25). Other mental illnesses can also be chronic and enduring whilst causing significant functional impairment of daily life (26). We therefore also included preconception interventions aimed at more severe experiences of other mental disorders such as severe depression, personality disorders, eating disorders (ED), obsessive-compulsive disorder (OCD), post-traumatic stress disorder (PTSD), and severe anxiety disorders, requiring contact with secondary care.

#### Inclusion criteria

RCTs, systematic reviews, narrative reviews, editorials, clinical guidelines, online information resources or websites (either targeted at women themselves, their support networks or health care providers) describing or testing preconception care.

#### Exclusion criteria

Literature or resources exclusively describing interventions delivered after conception has occurred or to men only. Literature or resources exclusively describing the prevention of pregnancy or the screening of sexually transmitted infections will be excluded if no mention is made of planning for pregnancy or preconception care.

### Peer-reviewed literature search

The search was conducted using the Ovid platform on both MEDLINE and PsychINFO databases. Human studies published after 2000 with no language restrictions were included. MESH terms, as well as keyword searches, were used. See Appendix Figure 2 (appendix) for the full search strategy. Duplicates were removed and records from were screened by title and abstracts against the inclusion or exclusion criteria. After screening by title and abstract, the articles remaining were assessed for eligibility by full-text screening. Forward citation tracking was performed on included peer-reviewed literature to identify further relevant literature. These articles were checked and verified by 2 additional researchers in the Section of Women's Mental Health at King's College London. See Appendix Figure 3 for a flow diagram of included literature.

### Grey literature search

The OpenGrey database and Google were searched to identify both online information resources and clinical guidelines. Search terms were used to reflect concepts of 'preconception' and 'serious mental illness' and limited to resources published after the year 2000. URLs from Google searching were exported for screening using SEOquake software.

### Expert consultation

A perinatal mental health Expert Stakeholder Group were contacted via email to guide the project and for additional papers or interventions or resources that had not been identified through other search strategies. Experts included women with lived experience and experts in mental health and preconception care, including academics, clinicians, healthcare providers. We also contacted the Marcé International Society for Perinatal Mental Health listserv for resources. See Appendix Figure 4 for resources included as a result of expert consultation.

# 2.2 Rapid Evidence Review 2: What is the effectiveness of interventions for modifiable factors impacting on pregnancy outcomes in women with SMI such as smoking and diet?

## Background

Our expert stakeholder group noted  a number of modifiable factors that may impact on pregnancy outcomes which were of particular relevance to women with SMI. There is a much larger body of peer-reviewed literature for interventions for such modifiable factors which have previously been tested in populations with SMI (though not specifically in the context of preconception). The second evidence review therefore focused on searching for Cochrane reviews and RCTs of interventions for the modifiable factors identified by our expert stakeholders which had previously been tested in populations with SMI and could be adapted to a preconception context. These modifiable factors were as follows: alcohol, substance misuse, diet, nutritional supplementation, for example, vitamin D and folate, exercise, intimate partner violence (IPV), sexually transmitted infections (STIs), smoking, weight.

## Aim

To identify Cochrane reviews, and also RCTs published later than any identified Cochrane reviews, evaluating interventions for modifiable factors of adverse pregnancy outcomes in women with SMI.

## Inclusion criteria

Cochrane reviews and/or RCTs evaluating interventions targeting these modifiable factors in populations with SMI.

## Exclusion criteria

Systematic reviews not published on Cochrane database (that is, not reviews of RCTs). Reviews or RCTs exclusively carried out in male populations or in age groups not including WHO defined childbearing years aged 15 to 49.

## Search strategy

The Cochrane database was searched for systematic reviews of interventions for each modifiable factor which had explicitly been tested in populations with SMI after the year 2000. MEDLINE and PsychINFO databases were then searched for relevant RCTs for each modifiable factor which had not appeared in the included systematic reviews. For search strategy see Appendix Figure 5.

# 2.3 Healthcare Professional Survey

Preconception questions (Box 1) were added to an existing service survey sent by NHS England and NHS Improvement (NHSE/I) to clinicians via the Perinatal Mental Health (PMH) Clinical Networks and Adult Mental Health Clinical Networks sent November 2019 with 2 weeks to complete; one reminder went out to PMH networks.

**Box 1. Preconception questions sent via Healthcare Professional Survey**

1. Please choose which service you work in.
2. Are you using any preconception tools or resources in your current clinical practice? If so, what are they?
3. What content or topics do you feel it is most important to include within a preconception tool or resource for women with mental illness?
4. What would be the ideal format for a preconception tool or resource for health care professionals (tick all that apply: Online, Mobile app, Videos, Information sheet or guide, Decision aids, Other)?
5. What would be the ideal format for a preconception tool or resource for women (tick all that apply, same options as Q4)?
6. What support would you and your teams would need to use such tools?
7. When do you think is the most optimal time to engage women with mental illness in preconception care?

# Chapter 3 Results

## 3.1 Rapid Evidence Review 1

### Peer reviewed literature search

Searches for peer-reviewed literature were run in December 2019. Initial searches returned 495 results on Medline and 97 results on PsychINFO, 16 duplicates were removed at this stage. See Appendix Figure 3 for flow diagram, see Appendix Table 1 for details of included studies. After screening by title and abstract, 511 results were excluded and a further 55 results were excluded after full text screen. The database search yielded 16 eligible results and forward citation tracking of these results yielded a further 9 records. A total of 25 peer-reviewed articles were included in this review.

No RCTs evaluating the effectiveness of preconception interventions for women with SMI were identified. However, 8 studies described quantitative outcomes following the delivery of a preconception intervention for women with SMI, using a range of study designs including retrospective file audits of clinical records or phone calls to teratogen information services, and cohort studies; studies were predominantly in high-income countries other than one in Nigeria. Interventions involved the provision of preconception advice through psychiatric consultation (n=3) (27 to 29), teratology advice phone services (n=2) (30, 31), health screening (n=1) (32), family planning information (n=1) (33) and peripartum management plans (n=1) (34). Some studies focused on the individual diagnosis of bipolar disorder (28, 29, 31) and others had broader inclusion criteria for serious mental illness in general (27, 30, 32 to 34). In terms of the outcomes measures, most studies did not include a direct measure of the effectiveness of preconception interventions, instead reported process outcomes, such as the numbers of patients who received preconception care and type of care provided, and some studies described the rate of subsequent pregnancies (27, 31). Two studies did record changes in mental health following preconception care (for example, change in medication required, inpatient care required)(29, 34) and whether recommended changes in treatment plan were enacted (29).

Five studies utilised qualitative methods. One was a systematic review and meta-synthesis of 23 qualitative studies of the experiences of preconception care among women with SMI (35), the other 4 studies (published after the meta-synthesis) were primary studies of preconception care needs and experiences of women with SMI (2, 36 to 38). Two studies focused on bipolar disorder (2, 36), one eating disorders (38), and the others on SMI more broadly (35, 37). These studies were conducted in the UK, Australia, and the Netherlands.

The other 12 articles included in this rapid evidence review included recommendations for preconception care derived from non-systematic literature reviews (39 to 43), narrative reviews (14, 44), reviews of clinical practice (45 to 47), a book chapter (48), and an editorial (22).

## Delivery of preconception interventions

In the experimental studies where interventions were delivered, authors emphasised the need for partner involvement and sometimes described this happening in services. One study found that 55% of partners were involved in creating a peripartum management plan (34), though in other settings partners were rarely involved (33). Several studies reported general adherence to preconception recommendations, for example, one study followed women up for one year and found that out of 32 women who received a preconception consultation 84% of medication recommendations were followed during the preconception period, and 78% of recommendations for changes in psychosocial management were followed (29). However, in generic settings, there was very limited preconception care, for example, sexual health screening conducted within community mental health clinics asked less than 10% of women about their pregnancy plans (32).

Authors of several reviews identified a need for counselling interventions as the medium of delivery for preconception care for women with SMI but recommended a variety of health care professionals as the delivery agent, including psychiatrists, GPs, gynaecologists, generic mental health clinicians and fertility specialists. One paper recommended that a genetic counsellor should be available for individuals with SMI to answer questions around heritability of psychiatric disorders (44). Authors of 2 papers recommended that preconception interventions are delivered to both men and women with SMI (22, 44), whilst all others described interventions solely aimed at women.

## Women's experiences of care

Themes from qualitative studies included barriers and fears around accessing family planning, including ill-informed staff and discriminatory attitudes, stigma, the heritability of disorders and potential custody loss (36), risk of relapse and teratogenicity (2). Women also expressed the need for preconception conversations early in the illness course, preferably during a euthymic period and with the option to revisit these discussions, ideally with the same team at a later stage (2). Women wanted their health provider to be "sympathetic" (1), "informative, supportive, asking, understanding, and non-judgmental" (2). Women also wanted the opportunity to interact with other women with SMI (1), and to have a strong support system from professionals and family (36).

One study of women who had been treated for eating disorders identified that they had experienced the delivery of public health warnings regarding fertility as distressing (38). Women reported in quantitative studies that they were actively discouraged from becoming pregnant at some point by a health professional (28, 31). In an Australian study of 22 women with a mental disorder resulting in serious chronic impairment of day to day functioning, who were considering pregnancy, 64% said that the information provided during preconception counselling was not adequate or available (37).

