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Multicountry study protocol of COCOON: COntinuing Care in COVID-19 Outbreak global survey of New, expectant, and bereaved parent experiences

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ABSTRACT

Introduction Globally, the COVID-19 pandemic has significantly disrupted the provision of healthcare and efficiency of healthcare systems and is likely to have profound implications for pregnant and postpartum women and their families including those who experience the tragedy of stillbirth or neonatal death. This study aims to understand the psychosocial impact of COVID-19 and the experiences of parents who have accessed maternity, neonatal and bereavement care services during this time.

Methods and analysis An international, cross-sectional, online and/or telephone-based/face-to-face survey is being administered across 15 countries and available in 11 languages. New, expectant and bereaved parents during the COVID-19 pandemic will be recruited. Validated psychometric scales will be used to measure psychosocial well-being. Data will be analysed descriptively and by assessing multivariable associations of the outcomes with explanatory factors. In seven of these countries, bereaved parents will be recruited to a nested, qualitative interview study. The data will be analysed using a grounded theory analysis (for each country) and thematic framework analysis (for intercountry comparison) to gain further insights into their experiences.

Ethics and dissemination Ethics approval for the multicountry online survey, COCOON, has been granted by the Mater Misericordiae Human Research Ethics Committee in Australia (reference number: AM/MML/63526). Ethics approval for the nested qualitative interview study, PUDDLES, has been granted by the King's College London Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee (reference number: HR-19/20-19455) in the UK. Local ethics committee approvals were granted in participating countries where required. Results of the study will be published in international peer-reviewed journals and through parent support organisations. Findings will contribute to our understanding of delivering maternity care services, particularly bereavement care, in high-income, lower middle-income and low-income countries during this or future health crises.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is a multicountry collaboration that facilitates data collection across 15 countries to explore experiences following the birth or death of a baby in a diverse range of settings.
⇒ A mixed-methods approach to the data analysis will contribute to the increase of knowledge around maternity, neonatal and bereavement care during the COVID-19 pandemic to inform future guidelines for care during a pandemic.
⇒ Limitations of this cross-sectional study include lack of longitudinal data which limits exploration of change over time and inability to attribute outcomes to COVID-19 or variants, selection bias and the inability to study outcomes in relation to differential progression of the pandemic across countries, including timing of infection peaks and public health responses (eg, lockdowns and border closures).

INTRODUCTION

The COVID-19 pandemic, caused by the novel coronavirus SARS-CoV-2,[1] has led to global disruptions to healthcare systems resulting in direct and indirect impacts on physical and mental health outcomes, particularly for pregnant and postpartum women.[2–7] Evidence suggests maternal and perinatal outcomes have worsened during the pandemic including an increase in maternal deaths, stillbirth, ruptured ectopic pregnancies and maternal stress and depression.[8–10] Pregnant and postpartum women and their partners are particularly vulnerable for experiencing such a significant life course

transition amidst a time of great uncertainty and rapid change.[11 12]

Maternity care settings both in high and lower resourced settings have experienced specific challenges during COVID-19 such as reduced capacity and resources to provide maternal care services, care inaccessibility for parents and families and lack of perinatal care guidelines including bereavement care for parents following stillbirth and neonatal death.[9 13] Social distancing restrictions have resulted in reduced health-seeking behaviour, access to health services and practice relating to breast feeding, as well as postpartum and neonatal care.[4 5 13–17] Decreased access to normal social support systems due to travel restrictions within and between countries has led to increased isolation and loneliness, with several studies highlighting the increased rates of anxiety, and clinically relevant maternal depression.[4 6 18] Poor maternal mental health, particularly anxiety and depression, is associated with short-term and long-term adverse outcomes for both the mother and infant (eg, recurring course of maternal symptoms detrimental to the mother–infant relationship, increased risk of obstetrical complications, poor birth outcomes and later child developmental problems).[6 15 16]

An increase in the number of preventable stillbirths and neonatal deaths is one of the most crucial yet under-recognised indirect effects of the pandemic.[9 10 19] Prepandemic, substandard care has been identified as contributing to up to 50% of stillbirths, with 20%–30% considered preventable if optimal care had been provided.[20 21] The pandemic-related disruptions to maternal, newborn and child healthcare are known to have worsened the standard of care in many instances, leading potentially to an increase in many preventable losses of lives.[9] Prepandemic, research has shown that healthcare professionals often feel underprepared and unable to provide needed support to parents following the death of their baby including parent-centred care plans, bereavement-specific practices (eg, opportunities for parenting activities such as seeing and holding their baby, bathing and dressing their baby, creating memories, eg, photographs, handprints or footprints) and memorials and commemorative rituals.[22–25]

