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TITLE

Impact of Fear and Childbirth Experience in Pregnancy and the Postpartum Period during the COVID-19 Pandemic – an International Survey: Study Protocol

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ABSTRACT

Introduction

The 2019 Coronavirus Disease (COVID-19) pandemic has caused unprecedented disruptions around the world. Adding to the existing stress surrounding pregnancy and childbirth, the threat of infection and social isolation policies may negatively impact pregnant women and new mothers. Literature on the effect of COVID-19 on fear during pregnancy and childbirth experience is limited. As the COVID-19 pandemic continues to affect the global population, it is important to understand how it has impacted pregnant women and new mothers' experience around the world in order to better inform perinatal care and interventions.

Methods and analysis

It is a multi-country study involving two countries including China and Canada which targets to recruit 1000 pregnant women and new mothers in each participating country. Participants will be recruited online in the local language through mothers' groups, and at antenatal and postnatal clinics and hospital wards. All questionnaires will be completed online. Participants' level of fear, depression, and their childbirth experiences will be assessed along with other socio-demographic, medical, and COVID-related measures. Regression models will be used to compare the outcomes among the participating countries.

Ethics and dissemination

The study has been reviewed and approved by the institutional review boards of the participating countries. The findings will be disseminated in peer-reviewed journals and academic conferences. Results from this study may guide future health guidelines and policies in face of a pandemic.

KEYWORDS

COVID-19, Maternal medicine, Obstetrics, Mental health

Strengths and limitations of the study

- The study will provide an international view of the impact of the COVID-19 pandemic on pregnant women and their childbirth experience.
- The study includes women at different stages of pregnancy and new mothers who have given birth since 2020. As a result, varying cultural perspectives on the impact of the pandemic on women at different stages of pregnancy and childbirth will be assessed.
- The cross-sectional design may limit the exploration of longitudinal changes within each community. As different regions are faced with different severity and the measures implemented to combat the pandemic varies.
- The survey is exclusively online and self-administered. All collected data may be limited to represent participants with a very low level of digital literacy and low socioeconomic status. Consequently, self-selection bias is possible.

BACKGROUND

In 2019, the outbreak of the Coronavirus Disease (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was declared a pandemic by the World Health Organization (WHO) on 11 March 2020.[1] As of 4 January 2021, over 85 million confirmed cases have been recorded globally.[2] The largest proportion of confirmed cases was recorded in the United States (24.2%), followed by India (12.1%) and Brazil (9.1%).[2] While recorded case-fatality rates varied widely across countries, a WHO report in July estimated the infection-fatality rate to be between 0.5% and 1% in the general population.[3] The pandemic has caused unprecedented disruptions and placed an immense burden on healthcare systems worldwide.

With the aim to contain the outbreak, governments worldwide have implemented a range of public health measures, including travel restrictions, mandatory quarantine, local or national lockdowns, and social distancing.[4] Many hospitals have imposed limits on the number of support persons allowed in clinic visits, including antenatal and postnatal clinic visits, and deliveries.[5] Individuals are also advised to adopt preventive measures and maintain good personal hygiene, like avoiding crowds, frequent handwashing, and wearing face coverings.[4] Based on observations from previous virus outbreaks, experts have identified pregnant women as a vulnerable group and advised them to take extra precautions.[6]

The threat of COVID-19 infection and the abrupt changes to the daily routines may have an enormous impact on pregnant women and mothers with newborns around the world. Some studies and reviews have found that pregnant women with confirmed COVID-19 infection status were more likely to suffer from severe symptoms[7] and experience postpartum complications.[8] Other studies, however, have found no evidence of negative impact on maternal and neonatal outcomes,[9] and that transmission of the virus from mothers to children is uncommon.[9 10]

Additionally, restrictive public health measures and the uncertainties surrounding the pandemic would likely adversely impact the mental wellbeing of pregnant women and new

mothers. Studies have found that the COVID-19 lockdown measures have a negative impact, specifically on women.[11] The proportion of pregnant women with depressive symptoms has increased since the pandemic.[12-14] Pregnant women have also reported increased pregnancy-related anxiety.[12 13 15] Considering that anxiety has been linked to adverse maternal and neonatal outcomes,[16] it is important to understand the impact of COVID-19 on their childbirth experience and fear pregnant and postpartum women face during the pandemic.