## Healthcare professionals' recommendations

Healthcare professionals and academics stated that preconception interventions should include mental health considerations (for example, risk of relapse), medication, physical health, and relationships or sexual health. Authors highlighted the need to balance supporting a women's right to be a mother whilst also being realistic about challenges that she may face during pregnancy and parenting. Topics such as women's recent, current and future mental health status (14, 48), her family history (45) and her own experience of being parented (47) were recommended. Several authors recommended the creation of a relapse prevention plan (14, 46 to 48). Other literature recommended including an assessment of women's decision-making capacity along with discussions around poverty, adequate accommodation for parenting, non-supportive relationships and unemployment (14, 42). Some of the reviews cited the importance of involving a supportive family member or partner in the preconception counselling (46), as well as evaluating how much social support the women has in her life (14, 42, 47). Other aspects of intimate partner relationships were also mentioned, such as screening for domestic or sexual abuse and providing contraceptive education (14, 42, 46).

Discussions focusing on women's physical health were also recommended as part of preconception counselling (40). Topics included exercise, weight management and nutrition supplementation, for example, folic acid, and vitamin D (22), smoking, alcohol and substance abuse (22, 40, 42, 47) and screening for infectious diseases (for example, rubella or herpes) (14). One author also suggested discussing planning conception to avoid a winter birth if women have a diagnosis of schizophrenia (43) to avoid influenza, which has been associated with an increased risk of schizophrenia in children who would already be at genetic risk of schizophrenia.

## Grey literature search

The search of OpenGrey yielded no results. A total of 2,640 results were produced from the Google search of which 2,345 were duplicates. See Appendix Figure 4 for flow diagram. The 295 results were screened by title and 180 were removed then screened for in depth content relevance and a further 108 were removed. From the Google search a total of 6 resources were suitable for inclusion, 3 were online information resources and 3 were clinical guidelines. The expert advisory group recommended a further 7 resources for conclusion which has not been captured by the Google search, 2 were clinical guidelines and 5 were online information resources. See Appendix Table 2 and Table 3 for details of included resources.

## Online information resources

Eight online information resources were identified by the search, all of these were published in high-income settings., See Appendix Table 2 for details of included resources. Some resources were produced for an audience of women with SMI and some for clinicians providing preconception care to these women. Most were designed for generic services but the Pan-London Perinatal Mental Health Networks resource (21) provides preconception information for delivery by specialist perinatal mental health services in the UK. This includes a very detailed toolkit on how to provide successful preconception consultations including sections on the tone

of the conversation, physical health, mental health, parenting, medication, and risk-benefit analysis.

## Clinical guidelines

Five clinical guidelines on perinatal mental health were identified by the search, covering preconception care for a variety of serious mental illnesses. See Appendix Figure 4 for flow diagram, see Appendix Table 3 for details of included guidelines. Guidance relating to the preconception period in women with a pre-existing mental health condition includes how to have discussions regarding pregnancy plans and contraception with women of childbearing potential, the effects of pregnancy and childbirth on mental health, the impact of mental health on parenting, risk of relapse and medication counselling. For women with SMI, preconception counselling with secondary mental health services or specialist perinatal mental health services is recommended for those actively planning a pregnancy in the UK.

The Scottish Intercollegiate Guidelines Network recommends that women who are prescribed antiepileptic drugs as mood stabilisers should take 5mg of folic acid from preconception until the start of the second trimester as some mood stabilisers act as folate antagonists. All highlight that valproate should not be prescribed in women of childbearing potential and The British Association for Psychopharmacology notes that impaired fertility in women with psychiatric disorders should not be assumed. The Centre for Disease Control also recommends that women with SMI should be in remission for at least a year before considering pregnancy. Finally, an Australian Clinical Practice Guideline highlights that preconception care should begin at the time of diagnosis and should include the topics of medication, risk of relapse and risk of stopping medications as well as how SMI may impact their experience of motherhood. The guidance also noted that some women may have poor health literacy and that healthcare provided should be aware of and accommodate for this.

## Expert consultation

The expert perinatal stakeholder group were contacted by email and in 3 meetings throughout the process of conducting this report. The resources sent in response to email requests for preconception resources for women with SMI replicated those identified during the formal literature search.

One topic which was raised during these discussions was the epidemiological association between low neonatal vitamin D and the risk of developing schizophrenia in adult life (49). Though to date, no RCTs of vitamin D in pregnancy in relation to schizophrenia outcomes have been conducted, it was suggested that during preconception visits vitamin D levels are taken and vitamin D supplements are given according to standard guidelines.

The suggestion in one review to avoid a winter birth if women have a diagnosis of schizophrenia (43) to avoid influenza, which has been associated with an increased risk of schizophrenia in children who would already be at genetic risk of schizophrenia, was also discussed. However, our stakeholders felt this would be difficult to achieve in practice, was not sufficiently evidence

based (that is, it may not impact on risk of schizophrenia in the children) and cause undue worry among women

The stakeholder group also identified that the Maudsley Prescribing Guidelines detail principles for prescribing psychotropic medication during pregnancy which applies to preconception care (50). This guidance notes that the possibility of pregnancy should be discussed in with all fertile women and that contraindicated psychotropic medications such as valproate and carbamazepine should be avoided during this time. They also note that clinicians should consider prescribing folate. In cases where women are well and relapse risk is considered low, medication may be lessened or discontinued, however for women with SMI this is less advisable and substitutions to lower risk medications may be considered.

It was also noted that the Medicines and Healthcare products Regulatory Agency updated the Valproate Pregnancy Prevention Programme in November 2019 to provide further clarifications on the advice that "Valproate should not be used in girls and women of childbearing potential unless other treatments are ineffective or not tolerated".

Finally, it was noted by our stakeholders that both Article 16 of the Universal Declaration of Human Rights and Article 23 of the International Covenant on Civil and Political Rights provide basis for the right to family life as a fundamental human right. This is relevant to the provision of preconception care as clinicians should be aware that decisions around family life are a human right and consequently, women must not be told that they 'should not' or 'cannot' become mothers.

## 3.2 Rapid Evidence Review 2

Cochrane reviews of interventions were identified for 5 of the preidentified modifiable factors relevant to preconception care and tested in populations with SMI, these papers reviewed a total of 44 RCTs. When individual RCTs were searched for using other databases a further 5 relevant RCTs were identified. See Appendix Table 4 for details of reviews and RCTs.

### Alcohol use

One RCT was found measuring a change in alcohol consumption (51). This RCT used an integrated psychosocial health promotion intervention delivered by care coordinators to address multiple health behaviours in patients with psychosis. Mean difference in alcohol use was not significantly changed following the intervention 0.19 (CI −0.02 to 0.39; p=0.07) and neither were measures of smoking, cocaine, cannabis use or BMI.

### Diet, weight, exercise

Two Cochrane reviews and 2 RCTs were identified by the search. One Cochrane review of diet interventions for schizophrenia found no relevant RCTs for inclusion (52). The Cochrane review of exercise therapies for schizophrenia included 3 RCTs tested in both men and women, one RCT involved a 3 times a week weekly walking programme with 8 men, 2 women and a mean

age of 52 (53). This RCT found a significant effect of exercise on negative symptoms of schizophrenia, where the mean difference (MD) was -8.5, with a 95% confidence interval (CI) -11.11 to -5.89. There was also a significant impact of the intervention on positive symptoms MD -2.5, CI -4.73 to -0.27 compared to control group. Another RCT tested a mixed exercise program of jogging or walking compared to a group exclusively practising yoga. The yoga group showed a greater overall improvement in positive and negative schizophrenia symptom scores than exercise MD.14.95, CI 2.60 to 27.30. The other RCT included in this Cochrane review used a 3-month strength and aerobic training programme which resulted in significant improvements in Mental Health Inventory scores for depression MD 17.50, CI 6.70 to 28.30 and anxiety MD 8.00, CI 0.80 to 15.20. There was no significant change on participant BMI for any of the RCTs included in this Cochrane review.

An additional 2 individual RCTs were also included. The first provided free fruit and vegetables to people with a schizophrenia diagnosis (54). Participants receiving the fruit and vegetables ate significantly more fruit than the control group during the trial but this effect was not sustained. Significant changes were also not found between groups for BMI, blood micronutrients or coronary heart disease risk. The other RCT tested 3 groups receiving lifestyle coaching, care coordination or treatment as usual in overweight patients with SMI (55). No significant change was reported for the primary outcome of 10-year cardiovascular risk. No significant effects were found for secondary outcome including weight, BMI, daily smoking, positive and negative schizophrenia symptoms.

## Intimate partner violence

No Cochrane reviews or RCTs were identified by the search.

## Nutritional supplementation

One RCT for people with schizophrenia (56), provided daily omega-3 dietary supplementation which led to improved Erythrocyte fatty acid composition as well as changes in one omega- 3 acid (DHA) composition which was negatively correlated to changes in positive schizophrenia symptoms ($r=-0.46$, $p<0.01$).

## Sexually transmitted infections

One Cochrane review (57) was published on HIV prevention advice in people with SMI, but no RCTs were included.

## Smoking

One Cochrane review had been published including no RCTs (58). One RCT was also found (59) of a behavioural and pharmacological intervention from a mental health smoking cessation professional and reported that 14% of participants who received the intervention vs 6% in usual care group had quit at 6 months OR 2.4 (CI 1.2 to 4.6, p=0.01) though a significant difference was not sustained at 12 months OR 1.6, (CI 0.9 to 2.9, p=0.10).