The COVID-19 pandemic may have caused further disparities in service provision and care for women and families worldwide, particularly parents who have experienced the death of their baby.[5 14] It is critical we understand the clinical and psychosocial experiences of pregnancy and childbirth during the pandemic if we are to improve mother, baby and family outcomes during this current global crisis and other future health events. It is particularly important to understand bereaved parent experiences of care during this time, and the extent to which recommended perinatal bereavement care practices—which are known to vary widely between countries even in non-pandemic times—are being provided.[24 26]

Study aims

This study will explore the psychosocial impact of COVID-19 and the experiences of parents who have accessed maternity, neonatal and/or bereavement care services during the pandemic to provide an international picture of maternal healthcare during the COVID-19 pandemic. We aim to explore the perspectives and experiences of parents to understand:

- Maternity and perinatal bereavement care practices during the COVID-19 pandemic (eg, labour and birth practices) including the support services available (both formal and informal), and public health limitations (eg, visitors to hospital, presence of partners during prenatal care and childbirth); and how these vary across countries, hospital settings and geographical locations (ie, metropolitan vs rural).
- The psychosocial impact of COVID-19 including stress, social loneliness, anxiety and depression symptoms.
- Satisfaction with information provided about COVID-19 during pregnancy and post partum.
- Preventive measures taken by parents to protect themselves and others against COVID-19 (eg, decreased health service utilisation).

METHODS

Study design and setting

The *multicountry 'COntinuing Care in COVID-19 Outbreak global survey of New, expectant, and bereaved parent experiences'* (COCOON) study is an international, cross-sectional online survey of parents who have accessed maternity, neonatal and/or bereavement care services during the COVID-19 pandemic. The online survey is coordinated and managed by the Centre of Research Excellence in Stillbirth (Stillbirth CRE) based in Brisbane, Australia. Several countries have delivered the online survey items via a face-to-face or telephone interview, depending on local social distancing restrictions and safety, each managed by the country coordinating centre (see table 1). Ethics approval for this research project (reference number: AM/MML/63526) has been granted by the Mater Misericordiae Human Research Ethics Committee in Australia and all processes within this study are compliant with Australia's National Health and Medical Research Council (NHMRC) Statement on Ethical Conduct in Human Research and reflect international guidance on ethical principles, with country-specific ethics and governance approval gained, where required.

Survey development

The COCOON survey was developed at the beginning of the COVID-19 pandemic as part of an international collaboration to investigate the psychosocial impact of COVID-19 and parent experiences of maternity, neonatal and perinatal bereavement care during this time. A total of eight surveys were developed, each tailored for a specific parent group: (A) pregnant women; (B) postpartum women; (C) partners of pregnant women; (D) partners of postpartum women; (E) mothers who

Table 1 List of participating countries, survey languages, modes of survey delivery, start month and year and survey types being implemented across COCOON collaboration (ordered by launch date)

				COCOON survey								
				Pregnancy/post partum				Bereavement				
Country	Language	Mode	Survey administration period	A	B	C	D	E	F	G	H	PUDDLES nested qualitative study
Australia	English	Online	May 2020 to October 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
UK	English	Online	July 2020 to January 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
Italy	Italian	Online	July 2020 to October 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
USA	English	Online	July 2020 to October 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Quebec, Canada*	French	Online*	July 2020 to October 2021	▲	▲	▲	▲	▲	N/A	▲	N/A	▲
Ireland	English	Online	September 2020 to October 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Spain	Spanish	Online	October 2020 to October 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Brazil	Portuguese	Online	October 2020 to October 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
India (North)*	Hindi	Face to face/telephonic*	October 2020 to October 2021	▲	▲	N/A	N/A	▲	N/A	N/A	N/A	▲
Germany	German	Online	November 2020 to October 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
India (South)*	Telugu	Online*	December 2020 to October 2021	▲	▲	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Netherlands	Dutch	Online	May 2021 to October 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
New Zealand	English	Online	May 2020 to October 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
Vancouver, Canada	English	Online	April 2021 to May 2022	N/A	N/A	N/A	N/A	▲	▲	▲	▲	N/A
Argentina	Spanish	Online	September 2021 to May 2022	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Laos*	Lao	Face to face*	May 2022 to July 2022	▲	▲	N/A	N/A	▲	N/A	▲	N/A	N/A
Philippines*	English Filipino	Online and face to face	July 2022 to December 2022	▲	▲	▲	▲	▲	▲	▲	▲	N/A

