EVIDENCE BASED MIDWIFERY

Contents

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Editorial

The wonder world of fetal microchimerism

Wonders unfold every day and the mind boggles at the hidden power of our human bodies to hold secrets that the human eye can never see but the heart and soul feel and intuitively, *just know*. We cannot see the microscopic world of the blood that flows through our veins, however, with modern technological enhancements and powerful microscopes we can visualise our genetic traits through blood profiles. The lifeworld of our blood cells that once was hidden is now visible! I believe it is ocularcentrism that drives us to seek the visual evidence for 'proof' of concept and with the revealing power of technology comes the 'aha' moment when we first *see* (Sinclair et al 2019). The realisation of the gift of precious life that flows from the beginning of time and lasts forever is mesmerising stuff that can set the imagination on fire! The new evidence on 'fetal microchimeria'(FMc) indicates that at conception, transference of maternal and fetal cells occur and that new life lives in us, regardless of whether or not we abort or have a stillbirth or the child or the adult dies. The definition of motherhood is called into question if we consider this fact. What a thought to consider and it brings us a new lens to look at the role of being a mother and the longevity of human cells. The thought of your child's cells remaining in your body for the lifespan is now factual not fictional. The facts are simple: cells from your baby (aborted, miscarried or born) remain in your body for a very long time and your cells also remain in your child, resulting in reciprocal transference, known as 'fetal microchimerism' (FMc) (Shrivastava et al 2019). This fact supports the intuition that mothers often express when they sense their child is in trouble although they have nothing but a feeling to go on. The shared cellular life identified through FMc provides the scientific basis to prove the life line theory. Furthermore, the often heard statement: 'a part of me died when my mother died' can also be scientifically proven …with our understanding of FMc. Fetal microchimerism refers to the bi-directional transfer of cells from the mother to the fetus and from the fetus to the mother and can occur at any time from conception to birth. These cells remain in circulation for the lifespan and have been implicated in both positive and negative autoimmune disease progression (Shrivastava et al 2019). The understanding of FMc is an emerging body of knowledge that is focused on determining the role and function of transferred cells from the fetus to the mother during conception, pregnancy and the puerperium (Berencsi et al 2012). Some studies have reported positive associations such as protection from breast cancer (Gadi 2010) and Florim et al (2015) report positive associations with lupus. However, negative associations have been reported with increased risk of pre-eclampsia and cardiovascular disease (Berencsi et al 2012), yet others report both positive and negative associations (Yeung & Dendrou 2019). There is no doubt that this is an area for future research as the facts are still in the process of being collected and synthesised. Another explosive and controversial application of this important new knowledge for religious believers is with regard to the evidence that can be extrapolated to confirm the very special role and veneration of the Virgin Mary, the mother of Jesus Christ. Ministers and faith writers have written books (Calloway 2013) and social media postings, blogs and online commentaries about FMc referring to the evidence from research as confirmation of Mary's virgin birth and her ascension into heaven (Dobkowski 2017). Personal beliefs are to be respected but as midwives we are bound to seek the evidence from the genomics and immunology first and then we must remain sensitive and respectful to the religious beliefs of all the women we serve. We are cognisant of the complexity of human nature and our training prepares us to care for the mind, body and soul, of all those who place their trust in us. Each component of our human nature requires respect, protection and nurturing and FMc is definitely an amazing discovery with soul magnifying potential.

I do hope this brief introduction will encourage you to read more about FMc and some of you may be inspired to undertake research in this subject.

Key words: fetal microchimerism, evidence-based-midwifery, motherhood, genetics, ocularcentrism, spirituality and intuition

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Exploring the psychometric validity and reliability of the Stillbirth Stigma Scale

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ORIGINAL

Background: In 2011 and 2016, the Lancet Stillbirth Series released a call for action to identify mechanisms which could lead to a reduction in stillbirth stigma. Despite this repeated call, stillbirth stigma remains a relatively unexplored area. This research is answering that call by providing further psychometric assessment on the recently developed 20-item Stillbirth Stigma Scale.

Methods: Bereaved parents (n=1015) from high-income countries (Australia, United States of America (USA), United Kingdom (UK), New Zealand and Canada) who have endured a stillbirth were surveyed. A confirmatory factor analysis was undertaken, to confirm the factor structure.

Reliability analysis and convergent validity were conducted to further determine the reliability and validity of the scale.

Ethics: This study was approved on 5 December 2016 by the University of South Australia Human Research Ethics Committee, protocol number 0000036017.

Results: Based on the initial findings of the exploratory factor analysis, 20 items contained within four factors (Perceived Devaluation, Discrimination, Self-stigma and Disclosure) were entered into the confirmatory factor analysis. Results supported a four-factor structure of the Stillbirth Stigma Scale and goodness of fit measurements were satisfactory. Internal consistencies of each sub-scale, and the total scale were good (α =.89). Convergent validity was also established with other related measures (Rosenberg Self-esteem Scale).

Conclusion: Analysis suggests the Stillbirth Stigma Scale is a theoretical and statistically sound scale, which can be used within health promotion and clinical settings to identify bereaved parents at risk of experiencing higher levels of stillbirth stigma.

Keywords: scale development, stigma, stillbirth, perinatal health, methodology, psychology, health, midwifery

Introduction

In 2011 and 2016, the Stillbirth Lancet Series made a call to action urging researchers (or others) to identify mechanisms that result in a reduction in the stigma associated with stillbirth (Goldenberg et al 2011, Scott 2011, Horton & Samarasekera 2016). Stigma has been identified as a barrier in addressing stillbirth, due to its impact which may leave bereaved parents with a sense of shame or failure (Horton & Samarasekera 2016). Progress on this call from a research, political and health promotion level has been limited.

Stigma is a complex and multifaceted concept which is often altered to meet the changing social context in which it is applied (Deacon et al 2005, Pescosolido & Martin 2015). Goffman (1968) states that stigma serves to devalue a person's standing within their community. Link & Phelan (2001) built upon the work of Goffman (1968), as they believed he had focused too heavily on the micro-interactions – in which the onus is placed on the stigmatised – rather than addressing the potential macro causes of stigma, including the impact of policy and legislations, potentially allowing for discrimination. They define stigma as the convergence of labelling, stereotyping,

separation, status loss and discrimination, which are interrelated components and must occur together when power is exercised by a dominant group. Utilising Link & Phelan's (2001) definitions subsequently allow for stigma to be analysed on an individual and structural level.

Stigma is considered a fundamental cause of health inequalities (Hatzenbuehler et al 2013), and has been examined in several areas, mainly mental health, and sexually transmitted diseases (Van Brakel 2006), however, not in stillbirth. The presence of stigma has been associated with numerous adverse outcomes, such as lowered self-esteem (Link et al 2002), depression, and poorer quality of life. Furthermore, stigma can hinder help-seeking behaviour which can contribute to further co-morbidities (Corrigan et al 2014).

Concerningly, those with stigmatised conditions have higher rates of experiencing poorer quality of health care from their health care providers (Phelan et al 2015).

Qualitative research suggests that bereaved parents endure stigma (Haws et al 2010, Brierley-Jones et al 2015). Evidence suggests that bereaved parents endure social consequences such as increased isolation, rejection and, most notably, silence (Burden et al 2016) which are all components of stigma. In a mixed-methods international survey, 817 bereaved parents' open-ended questions found examples of feelings of being 'contagious' and workplace discrimination (Pollock et al 2019a). Such feelings of blame, shame, isolation and feeling contagious may be symptoms of stigma. Until recently, there has been no quantification on the extent and type of stigma endured by bereaved parents. Pollock et al's (2019a) international survey of 817 bereaved parents, found 38% (n=313) of them identified as having been stigmatised due to their stillbirth. However, this was based on self-perception and yes or no responses, not a validated psychometric scale. As such, neither the extent of stillbirth stigma, nor an understanding of the type of stigma experienced by bereaved parents, could be determined as there was no available psychometric tool. Several psychometric tools which measure stigma have been developed in other areas, such as mental health, HIV and abortion (Van Brakel 2006) however, a stigma scale specific to stillbirth had not been developed. Without a validated psychometric scale, greater understanding of stillbirth stigma cannot be gained and therefore the goal of determining mechanisms via which to reduce stigma and associated adverse outcomes for bereaved families cannot be explored (Van Brakel 2006). These existing scales are not appropriate for measuring stillbirth stigma, as they do not capture the specific experience of the loss endured by bereaved parents after stillbirth.