The COVID-19 pandemic continues to affect societies worldwide, with some countries experiencing second or third peaks of infections and imposing new mitigation measures. Many women worldwide will have to face pregnancy, childbirth, and the postpartum period under the uncertainties and different government restrictions enforced caused by the pandemic. There is, thus, an urgent need for more extensive research on the impact of the pandemic on fear and the pregnancy and childbirth experience. It could provide important information with regards to the level of fear and childbirth experiences of new mothers during the COVID-19 pandemic, and help the development of appropriate interventions and adjustments to the antenatal and postnatal care in face of a pandemic.

To our knowledge to date, there is no international study on the impact of the COVID-19 pandemic on the fear and childbirth experience in pregnant and postpartum women. In addition, how the differences in the pandemic severity and responses across countries and regions influence childbirth experience remains to be examined. This study aims to address this gap and provide important information for healthcare professionals and governments.

Aims

1. To determine the extent that pregnant women and new mothers are fearful of COVID-19
2. To assess the childbirth experiences of new mothers under COVID-19 globally

METHODS AND ANALYSIS

Study design

This study will use a cross-sectional international survey, with questionnaires available in English, Traditional Chinese, and Simplified Chinese. The survey will be available online on Qualtrics involving two countries including China and Canada.

Subjects and sampling

We seek to enroll 1000 individuals who are aged 18 years or above, in each country. Eligible individuals will be recruited by survey service providers, social media, or/and snowball sampling, whichever is/are feasible in a country. To enhance the participation rate, the first 500 participants in Hong Kong will be given a HK$50 coupon after completion.

The sample size calculation was based on estimating the prevalence of a health issue. We take the most conservative scenario of 50%, with a 5% margin of error in a 95% confidence interval. Therefore, we need at least 385 subjects in a country. To allow incomplete questionnaires, we shall target 500 pregnant women and 500 individual who have recently given birth in Hong Kong and other participating countries.

Inclusion and exclusion criteria

Individuals are included in the study if they (1) are 18 years or older, (2) pregnant or have given birth since 2020, (3) plan to or have given birth in the participating countries, (4) are able to read English, traditional Chinese or simplified Chinese, and (5) have access to the internet.

Individuals who do not meet the inclusion criteria, or due to psychological or physical reasons, will be excluded.

Data collection procedures

A webpage has been developed to allow the completion of the questionnaires online. Potential participants will be recruited via online promotions on social media and mother's groups in Hong Kong. Also, research nurses or assistants will recruit participants in

antenatal clinics or postnatal wards in public and private hospitals in Hong Kong, invite and provide them with a link to the online questionnaires.

Individuals will be screened for eligibility on the website. Eligible individuals will be invited to participate in the study. They will be shown an information sheet on the study and be asked to provide informed consent. After signing the online consent form, participants will complete the questionnaire. Each participating country will use the same survey set up in the corresponding institution licensed, Qualtrics. All of these platforms will be tested by the study team and piloted in at least ten subjects before they will be used. In addition, the survey will be promoted by snowball technique, or in social media, including Facebook, Twitter, WeChat and LinkedIn.

Outcome measures

Three key outcome measures will be collected, namely the fear associated with COVID-19 infection and adverse events, the level of fear, depressive symptoms, and the childbirth experience.

1. Fear associated with COVID-19 infection and adverse events

Participants will be asked to indicate their level of fear of their family members or themselves in infecting COVID-19, the burden of childcare provision and restrictions related to social distancing and childbirth. The rating will be ranged from 0 to 10, while a higher score means a higher level of fear, increased burden and restrictions.

2. Fear Scale

The Fear Scale was modified to assess the fear level on COVID-19 on 8 items, each rated on a 5-point Likert scale while "1" indicates "strongly disagree" and "5" indicates "strongly agree".[17] A higher total score indicates a higher fear level.

3. Depressive symptoms

The Patient Health Questionnaire-9 (PHQ-9) will be administered for assessing depressive symptoms.[18] It has been validated among the pregnant women and is highly specific for identifying women with postpartum depression.[19 20] It comprises nine items, each rated on a 4-point Likert scale. In the scale, "0" indicates "not at all" and "3" indicates "nearly every

day". A higher total score of each scale indicates a higher level of depression. A translated and validated Chinese version of the PHQ-9 was used.[21 22]

4. Childbirth experience

Childbirth Experience Questionnaire (CEQ2) will be used to assess the participants' childbirth experience [23] CEQ2 consists of 22 statements that assesses four domains of childbirth experience, i.e. own capacity, professional support, perceived safety, and participation.[23] Nineteen of the items adopt a 4 point Likert scale, with "1" indicating "totally agree" and "4" indicating "totally disagree", while the remaining three use a visual analogue scale (VAS). Higher scores indicate a better childbirth experience. CEQ2 was originally developed in English. It has been translated into traditional and simplified Chinese.