Specific parent group: A, pregnant women; B, postpartum women; C, partners of pregnant women; D, partners of postpartum women; E, mothers following stillbirth; F, partners following stillbirth; G,mothers following neonatal death ; H, partners following neonatal death.
*Hosting and management of own data in the country.
N/A, not applicable/this aspect of the study is/was not being implemented.

experienced a stillbirth; (F) partners who experienced a stillbirth; (G) mothers who experienced a neonatal death; and (H) partners who experienced a neonatal death. The study design and development of the core set of items for each survey was driven by the Stillbirth CRE in partnership with the COCOON working group and the following coordinating centres (in alphabetical order): Canada (FdM), Ireland (MM, KO'D), Italy (CR, AV), Spain (JC), UK (SAS, JS) and the International Stillbirth Alliance (SHL, CS, PQ). This study was informed by previous research conducted by investigators including the COVID-ASSESS study investigating anxiety and stress in pregnant and postpartum women in Italy during the pandemic[27] and international stillbirth studies published in the 2011 and 2016 *The Lancet* stillbirth series.[20 21 28] The final core set of items for each survey ranged from approximately 70 to 115 open-ended and closed-ended questions across four main sections (see table 2). Closed-ended questions were included to minimise respondent time burden, while inviting extended feedback through open-ended comment response options. Validated psychometric scales were included to explore psychosocial outcomes.

All country coordinating centres which joined the COCOON collaboration reviewed the core set of survey items for each survey before minor contextual changes were made around terminology (eg, health practitioner terms) and translated into local languages. All study information (including consent) and survey items were translated from English to the local language (including independent review for accuracy) by each country coordinating centre. Where validated translations of psychometric scales were not available, these scales were translated from English by each country coordinating team. In addition to the core set of survey items and psychometric scales, each country coordinating centre was able to include additional survey items relevant to understanding the impact of the pandemic in their country and will be reported separately.

Procedures

Inclusion criteria

This study will recruit women aged over 18 years, who were pregnant or gave birth to their baby during the COVID-19 pandemic, including women who experienced stillbirth (ie, baby died before birth, during pregnancy or labour) or neonatal death (ie, a live born baby dying up to 28 days after birth). For the purposes of this study, the COVID-19 pandemic is defined as starting from 30 January 2020 onwards when it was declared a Public Health Emergency of International Concern by the WHO.[29] Men and women whose partner was pregnant or gave birth to their baby during the COVID-19 pandemic, or those who suffered a stillbirth or neonatal death (referred to hereafter as 'partners'), will also be recruited.

For the bereavement surveys, country-specific changes were made to the definition of stillbirth in accordance with differing gestational age criteria in each country (eg, in Australia stillbirth is defined as a baby dying before birth and of at least 20 weeks' gestation[30]; UK is of at least 24 weeks' gestation[31]; Brazil is of at least 22 weeks' gestation[32]; India is of at least 28 weeks' gestation).[33] Additional inclusion criteria include participants providing informed consent online and reliable access to a computer (or similar device) and internet to complete the online survey (for countries using this mode of survey delivery). For participants who reside in countries where computer and internet access is limited, additional inclusion criteria include willingness to attend a face-to-face meeting or participate in a telephone interview to complete the survey items.

Exclusion criteria

For the bereavement surveys, parents who experienced the death of their baby prior to the definition of stillbirth in each country, or after the definition of neonatal death in each country, will be excluded and redirected to country-specific support services. (For the UK, women and partners who experienced a late-term miscarriage and who are therefore not eligible to participate in the COCOON online survey will able to take part in the nested qualitative study (PUDDLES).

Recruitment

For this international study an opportunity sample of self-selecting participants will be recruited during the pandemic across the four parent groups: (1) women who are pregnant or post partum; (2) partners of women who are pregnant or post partum; (3) women who have experienced a stillbirth or neonatal death; and (4) partners who have experienced a stillbirth or neonatal death. Participants will be predominantly recruited via online advertising including social media and other electronic communication tools (eg, newsletters) through each coordinating centre, parent support organisation partnerships and both local and national charities in each country, and the International Stillbirth Alliance member network. For those countries conducting face-to-face/telephone interviews instead of the online survey (India, Laos, The Philippines), recruitment will occur through word of mouth (eg, obstetricians, midwives), referral by practitioners/service providers in local service settings and advocate groups (snowball sampling). Each COCOON coordinating centre has in-country partnerships with parent organisations, maternal healthcare services and parent bereavement organisations (see online supplemental appendix 1). From each participating country, we aim to recruit a minimum sample of 500 women and partners during pregnancy, 500 women and partners during the postpartum period and 200 bereaved parents following a stillbirth or neonatal death.