### Substance misuse

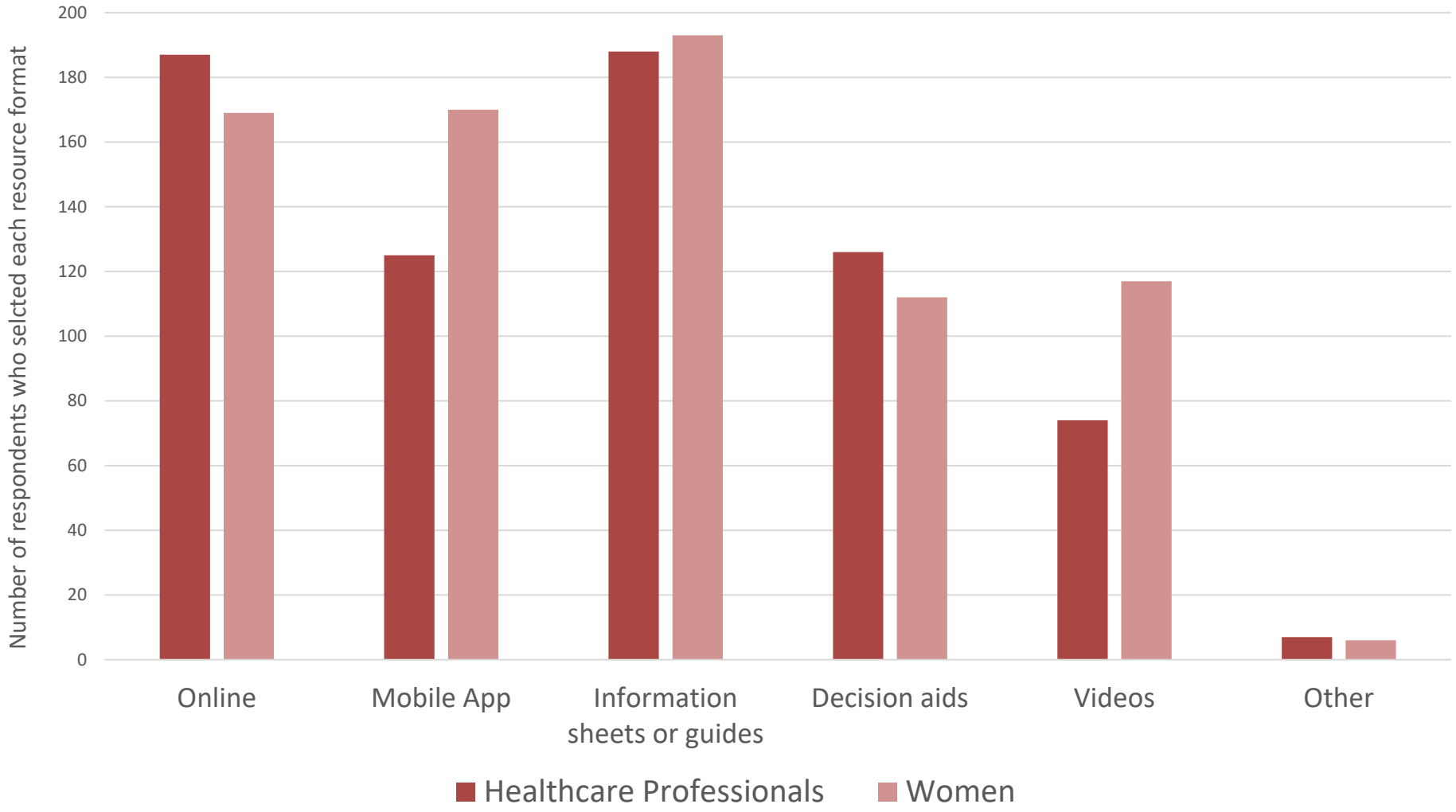
One Cochrane review of psychosocial interventions for people with SMI and substance misuse included 41 RCTs (60). Interventions included various programmes of motivational interviewing, CBT and contingency management. However, many RCTs were rated as low-quality, with no meta-analysis and authors concluded that there was limited evidence to show efficacy in the included RCTs.

## 3.3 Healthcare Professional Survey

The health professionals survey received 235 responses (denominator unknown as the service survey was sent by NHS England and NHS Improvement (NHSE/I) to clinicians via the Perinatal Mental Health (PMH) Clinical Networks and Adult Mental Health Clinical Networks). Most respondents were from Specialist Community Perinatal Mental Health Teams (CPMHT) (26%) and Community Mental Health Teams (CMHT) (24%); other services included both mental health specialities and maternal specialities in adult and children's services.

Overall, 22% reported using existing preconception tools or resources to support the provision of preconception advice or care. Some of the topics more commonly regarded as important for inclusion in preconception care were medication, risk assessment, physical health, links to other supportive services (for example, peer support) and clarity of information. Preconception tools or resources used in current practice included providing contraceptive care (mentioned by 3 respondents), 14 mentioned counselling and forty mentioned preconception resources (respondents could choose more than one response). When service providers were asked 'What would be the ideal format for a preconception tool or resource for health care professionals' the most popular answers were online resources and information sheets or guides, more than one option could be selected (Figure 1). Similar responses were given when health professionals were asked which resources would be ideal for women themselves, including online resources, information sheets or guides and mobile apps. Professionals stated that the support that they would need to effectively use preconception tools should include clear and easily accessible resources as well as training on how to use them. Responses to the free text question, 'What is the optimal time to engage with women with mental illness in preconception care?' included 'at the time of diagnosis', 'when prescribed any new medication', 'when referred to mental health services', 'when they are well', 'after they have had a baby', 'every year' and 'as early as possible'.

**Figure 1. Health professional responses to 'What would be the ideal format for a preconception tool or resource for healthcare professionals?' and 'What would be the ideal format for a preconception tool or resource for women?' (more than one option could be selected)**



# Chapter 4 Discussion

## 4.1 Main findings

The findings of this report on preconception care for women with SMI were synthesised information from a variety of sources, to inform the development of 2 new resources, a resource for health professionals involved in the care of women with SMI, including a family planning tool, and an interactive online pregnancy planning tool with tailored content for women with SMI.

The first rapid evidence review demonstrated that there is a growing body of research identifying a clear need for preconception care tools for women with SMI and healthcare professionals. However, research on the effectiveness of such interventions or resources is lacking. Studies of women's experiences demonstrate that they often feel stigmatised and judged about their desire for motherhood, which is further highlighted by the high proportion of women with SMI who are advised to actively avoid pregnancy.

The proposed content of preconception care for women with SMI, arising from previous reviews, noted that this should be broad-ranging and involve a holistic care plan, covering mental health considerations (for example, risk of relapse), medication, physical health, and relationships or sexual health, social support and domestic abuse and violence. However, whether this model of care for women with SMI is effective in improving preconception health, or longer-term maternal and child outcomes, has not been evaluated. Expert consultation emphasised the need to see preconception care within the context of a woman's human right to family life and also noted that that there is limited evidence around Vitamin D supplementation which may be particularly relevant to women with a diagnosis of schizophrenia and BAME women. There was a general consensus in the literature and our expert stakeholder group regarding the content of preconception care for women with SMI other than the review recommending avoiding a winter birth for women with schizophrenia which our stakeholders did not support as this may be difficult to achieve in practice and cause undue worry among women (43). As such, there is a balance to strike between providing evidence-based information on the risks and benefits of pregnancy whilst not distressing or overwhelming women.

Given the lack of evidence for preconception interventions delivered to women with SMI, the second rapid evidence review aimed to investigate the effectiveness of interventions targeted at potentially modifiable risk factors for adverse pregnancy outcomes, which tend to be more prevalent among women with SMI. These interventions included those aimed at reducing alcohol intake, smoking, substance misuse and/or sexually transmitted infection, or improving diet, weight, exercise, and/or nutritional supplementation. Several RCTs have tested the delivery of complex, behavioural or psychosocial interventions in participants with SMI, and their benefit for physical and mental health. However, there was limited evidence for the effectiveness of these interventions from RCTs and the quality of evidence was found to be mixed. While smoking interventions demonstrated a short-term benefit on cessation rates, and exercise interventions had a positive benefit on psychological well-being in populations with

SMI, there was no evidence of effectiveness for interventions targeting other potentially modifiable factors.

Furthermore, RCTs tended to be undertaken in older populations where mean participant age was over 40 years, limiting the relevance to preconception care for women of childbearing age. It should also be noted that making lifestyle changes requires motivation of the individual and hence women of childbearing age seeking preconception care may obtain better results when receiving interventions for modifiable factors if they understand that these changes will improve the health of future children.

It is clear from the studies reviewed that women have a strong desire for evidence-based information, which is easily accessible and supported by discussions with their clinicians. The preconception care survey of healthcare professionals revealed that although healthcare providers were aware of preconception resources, and their importance, they are not used consistently with women with SMI. Similarly, there is currently a lack of published research on preconception care delivered by generic services or indeed by specialist perinatal mental health services, despite the considerable expansion of specialist services since 2016, with further expansion planned within the NHS Long Term Plan (20).

## 4.2 Gaps in the literature

As highlighted, there is a lack of research literature on preconception care for women with SMI. This review did not identify any studies or RCT's which assessed the effectiveness of preconception interventions for women with SMI. These findings are possibly unsurprising, given that a recent Lancet series on preconception care concluded that there was insufficient research on preconception care interventions in general, and in particular the longer-term benefit for maternal and child health (61). Interestingly mental health was out of scope for the Lancet Preconception Series though this omission was highlighted subsequently and is included in ongoing Preconception Partnership work (62).

The studies identified in this report did not usually disaggregate findings for women of childbearing potential, those not wishing to become pregnant, those planning a pregnancy, and those who were already pregnant. Moreover, findings from RCTs investigating the effectiveness of interventions targeted at modifiable factors often did not present disaggregated data for women and men making it difficult to make specific recommendations about preconception interventions for these different subgroups who may need tailored care around their different needs.