Covariates

In addition to three key outcome measures, socio-demographic data, pregnancy risk assessment questions, infant feeding practices and COVID-19-related information will also be collected. Firstly, socio-demographic information to be collected includes basic demographics, perceived social status, gestational status, and household size. Secondly, pregnancy risk assessment questions, including height, body weight, and physical and psychological health history will be asked. In addition, participants will be asked to report their breastfeeding intention and current infant feeding practices. Participants' self-perception on their knowledge of COVID-19 will be assessed. Information with regards to whether they or someone in their immediate social circle have been infected with COVID-19, their source of information, and their plans for childbirth will be also collected.

Questionnaire

The questionnaire will be self-administered online to measure the impact of the COVID-19 pandemic on the fear and childbirth experience in pregnant and postpartum women, and identify future needs or preparation for a pandemic. The developments, translation, validation and description of the questionnaire are discussed in a previous article (Lok KY,

Fong DY, Wong JY, et al., 2021. An International Survey for Assessing COVID-19's Impact on Fear and Health: Study Protocol [Unpublished work]).

The final questionnaire consisted of 9 sections: (i) socio-demographic characteristics, (ii) pregnancy risk assessment, (iii) COVID-19 status, (iv) impact of the COVID-19 pandemic, (v) COVID-19 related knowledge (vi) PHQ-9, (vii) lifestyle, (viii) fear and (ix) childbirth experience.

Planned analysis

Data will be exported from the corresponding institution licensed Qualtrics into files of excel and transported and cleaned in Stata. Records without any responses on all outcome measurements will be discarded. For each country, descriptive statistics will be used to describe the participants' characteristics, perceptions on the health impact of COVID, fear, depression, anxiety, childbirth experience and other measures. Cross-countries comparisons on outcomes will be made by univariable and multivariable regression models, with weighting adjustment with age and gender of the corresponding population[24].

All analyses will be conducted using Stata version 16 statistical software.[25] A 95% confidence interval and a $P<.05$ will be considered statistically significant.

DISCUSSION

As the severity of the COVID-19 pandemic increases, with the rising number of confirmed cases, understanding of the impact on fear and childbirth experiences remained limited in pregnant and postpartum women. To address the health-related impacts of this vulnerable population group, this study will explore the fear and childbirth experience of pregnant women and new mothers in the COVID-19 pandemic internationally. The results could provide important information on the impact of pandemic and pandemic responses on pregnant women and new mothers. It would be an important first step in understanding and addressing the unique needs of pregnant women and new mothers under different pandemic restrictions. It could help inform intervention and healthcare policy in perinatal care for women who are pregnant or have given birth recently. Moreover, the large sample size in

each country will enable significant subgroup analyses and could help inform international and local policy and strategy on COVID-19 and future pandemic response.

The inclusion of both participants who are currently pregnant and those who have recently given birth would allow for exploration on the potential difference in the impact of the pandemic on women at different stages of pregnancy and with different childbirth experience. Maternal mental health problems are an important issue and have a significant impact on the women and child health. Studies show that maternal mental health problems, including antenatal depressive symptoms,[26 27] anxiety[28] and increased stress level[29] were associated with increased risk of perinatal complications or adverse outcomes. Maternal mental health problems would also affect the child health outcomes. Studies show that maternal depression was associated with delayed child development[30] while high stress level during pregnancy was associated with children's emotional and behavioral problems.[31] Therefore, the information provided in this study would be valuable for informing the needs of the pregnant women and new mothers and providing target support to them.

The international design, additionally, allows for cross-cultural comparison and comparisons across different levels of pandemic severity and different policies in response to pandemic. Considering policies implemented often change rapidly in response to changing pandemic severity, results from this study could provide valuable insights for healthcare professionals to adjust the intervention and care strategies for pregnant women and new mothers accordingly. It would also be useful in preparation for future epidemic or pandemic response.

Despite the strengths of the study, the cross sectional design might limit the extent to which the results might be comparable for countries at vastly different stages of pandemic or pandemic responses during survey administration. With voluntary participation, it may be susceptible to self-selection bias. In addition, the survey is conducted online. Women with limited internet access may not be able to participate in this study. However, the number of smartphone users were high, which were ranged from 31.83 million to 882 million in

the participating countries,[32] which is about 60% -95% of the population. While the survey website has been developed specifically for this study and is easily navigated on all devices, this may limit the participation of individuals with a very low level of digital literacy. Additionally, the comparability of the impact in different countries may be limited by the differences not just in the severity and public health measures, but also in the difference in the healthcare system, particularly in terms of antenatal and postnatal care.

