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***Factors contributing to emotional distress and wellbeing among women and men who experience miscarriage and attend hospital settings:
A systematic scoping review protocol***

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Introduction

Miscarriage is the most common complication during gestation. Definitions of miscarriage vary according to different countries. In Canada, the USA and Australia it is defined as a pregnancy loss occurring within the 20th week of the total gestational period. In the United Kingdom (UK) the term miscarriage includes all pregnancy losses from conception up to the 24th week of gestation. Similarly, the definition of recurrent miscarriage also varies among countries. For example, in the UK it is defined as the loss of *three* or more consecutive pregnancies (RcOG, 2011), while in China it is the loss of *two* or more consecutive pregnancies (Chen *et al.*, 2019).

Women who miscarry can experience short- and long-term psychological complications such as depression, anxiety and post-traumatic stress disorder (Nikcevic *et al.*, 2000; Sham, Yiu and Ho, 2010; Farren *et al.*, 2016, 2018, 2020). Further, many women and men report experiencing intense grief as a result of their pregnancy loss (Kerstin and Wanger, 2012; Williams *et al.*, 2020). It is important to establish which factors might contribute to women and men's emotional distress or wellbeing while in hospital, to help improve the provision of appropriate support and help reduce the risk of developing psychological morbidities. Research has indicated that experiences in hospital, in particular interactions with, and the provision of information by, health professionals may have an impact on emotional wellbeing (Simmons *et al.*, 2006; Murphy and Philpin, 2010; Norton and Furber, 2018; Bellhouse *et al.*, 2019).

Previous systematic reviews in the area have mainly focused on the psychological and emotional implications of miscarriage (Murphy, Lipp and Powles, 2012; San Lazaro Campillo *et al.*, 2017; Farren *et al.*, 2018) and women's satisfaction with the care provided when attending hospitals due to miscarriage (Geller, Psaros and Kornfield, 2010). Searches of the PROSPERO and Cochrane databases have established that no similar systematic reviews have been registered and only one similar scoping review was found from other database searches. That review

(Freeman, Neiterman and Varathasundaram, 2020) differs from our review in that it aimed to explore the experiences of women accessing and utilising health care services during or after miscarriage with a focus on whether these experiences were negative or positive rather than on factors relating to emotional distress and wellbeing. Further, unlike our review, it does not include literature relating to men's emotional distress and wellbeing, focuses on early pregnancy loss only (less than 13 weeks), does not include grey literature, and does not appraise included studies for quality.

Synthesising the evidence on factors that contribute to women and men's emotional distress and wellbeing following miscarriage would help to guide future research and inform recommendations for improving services provided in hospital settings. This systematic review is part of a larger doctoral project that aims to explore women's emotional needs when they experience miscarriage in hospital settings.

Review Question

What factors contribute to the emotional distress and wellbeing of women and men who attend hospital facilities when experiencing miscarriage?

Objectives

- To map the available evidence and synthesise findings highlighting factors contributing to women and men's emotional distress and wellbeing in hospital settings;
- To identify areas for further research on how best to support women and men experiencing miscarriage in hospital settings; and
- To assess quality of available evidence on factors contributing to women and men's emotional distress and wellbeing in hospital settings.

Study Design

This review will be guided by the methodological framework for scoping reviews provided by Arksey and O'Mally which includes: 1) identifying the research question; 2) identifying relevant studies; 3) study selection; 4) charting the data; and 5) collecting, summarising and reporting the results (Arksey and O'Malley, 2005).

To promote rigour and compatibility with scoping review guidelines the PRISMA for Scoping Review Checklist will be used (Tricco *et al.*, 2018). Finally, the Joanna Briggs Institute

(JBI) Manual for Evidence Synthesis (Peters *et. al*, 2020) will provide guidance throughout the review process.

Inclusion Criteria

Inclusion criteria have been developed using the Population, Concept and Context (PCC) framework suggested by the JBI (Peters *et. al*, 2020).