Procedures

Parents interested in participating access the online survey via the Stillbirth CRE website which is delivered in seven languages (except French, Hindi, Telugu and Lao;

Table 2 Core questions for different sections of the surveys

Types of questions	Survey A	B	C	D	E	F	G	H
1. Maternity care experiences								
Pregnancy, labour, birth and neonatal care (eg, primary care provider; setting; gestation)	✔	✔	✔	✔	✔	✔	✔	✔
Postpartum and follow-up care (eg, breast feeding)		✔		✔				
Elements of quality, respectful care (eg, shared decision-making)	✔	✔	✔	✔	✔	✔	✔	✔
Impact of COVID-19 pandemic (eg, changes to care provider and mode of delivery; changes to birth plan)	✔	✔	✔	✔	✔	✔	✔	✔
Quality of care (eg, satisfaction)	✔	✔	✔	✔	✔	✔	✔	✔
1a. Bereavement-specific care experiences								
Pregnancy, labour and birth, neonatal, postpartum and follow-up care (eg, special nursery/intensive care unit; follow-up visits at home)					✔	✔	✔	✔
Difficulties with care due to COVID-19 restrictions and the occurrence of best practice bereavement care (eg, opportunity to spend time with the baby; creation of memories such as photos)					✔	✔	✔	✔
Investigations including autopsy or postmortem examination (eg, counselling; investigations received) and care around understanding the reasons behind their baby's death					✔	✔	✔	✔
2. Psychosocial outcomes								
Impact of COVID-19 (eg, financial pressures, impact on daily life; social support)	✔	✔	✔	✔	✔	✔	✔	✔
State anxiety—STAI-S	✔	✔	✔	✔	✔	✔	✔	✔
Trait anxiety—STAI-T	✔	✔	✔	✔	✔	✔	✔	✔
Postpartum anxiety—PSAS-RSF-C		✔						
Depression—EPDS	✔	✔	✔	✔	✔	✔	✔	✔
Perceived stress—PSS-4	✔	✔	✔	✔	✔	✔	✔	✔
Social loneliness—DJGLS	✔	✔	✔	✔	✔	✔	✔	✔
Perinatal grief—PGS-SF					✔	✔	✔	✔
3. Satisfaction with COVID-19 information								
Helpfulness of information	✔	✔	✔	✔	✔	✔	✔	✔
Sources of trusted information	✔	✔	✔	✔	✔	✔	✔	✔
4. Sociodemographic characteristics								
Demographic characteristics (eg, age, education level, employment status)	✔	✔	✔	✔	✔	✔	✔	✔
Mental and physical health conditions	✔	✔	✔	✔	✔	✔	✔	✔
Family and domestic violence	✔	✔	✔	✔	✔	✔	✔	✔
COVID-19 status (eg, diagnostic, isolation)	✔	✔	✔	✔	✔	✔	✔	✔

Specific parent group: A, pregnant women; B, postpartum women; C, partners of pregnant women; D, partners of postpartum women; E, mothers following stillbirth; F, partners following stillbirth; G,mothers following neonatal death ; H, partners following neonatal death.
DJGLS, De Jong Gierveld Loneliness Scale; EPDS, Edinburgh Postnatal Depression Scale; PGS-SF, Perinatal Grief Scale-Short Form; PSAS-RSF-C, Postpartum Specific Anxiety Scale-Research Short Form for use in global Crises; PSS-4, Perceived Stress Scale-4; STAI, State-Trait Anxiety Inventory.

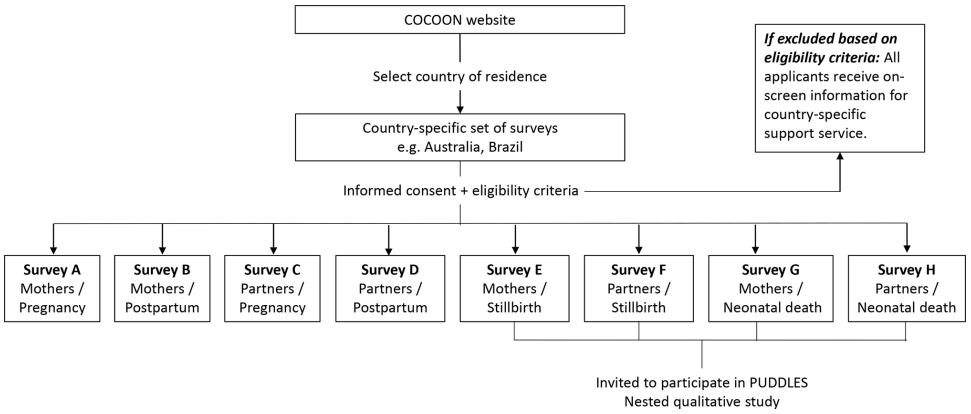

Figure 1 Schematic depiction of participant flow through COCOON study.

