BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-061550
Article Type:	Protocol
Date Submitted by the Author:	28-Jan-2022
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Keywords:	COVID-19, PERINATOLOGY, PSYCHIATRY, OBSTETRICS, PUBLIC HEALTH

Study title: A 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. Findings will inform strategies to improve care for women and their families during this and future health crises.

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. 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 with data analysed using a grounded theory analysis (for each country) and thematic framework analysis (for inter-country comparison) to gain further insights into their experiences.

Ethics and dissemination

Ethics approval for the global online survey: COCOON, has been granted by the Mater Misericordiae Ltd Human Research Ethics Committee in Australia (ref: AM/MML/63526) and local ethics committees in participating countries where required. 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 Sub-Committee [ref: HR-19/20-19455] in the UK, and local ethics committees 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 pandemics.

Strengths and limitations of this study

- This study is a global collaboration across 15 countries to explore maternity care experiences in both high- and lower-resourced settings following the birth or death of a baby and the related psychosocial impact of the COVID-19 pandemic.
- This study will identify areas for maternity, neonatal, and bereavement care improvement, examples of best practice, and provide baseline data for ongoing monitoring and evaluation.
- Limitations of this cross-sectional study include lack of longitudinal data which limits exploration of change over time, including the 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 (e.g., lockdowns and border closures).

Keywords

COVID-19, pandemic, parents, pregnancy, postpartum, stillbirth, neonatal death, service delivery

Background

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 lifecourse 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 breastfeeding, 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 have 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- and long-term adverse outcomes for both the mother and infant (e.g., 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] 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 the current global crisis as well as in response and recovery.

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] Pre-pandemic, sub-standard 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 health care are known to have worsened the standard of care in many instances, leading potentially to an increase in many preventable losses of lives. [9] Pre-pandemic, research has shown healthcare professionals often feel

underprepared and unable to provide needed support to parents following the death of their baby including parent-centred care plans, and bereavement-specific practices (e.g., opportunities for parenting activities such as seeing and holding their baby, bathing, and dressing their baby, creating memories e.g., 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. [5,14] Hence, it is 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 implemented. [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 a comprehensive global picture of maternal healthcare during the COVID-19 pandemic. We aim to explore the perspectives and experiences of parents to understand:

- how the COVID-19 pandemic has affected care delivery (e.g., labour and birth practices) including the support services available (both formal and informal), and public health limitations (e.g., visitors to hospital, presence of partners during prenatal care and childbirth).
    - how these vary across countries, hospital settings, and geographical locations (i.e., metropolitan vs. rural)
- how bereavement care practices have been affected by the pandemic.
- the psychosocial impact of COVID-19 including stress, social loneliness, anxiety, and depression symptoms.
- satisfaction with information provided about COVID-19 during pregnancy and postpartum.
- preventive measures taken by parents to protect themselves and others against COVID-19 (e.g., decreased health service utilisation).

Methods

Study design and setting

The *'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 co-ordinated and managed by the 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 co-ordinating centre (see Table 1). Ethics approval for this research project (reference number AM/MML/63526) has been granted by the Mater Misericordiae Ltd Human Research Ethics Committee in Australia and all processes within this study are compliant with Australia's National Statement on Ethical Conduct in Human Research and reflect international guidance on ethical principles, with country-specific ethics and governance approval gained, where required.

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)

Country	Language	Mode	Planned Start	COCOON Survey								PUDDLES Nested Qualitative Study
				Pregnancy/postpartum				Bereavement				
				A	B	C	D	E	F	G	H	
Australia	English	Online	May 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲
UK	English	Online	July 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲
Italy	Italian	Online	July 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲
US	English	Online	July 2020	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Quebec, Canada	French	Online*	July 2020	▲	▲	▲	▲	▲	▲	N/A	N/A	▲
Ireland	English	Online	Sept 2020	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Spain	Spanish	Online	Oct 2020	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Brazil	Portuguese	Online	Oct 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲
India (North)	Hindi	Face-to-face and Telephonic*	Oct 2020	▲	▲	N/A	N/A	▲	N/A	N/A	N/A	▲
Germany	German	Online	Nov 2020	▲	▲	▲	▲	▲	▲	▲	▲	N/A
India (South)	Telugu	Online*	Dec 2020	▲	▲	N/A	N/A	N/A	N/A	N/A	N/A	
Netherlands	Dutch	Online	May 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A

New Zealand	English	Online	May 2020	▲	▲	▲	▲	▲	▲	▲	▲	▲
Vancouver, Canada[a]	English	Online	April 2021	N/A	N/A	N/A	N/A	▲	▲	▲	▲	N/A
Argentina	Spanish	Online	Sept 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Laos	Lao	Face-to-face*	Feb 2022	▲	▲	N/A	N/A	▲	▲	N/A	N/A	
Philippines	English Filipino	Online and Face-to-face	Feb 2022	▲	▲	▲	▲	▲	▲	▲	▲	N/A

Notes.; *hosting and management of own data in country; A=Pregnant women; B=Postpartum women; C=Partners of Pregnant Women; D=Partners of Postpartum Women; E=Mothers following stillbirth; F=Mothers following Neonatal Death; G=Partners following stillbirth; H=Partners following Neonatal Death; N/A=Not applicable/this aspect of the study is/was not being implemented.

Patient and Public Involvement

Patients and/or public were not expressly involved in the design or conduct of the current study.

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 experienced a stillbirth; (F) mothers who experienced a neonatal death; (G) partners who experienced a stillbirth; 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 (de Montigny), Ireland (Murphy, O'Donoghue), Italy (Ravaldi, Vannacci), Spain (Cassidy), UK (Silverio, Sandall), and the International Stillbirth Alliance (Leisher, Storey, Quigley). 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 between approximately 70 and 115 open- 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.

Subsequent country co-ordinating centres which joined the COCOON collaboration reviewed the core set of survey items for each survey before country-specific changes were made for context and cultural acceptability, and translation into local languages. If available, psychometrically validated versions of the tools were used in countries without English as the main language. Investigators were also able to include additional questions related to the COVID-19 pandemic in their country.