In summary, this study will represent an international survey on the impact of the COVID-19 pandemic on pregnant women and new mothers. The study will further our understanding on how the pandemic and various public health measures impact the fear and mental health status during pregnancy and the postpartum period, and the childbirth experience of women. Consequently, the findings will help us better understand the impacts of COVID-19 in comparison to other countries in this population group. The implications of these findings will help inform policy makers and healthcare professionals of the needs and better support this vulnerable group during the pandemic locally and globally.

ETHICS AND DISSEMINATION

The study has been reviewed and approved by the Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster (UW 20-490). Participation is entirely voluntary and online informed consent will be obtained from all participants. Ethical and R&D approvals have been sought and obtained in each country involved in the study, where local ethics approval is needed. Subjects will be given information online and informed consent will be taken. Only those who agree to participate in the study will start completing the survey. Respondents can withdraw from the study at any time during the survey without any consequences, all information will be kept confidential, and results will be reported in aggregate form. No personal identifiable information will be collected in order to maintain the anonymity of the participants.

The research findings will be disseminated through a strategic method. The dissemination plan will include various forms of media to reach out to a wide range of stakeholder groups

and individuals at the local, national, and international levels. This will inevitably include the use of academic media (i.e., peer-reviewed journal articles, national and international conference presentations), social media (i.e., Facebook, Instagram, Twitter, LinkedIn), print media (i.e., newspaper), broadcast media (i.e., radio, television) and community engagement activities such as community forums or stakeholder meetings to widen our reach of dissemination.

Patient and public involvement

No patient involved.

Authors' Contribution

KL and RK drafted the manuscript. KL is the principal investigator of the study and is responsible for conducting the study overall. KL, DF, EC, JW and MT conceived the study. KL, RK, HF, JW, EC, DF, MT, NS, HN contributed to the design of the study. All authors contributed to the data acquisition, critically appraised and approved the manuscript, and assume responsibility for the contents of the manuscript.

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Competing Interest

None declared.

Ethics approval

The study was approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (UW 20-490). Participants will be informed about the study via the Qualtrics cover sheet. Informed consent will be implied through the completion of the survey.

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An International Survey on Fear and Childbirth Experience in Pregnancy and the Postpartum Period during the COVID-19 Pandemic: Study Protocol

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ABSTRACT

Introduction

The 2019 Coronavirus Disease (COVID-19) pandemic has caused unprecedented disruptions around the world. Adding to the existing stress surrounding pregnancy and childbirth, the threat of infection and social isolation policies may negatively impact pregnant women and new mothers. Literature on the effect of COVID-19 on fear during pregnancy and childbirth experience is limited. As the COVID-19 pandemic continues to affect the global population, it is important to understand how it has impacted pregnant women and new mothers' experiences worldwide to inform perinatal care and interventions.

Methods and analysis

This multi-country study involving China and Canada targets to recruit 1000 pregnant women and new mothers who gave birth since 2020 in each participating country. Participants will be recruited online in the local language through mothers' groups, antenatal and postnatal clinics, and hospital wards. All questionnaires will be completed online. Participants' level of fear, depression and childbirth experience will be assessed along with other socio-demographic, medical, and COVID-related measures. Regression models will be used to compare the outcomes among the participating countries.

Ethics and dissemination

The study has been reviewed and approved by the institutional review boards of the participating countries. Findings will be disseminated in peer-reviewed journals and academic conferences. Results from this study may guide the formulation of future health guidelines and policies in the face of a pandemic.

KEYWORDS

COVID-19, Maternal medicine, Obstetrics, Mental health

Strengths and limitations of the study

- The study will provide an international view of the impact of the COVID-19 pandemic on pregnant women and their childbirth experience.
- Measuring a large sample size in each country allows researchers to conduct subgroup analysis and cross-cultural comparisons.
- The cross-sectional design may limit the exploration of longitudinal changes within each community.
- The study results may have limited generalizability as the survey is exclusively online and self-administered, limiting the representativeness of mothers with no internet access and low socioeconomic status.