Recently, Pollock et al (2019b) developed a psychometric scale which aimed to measure stigma amongst bereaved parents who have endured stillbirth. The scale was developed using literature which explored the consequences of stillbirth stigma in combination with the lived experience of two of the researchers and consultation with an end-user organisation (Still Aware). An exploratory factor analysis (EFA) found four factors – Perceived Devaluation, Discrimination, Self-stigma and Disclosure. Cronbach's alpha, which describes how the individual items in the sub-scales and total sub-scales are closely related to each other and therefore measuring the same concept (Tavakol & Dennick 2011), indicated that the scale had appropriate internal consistency, (overall scale α=.77, minimum subscale α=.73). Test-retest reliability as measured by Pearson correlation was similarly high, with r=.90 for the overall scale (Pollock et al 2019b). However, the initial scale development and validation needed further psychometric testing in order to assess the goodness of fit, reliability and validity of the model.

Therefore, in response to the Lancet call to action to reduce stillbirth stigma, the current study aims to further develop the Stillbirth Stigma Scale through confirmatory factor analysis, further reliability analysis and the relationship of stigma and self-esteem to determine convergent validity.

Participants

Bereaved parents in Australia, New Zealand, the USA and the UK were offered an opportunity to participate in a study. These countries were targeted as they have a similar stillbirth definition (20-24 weeks) and the USA and Australia are countries that have been identified as stagnant in their stillbirth rate (Flenady et al 2016), and the UK and New Zealand have made a large amount of changes in reducing their stillbirth rate (Perinatal and Maternal Mortality Review Committee (PMMRC) 2018, Knight 2019). Inclusion criteria included those who self-identified as a bereaved parent and had experienced a stillbirth (20 weeks gestation and/or baby was 400g), were over the age of 18, able to read and write in English and resided in one of the above countries. There was no limit placed on the year the stillbirth occurred. Participants were excluded if they indicated their pregnancy loss was a medical termination.

Method

A previously used internet-based survey (Pollock et al 2019b) was utilised. The survey took participants about 45 minutes to complete and was available from May to September 2018. The principal author contacted several organisations in the identified target countries (Australia, UK, USA and New Zealand), which focused on stillbirth advocacy (Still Aware, Star Legacy Foundation) and

bereavement support (memorabilia, professional counselling, peer support) (Red Nose, SIDS and Kids SA, Heartfelt). Organisations were asked to advertise the survey on their social media pages. Each organisation was informed that their support of the survey was voluntary, and they were able to remove this permission at any time. Some organisations asked to see the survey before promoting it to their members, and the survey was provided by the research team. Through snowball recruitment, individuals and organisations were able to share posts to spread awareness about the research study. Potential participants were offered the opportunity to read through an information page before starting the survey, which detailed a general overview of the study, how their data were to be stored, and that participation was voluntary. To avoid potential bias, no mention of stigma was present on the advertisement or the information sheet. Furthermore, participants were informed that no identifying information would be collected.

Support services in each identified country which specifically care for bereaved parents after stillbirth were listed at the start and end of the survey. Consent was assumed once participants clicked 'I accept.' Participants were then asked to complete a series of psychometric scales including the Perceived Social Support Scale (Osman et al 2014), the Perinatal Grief Scale (Potvin et al 1989), the Rosenberg Self-esteem Scale (RSES) (Rosenberg 1965), and the new Stillbirth Stigma Scale (Pollock et al 2019b). The RSES is only reported within this article to determine the convergent validation of the Stillbirth Stigma Scale. The author sought the necessary permissions to include the scales in the survey.

Measurements

Socio-demographic

Socio-demographic information incorporated in the survey, including questions on sexual orientation, mental health status and if they lived with a disability, were asked of participants as these are well-established stigmatising conditions. Participants were also asked to identify their age, gender, ethnicity and stillbirth history.

Rosenberg Self-esteem Scale

It is widely recognised that stigma impacts on an individual's feelings of self-worth and esteem and this scale was included to establish an anticipated relationship between higher stigma and lower self-esteem. The RSES measures a person's perception of their worthiness and, subsequently, global self-esteem (Rosenberg 1965). The RSES has strong internal consistency (.77) and reliability (r=.90) (Rosenberg 1965).

Stillbirth Stigma Scale

Twenty items of the Stillbirth Stigma Scale were developed from a literature search on the stillbirth experience endured by bereaved parents in combination with the lived experience of researchers on the team, and the adaption of existing stigma scales (the Mental Health Stigma Scale (King et al 2007)); the Perceived Devaluation/discrimination Scale (Donaldson et al 2015) and, the Internalized Stigma Scale (Phillips et al 2011).

Items include statements such as: '*Most people will accept your child as one of your own*' and '*I have been discriminated against by my friends because of my stillbirth*.' Initial psychometric testing (exploratory factor analysis and reliability analysis) of the Stillbirth Stigma Scale was undertaken and reported in Pollock et al (2019b).

Analysis

Descriptive statistics were calculated using IBM SPSS software (version 23.0.0; SPSS Inc., Chicago, IL). The pattern and distribution of results to assess variation in item response, missing variables were removed, normality and distribution were all assessed.

Prior to a confirmatory factor analysis (CFA) all but one item (item 4) was reverse coded to reflect higher scores equalling higher levels of stigma. A CFA was undertaken to confirm the dimensionality of the Stillbirth Stigma Scale and was conducted in Stata 15.1. Modification indices were evaluated to assess if any changes would provide a better model fit. Items 10 and 11, and 15 and 16 were co-varied to improve goodness-of-fit. The determination of the model fit was based on the suggested cut-offs cited by Cangur & Ercan (2015) for the goodness-of-fit indices including the comparative fit index (CFI), the root mean square error of approximation (RMSEA) and the standardised root mean square residual (SRMR) index. These analyses were utilised as they are the least affected by sample sizes (Hu & Bentler 1999, Cangur & Ercan 2015).

Cronbach's alpha was then determined on the final scale and subscales to confirm internal consistency. Pearson's correlation was used to assess convergent validity between the total stigma scale and sub-scales and the Rosenberg Self-esteem Scale.

Findings

Initially, 1318 participants responded to the survey, however, 108 did not meet the inclusion criteria. A further 195 participants did not sufficiently complete the Stillbirth Stigma Scale and, therefore, 1015 participants (female: 97.1%, n=986; male: 2.4%, n=24; not disclosed: .49%, n=5) were included within this study. Participants were mainly Caucasian (89.4%; n=907), between the ages of 26-35, mostly married (79.5%, n=807) and resided in Australia (43.3%, n=439). Full demographic details are noted in Table 1.

Table 1. Demographics of bereaved parents.		
	n	%
Gender		
Female	986	97.1
Male	24	2.4
Not disclosed	5	0.49
Age		
18-25	72	7.1
26-35	496	48.7
36-45	345	33.9
46-55	66	6.5
56-65	17	1.7
65+	8	0.8
Missing	11	1.1
Residing country		
Australia	439	43.3
United States of America	360	35.5
United Kingdom of Great Britain and Northern Ireland	99	9.8
New Zealand	61	6.0
Canada	32	3.2
Ireland	9	0.9
Other	12	0.6
Missing	3	0.3
Relationship status		
Married	807	79.5
Defacto/Common Law Marriage	116	11.5
Single	72	7.1
Widow	1	0.1
Prefer not to answer	19	1.9
Ethnicity		
Caucasian	907	89.4
South Asian	17	1.7
Latin American	19	1.9
Mixed Ethnicity	15	1.5
Aboriginal Australian/Torres Strait Islander	9	0.9
Maori	7	0.7
East Asian	6	0.6
Caribbean	3	0.3
African	4	0.4
African American	3	0.3
Native American	1	0.1
Other	7	0.7
Missing	17	1.7

Table 2. Stillbirth history of participants.		
	n	%
Number of stillbirths		
1	963	94.9
2	45	4.4
3	5	0.5
4	2	0.2
Year of last stillbirth		
2016-2018	466	45.9
2010-2015	339	33.4
2000-2009	136	13.4
<2008	73	7.2
Missing	1	0.1

Participants' stillbirth history is shown in Table 2. The majority had their last stillbirth within three years (n=466; 45.9%) of this study (conducted 2018), however the range was 2018 to 1970. Most participants had experienced one stillbirth (94.9%; n=963), however, 52 participants (5.1%) had endured multiple stillbirths. There were 464 participants (45.7%) who stated they had a living child prior to their stillbirth, and a further 13.6% (n=138) stating they were currently pregnant at the time of completing this survey.

Confirmatory factor analysis

A CFA analysis was conducted to assess the measurement properties of the Stillbirth Stigma Scale, a summary of the CFA results can be seen in Table 3. Initial analysis indicated that the model was close to a satisfactory fit (RMSEA=.058; CFI=.93; SRMR=.045), however, the p-close of the RMSEA was problematic as it was less than .05 (p-close=.001). The chi-square was statistically significant which was not surprising as this is a common problem with large sample sizes (Gatignon 2009).