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 (e.g., primary care provider; setting; gestation)	✓	✓	✓	✓	✓	✓	✓	✓
Postpartum and follow-up care (e.g., breastfeeding)		✓		✓				
Elements of quality, respectful care (e.g., shared decision-making)	✓	✓	✓	✓	✓	✓	✓	✓
Impact of COVID-19 pandemic (e.g., changes to care provider and mode of delivery; changes to birth plan)	✓	✓	✓	✓	✓	✓	✓	✓
Quality of care (e.g., satisfaction)	✓	✓	✓	✓	✓	✓	✓	✓
1a) Bereavement-specific care experiences								
Pregnancy, labour and birth, neonatal, postpartum and follow-up care (e.g., 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 (e.g., opportunity to spend time with baby; creation of memories such as photos)					✓	✓	✓	✓
Investigations including autopsy or post-mortem examination (e.g., counselling; investigations received) and care around understanding the reasons behind their baby's death					✓	✓	✓	✓
2) Psychosocial outcomes								
Impact of COVID-19 (e.g., 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 – SLS	✓	✓	✓	✓	✓	✓	✓	✓
	Perinatal grief – PGS-SF					✓	✓	✓	✓
3)	**Satisfaction with COVID-19 information**								
	Helpfulness of information	✓	✓	✓	✓	✓	✓	✓	✓
	Sources of trusted information	✓	✓	✓	✓	✓	✓	✓	✓
4)	**Sociodemographic characteristics**								
	Demographic characteristics (e.g., age, education level, employment status)	✓	✓	✓	✓	✓	✓	✓	✓
	Mental and physical health conditions	✓	✓	✓	✓	✓	✓	✓	✓
	Family and domestic violence	✓	✓	✓	✓	✓	✓	✓	✓
	COVID-19 status (e.g., diagnostic, isolation)	✓	✓	✓	✓	✓	✓	✓	✓

Procedures

Inclusion criteria

This study will recruit women aged over 18 years of age, who were pregnant or gave birth to their baby during the COVID-19 pandemic, including women who experienced stillbirth (i.e., baby died before birth, during pregnancy or labour) or neonatal death (i.e., 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 the 30 January 2020 onwards when it was declared a Public Health Emergency of International Concern (PHEIC) by the World Health Organisation (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 (e.g., 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 includes 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.[i]

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 postpartum; (2) partners of women who are pregnant or postpartum; (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 (e.g., newsletters) through each co-ordinating 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 (e.g., obstetricians, midwives), referral by practitioners/service providers in local service settings and advocate groups (snowball sampling). Each COCOON co-ordinating centre has in-country partnerships with parent organisations, maternal healthcare services, and parent bereavement organisations (see appendix). 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; 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

[i]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).

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, webpages, e-mail addresses, and contact numbers).

<Insert Figure 1 Here>

The time required for each COCOON survey completion is approximately 30-35 minutes. 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 wellbeing 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 (e.g., 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 outcomes measures (see Table 2).

Anxiety. The *State-Trait Anxiety Inventory for Adults (STAI)* consists of two 20-item subscales assessing state and trait anxiety. [34] Items from both the state subscale (e.g., "I am tense"; "I feel indecisive") and trait subscale (e.g., "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 population, has been validated in perinatal populations, and has been translated into multiple languages. The *Postpartum Specific Anxiety Scale – Research Short Form – for use in global Crises (PSAS-RSF-C)* is administered in Survey B only and consists of 12 items to assess anxiety symptoms specific to the postpartum period for new mothers. [7] Items (e.g., "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]

Depression. The *Edinburgh Postnatal Depression Scale (EPDS)* consists of 10 items to assess both antenatal and postpartum depressive symptoms over the past seven days. [35] Items (e.g., 'I feel sad or miserable') are rated on a scale from 0 (e.g., Not at all) to 3 (e.g., Yes, most of the time) with a maximum total score of 30 (>12 indicative of possible depression).[ii] The EPDS has strong psychometric properties and has been translated and validated in 20 different languages. [36]

S**tress.** 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. [36] Items (e.g., "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 and has shown good psychometric properties in perinatal populations. [37,38]

Social loneliness. The *De Jong Gierveld Loneliness Scale* (SLS) consists of six items to assess loneliness [39] which is an indicator of social wellbeing and pertains to the feeling of missing an intimate relationship (emotional loneliness) or missing a wider social network (social loneliness). Items (e.g., "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. [40]

[ii]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.

Perinatal grief. The *Perinatal Grief Scale – Short Form (PGS-SF)* is administered in the bereavement-specific surveys only [41] and consist of 33 items to assess behavioural and affective symptoms of grief and symptoms specific to perinatal death. Items (e.g., "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. [41]

Satisfaction with COVID-19 information

We included items to explore parents' satisfaction with COVID-19 related information provided during pregnancy and postpartum 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 (e.g., age). Several multiple choice and Likert items were also developed to assess COVID-19 status (e.g., diagnostic; isolation; availability of testing) and personal measures taken by participants to protect and prevent the spread of COVID-19 (e.g., 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 co-ordinated and managed by the Centre of Research Excellence in 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 co-ordinating centres will host and manage their own data which will then be collated into a central database (see Table 1).

Analytical Approach

Online survey

The survey data will be downloaded from Qualtrics software and further cleaned by removing the entries with more than 50% missing data. The primary outcome variables will

primarily be presented using descriptive statistics and expressed in terms of frequencies, averages, and proportions. Secondary outcome variables measuring psychosocial wellbeing will be expressed primarily in terms of average scale scores, and categorised (e.g., high, medium, low, etc.) based on recommended cut-offs (if relevant). Other secondary outcomes will be presented descriptively in terms of frequencies and proportions. Aggregated comparisons between countries will be made by grouping them based on policy responses by governments and the difference in outcomes between them will be measured using t-tests, ANOVA, or chi-square tests. We will also undertake sub-group analyses of the outcomes, subject to responses being sufficient, examining sociodemographic characteristics such as geographical location (e.g., urban, rural, remote) and location of birth (e.g., public vs. private hospital vs. home birth). For the bereavement-specific surveys, we will also examine early vs. late neonatal death and occurrence of best practice perinatal bereavement care practices. [23] Inferential analyses of explanatory factors influencing the outcome variables will be carried out via multivariable linear and logistic regression.