see table 1). Parents will then be required to select the country they currently reside in to enter the survey and review the participant information and eligibility criteria for the study and provide online consent to participate. Eligibility questions determine the logic branching of the survey to ensure parents are directed to the appropriate survey (see figure 1). Parents who do not reside in any of the participating countries listed will be directed to a generic (non-country-specific) survey version available in English. Those who are ineligible for participation will be excluded and redirected to an end-of-survey page where country-specific support services are listed (with information, web pages, email addresses and contact numbers).

The time required for each COCOON survey completion is approximately 30–35 min. Following completion of the survey, information on country-specific support services will be provided on screen. For concerns regarding pregnancy or postpartum care during COVID-19, all participants are advised to speak with their general practitioner (family doctor) or other service provider.

Outcomes

The primary outcome for this study is parent experiences of quality of care including bereavement care (see table 2). Secondary outcomes include psychosocial well-being and satisfaction with COVID-19 information.

Experience of maternity, neonatal and bereavement care services

This section aims to understand the experiences, main concerns and perceived needs of parents accessing maternity care services during the COVID-19 pandemic. Most items in this section are multiple-choice Likert items rated on a scale between Strongly Disagree and Strongly Agree. The bereavement-specific surveys (E, F, G, H) also include questions to understand the experiences of care offered to parents following stillbirth or neonatal death.[24] This section also includes several open-text fields for further information.

Psychosocial impact of COVID-19

This section includes several items to explore coping with COVID-related stressors (eg, financial pressures; worry about the health of self and baby, concerns about those at greater risk of COVID-19 including elderly relatives; impact on daily life; social support) and the following validated self-report outcome measures (see table 2).

Anxiety

The *State-Trait Anxiety Inventory* (*STAI*) consists of two 20-item subscales assessing state and trait anxiety.[34] Items from both the state subscale (eg, 'I am tense'; 'I feel indecisive') and trait subscale (eg, 'I feel satisfied with myself'; 'I feel nervous and restless') are rated on a 4-point scale from 1 (Almost never) to 4 (Almost always) with a maximum total score of 80. Higher total scores are indicative of greater anxiety. The STAI has strong psychometric properties in the general adult and perinatal populations and has been translated into multiple languages including Dutch,[35] French,[36] German,[37] Hindi,[38] Italian,[39] Portuguese[40] and Spanish.[41] The *Postpartum Specific Anxiety Scale* (*PSAS*)*-Research Short Form for use in global Crises* is administered in Survey B only and consists of 12 items to assess anxiety symptoms specific to the postpartum period for new mothers, across four factors.[7] It was developed in rapid response to the pandemic with translations provided in Italian, French, Spanish, Chinese and Dutch. Items (eg, 'I have repeatedly checked on my sleeping baby'; 'I have felt that my baby would be better cared for by someone else') are rated on a scale from 1 (Not at all) to 4 (Almost always). The PSAS shows good psychometric properties[7] and the research long form[42] has been subject to multiple translations including French,[43] with ongoing translations and validations taking place in Italian, Spanish, Dutch and more. A research short form has also been developed.[44]

Depression

The *Edinburgh Postnatal Depression Scale* (*EPDS*) consists of 10 items to assess both antenatal and postpartum depressive symptoms over the past 7 days.[45] Items (eg, 'I feel sad or miserable') are rated on a scale from 0 (eg, Not at all) to 3 (eg, Yes, most of the time) with a maximum total score of 30 (>12 indicative of possible depression). (All participants who self-reported thoughts of self-harm are advised on screen to speak with their general practitioner

or other service provider for support.) The EPDS has strong psychometric properties[46] and has been translated and validated in 20 different languages including Dutch,[47] French,[48] German,[49] Hindi,[50] Italian,[51] Portuguese[52] and Spanish.[53]