Most studies focused on face to face delivery of preconception care but given the increasing reliance on telehealth and digital interventions, more research is needed to assess the role that technology will play in the future of preconception care. Further research is also needed to improve the delivery of evidence-based preconception care and should consider different elements and delivery styles of preconception interventions to ascertain which methods of

delivery are most effective in leading to healthy, supported and planned pregnancies in this population

## 4.3 Ethical Issues

Though the present report has only examined studies and resources from the year 2000 onwards, unethical practices namely reproductive control of women with SMI must be acknowledged (63); such practices prevailed in the past and the extent to which these continue today is not known (64). Such injustices within reproductive care for women with SMI may continue to be reflected by many research studies focusing exclusively on pregnancy prevention, compared to far fewer pregnancy planning interventions studies indicating a bias towards preventing motherhood (42, 65, 66). Similarly, recent research has found that discriminatory attitudes still prevail among mental health professionals towards family planning and parenthood in people with SMI (67, 68), as well as varying levels of knowledge reported by practitioners (69, 70). Women typically perceive judgemental attitudes as a barrier to accessing reproductive health care (71), this, in combination with high levels of self-stigma amongst this population (72), as well as concerns about the difficulties involved in parenting (73), indicate a high level of need for tailored, evidence-based interventions to be effectively delivered.

## 4.4 Limitations of the review

This rapid evidence review was broad in scope, covering all study designs, qualitative research, systematic reviews, websites, comments and guidelines and grey literature. However, limitations include lack of resources to conduct data screening and extraction by more than one researcher and formal quality appraisal and risk of bias assessment; only 2 academic databases were searched for peer-reviewed literature. While Cochrane reviews will have carried out quality appraisals of RCTs included resource constraints meant that we could not carry out a comprehensive systematic review when searching for RCTs published since an identified Cochrane review, or where no Cochrane review for a specific risk factor was available.

## 4.5 Implications for practice

According to the WHO, preconception care has the potential to improve the health status of women before pregnancy and contribute to better outcomes for mother and child (7). The provision of preconception care is particularly critical for women of child-bearing age with SMI, who may have additional needs which must be carefully considered to promote healthy pregnancies, notably around the effects of psychotropic medication during the perinatal period and support to minimise SMI relapse.

Overall, the review found the tone of the conversation around preconception care to be of critical importance. This was sometimes described as a ‘holistic’ approach to care with the emotional and physical health of both mother and infant promoted within discussions (40). Language was highlighted as an important factor in providing preconception care: for example,

women with bipolar found the term ‘high-risk’ to be worrying (36). An open, non-judgmental environment is needed to encourage women to speak about their concerns without stigma, these concerns may include loss of custody, previous miscarriage, and thoughts on their suitability for motherhood. Finally, conversations should promote choice and advocacy, ensuring that women are informed and supported to make reproductive choices and do not feel judged or coerced not only by health professionals but also by family members and the media.

This report highlighted the wide range of healthcare professionals involved in providing preconception care. Given the potential for unplanned pregnancies, preconception care needs to be embedded within routine care delivered by a healthcare professional in regular contact with each women of childbearing age with an SMI diagnosis. Principles of ‘making every clinical contact count’ should be applied at routine mental health appointments, such as medication reviews, to enable longer-term planning and empower women to make informed decisions (22).

Conversations about physical health are already part of adult mental health service care and preconception care is, therefore, a natural extension of the integration of physical and mental health care provision. In addition, as women with SMI are at increased risk of domestic violence and abuse, sexual assault and rape, exploitation and unsafe sex, healthcare professionals should be trained and supported to ask and respond safely to disclosures in these areas and be aware of referral and care pathways in their locality. These topics are included within the resources for healthcare professionals arising from this report, but the necessary brevity of this resource means that it should be read alongside other potential resources. (Download a resource about domestic abuse intended for use in mental health services).

Preconception care needs to balance family planning and contraception information without stigmatising either reproductive choice, mobilising social support where possible, providing women with realistic information about what to expect from services during pregnancy and the postnatal period (including discussion of relapse prevention plans and where relevant, the involvement of social care). Such discussions need to start early (32), potentially at the point of diagnosis, and ideally when women are well, as pregnancy may occur in an unplanned way (33) and women need to be aware of the impact of pregnancy and the postnatal period on their mental health.

The findings of this report have informed the collaborative development of preconception resources, which can be found on the Tommy’s website. This includes Tommy’s ‘Planning for Pregnancy Tool’, which has been updated to include information for women with SMI, and the ‘Delivering preconception care to women of childbearing age with severe mental illness’ guide for healthcare professionals involved in the care of women with SMI in primary and secondary care published by NHS, Tommy’s PHE and KCL.

# Conclusion

The evidence from these reviews highlights the lack of robust evidence on the effectiveness of preconception care on physical and mental health outcomes in women with SMI as well as in their children. Despite this, the need for effective preconception care is widely acknowledged and it is critical that women feel informed and that they have agency and support over their family planning choices. This can be achieved by providing evidence-based, clear, and unbiased information in a way that allows for an open conversation between the women and service providers. These conversations should be started early particularly at first diagnosis or when first prescribing or changing psychotropic medication so that women are aware of the link between their pharmacological treatment and family planning. Preconception information should also be part of routine conversations about physical health so that it is provided universally to all women of reproductive age with SMI.

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# Appendices

## Rapid Evidence Review 1

**Figure 2. Peer-reviewed literature search strategy**

| | |
|---|---|
| 1 | exp Schizophrenia/ |
| 2 | exp Bipolar Disorder/ |
| 3 | exp Psychotic disorders/ |
| 4 | exp Expressive Disorder, Major/ |
| 5 | exp Personality Disorders/ |
| 6 | exp “Feeding and Eating Disorders”/ |
| 7 | exp Stress Disorders, Post Traumatic/ |
| 8 | severe anxiety.mp. |
| 9 | severe OCD.mp. |
| 10 | severe mental.mp. |
| 11 | exp Secondary Care/ |
| 12 | exp Hospitals, Psychiatric/ or exp Involuntary Treatment, Psychiatric/ |
| 13 | psychiatric history.mp. |
| 14 | psychiatric care.mp. |
| 15 | exp Antipsychotic Agents/ or psychiatric medication.mp. |
| 16 | mood stabili*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] |
| 17 | exp Antidepressive Agents/ |
| 18 | 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 |
| 19 | exp Preconception Care/ |
| 20 | exp Perinatal Care/ |
| 21 | exp Reproductive Health Services/ or exp Reproductive Health / or exp Reproductive Behaviour |
| 22 | exp Contraception/ or exp Contraception Behaviour |
| 23 | exp Fertility/ |
| 24 | exp Family Planning Services/ |
| 25 | pregnancy.mp. |
| 26 | interconception.mp. |
| 27 | exp Teratogens/ |
| 28 | 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 |
| 29 | 18 and 28 |
| 30 | limit 29 to humans |
| 31 | limit 30 to yr=”2000-Current” |