Nested Qualitative Interview Study

Methods

Several COCOON country co-ordinating 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 die 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 (defined as after 14 weeks, but before the country-specific cut-offs for stillbirth e.g., ≥20 weeks in Australia; ≥24 weeks in the UK; etc.), 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 Sub-Committee [ref:- 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 (e.g., 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 leave their contact details to be contacted to participate in a qualitative interview. All qualitative interviews will be conducted by researchers in each country co-ordinating centre, with oversight provided by the PUDDLES Chief Investigator and the UK co-ordinating 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 video-conferencing 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 to make an assessment of the country-specific experiences. Subsequently, the entire PUDDLES Global dataset, comprised of seven countries' data, will be subject to a secondary Thematic Framework Analysis to identify and interpret important inter-country patterns across the dataset. 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. [42] 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. [6,43] 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. The COCOON study will help identify the needs of parents globally and provide 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. [44–46] 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 surveys conducted during the pandemic to explore parent experiences of bereavement care and the psychosocial impacts of COVID-19. Understanding current practices in maternity and neonatal settings, both locally and globally, 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, 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 (i.e., timing of peaks and subsequent waves) and public health responses (e.g., lockdowns, border closures) and available health services which have varied globally. Second, 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. [47] Despite such selection bias, the study will provide key insights and information that should be integrated into pandemic response.

The care parents receive during pregnancy and postpartum, including the care received following stillbirth or neonatal death, has important implications for immediate and longer-term wellbeing. Given the emerging evidence of negative impacts of COVID-19 on the health and wellbeing 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.

Figure legend:

Figure 1 – Schematic depiction of participant flow through COCOON study.

Involvement of parents and families: The ISA network and the Stillbirth CRE as its Western Pacific regional office are committed to ensuring that the voices of parents who have experienced the tragedy of stillbirth are heard. Effective and meaningful parent engagement in all Stillbirth CRE research projects is facilitated by the Stillbirth Foundation Australia, as an integral partner of the Stillbirth CRE, and through partnerships with other parent support and advocacy organisations such as Still Aware, Bears of Hope, Red Nose/Sands Australia, Women's Healthcare Australasia, and others. Similarly, parent support and advocacy organisations in other COCOON collaboration countries have also been promoting the study through their communication channels (see acknowledgements and appendix for details).

Study status: The first participant of the study was enrolled on 13 May 2020 in Australia. In the twelve months after the recruitment first began (13 May 2021), 5,668 pregnant and 8,562 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.

Collaboration (listed alphabetically by surname): Joycelyn Abiog-Filoteo, Neelam Aggarwal, Roberto Bonaiuti, Billie Bradford, Belinda Buenafe, Robin Cronin, Rakhi Dandona, Joanne Durham, Abigail Easter, Sanne Gordijn, Mechthild M. Gross, , Rebecca Guarino, Wendy Hall, Katharina Hartmann, Guilherme de Jesus, Inderjeet Kaur, Joemer Calderon Maravilla, Lesley McCowan, Lucila Castanheira Nascimento, Alonkone Phengsvanh, Wilfredo Quijencio Jr, Larissa Rossen, Jessica Ruidiaz, Vanphanom Sychareun, Alma Taragua, Sowmya Thota, Fatima Vera.

Acknowledgements: We gratefully acknowledge all parents who participated in this study and shared their personal experiences of pregnancy and birth during the COVID-19 pandemic to help improve future care for families around the world. We would like to thank all organisations and partners that promoted this study (listed in appendix).

We would also like to acknowledge the contribution of the following colleagues (listed alphabetically by surname): Christine Andrews, Naiara Barros Polita, Hannah Blencowe, Kia-Chong Chua, Sara Crocker, Miranda Davies-Tuck, Willyane de Andrade Alvarenga, Julie Dean, Madeline Forbes, Adrienne Gordon, Alison Griffin, Cameron Paul Hurst, Rafat Jan,

Sailesh Kumar, James Locher, Philippa Middleton, Laura Mosconi, Christine Ou, Mira Pflanz, Tosin Popoola, Valdo Ricca, Janet Scott, Laura Singline, Jet van der Hulst, Jane Warland, Megan Weller.

Funding: This study is funded by Investigator Flenady and Mater Research Institute, University of Queensland, Brisbane Australia. Silverio & Sandall (King's College London) are supported by the National Institute for Health Research Applied Research Collaboration South London [NIHR ARC South London] at King's College Hospital NHS Foundation Trust. Silverio is also in receipt of a Personal Doctoral Fellowship Award from the NIHR ARC South London Capacity Building Theme; and Sandall is also supported by NIHR Senior Investigator Awards. The views expressed are those of the authors and not necessarily those of the funders. The training and infrastructure of the PUDDLES Global Collaboration on Perinatal Bereavement is supported by the King's College London Global Engagement Partnership Fund successfully awarded to Silverio[ref:- PF2021_Mar_039].

Ethics approval: This study was approved by the Mater Misericordiae Ltd 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. Local ethics committee approvals in participating countries have been granted as required.

Authors' contributions: VF and CH conceived the study. SL led the development of the study protocol with RG, SAS, FB, JC, VF, CH, DH, SHL, FM, MM, KO, PQ, CR, CS, JS, AV, AW. All co-authors listed in the COCOON collaboration participated in the development and design of the COCOON study for their country co-ordinating centre. SL and RG drafted the manuscript with SAS, FB, DE, and VF. All co-authors have contributed to the revision of the first draft and have approved the final manuscript.

Conflict of interest: The authors declare that they currently have no competing interests.