Stress

The *Perceived Stress Scale-4* (*PSS-4*) consists of a 4-item scale to assess the degree to which individuals believe their life has been unpredictable, uncontrollable and overloaded during the past month.[54] Items (eg, 'In the last month, how often have you felt that you were unable to control the important things in your life?') are rated on a scale from 0 (Never) to 4 (Very often). The PSS-4 is one of the most widely used instruments for measuring the perception of stress; has shown good psychometric properties in perinatal populations[55]; and has been translated into multiple languages including French,[56] German,[57] Hindi,[58] Italian,[59] Portuguese[60] and Spanish.[61]

Social loneliness

The *De Jong Gierveld Loneliness Scale* (DJGLS) consists of six items to assess loneliness[62] which is an indicator of social well-being and pertains to the feeling of missing an intimate relationship (emotional loneliness) or missing a wider social network (social loneliness). Items (eg, 'There are plenty of people I can rely on when I have problems') are rated on a scale between 'no', 'more or less' and 'yes'. The scale has shown good psychometric properties[63] and has been translated into multiple languages including Dutch,[64] French,[65] German[66] and Spanish.[67]

Perinatal grief

The *Perinatal Grief Scale-Short Form* (*PGS-SF*) is administered in the bereavement-specific surveys only[68] and consists of 33 items to assess behavioural and affective symptoms of grief and symptoms specific to perinatal death. Items (eg, 'I find it hard to get along with certain people') are rated on a scale from 'strongly agree' to 'strongly disagree'.[ii] Higher scores reflect more intense grief. The PGS-SF has been widely used and validated for pregnancy loss and translated into multiple languages including Dutch,[69] French,[70] German,[71] Italian[72] and Portuguese.[70]

Satisfaction with COVID-19 information

We included items to explore parents' satisfaction with COVID-19-related information provided during pregnancy and post partum including helpfulness of information and most trusted source of information. This section also includes multiple open-text fields for further information.

Sociodemographic characteristics

The final section of the survey includes a range of multiple-choice response items to explore participant characteristics (eg, age). Several multiple-choice and Likert items were also developed to assess COVID-19 status (eg, diagnostic; isolation; availability of testing) and personal measures taken by participants to protect and prevent the spread of COVID-19 (eg, self-isolating). For questions on family violence, a pop-up message was displayed on screen showing support services relevant to the population and country.

Data management

The COCOON international online survey is coordinated and managed by the Stillbirth CRE located at Mater Research Institute within The University of Queensland Faculty of Medicine in Brisbane, Australia. The online survey is hosted on the Qualtrics platform and available via the Stillbirth CRE website in seven languages. Several COCOON coordinating centres will host and manage their own data which will then be collated into a central database (see table 1).

Analytical approach

Online survey

All survey data will be downloaded from Qualtrics software into a single data set including all surveys. We will analyse and report the findings for two groups: (1) pregnancy and post partum (surveys: A, B, C, D); and (2) bereaved parents (surveys: E, F, G, H). The primary outcome variables for each group will be presented primarily using descriptive statistics and expressed in terms of frequencies, averages and proportions. Secondary outcome variables measuring psychosocial well-being will be expressed primarily in terms of average scale scores, and categorised (eg, high, medium, low, etc) based on recommended cut-offs (if relevant). Other secondary outcomes will be presented descriptively in terms of frequencies and proportions. Comparisons of responses between countries will be undertaken subject to sufficient numbers in each country. Comparison of responses by sociodemographic groupings such as geographical location (eg, urban, rural, remote) and location of birth (eg, public vs private hospital vs home birth) will also be undertaken, subject to sufficient numbers in each. Univariable associations will be assessed using t-tests, analysis of variance, χ^2 test or Fisher's exact test. Inferential analyses of explanatory factors influencing the outcome variables will be carried out via multivariable linear and logistic regression. Mixed-effects models will be used to account for clustering by country when evaluating the association between potential explanatory factors other than country on outcomes. To account for variation in COVID-19 severity in each country, we will calculate and explore in multivariable models a stringency index for each participant based on country and survey completion date using the *Oxford Coronavirus Government Response Tracker* data set available online (https://ourworldindata.org/coronavirus) and provide a COVID-19: Stringency Index.[73]