**Figure 3. Flow diagram of peer-reviewed literature** (Full explanation in text above)

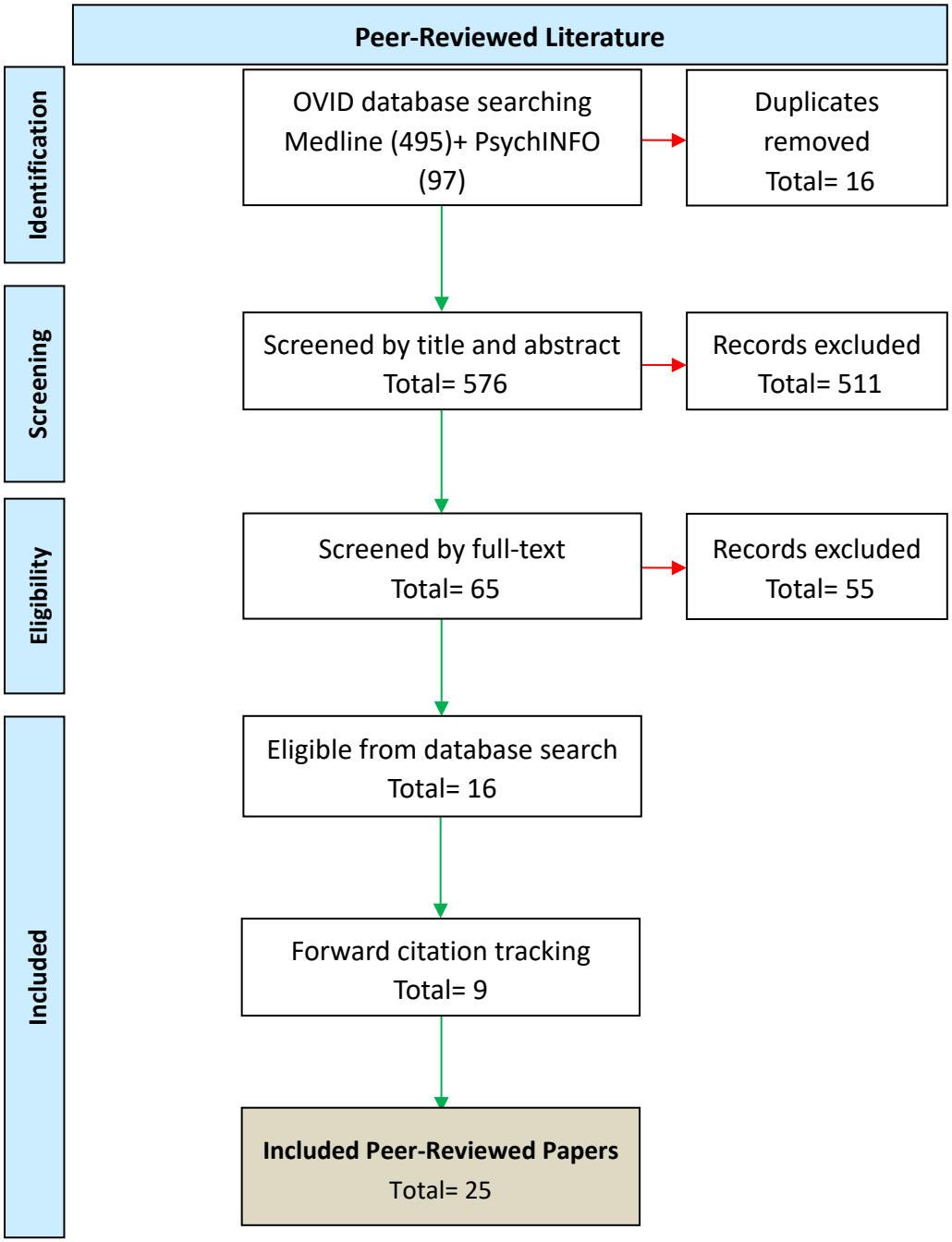

**Figure 4. Flow diagram of guidelines and online information resources** (Full explanation in text above)

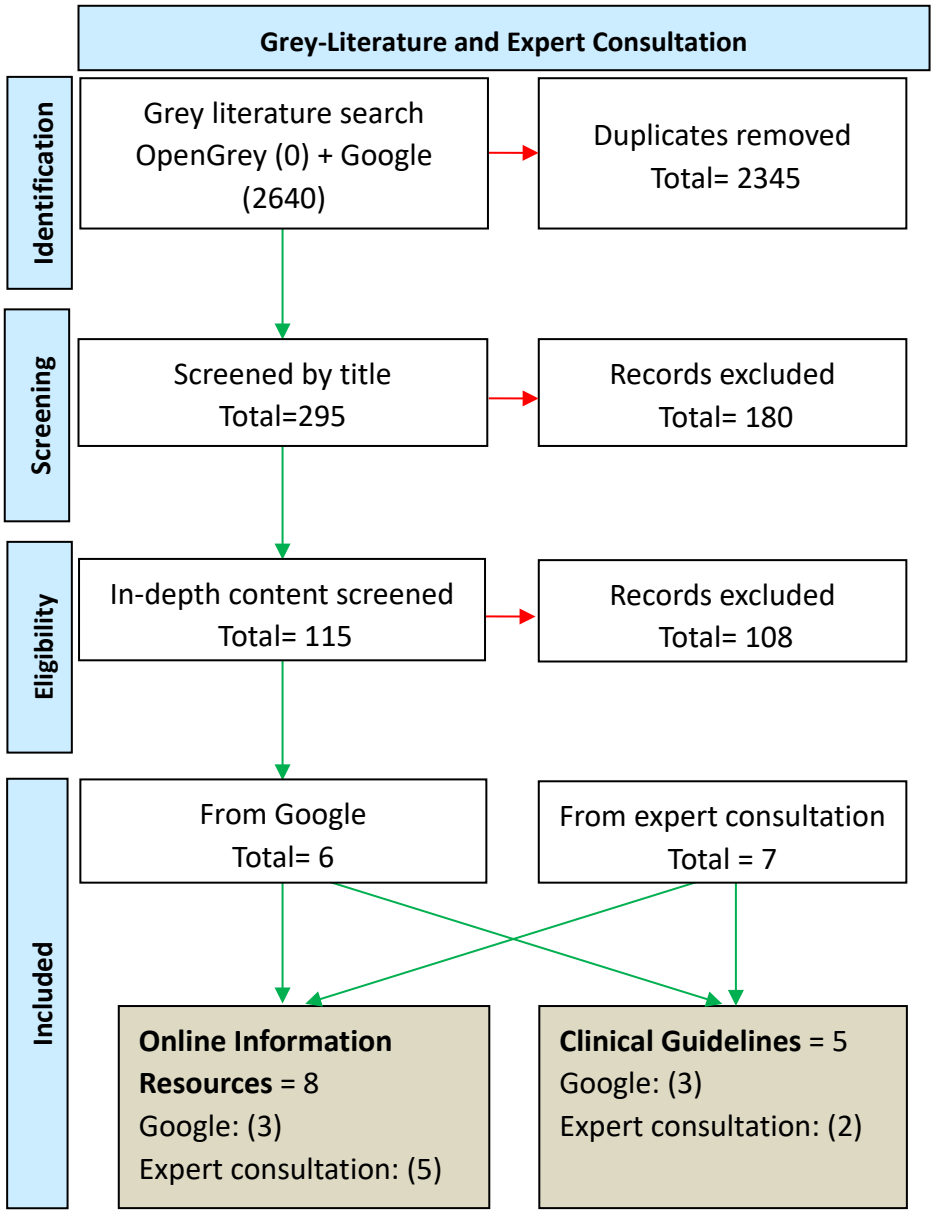

**Table 1. Peer-reviewed literature**

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| Austin, J. C. and W. G. Honer (2007). Psychiatric Services (44) | The genomic era and serious mental illness: a potential application for psychiatric genetic counselling. | Narrative review | People with SMI | n/a | Psychiatric genetic counselling recommended for individuals with SMI (and partners) planning families, delivered in a manner sensitive to ethical considerations whilst responding to the couple's questions and fears as well as health risks to parent and foetus. The counsellor should facilitate a safe and open environment to promote decision making and question-asking. The genetic counsellor should recommend the need to also create a pregnancy plan with a psychiatrist. |
| Catalao, R., et al. (2019). The British Journal of Psychiatry (22) | Preconception care in mental health services: planning for a better future. | Editorial | Men and women with mental health conditions (including SMI) in contact with psychiatric services). | n/a | Editorial highlights that perinatal community mental health teams in England offer preconception counselling to all women with a moderate-severe mental illness pursuing parenthood. For generic services including early intervention services, inpatient services and so on, use of medication reviews seen as an opportunity to offer contraception advice as well as information on weight, nutrition, smoking, alcohol, folic acid, exercise and substance use. The paper also advocates for the delivery of preconception care to men as part of their mental health care provision. |
| Corbett, R., et al. (2017) Internation al Journal | An exploratory investigation of sexual health screening in the first 12 weeks of | Retrospective file audit: Clinical records. | Women (n=95) and men (n=91) aged 25 to 65 who received case | Sexual health screening (including intention to become | 73 out of 186 people (39.2%) were screened for sexual health problems. Only 9.3% of 54 women were asked about the intention to become pregnant. People with bipolar disorder were 8 times more likely to receive sexual health screening compared to those with schizophrenia (OR = 8.00, |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| of Mental Health Nursing (32) | case management in populations with severe mental illness | | management for schizophrenia, depression, schizoaffective, psychosis, bipolar or other for 12 consecutive weeks In Australia | pregnant) at 5 Community mental health clinics, | P < 0.05). Results were not all separated by gender, but women were significantly more likely to receive sexual health screening than men (P=0.000). |
| Ceysens, G. and S. Alexander (2015). Revue de médecine perinatal (39) | Preconception checkup and psychopathology | Literature review (non-systematic) | Women with mental health conditions including depression, bipolar, schizophrenia | n/a | PubMed search for preconception and mental disease terms up to the year 2015, 20 papers identified. A complete preconception management plan is recommended by authors, to be delivered by a gynaecologist or general practitioner (GP) with additional pharmacologic management by a psychiatrist. Preconception health should be discussed rapidly after the initial diagnosis. |
| Dolman, C., et al. (2013). Archives of Women's Mental Health (1) | Pre-conception to parenting: a systematic review and meta-synthesis of the qualitative literature on | Systematic review and meta-synthesis of qualitative studies | 23 qualitative studies (355 women with SMI) | n/a | 11 databases searched for qualitative research on the experiences of preconception and motherhood in women with SMI up to April 2012. Meta-synthesis themes included 'Experiences of Motherhood' with subthemes: 'Stigma', 'Guilt', 'Custody Loss', 'Concern over the impact on the child', 'Isolation Coping with Dual Identities' and 'Centrality of motherhood'; and 'Experiences of Services' with subthemes: |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| | motherhood for women with severe mental illness | | | | 'Problems with service provision' and 'Positive experiences of services'. Women reported that a sympathetic health professional as well as interactions with other mothers who had SMI was desirable. Overall, the study noted there was an information and service provision gap regarding preconception issues for women with SMI. |
| Dolman, C., I.R. Jones, and L.M. Howard (2016) BJPsych open (36) | Women with bipolar disorder and pregnancy: factors influencing their decision-making. | Qualitative study: individual semi-structured interviews | Women (n=21) with a diagnosis of bipolar who were interviewed and women (n=50) who posted on Bipolar UK e-forum.<br>UK | n/a | Women were interviewed regarding the factors influencing their decision making around pregnancy. Recruitment was via a London NHS trust (n=16) and Bipolar UK charity workshops (n=5). The themes from the analysis were 'Centrality of motherhood', 'Contextual factors', 'Stigma' and 'Fear'. Participants described accessing information to inform family-planning decision making as very difficult. Health professionals were described as lacking knowledge and displaying discriminatory attitudes, this discouraged help-seeking. Women found the term 'high-risk' to be worrying and unhelpful and had many other concerns around the risk of relapse. Women desired strong support systems from professionals and family to help with decision making. |
| Frayne, J., et al. (2009). Australian Family | Motherhood and mental illness: Part 1-toward a general understanding. | Non-systematic review of practice and recommendations | Women with chronic mental disorders | n/a | Recommendation for preconception counselling to be delivered by the GP to develop a management plan with a risk-benefit analysis should include consideration of:<br>• medication<br>• personal and family history of mental illness<br>• recent and current mental state |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| Physician (45) | | | | | • support network<br>• addressing any specific fears women may have around pregnancy and motherhood |
| Frieder, A., et al. (2008). American Journal of Obstetrics and Gynecology (46) | The clinical content of preconception care: women with psychiatric conditions. | Non-systematic review of practice and recommendations | Women of reproductive age with psychiatric disorders (depression, anxiety, bipolar and schizophrenia) | n/a | Bipolar<br>Women should be counselled on the risk of relapse and a management strategy should be devised before conception with the involvement of family or partner where possible and strategies to mobilise social support discussed. Discussions should include planning for pregnancy and availability of long-acting contraceptive methods.<br>Schizophrenia<br>Women should be counselled on risks of their condition on their pregnancy and risks of pregnancy on their condition. A management plan should be devised in advance, with the involvement of family or partner where possible.<br>Contraceptive methods should be discussed to prevent unintended pregnancies. |
| Frieder, A. (2010) Current Women's Health Reviews (14) | Preconception Counseling for Women with Schizophrenia | Narrative review | Women of reproductive age with schizophrenia | n/a | Preconception care delivered by mental health clinicians recommended to include:<br>• sexual abuse, safety, health<br>• family planning and contraceptive education<br>• socioeconomic situation (assistance or signposting to improve the environment for offspring)<br>• relationships and social support<br>• screening for use of tobacco, alcohol, illicit drugs. |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| | | | | | • discuss fears, loss of custody, stigma<br>• genetic counselling and infectious risk factors (rubella or herpes)<br>• nutritional information<br>• parenting skills and impact of schizophrenia<br>• medication advice<br>• assessment of the patient's decision-making capacity<br>• relapse prevention plan |
| Green, L., et al. (2013). British Journal of Hospital Medicine (47) | Preconception care for women with mental health conditions. | Non-systematic review of practice and recommendations | Women of childbearing age with mental health conditions | n/a | Individualised preconception counselling recommended on physical health, relapse risk, genetic heritability and medication by a (perinatal) psychiatrist. Including considerations of:<br>• the frequency and severity of episodes of illness<br>• her experience of current and previous treatments<br>• the impact of her illness on her daily functioning and her relationships with others<br>• her own experience of being parented<br>• her social circumstances<br>• the presence or absence of a supportive partner or other family members |
| Hauck, Y., et al. (2008). Internation al Journal | Healthy babies for mothers with serious mental illness: a case management | Literature review (non-systematic) and | Women with SMI | n/a | Framework developed through consultation involving group interviews with 55 community mental health clinicians and around 20 individual interviews with stakeholders (consumers, community mental health clinicians, general practitioners and midwives) in Australia. The framework is for |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| of Mental Health Nursing (40) | framework for mental health clinicians. | stakeholder consultation | | | community mental health clinicians so that they can target factors suitable for intervention, such as antenatal care attendance fidelity, smoking cessation, nutrition, and referrals to other support services. Essential components of the framework were as follows:<br>• holistic approach to care with the emotional and physical health of mother and infant promoted<br>• choice advocacy, ensuring women are informed and empowered to make reproductive choices<br>• continuity of care |
| Holmes, S. (2018) Sociology of Health & Illness (38) | Responses to warnings about the impact of eating disorders on fertility: a qualitative study. | Qualitative study: Semi-structured interviews | Women (n=24) aged 18+ with experiences of treatment for anorexia, bulimia nervosa, binge eating disorder or eating disorder not otherwise specified.<br>UK | Fertility warnings to women with ED delivered by health care professionals or internet source | In Skype interviews with recruitment via Beat, (UK ED charity) 23 out of 24 women had been told verbally that an eating disorder may impact fertility during treatment, one had found this information on the internet. The themes were (1) 'Fertility warnings: communication and power' (2) 'Menstruation, amenorrhea and constructions of femininity', and (3) 'Imagining or resisting maternal futures'. Those with experience of anorexia nervosa received more frequent warnings than other types of ED. Women perceived the information as threats, and manipulative strategies to change their behaviour. Warnings were seen as problematic assumptions about the aspirations of female patients, which may curtail feelings of agency and choice. One participant felt that the fertility warnings drove her to pursue recovery. |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| James, L., et al. (2007) Journal of Psychopharmacology (27) | Informing patients of the teratogenic potential of mood-stabilizing drugs: a case note review of the practice of psychiatrists | Retrospective file audit: Clinical records. | Women aged 18 to 45 in receipt of psychiatric care for >1 year (n=837) and prescribed one or more of the following (n=138/837): lithium, carbamazepine or valproate for bipolar, depression, schizophrenia, borderline personality disorder, Other UK | Psychiatrist-led discussion on teratogenic potential of medications in a Mental Health Trust | 29 out of 138 women (21%) were informed about the teratogenic potential of their prescribed medication, 33 (24%) were advised about contraception and only 2 (1%) were advised about folate. 14 women (10%) became pregnant while taking lithium, carbamazepine or valproate; 3 of these pregnancies were carried to term, 5 were spontaneously aborted, 2 were electively aborted, 3 women were still pregnant at the time of the survey and one infant died shortly after birth. |