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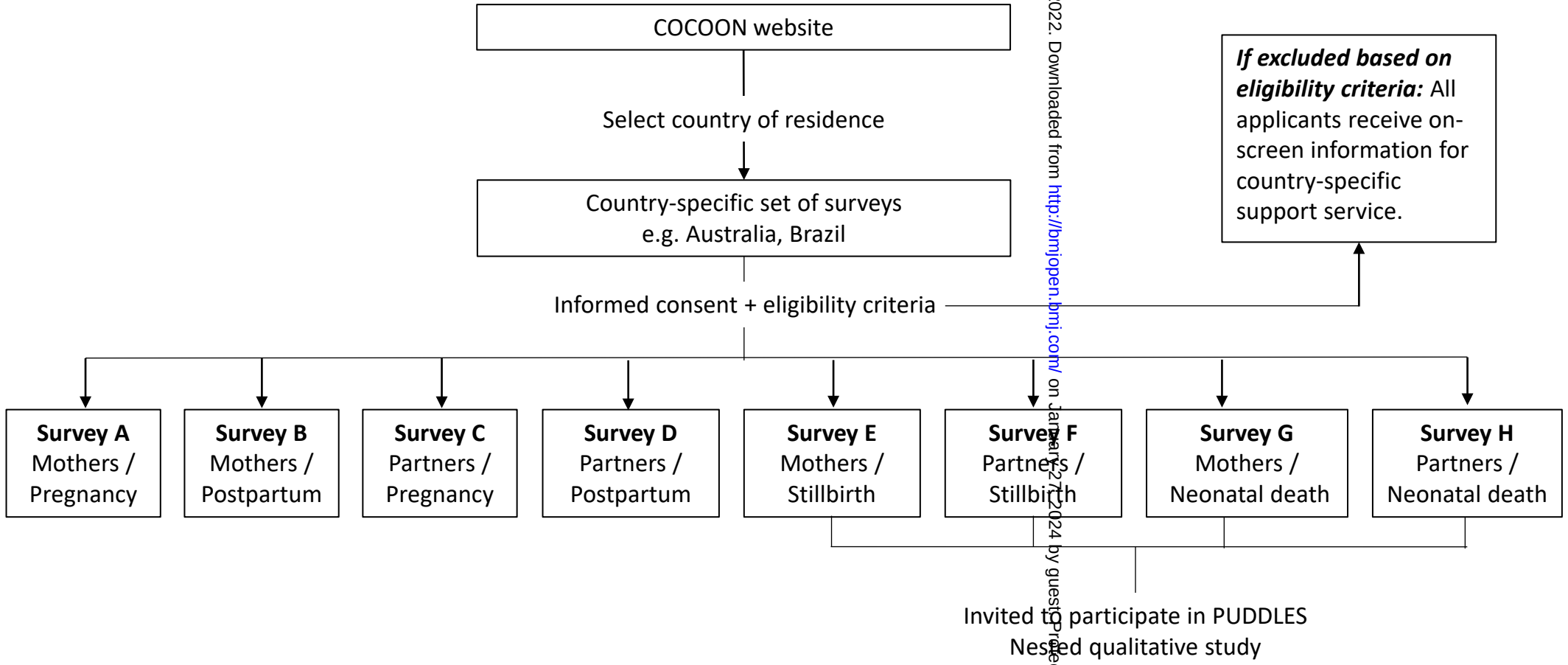

Figure 1. Schematic depiction of participant flow through COCOON study.

Appendix. COCOON country coordinating centres and partners

Country	Coordinating Centre/s	Academic and organisation partners
Argentina	• Era En Abril, Buenos Aires	• International Stillbirth Alliance (ISA)
Australia	• NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland (MRI-UQ), Brisbane, Queensland; Australasian Regional Office of the International Stillbirth Alliance (ISA)	• Burnet Institute, Melbourne • Stillbirth Foundation Australia • Red Nose / Sands • Bears of Hope • Raising Children's Network
Brazil	• Hospital Universitário Pedro Ernesto • University of São Paulo, Ribeirão Preto College of Nursing	• Do luto à luta: Apoio à Perda Gestacional e Neonatal • SobreViver: Apoio à Perda Gestacional ou do Recém-Nascido
Canada	• Paternite Famille et Societe, University of Quebec • The University of British Columbia, Vancouver Canada	• International Stillbirth Alliance (ISA)
Germany	• Hannover Medical School • Mother Hood e.V.	• Schatten & Licht e.V. • Hope's Angels • Telefonseelsorge • Verein Pusteblume • Kindsverlust.ch
India	• Public Health Foundation of India, Gurugram	• International Stillbirth Alliance (ISA)

	• Post Graduate Institute of Medical Education & Research (PGIMER) Chandigarh • Fernandez Hospital Educational & Research Foundation, Hyderabad	
Ireland	• Pregnancy Loss Research Group, INFANT Research Centre, University College Cork	• International Stillbirth Alliance (ISA)
Italy	• Ciao Lapo Foundation • Perinatal Research Laboratory (PeaRL), University of Florence, NEUROFARBA	• International Stillbirth Alliance (ISA)
Laos	• University of Health Sciences: Faculty of Medical Sciences, Vientiane, Lao People's Democratic Republic	• Queensland University of Technology (QUT)
Netherlands	• University Medical Center, Groningen	• Kenniscentrum Stille levens • Steunpunt Nova
New Zealand	• Te Herenga Waka Victoria University of Wellington • University of Auckland	• Sands • SIDS and Kids NZ
Philippines	• Far Eastern University • Filipino Nursing Diaspora Network	•
Spain	• Umamanita Foundation, Girona	• El Parto es Nuestro • La Leche League International
UK	• Department of Women & Children's Health, School of Life Course & Population Sciences, King's College London	• International Stillbirth Alliance (ISA) • Tommy's

		• Sands • The Lily Mae Foundation
US	• NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland (MRI-UQ), Brisbane, Queensland; Australasian Regional Office of the International Stillbirth Alliance (ISA)	• Star Legacy • Miss Foundation • First Candle

Note: Countries ordered alphabetically.