Nested qualitative interview study

Methods

Several COCOON country coordinating centres are also participating in an international, nested, qualitative

interview study. This study is titled *'The experiences of Parents who sUffer pregnancy loss and whose babies died During the panDemic: A quaLitative study of latE-term miscarriage, Stillbirth and neonatal death'* (PUDDLES). The aim is to further explore the experiences of bereaved parents following a late-term miscarriage, stillbirth or neonatal death during the COVID-19 pandemic. Ethics approval for the PUDDLES study has been granted by the King's College London Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee (reference number: HR-19/20-19455) in the UK, and local ethics committees in participating countries where required. COCOON survey respondents who experienced a bereavement will be invited to participate in this nested qualitative study by leaving their contact details at the end of the screen-out page. This nested study will be conducted in seven of the countries participating in the COCOON Global Collaboration and this group is known as the PUDDLES Global Collaboration, and is led by investigators at King's College London, UK (see table 1). As part of this nested qualitative study, a knowledge mapping exercise will be undertaken with the view of developing a 'maternal health system shock and resilience index' to allow for a simple comparison on deficits in care at a national, local and individual level for data available through the COCOON survey, other COVID-19 pandemic data and for maternal health system data collected in future health crises.

Procedures

At the end of the COCOON survey for participants in the UK, Australia, Brazil, Canada, India, Italy and New Zealand, parents who had experienced a stillbirth or neonatal death will be invited to leave their contact details (eg, name, email address and/or contact number) to participate in a qualitative interview (see table 1). Likewise, those parents who had experienced a late-term miscarriage and so will be screened out of the COCOON survey as ineligible to participate will also be able to leave their contact details to be contacted to participate in a qualitative interview. All qualitative interviews will be conducted by researchers in each country coordinating centre, with oversight provided by the PUDDLES chief investigator and the UK coordinating centre. Participants will be notified that by leaving their contact details their responses to this survey no longer remain anonymous.

Data management and analytical approach

The international, nested, qualitative interview study will explore parents' lived experiences of late-term miscarriage, stillbirth and neonatal death during the pandemic, the bereavement care they received and implications for how bereavement care might be optimised. Qualitative interviews will be conducted using videoconferencing software or by phone (rarely: face to face depending on the country and public health guidance), digitally recorded (with the interviewee's permission) and transcribed verbatim. Interview transcripts will be subject to a primary analysis in each country using grounded theory analysis[74 75] (for investigation into psychological experiences) or template analysis[76 77] (for an assessment of the reconfiguration of maternal, neonatal and bereavement services) to make an assessment of the country-specific experiences. Subsequently, the entire PUDDLES Global data set, which comprised participating countries' data, will be subject to a secondary thematic framework analysis[78 79] to identify and interpret important intercountry patterns across the data set. NVivo will be used to assist with storage, management and coding, where appropriate. At key points in this iterative process, review and discussion with members of our interdisciplinary research team will take place to strengthen the credibility and validity of findings.

DISCUSSION

The COVID-19 pandemic has impacted the lives of millions of pregnant and postpartum women and their families.[80] Globally, parents have experienced modifications to care practices and endured significant health service reconfiguration which have resulted in restricted access to routine healthcare, increased dependence on virtual rather than face-to-face care and limitations around labour and birth.[9] Mental health and social impacts have been experienced on a global scale because of interventions to prevent and/or limit the spread of COVID-19. Public health measures to reduce the spread of disease including social and physical distancing have significantly affected interpersonal support and social connectedness, which are robust predictors of maternal and parental mental health, in turn leading to increased rates of anxiety and depression.[6 81] It is important that parent experiences of maternity care during the initial stages of the COVID-19 pandemic as well as long term are explored. Given the global impact of the pandemic, it is also important that these studies are conducted on an international scale to allow for cross-country comparisons. Findings from the COCOON study will provide a snapshot of parent experiences during the pandemic in multiple countries and will add to the growing literature to inform guidance to care providers and families in times of social isolation and for other pandemic-related public health strategies.

Prior to the COVID-19 pandemic, 2 million stillbirths were reported every year globally with profound economic and psychosocial burden on families and societies.[82–84] The COVID-19 pandemic has contributed to an increase in stillbirths[9 19] and also resulted in limitations to appropriate bereavement care and support for parents experiencing the loss of their baby both in hospital and community settings.[9] The COCOON study will represent one of the largest international cross-sectional surveys conducted during the pandemic to explore parent experiences of bereavement care following the death of a baby. Understanding current practices in maternity and neonatal settings, both locally and across countries,

during the COVID-19 outbreak is a critical first step in improving care for women and their families during this current outbreak and any similar future outbreaks. The PUDDLES qualitative interview study, nested within COCOON, will also allow a more thorough investigation of the experiences of bereaved parents at this time, and represents the largest international qualitative investigation into perinatal bereavement response to the COVID-19 pandemic.