Examination of the modification indices indicated that two pairs of items could be correlated to improve the model. Items 10 and 11 were both on the discrimination subscale, with item 10 describing whether a bereaved parent had been insulted due to their stillbirth and item 11 asking if they had been emotionally abused. Both were considered conceptually similar, however different, so therefore correlating items 10 and 11 seemed sensible. Further analysis of the modification indices also suggested that items 15 and 16, which are both on the Self-stigma Scale, should be correlated. Item 15 examines if bereaved parents blame themselves, and item 16 refers to if they feel blemished due to their stillbirth. Again, both considered conceptually similar, however different and therefore correlating these two items was also deemed sensible.

Based on the corrections made to the model, a satisfactory fit was obtained. The chi-square remained statistically significant (p <0.001, as expected with the large sample size), but the measures of goodness of fit were improved with RMSEA=.051 (p-close=.36), CFI =.95, and SRMR =.043 all meeting the required values as suggested by Cangur & Ercan (2015).

In order to score each sub-scale (factor) and the total score, a summative score was created by adding the score for each item (the range of each sub-scale and total scale score can be seen in Table 4). The potential overall scale scores range from 20 to 100, where 20 represents a bereaved parent who reports experiencing no stigma and 100 a bereaved parent with very high levels of stigma. Please refer to *Supplementary Information 1* for further scoring information.

Table 3. Confirmatory factor analysis.

Item		Stand coef	95% CI	Sig
	Factor 1: Perceived Devaluation			
1	Most people will not say your child's name	1		
2	Most people will not look you in the eye when you speak about your stillbirth	0.944	.884-1.003	0.001
3	Most people will avoid discussing your stillbirth or stillborn child	0.702	.650-754	0.001
4	Most people will accept your child as one of your own	0.547	.487-.607	0.001
5	Most people will not look at momentos of your child if offered	0.771	.711-831	0.001
6	Most believed that you are not a mother/father if you have had a stillbirth	0.689	.620-.758	0.001
	Factor 2: Discrimination			
7	I have been discriminated against by my friends because of my stillbirth	1		
8	Sometimes I feel that I have been talked down to because of my stillbirth	0.914	.843-.986	0.001
9	I have been discriminated against by my extended family because of my stillbirth	0.991	.917-1.066	0.001
10	People have insulted me because of my stillbirth	0.852	.771-.932	0.001
11	I have been emotionally abused because of my stillbirth	0.731	.661-.802	0.001
12	Nobody has been interested in talking to me since having had a stillbirth	0.721	.650-.793	0.001
13	I have been discriminated against by health professionals because of my stillbirth	0.718	.646-.791	0.001
	Factor 3: Self-Stigma			
14	Having had a stillbirth makes me feel that life is unfair	1		
15	I blamed myself after my stillbirth	1.249	1.069-1.430	0.001
16	I am disappointed in myself since having a stillbirth	1.739	1.523-1.955	0.001
17	I feel blemished	1.979	1.744-2.214	0.001
	Factor 4: Disclosure			
18	I feel the need to hide my stillbirth	1		
19	I find it hard telling people I have had a stillbirth	0.995	.885-1.105	0.001
20	I worry about others telling people I do not know I have had a stillbirth	0.691	.598-.784	0.001

Table 4. Descriptives of sub-scales and overall Stillbirth Stigma Scale.

Scale	N	Range	Mean	SD	Cronbach α
Perceived Devaluation	1015	6-30	20.39	5.14	0.86
Discrimination	1015	7-35	17.69	6.47	0.87
Self-stigma	1015	4-20	15.53	3.56	0.79
Disclosure	1015	3-15	8.40	2.95	0.72
Total Stigma Scale	1015	20-100	62.01	13.66	0.89

Table 5. Correlations between full-scale score, sub-scores and global self-esteem scores.

	Stillbirth Stigma Scale	Perceived Devaluation	Discrimination	Self-Stigma	Disclosure
Perceived Devaluation	.825[1]				
Discrimination	.840[1]	0.554[1]			
Self-stigma	0.656[1]	0.378	0.378[1]		
Disclosure	0.569[1]	0.377[1]	0.258[1]	0.342[1]	
Global Self-esteem score	-0.306[1]	-0.161[1]	-0.240[1]	-0.331[1]	-0.194[1]

Internal consistency of the Stillbirth Stigma Scale and sub-scale

Cronbach's α for the sub-scales and total scale can be seen in Table 4. As shown in Table 4, the Cronbach alpha for each of the sub-scales Perceived Devaluation, Discrimination, Self-stigma and Disclosure were all acceptable at .86, .87, .79 and .72 respectively. The total Cronbach alpha score for the scale was strong at .89.

Sub-scale scores

As seen in Table 4, mean scores of the sub-scales were, Perceived Devaluation 20.39 (SD=5.14), Discrimination 17.69 (SD=6.47), Self-stigma 15.53

(SD=3.56) and Disclosure 8.40 (SD=2.95). The total stigma scale was 62.01 (SD=13.66). As seen in Table 5, the subscales had higher correlations to the total Stillbirth Stigma Scale, rather than each other, indicating they are distinct but related aspects of stigma.

Convergent validation

Scores on the Rosenberg Self-esteem Scale (low scores indicate low levels of self-esteem) were statistically significant and negatively correlated to the Stillbirth Stigma Scale and the sub-scale scores, as noted in Table 5. Higher stillbirth stigma scores are associated with lower self-esteem.

Discussion

The Stillbirth Stigma Scale was created to answer the call set by the 2011 and 2016 Lancet Series to identify mechanisms to reduce stillbirth stigma (Goldenberg et al 2011, Scott 2011, Horton & Samarasekera 2016). The current study further extends the work of Pollock et al (2019b) and indicates that the Stillbirth Stigma Scale is psychometrically robust. The confirmatory factor analysis confirmed the four factors: Perceived Devaluation, Discrimination, Self-stigma and Disclosure. Reliability analysis shows good internal consistency of each sub-scale and the overall scale. Furthermore, convergent validity between self-esteem and total stigma, and sub-scales also show the expected direction, with higher stigma associated with lower self-esteem, as seen in King et al (2007) on the development of the stigma scale specialising in mental health. The multidimensional nature of the four sub-scales – Perceived Devaluation, Discrimination, Self-stigma and Disclosure – is also a strength of this scale. Stigma remains a complex phenomenon and capturing the stigma experience cannot be achieved using a global unidimensional scale (Pescosolido & Martin 2015). Furthermore, the four sub-scales found within this scale reflect the stigma experiences often reported within the literature. For example, bereaved parents often report being blamed about the death of their baby and therefore feel they are unable to show memorabilia (Perceived Devaluation) (Brierley-Jones et al 2015); they feel shame (Haws et al 2010, Kelley & Trinidad 2012, Brierley-Jones et al 2015, Pollock et al 2019a), are commonly treated differently in their workplace (Discrimination) (Hazen 2003, self-cite 2019), and feel they are unable to talk about their experience (Disclosure) (Brierley-Jones et al 2015). Furthermore, the four sub-scales reflect well-established stigma theory; for example, discrimination is a crucial feature of Link & Phelan's (2001) and Sheehan et al's (2016) conceptualisation of mental health stigma. The sub-scales found within this scale, also align with existing scales which measure stigma in health-related fields. Van Brakel's (2006) literature review of 63 articles on stigma measurement tools, found that discrimination, perceived and self-stigma

were three of the five categories often found within the stigma scales, and therefore key components of the stigma experience. Van Brakel (2006) also found items describing a person's ability to disclose their stigmatising identity in seven existing stigma scales.

Therefore, the Stillbirth Stigma Scale is psychometrically and theoretically robust and is relevant to the stigma experiences endured by bereaved mothers. The Stillbirth Stigma Scale may be applied in various settings. However, its initial application should be analysing the predictors of high levels of stigma, and the consequences of such levels on the bereaved parent in a research setting. Ideally, future research would identify how this scale could potentially be utilised in clinical settings, however, in its current format it is not appropriate. Furthermore, future research on the clinical applications of this scale should consider if developing such a screening tool should be delayed until there are appropriate interventions to assist those identified as at higher risk of stigma. The Stillbirth Stigma Scale can be used by researchers to assess the effectiveness of stigma-reducing interventions and therefore, answer the call set out by the 2011 and 2016 Lancet series to identify mechanisms to reduce stillbirth stigma.

Strengths and limitations

A key criticism of stigma research is that it often does not include the voice of those enduring the stigmatising condition. This scale was developed by lived-experience researchers (DP and JW), and in consultation with Still Aware (stillbirth advocacy and prevention organisation). International data collection further strengthens the relevance of this scale.

A strength of this study is the relatively large sample size across multiple countries. However, despite the international recruitment, this study still lacks representation. The sample within the current study was predominately Caucasian, with a high percentage of highly educated bereaved mothers and, therefore, further research on the validity and reliability of the scale in low-income settings and minority groups is needed. There was no time limitation of stillbirth placed on this study and, therefore, there were many participants within this study who experienced their stillbirth 10 years prior to undertaking the study. This could have potentially led to recall bias (Althubaiti 2016). Furthermore, despite concerted efforts to recruit bereaved fathers, only 20 fathers completed the survey, and further research is required to determine if this scale can accurately measure the father's stigma experience after stillbirth.