Participants

Studies including:

- Women and men who experienced miscarriage and attended hospital as a result.
- Health professionals' (e.g. physicians, doctors, nurses and midwives, health care assistants, technicians, mental health professionals) with experience of working with women experiencing miscarriage in hospital settings.

Context

Studies referring to any hospital setting including, but not limited to, outpatients' clinics, Emergency Departments and obstetrics/gynaecology wards.

Concept

Studies reporting hospital-related factors that contribute to the emotional distress and wellbeing of women and men experiencing miscarriage. All definitions of miscarriage will be included according to the country in which the study was conducted, also recurrent miscarriage will be included in the review.

Types of evidence sources

We will include all types of studies, both quantitative and qualitative, published in English, with no geographical restrictions. Primary research studies, reviews, guidelines and grey literature will be included in the review. Searches will be restricted to the last 20 years (2009-present).

Exclusion Criteria

Participants

Studies including:

- Women who experience stillbirth, molar pregnancy or ectopic pregnancy. Studies which do not clearly specify the type of pregnancy loss experienced.
- General practitioners, family practices and charities who have experiences of working

with women experiencing miscarriage in hospital settings.

Context

- Any non-hospital related factors which have influenced women and men's emotional wellbeing.

Search Strategy

The search strategy has been developed in consultation with an expert in database searching. It involves the following four stages:

1. Test and refine the search terms (see Table 1) in one database (MEDLINE).
2. Extend the search to CINAHL and PsycInfo.
3. Conduct grey literature search. Search terms previously indicated will be used to conduct adapted searches of relevant organisational websites including The Miscarriage Association, Tommy's, American Pregnancy Association and the World Health Organization (WHO) website. Further, a Google search will be conducted, and the first five pages of results will be screened. Finally, the OpenGrey database will be searched
4. Search the reference list of included studies for additional relevant articles.

Screening and Evidence Selection

Article titles and abstracts will be screened by one review author (MG) to remove obviously irrelevant articles and those that do not meet the review inclusion criteria using the Web Software Covidence. A second author (AA) will independently screen the first 100 records. Results will be compared, and any disputes resolved through discussion, consulting a third author if necessary. Next, full text screening of the remaining articles will be conducted to ensure all articles found are relevant for inclusion. Full-text screening will be carried out by one author (MG) with a random selection of 10% of full-text articles screened by a second author (AA). Comparisons will be discussed, and any issues resolved. In case of disagreement, a third author (GM) will be consulted.

A PRISMA flow diagram (PRISMA, 2015) will be used to present search results and number of articles screened and included in the review.

Concept	Miscarriage		Psychological/emotional wellbeing		Hospital setting
Search terms	Mesh headings 1. Abortion Spontaneous / OR Key words (.mp.) 1. Miscarriage OR 2. Pregnancy loss OR 3. F?etal death OR 4. Early pregnancy loss OR 5. First trimester loss OR 6. Second trimester loss	AND	Mesh headings 1. Mental Health/ OR 2. Emotions/ OR Key words (.mp) 3. Mental OR 4. Psychological OR 5. Emotional OR 6. Need* OR 7. Satisfaction* OR 8. Perspective* OR 9. Experience* OR 10. View* OR 11. Perception* OR 12. Opinion*	AND	Mesh headings 1. Heath services/ OR 2. Emergency service, Hospital/ OR 3. Maternal Health Services/ 4. Gynaecology/ OR 5. Obstetrics and Gynaecology Department, Hospital/ OR 6. Obstetrics/ OR Key words (.mp) 7. Healthcare OR 8. Health-care OR 9. Hospital* OR 10. Emergency unit* OR 11. Emergency department* OR 12. Early pregnancy unit* OR 13. Early pregnancy assessment unit*

Table 1. Search terms

Data Extraction

Data extracted will be conducted by one author (MG) using an adapted version of *JB* *Template Source of Evidence Details* (see Appendix 1). This will include details of the study characteristics including:

- Background information (authors, year of publication, country of origin)
- Aims/ purpose of the study
- Population and sample size

- Context in which the study was conducted (Emergency Department, Early Pregnancy Assessment Units)
- Methodology/methods
- Intervention type and duration of intervention (if applicable)
- Outcomes and details of these
- Key findings that relate to scoping review questions:
 1. Hospital-related factors perceived by women and men as having a negative or positive influence on their emotional wellbeing.
 2. Hospital-related factors perceived by health professionals as having a negative or positive influence women or men's emotional wellbeing.