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-061550.R1
Article Type:	Protocol
Date Submitted by the Author:	19-Jun-2022
Complete List of Authors:	Loughnan, Siobhan; The University of Queensland, NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Gautam, R.; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Silverio, Sergio; King's College London, Department of Women & Children's Health; University College London, Elizabeth Garrett Anderson Institute for Women's Health Boyle , Frances; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland; Institute for Social Science Research, University of Queensland Cassidy, J.; Umamanita Ellwood, David; Griffith University, School of Medicine; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Homer, Caroline ; Burnet Institute Horey, Dell; La Trobe University, Public Health Leisher, Susannah; International Stillbirth Alliance demontigny, Francine; Paternite Famille et Societe, University of Quebec Murphy, Margaret; University College Cork National University of Ireland, Nursing and Midwifery O'Donoghue, Keelin; Dept. of Obstetrics and Gynaecology, University College Cork Quigley, P.; International Stillbirth Alliance; DAI Global Health Ravaldi, Claudia; University of Florence; CiaoLapo Foundation for Perinatal Health Sandall, Jane; Kings College, London, Health and Social Care Research Division Storey, Claire; International Stillbirth Alliance Vannacci, Alfredo; University of Florence, NEUROFARBA; CiaoLapo Foundation for Perinatal Health Wilson, Alyce; Burnet Institute, International Development Flenady, Vicki; NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland Collaborator group, COCOON Global Collaboration ; Collaborator group
Primary Subject Heading:	Public health

Secondary Subject Heading:	Global health, Mental health, Obstetrics and gynaecology, Health services research
Keywords:	COVID-19, PERINATOLOGY, PSYCHIATRY, OBSTETRICS, PUBLIC HEALTH

Study title: A multi-country 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 wellbeing. 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 inter-country comparison) to gain further insights into their experiences.

Ethics and dissemination

Ethics approval for the multi-country online survey: COCOON, has been granted by the Mater Misericordiae Ltd Human Research Ethics Committee in Australia (ref: 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 Sub-Committee [ref: HR-19/20-19455] in the UK. Local ethics committee approvals 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 multi-country 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 (e.g., lockdowns and border closures).

Keywords

COVID-19, pandemic, parents, pregnancy, postpartum, stillbirth, neonatal death, service delivery

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 breastfeeding, 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 have 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- and long-term adverse outcomes for both the mother and infant (e.g., 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] Pre-pandemic, sub-standard 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 health care are known to have worsened the standard of care in many instances, leading potentially to an increase in many preventable losses of lives.[9] Pre-pandemic, research has shown healthcare professionals often feel underprepared and unable to provide needed support to parents following the death of their baby including parent-centred care plans, and bereavement-specific practices (e.g., opportunities for parenting activities such as seeing and holding their baby, bathing, and

dressing their baby, creating memories e.g., 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 world-wide, 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 (e.g., labour and birth practices) including the support services available (both formal and informal), and public health limitations (e.g., visitors to hospital, presence of partners during prenatal care and childbirth); and how these vary across countries, hospital settings, and geographical locations (i.e., 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 postpartum.
- preventive measures taken by parents to protect themselves and others against COVID-19 (e.g., decreased health service utilisation).

Methods

Study design and setting

The *multi-country '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 co-ordinated and managed by the 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 co-ordinating centre (see Table 1). Ethics approval for this research project (reference number AM/MML/63526) has been granted by the Mater Misericordiae Ltd Human Research Ethics Committee in Australia and all processes within this study are compliant with Australia's National Statement on Ethical Conduct in Human Research and reflect international guidance on ethical principles, with country-specific ethics and governance approval gained, where required.

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)

Country	Language	Mode	Survey Administration Period	COCOON Survey								PUDDLES Nested Qualitative Study
				Pregnancy/postpartum				Bereavement				
				A	B	C	D	E	F	G	H	
Australia	English	Online	May 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
UK	English	Online	July 2020 – Jan 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
Italy	Italian	Online	July 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
US	English	Online	July 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Quebec, Canada	French	Online*	July 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	N/A	N/A	▲
Ireland	English	Online	Sept 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Spain	Spanish	Online	Oct 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A

Brazil	Portuguese	Online	Oct 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
India (North)	Hindi	Face-to-face/ Telephonic*	Oct 2020 – Oct 2021	▲	▲	N/A	N/A	▲	N/A	N/A	N/A	▲
Germany	German	Online	Nov 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
India (South)	Telugu	Online*	Dec 2020 – Oct 2021	▲	▲	N/A	N/A	N/A	N/A	N/A	N/A	
Netherlands	Dutch	Online	May 2021 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	N/A
New Zealand	English	Online	May 2020 – Oct 2021	▲	▲	▲	▲	▲	▲	▲	▲	▲
Vancouver, Canada[a]	English	Online	April 2021 – May 2022	N/A	N/A	N/A	N/A	▲	▲	▲	▲	N/A
Argentina	Spanish	Online	Sept 2021 – May 2022	▲	▲	▲	▲	▲	▲	▲	▲	N/A
Laos	Lao	Face-to-face*	May 2022 – July 2022	▲	▲	N/A	N/A	▲	▲	N/A	N/A	
Philippines	English Filipino	Online and Face-to-face	July 2022 – Dec 2022	▲	▲	▲	▲	▲	▲	▲	▲	N/A

Notes. *hosting and management of own data in country; A=Pregnant women; B=Postpartum women; C=Partners of Pregnant Women; D=Partners of Postpartum Women; E=Mothers following stillbirth; F=Mothers following Neonatal Death; G=Partners following stillbirth; H=Partners following Neonatal Death; N/A=Not applicable/this aspect of the study is/was not being implemented.

Patient and Public Involvement

Patients and/or public were not expressly involved in the design or conduct of the current study.

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 experienced a stillbirth; (F) mothers who experienced a neonatal death; (G) partners who experienced a stillbirth; 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 (de Montigny), Ireland (Murphy, O'Donoghue), Italy (Ravaldi, Vannacci), Spain (Cassidy), UK (Silverio, Sandall), and the International Stillbirth Alliance (Leisher, Storey, Quigley). 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 between approximately 70 and 115 open- and closed-ended questions across four main sections (see Table 2). Closed-ended questions 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 co-ordinating centres which joined the COCOON collaboration reviewed the core set of survey items for each survey before minor contextual changes were made around terminology (e.g. 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 to 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.