Conclusion

Stillbirth stigma has been identified as a barrier to providing quality care for bereaved parents. The Stillbirth Stigma Scale answers the call set out by the 2011 and 2016 Lancet series to identify mechanisms

to reduce stillbirth stigma. This is the first scale which is specifically tailored for bereaved parents after stillbirth. The 20-item Stillbirth Stigma Scale is both psychometrically and theoretically robust and has been developed by those directly impacted by stillbirth. This 20-item scale should prove useful for researchers, policy makers and health care professionals attempting to identify bereaved parents most at-risk due to experiencing high levels of stigma and assess the effectiveness of stigma-reducing interventions which will ultimately help address the stigma endured by bereaved parents after stillbirth.

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Disclosure

Further details:

In addition to this current manuscript for other details on the factor structure, validity and reliability, please refer to the following article:

Pollock D, Esterman E, Pearson E, Cooper M, Ziaian T, Warland J (2019). Measuring the silence: development and initial psychometric testing of the Stillbirth Stigma Scale, *Evidence Based Midwifery* 17(3):77-83.

Contact details

We are happy for all researchers to use this scale, however, we ask that you cite the above papers and email Danielle Pollock: pomdk001@mymail.unisa. edu.au or Associate Professor Jane Warland: Jane. Warland@unisa.edu.au as they are interested in how the scale will be used. Also, please do not hesitate to email Danielle or Jane if you have any questions regarding the scale or would like to collaborate on any research.

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Supplementary Information 1: Scoring instructions for the Stillbirth Stigma Scale

The Stillbirth Stigma Scale (SSS) is a measure of the extent and type of stillbirth stigma experienced by bereaved parents after stillbirth.

Scoring

The bereaved parent completes all 20 items to the extent they agree with the item. The scoring is based on a five-point Likert scale: Strongly Agree (1), Agree (2), Neither Agree nor Disagree (3), Disagree (4), Strongly Disagree (5). There are four sub-scales relating to stillbirth stigma: Perceived Devaluation, Discrimination, Self-stigma and Disclosure. You can assess each sub-scale individually, or you can create a TOTAL stillbirth stigma score.

To calculate sub-scale scores

*Please note that all items besides item 4 will need to be reverse coded PRIOR to calculations.

Perceived Devaluation: Add up 1 to 6 (don't forget item 4 does not need to be reverse coded)

Discrimination: Add up 7 to 13

Self-stigma: Add up to 14 to 17

Disclosure: Add up 18 to 20

Total Stillbirth Stigma Scale: Add all items together.

Stillbirth Stigma Scale					
Please choose one response per statement that most relates to how you feel:					
	Strongly Agree (1)	Agree (2)	Neither Agree nor Disagree (3)	Disagree (4)	Strongly Disagree (5)
1	Most people will not say your child's name				
2	Most people will not look you in the eye when you speak about your stillbirth				
3	Most people will avoid discussing your stillbirth or stillborn child				
4	Most people will accept your child as one of your own.				
5	Most people will not look at momentos of your child if offered				
6	Most believe that you are not a mother/father if you have had a stillbirth				
7	I have been discriminated against by my friends because of my stillbirth				
8	Sometimes I feel that I have been talked down to because of my stillbirth				
9	I have been discriminated against by my extended family because of my stillbirth				
10	People have insulted me because of my stillbirth				
11	I have been emotionally abused because of my stillbirth				
12	Nobody has been interested in talking to me since having had a stillbirth				
13	I have been discriminated against by health professionals because of my stillbirth				
14	Having had a stillbirth makes me feel that life is unfair				
15	I blamed myself after my stillbirth				
16	I am disappointed in myself since having a stillbirth				
17	I feel blemished				
18	I feel the need to hide my stillbirth				
19	I find it hard telling people I have had a stillbirth				
20	I worry about others telling people I do not know I have had a stillbirth				

Factors that influence online medication purchasing behaviour in pregnancy: a qualitative study

Alison Little, Marlene Sinclair, Huiru Zheng, Patricia Gillen

ORIGINAL

Aim: To explore the factors that influence a pregnant woman's intention to purchase medication online.

Methods: Three online focus groups were conducted using asynchronous communication in a closed Facebook group during May 2018, to gauge a deeper understanding of this emerging phenomenon.

Results: A total of 23 women from six countries participated in the study. Strong predictive factors that influenced purchasing behaviour included the importance of rapid retrieval of information, cost-effectiveness, special offers, price comparison, time-efficiency and availability of more product options. Women had a lack of knowledge about medication safety and were likely to be influenced by product reviews and star ratings. Online purchasing enabled women to avoid consultations with health care providers and helped them feel more in control of their identity. Social norms impacted on women's decision making and women referred to the normalisation of online purchasing as being influential. Pregnancy groups/forums and social media were seen as influential sources of advice and previous experience of online purchasing was an important predictor of future behaviour.

Conclusion: Pregnant women who were internet-confident were more likely to have established online purchasing behaviour and therefore more inclined to purchase online medications. The internet offered women greater autonomy and rapid access to products.

Implications: Midwives need to be aware of this growing trend and ensure their knowledge about purchasing online medication safely is evidence-informed and that they facilitate pregnant women to make safe choices.

Keywords: pregnancy, medication, online purchasing, Facebook, theory of planned behaviour, social media

Introduction

Most pregnant women take at least one medication during their pregnancy despite limited evidence on the safe use of many medications (Mitchell 2011, Hartman et al 2016). The inclusion of pregnant women in randomised controlled trials (RCTs) raises ethical concerns, thereby creating a dependence on post-marketing epidemiologic studies to provide insight into the benefits and risks of medication use during pregnancy (van Gelder et al 2019a). The lack of evidence regarding the safety of medication use during pregnancy creates challenges for women and health care professionals when discussing or purchasing medication (Sinclair et al 2016).

Medication use in pregnancy can encompass a broad range of treatments from prescription-based pharmaceutical products to herbal, homeopathic and vitamin supplements. The term "Medicinal Product" is defined in Article 1 of Directive 2001/83/EC of the European Parliament and of the Council (2001):

'*Any substance or combination of substances presented as having properties for treating or preventing disease in human beings…*

Any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting pharmacological, immunological or metabolic action, or to making a medical diagnosis.'

As such, most herbal and homeopathic remedies fall under the remit of this definition of a medicinal product (Medicine and Healthcare products Regulatory Agency (MHRA) 2016a), and for the purpose of this study will be included within the context of discussion on medication.

Research studies highlight pregnant women's use of the internet to search for health-related information (Gao et al 2013, Song et al 2013, Weston & Anderson 2014, Lupton 2016, Wallwiener et al 2016)

particularly regarding what medications are safe to take in pregnancy (Hämeen-Anttila et al 2014, Sinclair et al 2018).

The evident ongoing virtual market of online pharmacy provision has been facilitated with the rapid expansion of the internet (Fittler et al 2013). An increase in digital eHealth, a movement towards self-diagnosis and self-medication has increased the general consumer experience of retail purchasing online, with easy accessibility of mail order trade and provision of access to products from different countries (Gabay 2015, Mackey & Nayyar 2016, Fittler et al 2018). The global online pharmacy (e-pharmacy) market in 2014 was estimated to be worth 29 billion US dollars and it is predicted to grow to around 128 billion dollars by 2023 (Statista 2015). This predicted extrapolated growth of the industry highlights worldwide demand for online medication sales.

Background

Much of the literature to date has focused on general online shopping behaviour (Kennedy & Wilson 2017, Katta & Patro 2018, Sharma et al 2019), with limited studies exploring purchasing online or purchasing behaviour in pregnancy (Little et al 2018). With the anticipated growth of the online medication industry, research is required to address the gap in the knowledge and explore the factors that influence a pregnant woman's online medication purchasing behaviour.

Consumer behaviour involves complex, multi-dynamic processes. When selecting the theoretical framework for the study, pregnant women who purchase medication online were viewed as purchasers, therefore it was appropriate to select a theoretical framework that focused on the pregnant woman as a consumer. Ajzen (1991) postulates that intentions to perform behaviours can be predicted with a high level of accuracy from attitudes towards a behaviour, subjective norms and perceived behavioural control; and these intentions, together with the perception of behavioural control, account for considerable variance in actual behaviour (Figure 1). As such, the Theory of Planned Behaviour (TPB) (Ajzen 1985) was selected to underpin this study and aid understanding of the modifiable factors that influence a pregnant women's intention to purchase medication.