| Karoshi, M. (2012). A textbook of preconceptional medicine | Chapter 13: Women with severe mental illness (Ian Jones) | Book chapter | Women with SMI | n/a | Recommended preconception care delivery topics are expressed as questions:<br>-How will pregnancy and birth impact psychiatric illness?<br>-What is the genetic risk of the child developing SMI?<br>-What are the risks/ benefits of medication during |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| and management. London, Sapiens. (48) | | | | | pregnancy?<br>-How can the risks of relapse be reduced? |
| Kennedy, D., et al. (2013) Australian and New Zealand Journal of Obstetrics and Gynaecology (30) | Review of calls to an Australian teratogen information service regarding psychotropic medications over 12 years. | Retrospective file audit: Calls to teratogen service. | Telephone calls (n=164864) made to MotherSafe service from patients (n=7,954) and health professionals (1,427) regarding antidepressants, antipsychotics (typical and atypical), between 2000-2011. Australia | MotherSafe Telephone service providing evidence-based information and counselling for women and healthcare providers about the risks of teratogens., | 7999 calls (4.8%) were made regarding planning a pregnancy. 16218 calls were made regarding antidepressants, 2415 of these were from callers planning a pregnancy. 3941 (2.39%) calls were regarding antipsychotics, 705 (0.43%) of these were about planning a pregnancy. |
| Neri, C., et al. (2018) | Managing fertile women under | Retrospective file audit: | Telephone calls made to | Telephone service | 140 calls from women taking lithium (50% Bipolar, 50% depression). 43 women (30%) called during preconception |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| Minerva Ginecologica (31) | lithium treatment: the challenge of a Teratology Information Service. | Calls to teratogen service and follow up of callers. | teratology service by 140 women under lithium treatment for bipolar and depression (ages 20-46) between May 2002- December 2015<br>Italy | providing information about the risks of teratogens, hosted by University Hospital | and 13 women (9%) did not disclose their fertility status. 34 callers were followed up, 5 of whom called during the preconception period. All callers had been previously discouraged from becoming pregnant by a health care professional and expressed fear and hesitation in their desire to become pregnant. None of those followed up during the study became pregnant after the initial phone call. |
| Nguyen, T., et al. (2015) Journal of Psychosomatic Obstetrics & Gynecology (37) | The preconception needs of women with severe mental illness: a consecutive clinical case series. | Qualitative study: Semi-structured interviews Consecutive clinical case series | Women (n=22) of reproductive age being treated for a psychotic or non-psychotic disorder with severe chronic impairment of day-to-day functioning and contemplating pregnancy in 2012 | Specialist preconception counselling at a tertiary obstetric hospital: a single consultation with a perinatal psychiatrist | This preconception intervention included an assessment and solution focussed counselling session for women and their partners with a perinatal psychiatrist delivered at a tertiary maternity hospital providing care to women and new-borns with high and complex needs, Three main themes from thematic analysis: (1) Maternal desire, (2) Age and time pressure with subthemes of fertility concerns and (3) Medication, mental health problems and their impact on motherhood. Most women reported concerns about the post-partum period, adjusting to motherhood and caregiving capabilities. 8 women (36%) rated information provided by health professionals as adequate or good, 64% said the information was not adequate or not available. 3 women (14%) rated information from their own reading/research as |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| | | | Australia | | adequate or good, and the remaining 86% said the information was not adequate or available. |
| Paslakis, G. and M. de Zwaan (2019). European Eating Disorders Review (41) | Clinical management of females seeking fertility treatment and of pregnant females with eating disorders. | Literature review (non-systematic) | Women with eating disorders | n/a | Recommends that GPs, gynaecologists and fertility specialists should receive training for screening and management of eating disorders to ensure that women begin ED treatment before they pursue pregnancy. The open discussion of eating behaviours should be encouraged, and appropriate referrals made to mental health specialists. They recommend the development of treatment algorithms to facilitate decision making processes when working with women with ED who wish to become pregnant. |
| Rohde, A., et al. (2016) Nervenarzt (34) | Peripartum management plan for patients with mental illnesses. Strategies to reduce the risk of postpartum relapse | Prospective cohort study | Women, (n=420) aged 19-45 with depression, schizophrenia spectrum disorders, anxiety disorders and other mental illnesses with a desire to have children and pregnancy. Planning of and | Bonn concept of peripartum management: provided at the Section for gynaecological psychosomatic illnesses in the university hospital Bonn, | This intervention involves the provision of information, risk assessment, development of 'birth plan' within a participatory process as well as perinatal care including medication management and behavioural strategies (e.g. supporting sleep, psychosocial support, stress and stimulus reduction). In 55% of cases, the woman's partner was involved in the planning process. During pregnancy, 66% of women took one psychotropic medication and 11% took two or more drugs. |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| | | | perinatal care for 196 pregnancies over 10 years (2006–2016) Germany. | | |
| Seeman, M. V. (2013). Acta Psychiatrica Scandinavica (42) | Clinical interventions for women with schizophrenia: pregnancy. | Literature review (non-systematic) | Women with schizophrenia | n/a | 3 databases searched for research on pregnancy and schizophrenia from the year 2000 onwards to elucidate clinical recommendations (it was not mentioned how many papers were found). Mental health providers are recommended to engage in discussion with women on:<br>-Sexual issues/ intimate relationship counselling<br>-Contraceptive counselling and education<br>-Risk factors: domestic abuse, socioeconomic status, substance abuse.<br>-Grieving over past custody losses<br>-Support system evaluation<br>-Genetic heritability and developmental outcomes of offspring<br>-Inclusion of family/partner<br>-Assessment if women's mental health is too severe to advise motherhood, concerning the patient's autonomy.<br>-Medication advice |
| Seeman, M.V. (2018) | Women who suffer from | Literature review (non-systematic) | Women with schizophrenia | n/a | This article is a review of the work of the author's research group along with recent papers from PubMed. It is recommended that women with schizophrenia who wish to |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| World journal of psychiatry (43) | schizophrenia: Critical issues. | | | | reproduce are counselled to have children ideally with young partners without a history of psychosis and to plan conception that will avoid a late winter/ early spring birth to lower the risks of their offspring from having schizophrenia.<br>Other topics included:<br>-Strategies to lower heritability risk<br>-Navigating the mental health care system<br>-Effective medication and side effects<br>-Vocational and avocational opportunities<br>-Stigma prevention<br>-Self harm and suicide reduction<br>-Physical and reproductive health |
| Stevens, A., et al. (2018) Journal of the American Psychiatric Nurses Association (2) | Thoughts and Considerations of Women With Bipolar Disorder About Family Planning and Pregnancy: A Qualitative Study. | Qualitative study: Semi-structured interviews | Childless women (n=15) with Bipolar I aged 28-45. Netherlands | n/a | Interviews were conducted with women from two mental health centres for bipolar, the Netherlands to discuss their thought around family planning and pregnancy. Women expressed a desire for preconception interventions involving early consultation with professionals which would inform them about the heritability of their disorder, teratogenicity of their current medication during pregnancy, and possible solutions to future problems. Most participants wanted an open discussion with their treatment team regarding family planning, at a relevant time during childbearing years. This conversation was preferable during a euthymic period, and initiating this conversation was thought of as a shared responsibility between themselves and their treatment team. |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| | | | | | Preconception information for those with a diagnosis of bipolar disorder in a leaflet was highly desirable; some already received this information, but others missed written information. The ideal attitude of the professional was being informative, supportive, asking, understanding, and non-judgmental. |
| Tunde-Ayinmode, M. F. (2013) Annals of African Medicine (33) | Current knowledge and pattern of use of family planning methods among a severely ill female Nigerian psychiatric outpatients: implication for existing service. | Cross-sectional descriptive study | Women (n=100) with severe mental illness schizophrenia, bipolar disorders, major depression and other psychotic disorders aged 18-52 years in remission in the preceding 2 months and attending the psychiatric outpatient facility. Nigeria. | Provision of family planning information from Psychiatric outpatient clinic in Ilorin, | Most (88%) had good knowledge of effective family planning methods, many (61%) were interested in its use but around half of them had never used any method and current use was only 27%. Only 5% of women had received any family planning information from the clinic or hospital, though 81% of women desired family planning information provision at the psychiatric clinic few of them discussed this with their partners. |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| Viguera, A. C., et al. (2002) American Journal of Psychiatry (28) | Reproductive decisions by women with bipolar disorder after prepregnancy psychiatric consultation. | Retrospective cohort study | Women (n=70) with bipolar disorder who had received outpatient preconception consultation 1997–2000 USA | Specialized consultation about the risks associated with pharmacologic treatment during pregnancy at the Perinatal and Reproductive Psychiatry Program Outpatient consultation at Massachusetts General Hospital | 29/70 women, (45%) had previously been advised to avoid pregnancy by a health care professional, 20 by psychiatrists or other mental health professionals and 4 by primary care physicians or obstetricians. Out of those who decided to avoid pregnancy one sought to adopt a child. Typical reasons given for avoiding pregnancy were fear of effects of medicines on the foetus (56%, 10/18) and fear of illness recurrence if treatment were discontinued (50%, 9/18). Fewer women expressed concerns about the heritability of bipolar disorder for their children (22%, 4/18), avoidance of repeating previous pregnancy-associated illness (17%, 3/18), and fear of illness adversely affecting their offspring (17%, 3/18). 52% (36/69), had been encouraged by a medical professional to seek such consultation, and 42% (29/69) sought “a second opinion”. 55% (38/69) considering becoming pregnant had sought information about the impact of their illness and the risks of the different treatment options, and 22% (15/69) were pregnant during consultation. 17 of 69 sought consultation because they had recurrences of bipolar disorder during a previous pregnancy or in the postpartum period. |
| Wieck, A., et al. (2010) Journal of | One-year outcome after preconception consultation in | Retrospective file audit: Clinical records. | Women (n=32) with DSM-IV diagnosis of Bipolar I, II or | Preconception consultation in a specialist perinatal | The clinic recommended continuing current medication in 9 cases (28.1%), stopping medication in 4 cases (12.5%), and changing medication in 19 cases (59.4%). Pharmacological recommendations were followed by the referring clinician in |