There are several limitations of this study. First, this cross-sectional study will provide an overall description of the sample during different stages of the COVID-19 pandemic but will not be able to identify reasons for individual outcomes or attribute outcomes to COVID-19 or variants. The cross-sectional study design makes it impossible to explore change over time, or comparison with outcomes before the pandemic. Despite our attempt to make cross-country comparisons, the study design may limit these comparisons due to differential progression of the pandemic (ie, timing of peaks and subsequent waves) and public health responses (eg, lockdowns, border closures) and available health services which have varied globally. Our study is also limited due to lack of low-income settings where unequal socioeconomic impacts of the COVID-19 pandemic have been experienced.[84] Voluntary participation and recruitment of participants predominantly conducted online and via social media will result in selection bias, and not account for potential participants' digital poverty (as only those with access to the internet can access these surveys and such respondents are likely to be more affluent and more highly educated). These factors might limit the generalisability of the findings.[85] Further, different sampling methods will be used in this study with several countries conducting telephone surveys/interviews, rather than online surveys, which may result in lower face validity of items. Finally, all survey items and where validated psychometric scales were not available, translation from English to local languages (eg, Italian) was completed by each country coordinating centre and independently reviewed; however, back translation was not conducted potentially impacting accuracy, consistency and quality. These factors may limit the generalisability of findings, particularly for low-income settings.[49] There is a need for further longitudinal studies to investigate the psychosocial impact of the pandemic over time, especially in low-income settings.

The care parents receive during pregnancy and post partum, including the care received following stillbirth or neonatal death, has important implications for immediate and longer term well-being. Given the emerging evidence of negative impacts of COVID-19 on the health and well-being of parents, pandemic preparedness and the development of evidence-based maternity care guidelines and practices is imperative. Findings from the COCOON study will inform strategies to improve care for women and their families, provide examples of best practice (both during peak times of outbreaks and during off-peak times) and provide baseline data for ongoing monitoring and evaluation in high-income and middle-income countries during this pandemic and possible future pandemic(s). This is particularly important for the delivery of appropriate and respectful bereavement care to parents following stillbirth or neonatal death.

ETHICS AND DISSEMINATION

This study was approved by the Mater Misericordiae Human Research Ethics Committee (EC00332) in Australia on 13 May 2020 (reference number: AM/MML/63526) and will be carried out in accordance with Australia's National Health and Medical Research Council Statement on Ethical Conduct in Human Research. The nested qualitative interview study, PUDDLES, obtained ethical approval from the King's College London Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee (reference number: HR-19/20-19455) in the UK. Local ethics committee approvals for each country coordinating centre were obtained where required: Brazil: Ethics Research Committee of Pedro Ernesto University Hospital Rio de Janeiro State University; Canada: The University of British Columbia Office of Research Services Behavioural Research Ethics Board (Anglophone surveys), Research Ethics Committee of the Université du Québec en Outaouais (Francophone surveys); Germany: Ethikkommission Medizinische Hochschule Hannover; India (North): Post Graduate Institute of Medical Education & Research Ethics Committee; India (South): Institutional Ethics Committee, Fernandez Foundation; Ireland: Clinical Research Ethics Committee of Cork Teaching Hospitals; Italy: Florence University Ethics Committee; Laos: The University of Health Sciences of Lao PDR; Netherlands: Universitair Medisch Centrum Groningen; New Zealand: Victoria University of Wellington Human Ethics Committee; Philippines: Far Eastern University-Nicanor Reyes Medical Foundation Institutional Ethics Review Committee; Spain: The University of Alicante Research Ethics Committee; UK: King's College London Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee. Results will be submitted for publication in international peer-reviewed journals and through parent support organisations.

STUDY STATUS

The first participant of the study was enrolled on 13 May 2020 in Australia. In the 12 months after the recruitment first began (13 May 2021), 5668 pregnant and 8562 postpartum women have completed the survey, and 496 partners (174 during pregnancy; 322 during postpartum period). For the bereavement surveys, 840 parents who experienced stillbirth and 270 who experienced neonatal death have participated.

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Contributors VF and CH conceived the study. SAL led the development of the study protocol with RG, SAS, FMB, JC, VF, CH, DH, SHL, FdM, MM, KO'D, PQ, CR, CS, JS, AV and ANW. All coauthors listed in the COCOON collaboration participated in the development and design of the COCOON study for their country coordinating centre. SAL and RG drafted the manuscript with SAS, FMB, DE and VF. All coauthors have contributed to the revision of the first draft and have approved the final manuscript.

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