Understanding online medication purchasing behaviour in pregnancy is important to enhance communications between health care professionals and pregnant women. It will also provide information for regulation, policy and guidelines on medication safety and inform the creation of technology applications to promote eHealth for pregnant women in the future. This paper reports the influencing factors that affect a pregnant woman's online purchase intention.

Aim

To explore the factors that influence a pregnant woman's intention to purchase medication online.

Design

With the advancement and popularity of internet technology the options for participant recruitment and data collection in health care have expanded dramatically (Tuttas 2015). Facebook is a global social media platform with over 2.38 billion monthly active members (Statista 2019) with over 80 million people using the group feature each month (Guynn 2016). The popularity of social media platforms such as Facebook have recently led researchers to investigate ways of recruiting and carrying out qualitative research in closed groups to enhance their empirical research (Medley-Rath 2019).

Online focus groups are valid for research purposes as interacting with participants on the internet avoids a significant amount of travel, expense and provides a more internationally representative sample (Moore et al 2015). Online focus groups have been identified as having equal potential as in-person focus groups for gathering high-quality information from hard-to-reach populations on sensitive topics (Wilkerson et al 2014).

In this study, online focus groups using asynchronous communication on the social media platform Facebook were selected. This allowed an in-depth examination of the experiences and perceptions of pregnant woman when purchasing medication online and provided a greater understanding of the theoretical constructs of purchase intention in the TPB (Ajzen 1985).
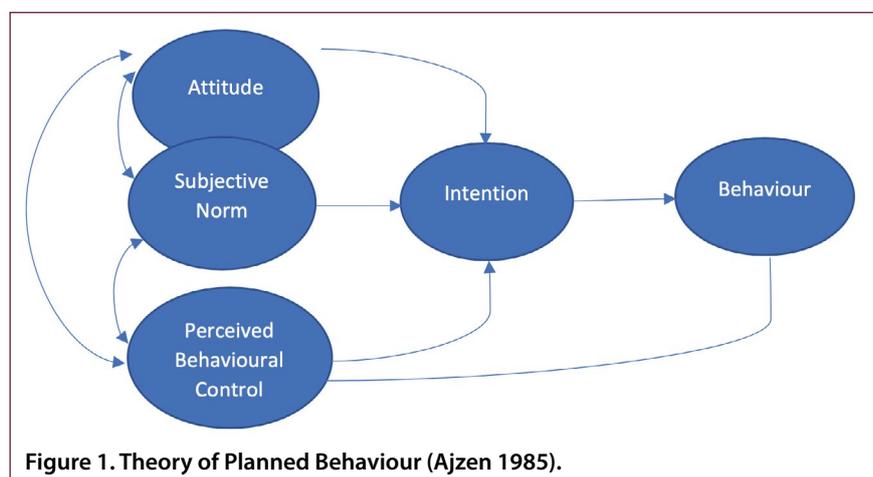

Figure 1. Theory of Planned Behaviour (Ajzen 1985).

Sample/participants

Women who had previously completed an online survey regarding online medication purchasing behaviour and were willing to engage in a closed Facebook focus group were invited to take part. A list was formulated of the women who had or had not purchased medication online during pregnancy so the focus group samples could be composed of different grouped women who had similar profiles regarding medication purchasing.

A purposeful sample of each grouping was then selected and an email of invitation with a Participant Information Sheet (PIS) attached was sent to each potential participant. If the woman wanted to contact the researcher directly for more information the researcher could be contacted by email or mobile telephone from a secure mobile purchased for the sole use of the research study.

All women were pregnant or had been pregnant in the past two years, were aged over 18 years and able to understand English. Women were added to the group by the researcher who controlled the group administration. The researcher invited each woman to join the focus group by clicking on the 'Invite by email' option in the top right-hand corner of the Facebook group page. This activated an email to each woman providing an invitation and link to join the closed Facebook group. If the woman had a Facebook account, they could automatically join the group at this point. If someone wished to participate who did not have a Facebook account, guidance on how to set up a personal account to join the group would be provided at this stage.

Data collection

Women were recruited into three focus groups: women who had purchased medication online during pregnancy (n=9) those who had not (n=8) and a mixed group of those who had/had not purchased medication online during pregnancy (n=6).

Online focus groups can be conducted synchronously or asynchronously (Williams et al 2012). For the purpose of this study an asynchronous communication method was adopted to allow participants time and freedom to respond at their own rate and pace allowing time for reflection prior to submitting a response (Reisner et al 2018). This was particularly important as the population involved were either pregnant or had young children and asynchronous communication would allow women to give responses at a time that was convenient to them (Medley-Rath 2019). This is particularly effective when participants are across different time zones and facilitates group participation from an internationally selective group. Questions were based on the TPB and followed a semi-structured format. The Facebook group was monitored three times a day by the researcher. The researcher allowed a period of one week following completion of questions asked in the focus group to allow time for any further comments. Following this period, the Facebook group was closed and all data transferred for analysis.

Ethical considerations

Ethical approval was sought and granted by the Ulster University Ethics Filter Committee. With current concerns regarding the protection of online identities, researchers must ensure online safety to protect anonymity, provide confidentiality and make women feel confident to participate and share their knowledge and experiences in the research process (Woodfield 2018). The group was a closed Facebook group account so that only members in the group could find and see posts, it was not accessible to the general public, therefore protecting the confidentiality of the members of group. The researcher also held the group administration role thereby controlling who could access the group. Participation in the online discussion was taken as an indication of voluntary consent. If any participant wished to withdraw from the focus group at any time they could do so.

Data analysis

Online focus group data were collected during May 2018, then transcribed and thematically analysed using Braun & Clarke's (2006) framework for analysing qualitative data (Table 1).

Table 1. Phases of thematic analysis (Braun & Clarke 2006).	
Phase	**Description of the process**
1	Familiarizing yourself with your data
2	Generating initial codes
3	Searching for themes
4	Reviewing themes
5	Defining and naming themes
6	Producing the report

Thematic analysis is a method of identifying themes and patterns of meaning across a dataset in relation to the research question (Braun & Clarke 2006). All group discussion was transcribed and checked for accuracy and formation of coding structure. The structure was then refined and categorised into codes and themes, verified with the research team and mapped to the TPB (Ajzen 1985).

In Phase 1, as the focus groups were carried out online using a closed Facebook group, the data were essentially already transcribed. The data were then transferred to a Word document and checked for accuracy with preliminary potential codes and ideas being noted.

In Phase 2 initial codes were generated from the data after reading the transcripts several times to enable the researcher to become familiar with the content. Phase 3 involved the interpretative analysis of collating all the codes into potential themes and

gathering all the data that were relevant to each potential theme (Braun & Clarke 2006). To facilitate theme development, codes were colour-coded beside the data on an Excel spreadsheet that allowed easy moving and pasting of themes during the process. An inductive approach to the data analysis was used where the themes came out of the data which were analysed without trying to fit them into a coding frame (Braun & Clarke 2006). This ensured pregnant women's experiences of purchasing medication online were well portrayed. To address the theoretical aspects of the study it was also necessary to explore the constructs of the TPB that influenced purchase intention, as such, a deductive or theoretical thematic analysis was carried out on the data and incorporated into the coding.

In Phase 4, all the themes were reviewed and a thematic map of the provisional themes and sub-themes was created to demonstrate the relationships between them. As the focus group questions were theory-driven, themes and sub-themes identified from the coding were mapped to the constructs of the TPB.

In Phase 5, the themes were reviewed and refined with clear names being given to each theme to reflect the overall story and ensure there was an appropriate fit to the theoretical constructs of the TPB. The researcher took care to identify themes that were reflective of what was portrayed in the data.

The final phase, Phase 6, involved writing up the findings to tell the story of the factors that influenced pregnant women purchasing medication online. Verbatim quotes from the data were included in the final write-up to support the development of the themes and sub-themes and highlight a clear audit trail.

Rigour and trustworthiness of the qualitative data

It was important that the study demonstrated methodological rigour so that an authentic and trustworthy reflection of pregnant women's experiences of purchasing medication online was achieved. To demonstrate trustworthiness in this study the four criteria of credibility, transferability, dependability and confirmability were incorporated (Lincoln & Guba 1985). The focus group transcripts were analysed and independently verified by an external assessor and the research team.

Credibility

Credibility is the truthful and accurate representation of a participant's lived experience and the measurement of internal consistency (Cypress 2017). Credibility was achieved by the researcher facilitating all the focus groups during data collection and this enhanced consistency by ensuring all questions were repeated and consistently stated (Singleton & Furber 2014).

Triangulation was achieved in this study by the research team members peer-validating the data coding, theme formation and interpretations to confirm consistency with the findings, helping to prevent bias in the analysis (Ritchie et al 2013). Verbatim quotes were used in the final report to provide 'thick descriptions' of factors that influenced women's online medication purchasing behaviour and to authenticate the study findings. An independent expert in qualitative analysis was used to independently analyse the data to confirm the findings.