| Reference | Title | Article type | Population | Intervention delivered and setting | Results of intervention or recommendations for intervention |
|---|---|---|---|---|---|
| Clinical Psychiatry (29) | women with bipolar disorder. | | single hypomanic episode / mixed affective episode without depression who attended perinatal psych clinic Dec 2001-Dec 2007 UK. | psychiatry service including pharmacological and psychosocial recommendations at perinatal psychiatry clinic | most cases (preconception period: 27/32, 84.4%; pregnancy: 12/15, 80.0%). Recommendations for a change in psychosocial management (type not specified) were made in 9/32 (28.1%) cases and followed in 7/9 (77.8%) cases. One of the 15 women who became pregnant in the follow-up period delivered during the study and was excluded from outcome analysis. In 5 cases, follow-up information was incomplete. Of the remaining 26 patients, 5 (19.2%) experienced a DSM-IV episode (depression: n=2, hypomania: n=1, mixed affective: n=2), typically in the first 6 months after the consultation (n=4) and received outpatient treatment. In all cases, pharmacologic recommendations were followed, but in only 1 involved stopping medication. Psychosocial recommendations were implemented in 2 of 3 cases. |

**Table 2. Online Information Resources**

| Source | Title | Audience | Hyperlink |
|---|---|---|---|
| APP - Action on Postpartum Psychosis (UK) | Insider Guide Planning pregnancy: a guide for women at high risk of Postpartum Psychosis | Women | https://www.app-network.org/wp-content/uploads/2011/10/2018-Insider-guide_PlanningPregnancy.pdf |
| Bipolar UK | Bipolar disorder, pregnancy and childbirth Information for women, partners and families | Women | https://www.bipolaruk.org/Handlers/Download.ashx?IDMF=fd8688dc-309e-4afd-8386-1bbef3f814da |
| BUMPS - Best use of medicines in pregnancy, UK Teratology Information Service (UKTIS) | Best use of medicines in pregnancy | Women | https://www.medicinesinpregnancy.org/Medicine--pregnancy/ |
| COPE - Centre of Perinatal Excellence Australia | Bipolar disorder in the perinatal period A guide for health professionals (2017) | Clinicians | https://www.cope.org.au/wp-content/uploads/2017/11/Bipolar_Disorder-in-Perinatal-Period_Health-Prof-Fact-Sheet.pdf |
| COPE- Centre of Perinatal Excellence Australia | Schizophrenia in the perinatal period: A guide for health professionals (2017) | Clinicians | https://www.cope.org.au/wp-content/uploads/2017/11/Schizophrenia-in-Perinatal-Period_Health-Prof-Fact-Sheet.pdf |
| Lactmed (USA) | Drugs and Lactation Database | Clinicians | https://www.ncbi.nlm.nih.gov/books/NBK501922/ |
| Pan-London Perinatal Mental Health Networks | Pre-conception advice: Best Practice Toolkit for Perinatal Mental Health Services | Clinicians | https://www.healthylondon.org/wp-content/uploads/2019/05/Pre- |

| Source | Title | Audience | Hyperlink |
|---|---|---|---|
| | | | conception-advice-Best-Practice-Toolkit-for-Perinatal-Mental-Health-Services.pdf |
| RCP - Royal College of Psychiatrists (UK) | Planning a pregnancy (Updated November 2018) | Women | https://www.rcpsych.ac.uk/mental-health/treatments-and-wellbeing/planning-a-pregnancy |

**Table 3. Clinical Guidelines**

| Source | Title | Audience | Hyperlink |
|---|---|---|---|
| BAP - British Association for Psychopharmacology | British Association for Psychopharmacology consensus guidance on the use of psychotropic medication preconception, in pregnancy and postpartum 2017 | Clinicians | https://www.bap.org.uk/pdfs/BAP_Guidelines-Perinatal.pdf |
| COPE - Centre of Perinatal Excellence Australia | Mental Health Care in the Perinatal Period Australian Clinical Practice Guideline (October 2017) | Clinicians | https://cope.org.au/wp-content/uploads/2017/10/Final-COPE-Perinatal-Mental-Health-Guideline.pdf |
| NICE - National Institute of Clinical Excellence (UK) | Antenatal and postnatal mental health: clinical management and service guidance (Updated February 2020) | Clinicians | https://www.nice.org.uk/guidance/cg192 |
| The National Preconception Curriculum and Resources | Guidance for Preconception Care of Women with Psychiatric Disorders (2010) | Clinicians | http://beforeandbeyond.org/uploads/Mental%20Health.pdf |

| Source | Title | Audience | Hyperlink |
|---|---|---|---|
| Guide for Clinicians (Centre for Disease Control, USA) | | | |
| SIGN - Scottish Intercollegiate Guidelines Network | SIGN 127 Management of perinatal mood disorders<br>A national clinical guideline (March 2012) | Clinicians | https://www.sign.ac.uk/assets/sign127_update.pdf |