Quality appraisal

A Mixed Methods appraisal tool (MMAT) will be used to assess the quality of primary studies (Hong *et al.*, 2018). Grey literature will be appraised using the AACODS checklist (Authority, accuracy, coverage, objectivity, date, significance) (Tyndall, 2010).

Data synthesis

Data will be analysed by MG adopting the Narrative Synthesis approach (Ryan, 2013) summarised in Figure 1. This will help to explore relationships among data by organising findings from included studies and describing patterns across them (Popay, *et al.*, 2006). The first author (MG) will use a diary to record how the synthesis of data was conducted to guarantee transparency and ensure same techniques are used across the process.

Synthesis of the data will take place in three phases. During data extraction each selected study will be systematically summarised using JBI Template Source of Evidence Details (Peters *et al.*, 2020) (see Appendix 1). This will facilitate a preliminary synthesis, Phase 1, by providing details of each study in the same order and highlighting possible relationships and differences between them (Ryan, 2013). During Phase 2, Nvivo Software will be used to conduct thematic analysis of the study findings according to Braun and Clark's framework (Braun and Clarke, 2006). Specifically, initial codes will be used to organise the data. Once this process is completed, new codes will be generated by grouping together the initial codes according to their meanings (Thomas and Harden, 2008). Next, descriptive themes will be created which will be revised and transformed into analytic themes (Phase 3). During this phase the robustness of the synthesis will also be assessed. For example, a validity assessment will be used along with the diary to critically reflect on the synthesis process (Kugley *et al.*, 2017). Final results will be presented in narrative and tabular form.

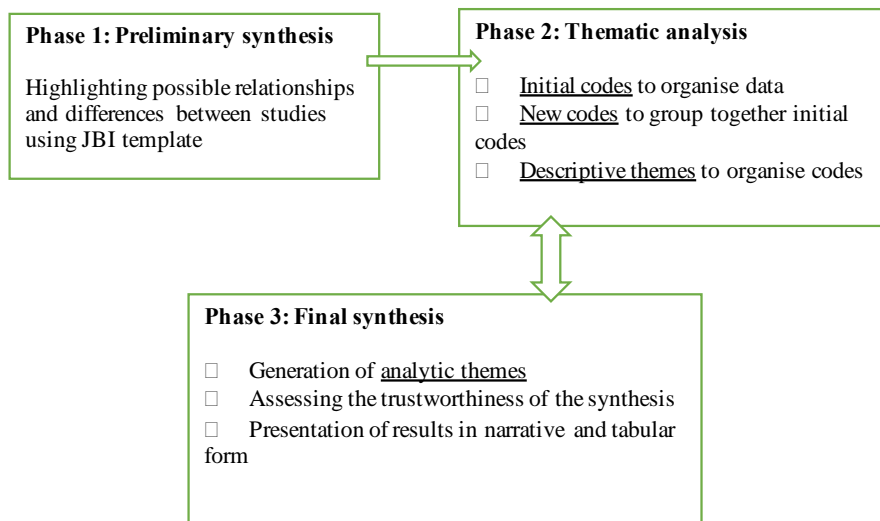


Figure 1. Narrative Synthesis Process

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Appendix 1: Data extraction table

Scoping Review Details	
Scoping Review title:	
Review objective/s:	
Review question/s:	
Inclusion/Exclusion Criteria	
Population	
Concept	
Context	
Types of evidence source	
Evidence source Details and Characteristics	
Citation details (e.g. author/s, date, title, journal, volume, issue, pages)	
Country	
Context	
Participants (details e.g. age/sex and number)	
Details/Results extracted from source of evidence (in relation to the concept of the scoping review)	
Factors perceived by women having negative or positive influence on their wellbeing	
Factors perceived by men having a negative or positive influence on their wellbeing	