Transferability

Transferability denotes the extent to which the findings from the study can be transferred or have applicability in other settings (Polit & Beck 2017). To enhance the transferability, women's demographic details were obtained during data collection which demonstrated the recruitment and representation of women from six different countries participating in the group. The participation of women from various countries enhances the generalisability of the study and provides descriptive data of the sample and settings so that similarities in some women from countries that were included could be observed in the discussion.

Dependability

Dependability refers to the stability of data over time under the same conditions (Lincoln & Guba 1985). In this study the researcher has provided a clear audit trail to demonstrate dependability to any external reviewers with a discussion of the analytic decision making throughout the research process detailing methodological decisions regarding recruitment, data collection, data analysis. Polit & Beck (2017) acknowledge that credibility cannot be attained in the absence of dependability. Consistent measures were taken during each focus group to use the same topic guide and questions which were well-defined, piloted and underpinned by the TPB to ensure dependability in the study. Verbatim quotes were used in the findings to demonstrate the formation of themes from the focus group data.

Confirmability

Confirmability refers to objectivity or the equivalence between independent people regarding the accuracy, relevance or meaning of the data (Polit & Beck 2017). This should be carried out to demonstrate the integrity of findings which should be devoid of any biases (Lincoln et al 2011). Throughout the study a clear audit trail was documented and reflexivity was demonstrated by the researcher carrying out a personal reflexive account to demonstrate how personal history and professional background influenced the philosophical aspects of the study.

Table 2. Demographic characteristics of the sample.			
Measures	**Predictors**	**Frequency**	**Percentage**
Age group	25-34 years	12	52.2%
	35-44 years	11	47.8%
Education	Technical college/Diploma	1	4.3%
	Undergraduate degree	12	52.2%
	Postgraduate degree	10	43.5%
Employment	Full-time	15	65.2%
	Part-time	4	17.4%
	Unemployed	1	4.3%
	Student full-time	2	8.7%
	Other	1	4.3%
Country	Australia	2	8.7%
	Canada	1	4.3%
	Ireland	2	8.7%
	Portugal	1	4.3%
	Sweden	1	4.3%
	UK and Northern Ireland	16	69.6%

Results

Participant characteristics

Women from six different countries participated in the study. Ages ranged from 25-45 years and the majority (65%) were employed full-time, with almost everyone educated to degree level (96%) (See Table 2). Less than a quarter of the women who took part (22%) paid for prescription medications during pregnancy and 30% of the sample took medications for a medical condition prior to becoming pregnant. Medical conditions described by women included asthma, bipolar disorder, diabetes, hyperlipidemia, hypertension, polycystic ovarian syndrome and stomach ulcer. Ten women had previously purchased medication or herbal supplements online during pregnancy.

The transcripts were analysed and structured under themes and sub-themes which were mapped to the TPB constructs of attitude towards a behaviour, subjective norm and perceived behavioural control (Figure 2).

Attitude

Knowledge of medication use in pregnancy

Women across all groups identified a lack of knowledge about medication safety in general. They also highlighted a lack of discussion with their health care providers regarding medication usage:

'This is my second pregnancy and I haven't had any conversations with a HCP about medications in general to be honest, let alone online purchasing'. FG1 200-202 P9

Women in the mixed focus group reported searching for information and purchasing homeopathic medications online:

'…I think there definitely is a growth in a holistic approach to many illnesses, which will lead to people researching a more natural approach to whatever and buying vitamins / supplements etc. I would be confident in ordering whatever from a chemist, such as the ones previously mentioned, online.' FG3 78-84 P3

Influence of online information on medication use in pregnancy

Women indicated a lack of basic information on safe medication consumption during pregnancy and a lack of understanding of the safety of online purchasing. They identified health/medical websites as reputable and they would use their advice to assist with decision making, self-diagnosis and self-medication:

'…I wouldn't think to prefer an independent medical source; I would just try to find sites that look official (an organization or science-y or government)' FG2 245-247 P5

A common pattern of behaviour was described when women searched for information on common ailments and found themselves getting redirected to pharmacy websites to purchase medications:

'…Google symptoms such as "restless legs" or whatever, and being led to a reputable pharmacy which sells something to resolve or alleviate the problem.' FG3 61-62 P3
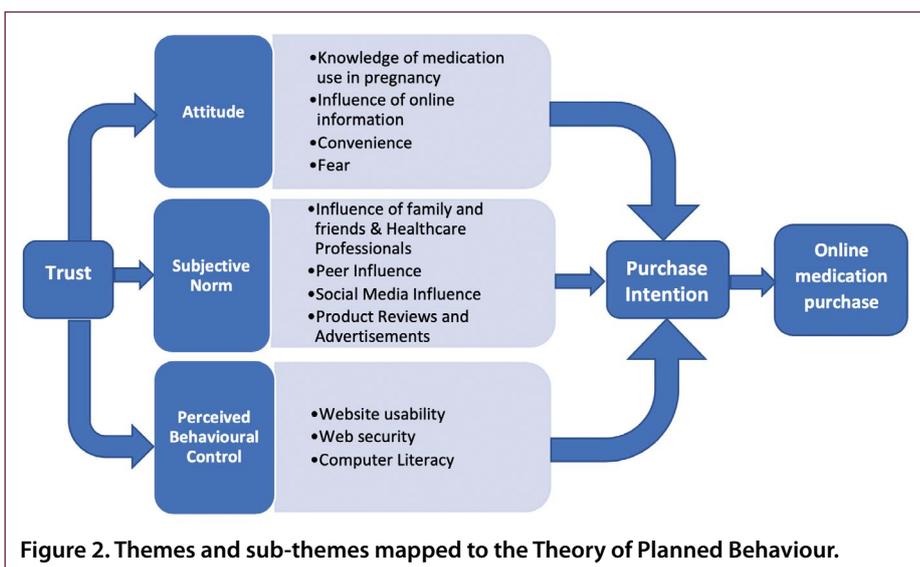

Figure 2. Themes and sub-themes mapped to the Theory of Planned Behaviour.

Convenience of purchasing medication online during pregnancy

Convenience is a key factor in purchasing behaviour:

'…Yes, convenience! Especially if you have morning sickness/other children, etc. Also, it could be perhaps a little easier to compare brands and prices while in the comfort of your own home instead of having to stand & look at your options while probably fairly tired...' FG2 66-70 P5

'I think it's cheaper and convenience that and u can just easily go online if u know what u want and have it delivered to your door the next day if u use amazon prime or something like that.' FG1 73-75 P7

Other aspects of convenience were 24-hour accessibility, optional delivery times, the ability to purchase medications as part of the weekly grocery shop and a reduction in effort required to go to a general practitioner (GP) whilst feeling unwell:

'…I can never be bothered to make a doc appointment for something like meds just easier to go online and buy! I had to take aspirin in pregnancy and used to buy with my Tesco groceries online for 30p! Also I believe we should pay for meds like that which cost the NHS £1000 but we can buy for so little else where! Also when I was on 'bedrest' for 10 wks. it was very handy to get my meds delivered to my door!' FG1 106-113 P7

Several women highlighted the lack of availability of timely GP appointments and the strain on GP services as contributing to purchasing medication online as a convenient solution:

'…Convenience, plus there is no need to make an appointment with your GP. Well it takes a couple of weeks to get an appointment in our surgery' FG1 66, 71 P6

'…If I needed prescription medications I probably would go through HCP first but if I didn't get what I needed I would be happy to buy online' FG1 287-288 P4

Women highlighted that purchasing medication online gave them the freedom to choose what they needed without judgement and confidentially, without having a face-to-face consultation with a health care provider. Anonymity and control were identified as benefits to purchasing medications, with women commenting they specifically like purchasing medication in early pregnancy without having to make the pregnancy public knowledge:

'… I think anonymity is a big thing, especially in the first 12 weeks when you might not have told anyone you're pregnant' FG1 258-259 P9

Fear of purchasing medication online during pregnancy

Women were concerned about the quality of the medication purchased online:

'…I would need to make sure it was from a source I was happy with; I would worry the quality might not be as good or it might not be what it actually says it is.' FG1 182-184 P9

Women also had concerns about whether the products were safe to take in pregnancy and whether the dosages were correct. Women who hadn't purchased medication online had reservations about purchasing without discussing with a health care professional:

'…I would be v cautious about buying meds online, especially when pregnant. When pregnant, I am generally a little more cautious anyway. I think I would rather present my bump to a pharmacist just to reinforce that I am pregnant and to make sure the meds are suitable' FG3 131-132, 137-139 P3

Women also suggested that, often, an online medical consultation service for a prescription is not free nor is it available on the NHS, despite demands on GPs being so high. Women highlighted their concerns regarding the ability of pregnant women to distinguish fake from real pharmacy websites to make a secure purchase:

'…I would know, but a lot of people wouldn't have the same understanding or the ability to distinguish between "fake" and real online pharmacies and might believe anything on them.' FG1 177-179 P5

By self-diagnosing and self-medicating women had concerns that by bypassing a health care professional's advice they may purchase medications contraindicated for pregnancy:

'…Maybe some women might make a conscious choice to purchase medication online if they don't think it is something they should be taking in pregnancy and maybe are worried to ask for it from a doctor or pharmacy…similarly if women bypass the doctor and pharmacy it may lead to them taking medications that are unsafe in pregnancy' FG1 96-100, 102-104, P5

Concerns about purchasing termination of pregnancy medication online to avoid judgement or prosecution were presented:

'…Some women may be embarrassed to purchase particular medications in person and may find that doing it online is much more discrete and private. Although dangers come with this with medications such as misoprostol being available online to buy. These women would not be receiving the support that they should from healthcare professionals.' FG3 193-197 P1

Subjective norm

Influence of family, friends and health care professionals

Women in the focus groups who had experience of purchasing medication online predominantly felt

confident to make their own purchasing decisions. Those women who had previously purchased medication online are not strongly influenced by family or friends, nor would ask their opinion. They tended to be more influenced by product reviews or star ratings:

'…Many of my family were concerned but it didn't stop me buying them…' FG1 391-392 P8

Women in the focus groups who had not purchased medication online had a perception that people including family and friends would disapprove as it is considered 'taboo' and would have concerns regarding the side-effects of the medications on the safety of the baby:

'…I think if I said to my family "oh I bought these tablets online" they would be horrified! I think there is a perception of buying medications online that makes people worried…' FG3 236-238 P3

'…Family and friends probably would advise against if the purchase would be made without doctor's approval or consent…' FG3 228-229 P4

Women viewed purchasing vitamins or homeopathic remedies online as safe and acceptable, and believed that health care professionals would find this acceptable:

'…I think HCPs approval/disapproval would be based on what drugs you were ordering…paracetamol or pregnancare that's ok in pregnancy I think their attitude would be different if you were buying something that wasn't licensed in pregnancy.' FG1 454-455, 458-460 P9

Variation in opinions from family/friends and health care professionals made the decisions difficult and this was not helped by some of the reviews:

'…I've definitely had lots of confusion!! Lots of different people say lots of different things. Some encourage some things whilst others discourage it or don't think it matters. This is what confused me, differences of opinion. eg My doctor said Panadol is fine but others (online, friends) strongly discouraged me from using it.' FG2 111-115 P5

Peer influence/effect

Some of the women in the group felt they would be judged by their peers for purchasing medication online during pregnancy as it was perceived by some as 'not something you do' social norms appear to impact on women's decision making and women referred to the normalisation of online purchasing as being influential:

'…I don't think I would ask others as part of me thinks it sounds stupid so therefore it's wrong others would then think I was being foolish and judge me. But as others have said, if it was more common practice among people I know, then I wouldn't be so wary of it.' FG2 279-283 P1

Peer pressure for normal and natural was a strong belief amongst some and taking medication or purchasing medication online would be frowned upon and this would reduce the likelihood of online purchasing:

'…There is a very strong social push in Australia to do and be "natural" - to not have any medical intervention pre, during and post birth. You are seen more favorably socially if you don't have any medical intervention I guess.' FG2 135-138 P5

Others thought differently:

'…Don't think I considered other's approval or not when buying online I guess it's more influenced by general purchasing behaviour.' FG1 483-484 P3

Social media influence

Pregnancy groups/forums and social media were seen as influential sources of advice for women and can affect a pregnant woman's decision to purchase:

'…Think Facebook and Twitter etc. would play a massive part if things are advertised there we tend to take note even if subconsciously!' FG1 497-498 P7

Other mothers and friends on social media were thought to be influential and increased their intention to purchase medications online during pregnancy:

'…I purchased some non-prescription medicine as recommended on a Facebook group on trying to conceive when breastfeeding. I started taking Floradix on the recommendation of a colleague and regularly purchase this online.' FG1 431-436 P3

Some voiced concerns in the focus groups as to the reliability of the advice provided on social media and pregnancy forums:

'…Most pregnant and new moms are in social media groups were they have access to multiple opinions and suggestions regarding symptoms of pregnancy and newborns… in a situation of discomfort they may be induced to buy online without doctor / pharmacist opinion…' FG3 254-257 P4

Product reviews and advertisements

Product reviews and advertisements had a strong impact:

'…The online star rating is one feature I would check before buying! And reviews to check that others have been satisfied with the product when it have arrived with them' FG1 515-517 P7

'…wouldn't look twice unless there were quite a number of reviews and obviously the majority positive. I would be swayed by any negative reviews to avoid purchasing.' FG3 291-293 P1

Online products with a celebrity endorsement positively influence a woman's intention to purchase medication online, as would visual imagery of a

healthy mum and healthy baby:

'…*Yes I agree, recommendations and advertising plays a big role. Pregnancy is a time when I feel women will do anything to ensure the health of her baby, so if adverts or other mothers say a product is the best then the woman will want to purchase it*' FG1 504-507 P5

Perceived behavioural control

Website usability

Women wanted to be able to find the product they were looking for with ease and the convenience of being able to make purchases in three clicks:

'…*I can buy in three clicks. If there is difficult signing in, remembering passwords, looking for payment cards etc. I can be put off*' FG3 305-308 P1

Women also favoured websites that facilitated prompt delivery timeframes, low shipping costs, free delivery, ensuring medication stability during transit with signed for delivery, displayed content and possible drug interactions to ensure it was safe to take in pregnancy before deciding to purchase.

Web security

Website financial security was also a major factor in a woman's decision to purchase online, with PayPal being the most commonly discussed in groups and trusted for safety:

'…*if PayPal is an option I tend to trust the website. I know there is a backup if something goes wrong and also its PayPal which has my information and not the actual website.*' FG1 531-534 P5

Women wanted not only financial security but also security around their personal data, with some women not wishing their details to go to third parties in order to minimise spam emails from other suppliers. Women also acknowledged difficulty in distinguishing between real and fake pharmacy sites prior to sharing and providing personal details:

'…*I would know they were legit and there are so many websites claiming to be pharmacies but I think it would be hard to distinguish them.*' FG1 545-546 P5

Computer literacy

Throughout all the focus groups, access to the internet was not discussed by any of the women as a factor that would influence purchasing, which is in keeping with the underlying assumption that almost everyone has internet availability. Pregnant women are of a younger population who are more internet-confident, more likely to have established online purchasing behaviour and therefore more inclined to purchase medication online if required:

'…*the younger population would be more accepting …mostly because they are more likely to have done*

online purchasing before but with other products.' FG2 261-262, 267-268 P3

None of the participants in the focus groups expressed concerns about their ability to navigate websites or carry out an online purchase.

Trust

Trust was identified as an underlying theme demonstrated throughout all of the constructs relating to purchase intention in the Theory of Planned Behaviour. Women commented they would only search for information or medications on websites they trusted. Trust was linked to brand familiarity with familiar high street shops that have online retail outlets. A combination of these factors relating to trust increased a woman's intention to purchase medication online.

'…*For me, it would have to be sources that are well known. For example, Boots, supermarkets etc. I think for me it's about brands I know and recognise*'. FG1 191-195 P9

'…*I would probably only use a company that I am already familiar with e.g. Boots or my local pharmacy (if they had an online option)*'. FG3 298-300 P3

Discussion

In relation to the TPB construct Attitude, this study demonstrated that women perceive they have inadequate information about the safety of medications during pregnancy and seek support from the internet. Medication safety advice is one of the most commonly searched topics on the internet for pregnant women (Hamëen-Anttila et al 2014, Sinclair et al 2018). Women are concerned about the evidence retrieved and cannot always tell real from fake pharmacy sites. Although the UK, US and other countries also have medication safety information that can be accessed online from UKTIS, FASS, Safe for Two, women still need advice from their midwives and doctors who can advise on medication usage in view of their clinical picture.

This study demonstrates that pregnant women are turning to the internet to purchase medications online for convenience, cost-effectiveness, better availability of products, with similar findings documented in the literature for general online medication purchasing sales (Kennedy & Wilson 2017, Tascu et al 2017). The ability to avoid consultations with health care providers strongly appealed to some women in this study to maintain privacy, anonymity and confidentiality, making online purchasing an attractive option. However, this is a concern, as a recent study found that 28.3% of women who took medication during pregnancy used medications classed as risky, including ibuprofen, metoclopramide and codeine (Trönnes et al 2017). This, with the combination of pregnant women avoiding health care professional

consultation and essentially self-medicating by purchasing medications online, highlights a real risk for pregnant women and the safety of their unborn baby. Targeting women preconceptionally, antenatally and in the inter-pregnancy period with safety information on how to purchase online medication safely can mitigate some of the potential risk, along with strict regulation of online medication sales.