# Rapid Evidence Review 2

**Figure 5. Cochrane review and RCT search strategy**

| | |
|---|---|
| 1 | Serious mental illness (SMI) |
| 2 | Schizophrenia |
| 3 | Bipolar disorder |
| 4 | Depression |
| 5 | Personality disorder |
| 6 | Eating disorder |
| 7 | Severe anxiety or OCD |
| 8 | Secondary care |
| 9 | Psychiatric |
| 10 | Antipsychotic |
| 11 | Antidepressant |
| 12 | 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 |
| 13 | Alcohol |
| 14 | Substance misuse |
| 15 | Diet or weight |
| 16 | Nutritional supplementation (vitamin D and folate) |
| 17 | Exercise |
| 18 | Intimate Partner Violence (IPV) or Domestic Violence, Abuse (DVA) |
| 19 | Sexually transmitted infections (STIs) |
| 20 | Smoking |
| 21 | 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 |
| 22 | 12 and 21 |

**Table 1. Cochrane reviews and randomised controlled trials of interventions for modifiable risk factors in women with serious mental illness**

| Modifiable factor | Reference | Paper type | Title | Participants | Intervention | Results summary |
|---|---|---|---|---|---|---|
| Alcohol | Gaughran, F., et al. (2017). BMC Psychiatry (51) | RCT | Randomised control trial of the effectiveness of an integrated psychosocial health promotion intervention aimed at improving health and reducing substance use in established psychosis (IMPaCT). | Patients in the UK with a diagnosis of psychosis. 45% female aged 22 to 65, | 9 months receipt of:<br>-n=213 IMPACT therapy health promotion intervention to target health behaviours contributing to cardiovascular risk including alcohol, substances use and diet or exercise, involving motivational interviewing and cognitive behavioural therapy (CBT) delivered by care-coordinators from UK Community Mental Health Teams or<br>-n=193 Treatment as usual | 78% of participants attended 12 month follow up and 74% attended at 15 months. Results were not disaggregated by gender. In the mixed model results, there were no treatment effects of the intervention on physical or mental health aspects of the primary outcome SF-36 tool −1.40 (CI −3.20 to 0.41; p= 0.13). Similarly, there was no significant change in the Alcohol Use Disorders Identification Test AUDIT scores 0.19 (CI −0.02 to 0.39; p=0.07). There was also no significant effect on smoking, cannabis, cocaine-use, or BMI. |

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| | | | | | | The only variable which showed significant change after the intervention was high-density lipoprotein cholesterol 0.085 (CI 0.007 to 0.16; p= 0.034). |
| Diet | Pearsall, R., et al. (2016) Cochrane Database of Systematic Reviews (52) | Cochrane Review (0 RCTs included) | Dietary advice for people with schizophrenia. | | | |
| Diet, Weight | McCreadie, R. G., et al. (2005). The British Journal of Psychiatry (54) | RCT | Dietary improvement in people with schizophrenia: randomised controlled trial. | Patients with a DSM–IV diagnosis of Schizophrenia in Scotland. 29% female, mean age 45 | 6 months of receipt of:<br>-n=32 Free fruit and vegetables with meal planning instruction<br>-n=37 Free fruit and vegetables alone<br>or<br>-n=33 Treatment as usual. | Individuals receiving free fruit and vegetables consumed significantly more of these during the intervention than treatment as usual group F=8.82, p=0.003 but this increased consumption ceased after the free provision stopped.<br><br>No significant change was detected at any time between groups for BMI, |

| Modifiable factor | Reference | Paper type | Title | Participants | Intervention | Results summary |
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| | | | | | | blood micronutrients or coronary heart disease risk. |
| Diet, Weight, Exercise | Jakobsen, A. S., et al. (2017). PLoS One (55) | RCT | Effect of lifestyle coaching versus care coordination versus treatment as usual in people with severe mental illness and overweight: Two-years follow-up of the randomized CHANGE trial. | Patients with ICD-10 schizophrenia, schizoaffective disorder or persistent delusional disorder and waist circumference larger than 102cm (men) or 88cm (women). 56% female, mean age 39 | One-year receipt of:<br>-n=138 CHANGE intervention coaching with healthcare professional with training in smoking, diet and lifestyle diseases utilising motivational interviewing, assertive techniques and transtheoretical model.<br>-n=142 Care coordination with a special trained psychiatric nurse to help ensure optimal physical health treatment through primary care.<br>-n=148 Treatment as usual | The primary outcome of the study; 10-year cardiovascular risk was unchanged at 2 years using linear mixed-models. The mean risk in the CHANGE group was 8.7% (CI 7.6–9.9%) in the care coordination group was 7.7% (CI 6.5–8.9%) and 8.9% (CI 6.9–9.2%) in the treatment as usual group (p= 0.24).<br><br>No significant effects were found for any other secondary outcome including weight, BMI, daily smoking, positive and negative schizophrenia symptoms. |

| Modifiable factor | Reference | Paper type | Title | Participants | Intervention | Results summary |
|---|---|---|---|---|---|---|
| Exercise | Gorczynski, P. and G. Faulkner (2010) Cochrane Database of Systematic Reviews (53) | Cochrane Review (3 RCTs included) | Exercise therapy for schizophrenia. | Patients with a DSM-IV diagnosis of schizophrenia. 20% female, mean age 52. (74) | -n=6 Walking exercise thrice weekly (5 to 30 minutes)<br>-n=6 standard care | Exercise group negative symptoms were significantly improved: MD -8.5 (CI -11.11 to -5.89) positive symptoms also improved MD -2.5 (CI -4.73 to -0.27). There was no significant effect on participant BMI. |
| | | | | Patients with a DSM-IV diagnosis of schizophrenia 31% female, mean age 31. (75) | 3-month receipt of:<br>-n=30 Walking, jogging and standing or seated postures. 1-hour 5x a week<br>-n=31 yoga 1-hour 5x a week | Those doing yoga showed a greater overall improvement in positive and negative schizophrenia symptom scores than those in the exercise group MD.14.95 (CI 2.60 to 27.30). |
| | | | | Patients with a DSM-IV diagnosis of schizophrenia 38% female, mean age 45. (76) | 3-month receipt of:<br>-n=7 weight and aerobic training 90 minutes 2x per week.<br>-n=6 standard care | Mental health inventory scores were significantly improved in the exercise group for depression MD 17.50 (CI 6.70 to 28.30) and anxiety MD 8.00 (CI 0.80 to 15.20). There was no significant effect on participant BMI. |

| Modifiable factor | Reference | Paper type | Title | Participants | Intervention | Results summary |
|---|---|---|---|---|---|---|
| Intimate partner violence | | No Cochrane reviews or RCTs found. | | | | |
| Nutritional supplementation, for example, vitamin D and Folate | Hibbeln, J. R., et al. (2003). Biological Psychiatry (56) | RCT | Smoking, gender, and dietary influences on erythrocyte essential fatty acid composition among patients with schizophrenia or schizoaffective disorder. | Patients with a DSM-IV diagnosis of schizophrenia, 35% female, 63% smokers, mean age 40. | 16 weeks supplementation with:<br>- n=36. 3 g daily of omega-3 fatty acid<br><br>-n=36. Daily placebo | After supplementation, there were significant changes in some percentage measurements of Erythrocyte fatty acid composition. Changes in mineral levels after supplementation were correlated to changes in psychometric test results, it was found that changes in one omega- 3 acid (DHA) composition were negatively correlated to changes in positive schizophrenia symptoms (r=-0.46, p<0.01). |
| Sexually transmitted infections (HIV) | Wright, N., et al. (2016) Cochrane Database of | Cochrane Review (0 RCTs included) | HIV prevention advice for people with | | | |

| Modifiable factor | Reference | Paper type | Title | Participants | Intervention | Results summary |
|---|---|---|---|---|---|---|
| | Systematic Reviews (57) | | serious mental illness. | | | |
| Smoking | Khanna, P., et al. (2016) Cochrane Database of Systematic Reviews (58) | Cochrane Review (0 RCTs included) | Smoking cessation advice for people with serious mental illness. | | | |
| Smoking | Gilbody, S., et al. (2019) The Lancet Psychiatry (59) | RCT | Smoking cessation for people with severe mental illness (SCIMITAR+): a pragmatic randomised controlled trial. | Patients with an ICD-10 diagnosis of bipolar disorder or schizophrenia and heavy smokers 41% female, mean age 47 | -n=265 received the behavioural and pharmacological intervention of individually tailored support from a mental health smoking cessation professional (up to 12 face to face sessions) and nicotine replacements or Varenicline.<br>-n=261 usual care | 14% (vs 6% in the usual care group) of participants who received the intervention had quit at 6 months OR 2.4 (CI 1.2-4.6, p=0.01). A significant difference was not sustained at 12 months OR 1.6, (CI 0·9 to 2.9, p=0.10).<br><br>Mental health and physical health outcomes were not significantly different between groups at 12 months. |

| Modifiable factor | Reference | Paper type | Title | Participants | Intervention | Results summary |
|---|---|---|---|---|---|---|
| Substances misuse | Hunt, G.E., et al. (Updated 2019) Cochrane Database of Systematic Reviews | Cochrane Review (41 RCTs included) | Psychosocial interventions for people with both severe mental illness and substance misuse. | | | Systematic review includes 41 RCTs (n=4024). Quality of studies typically rated as low meaning that high-quality meta-analysis of outcomes was not possible across studies. Types of interventions included motivational interviewing, CBT, contingency management and skills training.<br><br>The authors concluded that there was no high-quality evidence to show that any of the psychosocial interventions tested improved substance use outcomes due to small sample sizes, loss to follow up and methodological differences as reasons for difficulty in comparing across studies. |

# About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, research, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

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