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 (e.g., primary care provider; setting; gestation)	✓	✓	✓	✓	✓	✓	✓	✓
Postpartum and follow-up care (e.g., breastfeeding)		✓		✓				
Elements of quality, respectful care (e.g., shared decision-making)	✓	✓	✓	✓	✓	✓	✓	✓
Impact of COVID-19 pandemic (e.g., changes to care provider and mode of delivery; changes to birth plan)	✓	✓	✓	✓	✓	✓	✓	✓
Quality of care (e.g., satisfaction)	✓	✓	✓	✓	✓	✓	✓	✓
1a) Bereavement-specific care experiences								
Pregnancy, labour and birth, neonatal, postpartum and follow-up care (e.g., 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 (e.g., opportunity to spend time with baby; creation of memories such as photos)					✓	✓	✓	✓
Investigations including autopsy or post-mortem examination (e.g., counselling; investigations received) and care around understanding the reasons behind their baby's death					✓	✓	✓	✓
2) Psychosocial outcomes								
Impact of COVID-19 (e.g., 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 – SLS	✓	✓	✓	✓	✓	✓	✓	✓
Perinatal grief – PGS-SF					✓	✓	✓	✓
3) Satisfaction with COVID-19 information								
Helpfulness of information	✓	✓	✓	✓	✓	✓	✓	✓
Sources of trusted information	✓	✓	✓	✓	✓	✓	✓	✓
4) Sociodemographic characteristics								
Demographic characteristics (e.g., age, education level, employment status)	✓	✓	✓	✓	✓	✓	✓	✓
Mental and physical health conditions	✓	✓	✓	✓	✓	✓	✓	✓
Family and domestic violence	✓	✓	✓	✓	✓	✓	✓	✓
COVID-19 status (e.g., diagnostic, isolation)	✓	✓	✓	✓	✓	✓	✓	✓

Notes. A=Pregnant women; B=Postpartum women; C=Partners of Pregnant Women; D=Partners of Postpartum Women; E=Mothers following stillbirth; F=Mothers following Neonatal Death; G=Partners following stillbirth; H=Partners following Neonatal Death.

Procedures

Inclusion criteria

This study will recruit women aged over 18 years of age, who were pregnant or gave birth to their baby during the COVID-19 pandemic, including women who experienced stillbirth (i.e., baby died before birth, during pregnancy or labour) or neonatal death (i.e., 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 the 30 January 2020 onwards when it was declared a Public Health Emergency of International Concern (PHEIC) by the World Health Organisation (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 (e.g., 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.[1]

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 postpartum; (2) partners of women who are pregnant or postpartum; (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 (e.g., newsletters) through each co-ordinating 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 (e.g., obstetricians, midwives), referral by practitioners/service providers in local service settings and advocate groups (snowball sampling). Each COCOON co-ordinating centre has in-country partnerships with parent organisations, maternal healthcare services, and parent bereavement organisations (see appendix). 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.

[1]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).

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; 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, webpages, e-mail addresses, and contact numbers).

<Insert Figure 1 Here>

The time required for each COCOON survey completion is approximately 30-35 minutes. 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 wellbeing 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 (e.g., 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 outcomes measures (see Table 2).

Anxiety. The *State-Trait Anxiety Inventory for Adults (STAI)* consists of two 20-item subscales assessing state and trait anxiety.[34] Items from both the state subscale (e.g., "I am tense"; "I feel indecisive") and trait subscale (e.g., "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 – Research Short Form – for use in global Crises (PSAS-RSF-C)* 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 (e.g., "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 seven days.[45] Items (e.g., 'I feel sad or miserable') are rated on a scale from 0 (e.g., Not at all) to 3 (e.g., Yes, most of the time) with a maximum total score of 30 (>12 indicative of possible depression).[2] 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

[2]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.

overloaded during the past month.[54] Items (e.g., "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* (SLS) consists of six items to assess loneliness [62] which is an indicator of social wellbeing and pertains to the feeling of missing an intimate relationship (emotional loneliness) or missing a wider social network (social loneliness). Items (e.g., "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 consist of 33 items to assess behavioural and affective symptoms of grief and symptoms specific to perinatal death. Items (e.g., "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 postpartum 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 (e.g., age). Several multiple choice and Likert items were also developed to assess COVID-19 status (e.g., diagnostic; isolation; availability of testing)

and personal measures taken by participants to protect and prevent the spread of COVID-19 (e.g., 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 co-ordinated and managed by the Centre of Research Excellence in 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 co-ordinating 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 dataset including all surveys. We will analyse and report findings for two groups: (1) Pregnancy and postpartum (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 wellbeing will be expressed primarily in terms of average scale scores, and categorised (e.g., 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 (e.g., urban, rural, remote) and location of birth (e.g., 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, ANOVA, chi-square or Fisher's exact tests. 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 (OxCGRT) dataset available online (https://ourworldindata.org/coronavirus) and provides a COVID-19: Stringency Index.[73]

Nested Qualitative Interview Study

Methods

Several COCOON country co-ordinating 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 Sub-Committee [ref:- 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 (e.g., 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 leave their contact details to be contacted to participate in a qualitative interview. All qualitative interviews will be conducted by

researchers in each country co-ordinating centre, with oversight provided by the PUDDLES Chief Investigator and the UK co-ordinating 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 video-conferencing 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 dataset, comprised of participating countries' data, will be subject to a secondary Thematic Framework Analysis [78,79] to identify and interpret important inter-country patterns across the dataset. 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 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 (i.e., timing of peaks and subsequent waves) and public health responses (e.g., 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 (e.g. Italian) was completed by each countries 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 postpartum, including the care received following stillbirth or neonatal death, has important implications for immediate and longer-term wellbeing. Given the emerging evidence of negative impacts of COVID-19 on the health and wellbeing 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 Ltd 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 Sub-Committee [ref: 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 (PGIMER) 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 (FEU-NRMF) Institutional Ethics Review Committee; Spain: The University of Alicante Research Ethics Committee; United Kingdom; King's College London Biomedical and Health Sciences, Dentistry, Medicine and Natural and Mathematical Sciences Research Ethics Sub-Committee. Results will be submitted for publication in international peer-reviewed journals and through parent support organisations.