A large proportion of women either worked full time or part time, with almost half the sample having purchased medication or vitamins online during pregnancy. This highlights how modern mothers have a greater incentive to purchase medication because of convenience. More worryingly, several women in the focus groups commented on using the internet to obtain medication due to long waiting times to obtain appointments to see GPs. The most recent GP Patient Survey (National Health Service (NHS) 2018a) found 24% of the population had to wait a week or more to get a GP appointment.

Although the literature would suggest that more than 90% of pregnant women take a prescribed or over-the-counter (OTC) medication at some stage during their pregnancy (Mitchell et al 2011), fear about product safety and teratogenic factors remains paramount (Twigg et al 2016, Lynch et al 2018). Fears discussed by women in the focus groups regarding online medication purchasing included whether the product they would receive would be of a good quality and the recommended dosage. Previous verification studies testing product content demonstrated considerable variation in the drug concentrations (Lagan et al 2014, Murtagh et al 2018). Studies have highlighted a shortfall in packaging, labelling and patient information by the Medicines and Healthcare products Regulatory Agency (MHRA 2016b) thus validating the concerns raised by women in this study. Women in the study also highlighted that they tried not to take medications during pregnancy for fear of harmful outcomes for their baby. Twigg et al (2016) found similar findings in their study with some women experiencing heartburn and UTIs and not treating the condition. Further research is required to address women's concerns, explore risk perception around medication use in pregnancy and improve medication adherence.

More caution was displayed by women in this study for online purchase of prescription medications, with women who had not previously purchased medication online being fearful. This was generally in relation to protecting the safety of their unborn baby and limiting the teratogenic risk to the fetus; a finding similar to that of general medication usage in pregnancy (Twigg et al 2016, Lynch et al 2018). The dangers of online medication purchasing have been highlighted and guidance provided by the Food and Drug Administration (FDA) and NHS (FDA

2018, NHS 2018b). However, women generally felt purchasing vitamins and herbal supplements was safer for them and their baby and felt their family and peers would not have any issues with obtaining them online. Abdollahi & Chareti (2019) found most pregnant women were advised to take herbal medications by their families and did not disclose what they had taken to a health care provider as they perceived their use to be safe. Herbal medicines have been perceived by pregnant women to be more natural and safer for use in pregnancy compared to prescribed medicines (Pallivalappila et al 2013). Women also feel products that could be purchased OTC, such as paracetamol, are not considered a 'medicine' and therefore do not have as many safety concerns in comparison to prescribed medications (Bowman et al 2019). Thus, the level of caution when purchasing vitamins, herbal medications and OTCs is less when purchasing online than for prescribed medication.

Women on the Web (www.womenonweb.org) provides a telemedicine service that provides information, health care support and access to abortion pills online for women with restrictive health care systems. A recent study found self-managed medication abortion using online telemedicine was often preferred over travel for women in countries where abortion is illegal due to its convenience and safety, however women found the experience dominated by fear and isolation due to the high associated risk of prosecution (Aiken et al 2018). With findings from a systematic review by Endler et al (2019) showing medical abortion through telemedicine being highly acceptable to women, this supportive form of online medication purchasing should be supported in the future. In countries that demonstrate a contentious political environment with severe restrictions on access to medicalised abortion, the concern is that the future of abortion may be 'unsupported, online, and in the mail' (Painter 2019).

In relation to subjective norms, buying OTC medications, vitamins and herbal medications online during pregnancy was considered by women in the study to be safe, especially if approved by health care professionals. However, Kennedy et al (2016) found herbal medications recommended to pregnant women by a health care professional were three times more likely to be for medications contraindicated for pregnancy. This is concerning and suggests further education for health care professionals is required on the effects of herbal medications during pregnancy.

Women who had previously purchased medications online were less likely to be influenced by family and friends and more favorably disposed towards reviews and star ratings. Younger adults' purchasing decisions are strongly influenced by average consumer ratings (von Helversen et al 2018). However, negative reviews can exert a stronger influence than positive ones (Purnawirawan et al 2015).

In the group of women who had not purchased medication online, peer influence was identified as a factor that influences online purchasing behaviour. Women clearly indicated that if online medication was more prevalent, and more of their peers were doing it, they too would purchase medication online.

Social media was seen as influential and increased a woman's intention to purchase if they received advice from others that a medication had been helpful to them. Using social media to gain advice has also been found to increase prenatal attachment (Harpel 2018). However, in this study some women did demonstrate concern about the reliability of the advice on social media and pregnancy forums and preferred to see endorsement by health care professionals. A recent study by van Gelder et al (2019b) reviewed social media posts on medication safety in pregnancy and found that the safety classification on strict indication drugs (93%) and medications with insufficient knowledge on their safety during pregnancy (76%) were more likely to be incorrectly perceived by the public compared to medications with the TIS classification safe (24%). Lynch et al (2018) identified that women had a lack of knowledge regarding the effect of medication on their baby and turned to social media and online blogs to assist with their decision making regarding what medications were safe to use in pregnancy.

In relation to perceived behavioural control, women expected to find what they were looking for quickly and easily. Specific online stores were preferred by women if they had a function to store personal details and card payments for repeated purchases or PayPal options. The potential for online fraud was perceived as the most important risk identified in online purchasing (Wang & Chang 2013, Pappas 2016). Women also favoured websites that facilitated prompt delivery time frames, low shipping costs, free delivery, medication stability assurances and signed for delivery.

Women required security about the use of their personal data and there was a significant direct effect of privacy concerns on both attitude and intention. This attitudinal construct is an important mediator in explaining online purchase intention, with privacy concerns having been found to have a negative impact on trust but a positive impact on perceived risk (Fortes et al 2017).

All aspects of the constructs of attitude, subjective norm and perceived behavioural control were relevant and important in predicting purchase intention from the focus group data. However, what was evident from the focus groups was a core theme of trust that ran through all data gathered on the constructs of the TPB. Trust is a known factor which influences behaviour and purchase intention (Hong 2015, Thomas et al 2018). The current population of pregnant women who are Generation Y and Z are internet-confident, more likely to have established online purchasing behaviour and therefore more inclined to purchase medication online.

Women in this study commented that they would only search for information or medications on websites they trusted. Trust was also linked to women's perceived risk of online purchasing associated with the product purchased online and concerns regarding pharmaceutical quality. Li et al (2014) highlight that the concept of trust is more important for internet purchases than offline as consumers perceive more risk in online purchasing due to their inability to visit a physical shop and examine the product they wish to purchase. Trust was linked to brand familiarity, with women commenting that they trusted familiar high street shops that had online retail outlets, as they were familiar with their products. Women in the study commented that they trusted positive online reviews with a stronger intention to purchase, and negative reviews with less inclination to purchase medication online. Wang & Chang (2013) found that when there is an element of risk involved in online purchasing, the amount of trust a consumer places on sources of information, recommendations and reviews influences their purchasing decision. Midwives are therefore in an optimum position to discuss medication usage with women, advise on how to make online medication purchases safely and signpost to legally endorsed pharmaceutical websites.

Generation Z expects various new devices and electronic processes to be widely available, offering consumers greater autonomy and faster transactions with which to make more informed shopping decisions online (Priporas et al 2017). Future planning for health care should develop services to facilitate online pharmacy and medication information for women during pregnancy to provide convenient, safe, streamlined, effective health care in the future in keeping with the Department of Health eHealth and Care Strategy (Department of Health 2016).

Limitations

A core strength of this study is the new theoretical knowledge that provides insight into the application of the TPB to pregnant women's purchasing behaviour. Limitations were the sample bias towards internet users who are more motivated to participate than a general population of pregnant women. In addition, the women who participated in the study were highly educated to degree level. Opinions of women from different educational backgrounds would have enhanced the generalisability of the findings. Asynchronous online focus groups also have a higher drop-out rate due to the timeframe taken to complete the discussion and can lack depth.

Conclusion

In conclusion the current findings in this study identify the predictors of pregnant women's

intention to purchase medication online using the TPB. However, intention alone may not be sufficient to determine behaviour. As such, future research should investigate specific areas of online medication purchasing. Midwives and health care professionals need to be aware that pregnant women are purchasing medications online to ensure that their knowledge of this behaviour is evidence-informed and that they offer pregnant women appropriate advice. Understanding online medication purchasing behaviour is important to shape future communications between health care professionals and pregnant women and assist managers and policy makers in creating guidelines for medication safety and devising eHealth technology for pregnant women in the future.

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Author contributions

Criteria	Author initials
Made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;	AL, MS, HZ, PG
Involved in drafting the manuscript or revising it critically for important intellectual content;	AL, MS, HZ, PG
Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content;	AL, MS, HZ, PG
Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.	AL, MS, HZ, PG

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