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Figure legend:

Figure 1 – Schematic depiction of participant flow through COCOON study.

Involvement of parents and families: The ISA network and the Stillbirth CRE as its Western Pacific regional office are committed to ensuring that the voices of parents who have experienced the tragedy of stillbirth are heard. Effective and meaningful parent engagement in all Stillbirth CRE research projects is facilitated by the Stillbirth Foundation Australia, as an integral partner of the Stillbirth CRE, and through partnerships with other parent support and advocacy organisations such as Still Aware, Bears of Hope, Red Nose/Sands Australia, Women's Healthcare Australasia, and others. Similarly, parent support and advocacy organisations in other COCOON collaboration countries have also been promoting the study through their communication channels (see acknowledgements and appendix for details).

Study status: The first participant of the study was enrolled on 13 May 2020 in Australia. In the twelve months after the recruitment first began (13 May 2021), 5,668 pregnant and 8,562 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.

Collaboration (listed alphabetically by surname): Joycelyn Abiog-Filoteo, Neelam Aggarwal, Roberto Bonaiuti, Billie Bradford, Belinda Buenafe, Sara Crocker, Robin Cronin, Rakhi Dandona, Joanne Durham, Abigail Easter, Madeline Forbes, Alison Griffin, Sanne Gordijn, Mechthild M. Gross, Rebecca Guarino, Wendy Hall, Katharina Hartmann, Guilherme de Jesus, Inderjeet Kaur, Joemer Calderon Maravilla, Lesley McCowan, Lucila Castanheira Nascimento, Alonkone Phengsvanh, Wilfredo Quijencio Jr, Larissa Rossen, Jessica Ruidiaz, Vanphanom Sychareun, Alma Taragua, Sowmya Thota, Fatima Vera.

Acknowledgements: We gratefully acknowledge all parents who participated in this study and shared their personal experiences of pregnancy and birth during the COVID-19 pandemic to help improve future care for families around the world. We would like to thank all organisations and partners that promoted this study (listed in appendix).

We would also like to acknowledge the contribution of the following colleagues (listed alphabetically by surname): Christine Andrews, Naiara Barros Polita, Hannah Blencowe, Kia-Chong Chua, Miranda Davies-Tuck, Willyane de Andrade Alvarenga, Julie Dean, , Adrienne Gordon, Cameron Paul Hurst, Rafat Jan, Sailesh Kumar, James Locher, Philippa Middleton, Laura Mosconi, Christine Ou, Mira Pflanz, Tosin Popoola, Valdo Ricca, Janet Scott, Laura Singline, Jet van der Hulst, Jane Warland, Megan Weller.

Authors' contributions: VF and CH conceived the study. SL led the development of the study protocol with RG, SAS, FB, JC, VF, CH, DH, SHL, FM, MM, KO, PQ, CR, CS, JS, AV, AW. All co-authors listed in the COCOON collaboration participated in the development and design of the COCOON study for their country co-ordinating centre. SL and RG drafted the manuscript with SAS, FB, DE, and VF. All co-authors have contributed to the revision of the first draft and have approved the final manuscript.

Funding: This study is funded by Investigator Flenady and Mater Research Institute, University of Queensland, Brisbane Australia. Silverio & Sandall (King's College London) are supported by the National Institute for Health Research Applied Research Collaboration South London [NIHR ARC South London] at King's College Hospital NHS Foundation Trust.

Silverio is also in receipt of a Personal Doctoral Fellowship Award from the NIHR ARC South London Capacity Building Theme; and Sandall is also supported by NIHR Senior Investigator Awards. The views expressed are those of the authors and not necessarily those of the funders. The training and infrastructure of the PUDDLES Global Collaboration on Perinatal Bereavement is supported by the King's College London Global Engagement Partnership Fund successfully awarded to Silverio[ref:- PF2021_Mar_039].

Competing interests: The authors declare that they currently have no competing interests.

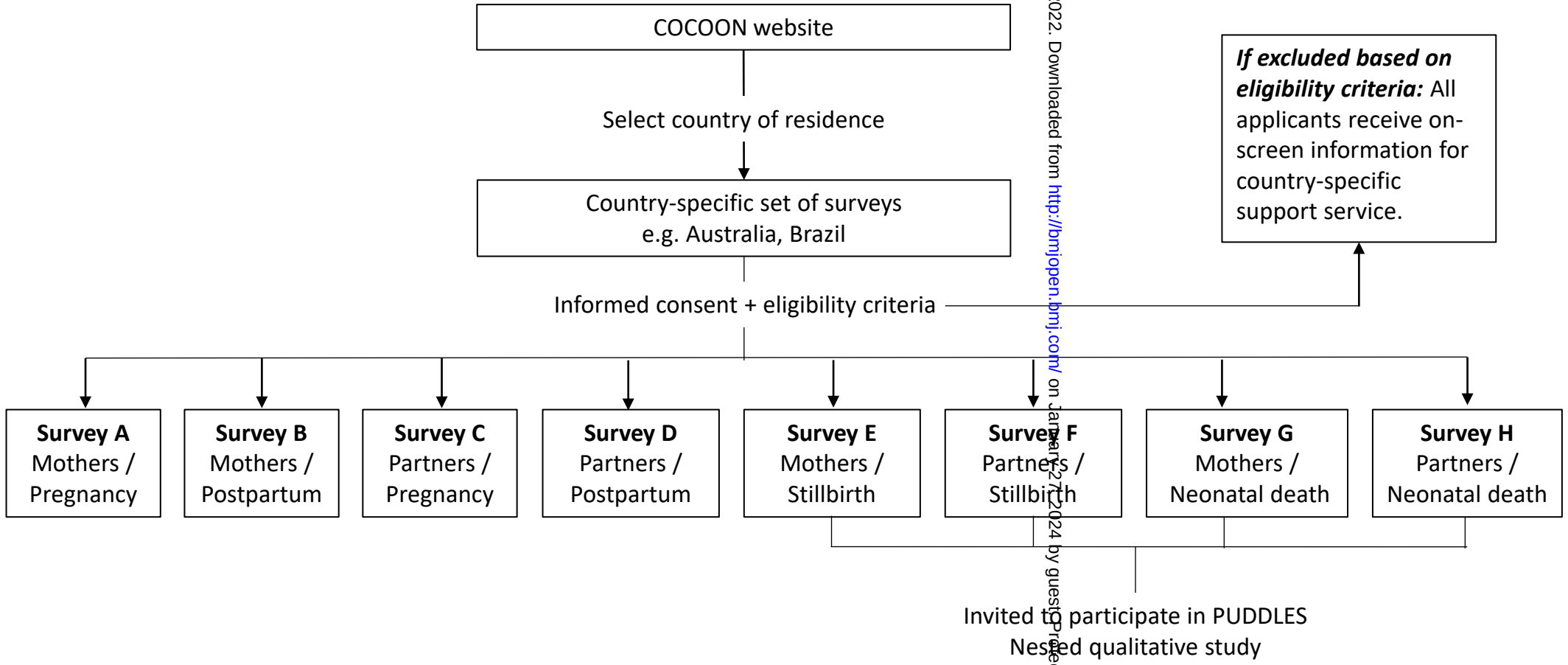

Figure 1. Schematic depiction of participant flow through COCOON study.

Appendix. COCOON country coordinating centres and partners

Country	Coordinating Centre/s	Academic and organisation partners
Argentina	• Era En Abril, Buenos Aires	• International Stillbirth Alliance (ISA)
Australia	• NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland (MRI-UQ), Brisbane, Queensland; Australasian Regional Office of the International Stillbirth Alliance (ISA)	• Burnet Institute, Melbourne • Stillbirth Foundation Australia • Red Nose / Sands • Bears of Hope • Raising Children's Network
Brazil	• Hospital Universitário Pedro Ernesto • University of São Paulo, Ribeirão Preto College of Nursing	• Do luto à luta: Apoio à Perda Gestacional e Neonatal • SobreViver: Apoio à Perda Gestacional ou do Recém-Nascido
Canada	• Paternite Famille et Societe, University of Quebec • The University of British Columbia, Vancouver Canada	• International Stillbirth Alliance (ISA)
Germany	• Hannover Medical School • Mother Hood e.V.	• Schatten & Licht e.V. • Hope's Angels • Telefonseelsorge • Verein Pusteblume • Kindsverlust.ch
India	• Public Health Foundation of India, Gurugram	• International Stillbirth Alliance (ISA)

	• Post Graduate Institute of Medical Education & Research (PGIMER) Chandigarh • Fernandez Hospital Educational & Research Foundation, Hyderabad	
Ireland	• Pregnancy Loss Research Group, INFANT Research Centre, University College Cork	• International Stillbirth Alliance (ISA)
Italy	• Ciao Lapo Foundation • Perinatal Research Laboratory (PeaRL), University of Florence, NEUROFARBA	• International Stillbirth Alliance (ISA)
Laos	• University of Health Sciences: Faculty of Medical Sciences, Vientiane, Lao People's Democratic Republic	• Queensland University of Technology (QUT)
Netherlands	• University Medical Center, Groningen	• Kenniscentrum Stille levens • Steunpunt Nova
New Zealand	• Te Herenga Waka Victoria University of Wellington • University of Auckland	• Sands • SIDS and Kids NZ
Philippines	• Far Eastern University • Filipino Nursing Diaspora Network	•
Spain	• Umamanita Foundation, Girona	• El Parto es Nuestro • La Leche League International
UK	• Department of Women & Children's Health, School of Life Course & Population Sciences, King's College London	• International Stillbirth Alliance (ISA) • Tommy's

		• Sands • The Lily Mae Foundation
US	• NHMRC Centre of Research Excellence in Stillbirth, Mater Research Institute-University of Queensland (MRI-UQ), Brisbane, Queensland; Australasian Regional Office of the International Stillbirth Alliance (ISA)	• Star Legacy • Miss Foundation • First Candle

Note: Countries ordered alphabetically.

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Pg No	Line No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2	45
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2	35-64
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4,5	83-125
Objectives	3	State specific objectives, including any prespecified hypotheses	5 18	128-142 385-390
Methods				
Study design	4	Present key elements of study design early in the paper	5-6 (online survey) 18 (qualitative nested study)	144-157 383-403
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6 7-8 18-19 (qualitative study)	144-157 160-164 405-415
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	12-14, 18-19 (qualitative study)	205-268 405-415
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-11 14-17	168-203 270-349
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	14	250-268
Bias	9	Describe any efforts to address potential sources of bias	20	474-479
Study size	10	Explain how the study size was arrived at	13-14	246-248
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	17	359-381
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	17 19	359-381 417-433
		(*b*) Describe any methods used to examine subgroups and interactions	17	369-372
		(*c*) Explain how missing data were addressed	17	359-381
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	Not applicable (N/A)	N/A

		(e) Describe any sensitivity analyses	N/A	N/A
Results				
n/a	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A	N/A
		(b) Give reasons for non-participation at each stage	N/A	N/A
		(c) Consider use of a flow diagram	N/A	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N/A	N/A
		(b) Indicate number of participants with missing data for each variable of interest	N/A	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	N/A	N/A
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A	N/A
		(*b*) Report category boundaries when continuous variables were categorized	N/A	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A	N/A
Discussion				
Key results	18	Summarise key results with reference to study objectives	N/A	N/A
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	20	465-487
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	N/A	N/A
Generalisability	21	Discuss the generalisability (external validity) of the study results	N/A	N/A
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	33-34	827-836

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.