BACKGROUND

In 2019, the outbreak of the Coronavirus Disease (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was declared a pandemic by the World Health Organization (WHO) on 11 March 2020.[1] As of 16 June 2021, over 176 million confirmed cases have been recorded globally.[2] The largest proportion of confirmed cases was recorded in the United States (19.0%), followed by India (16.8%) and Brazil (9.9%).[2] The case-fatality rate is approximately 2%.[2 3] The pandemic has caused unprecedented disruptions and placed an immense burden on healthcare systems worldwide.

To contain the outbreak, governments worldwide have implemented a range of public health measures, including travel restrictions, mandatory quarantine, local or national lockdowns, and social distancing.[4] Individuals are also advised to adopt preventive measures, avoid crowds and maintain good personal hygiene, such as frequent handwashing and wearing face coverings.[4] Based on observations from previous virus outbreaks, experts have identified pregnant women as a vulnerable group and advised them to take extra precautions.[5] Many hospitals have imposed limits on the number of support persons allowed in clinic visits, including antenatal and postnatal clinic visits and deliveries.[6]

The threat of COVID-19 infection and the abrupt changes to daily life may have an enormous impact on pregnant women and new mothers. Some studies and reviews have found that pregnant women with confirmed COVID-19 infection status were more likely to suffer from severe symptoms[7] and experience postpartum complications.[8] Other studies, however, have found no evidence of negative impact on maternal and neonatal outcomes,[9] and that transmission of the virus from mothers to children is uncommon.[9 10]

In addition, it is likely that the mental wellbeing of pregnant women and new mothers to be adversely affected by restrictive public health measures and the uncertainties surrounding the pandemic. Studies have found that the COVID-19 lockdown measures have a negative impact, specifically on women.[11] The proportion of pregnant women with depressive symptoms [12-14] and pregnancy-related anxiety[12 13 15] has increased since the pandemic started. As anxiety is linked to adverse maternal and neonatal outcomes,[16] it is important to understand the impact of COVID-19 on fear faced during the pandemic.

The COVID-19 pandemic continues to affect societies worldwide, with some countries experiencing second or third peaks of infections and imposing new mitigation measures. Our team has commenced an international study involving 30 countries to study the impact of the pandemic on fear and health in the general population.[17] As many women around the globe will have to face pregnancy, childbirth, and the postpartum period under uncertain circumstances, with various government restrictions enforced in response to the pandemic. There is, thus, an urgent need for more extensive research on the impact of the pandemic on pregnancy and childbirth experience. It could provide important information with regards to the level of fear and childbirth experience of new mothers during the COVID-19 pandemic and help the development of appropriate interventions and adjustments to antenatal and postnatal care in the face of a pandemic.

To our knowledge, to date, there is no international study on the impact of the COVID-19 pandemic on fear and childbirth experience in pregnant and new mothers. In addition, how the level of pandemic severity and responses across countries and regions influence childbirth experience are yet to be examined. This study aims to address this gap and provide important information for healthcare professionals and governments.

Aims

1. To assess the level of fear among pregnant women and new mothers.
2. To assess the childbirth experience of new mothers under COVID-19 internationally.

METHODS AND ANALYSIS

Study design

This study will use a cross-sectional international survey, with questionnaires available in English, traditional Chinese, and simplified Chinese. The survey will be available online on Qualtrics, accessible to mothers in China and Canada.

Subjects and sampling

The sample size calculation was based on an estimation of the prevalence of a health issue. We take the most conservative scenario of 50%, with a 5% margin of error in a 95% confidence interval. Therefore, we need to recruit at least 385 pregnant women and 385 new mothers. To ensure the number of responses collected is adequate after excluding incomplete questionnaires, we aim to recruit 500 participants from each group, i.e. 1000 individuals, in each country.

Inclusion and exclusion criteria

Individuals are included in the study if they (1) are 18 years or older, (2) are pregnant women or new mothers who have given birth since 2020, (3) plan to or have given birth in the participating countries, (4) can read English, traditional Chinese or simplified Chinese, and (5) have access to the internet. Individuals who do not meet the inclusion criteria will be excluded.

Data collection procedures

In both participating countries, a webpage has been developed to allow the completion of the questionnaires online. Individuals will be screened for eligibility on the website. Eligible individuals will be invited to participate in the study. They will be shown an

information sheet on the study and be asked to provide informed consent. After signing the online consent form, participants will complete the questionnaire. Each participating country will use the same survey set up in the corresponding institution licensed Qualtrics. All these platforms will be tested by the study team and piloted with at least ten subjects before they will be used. In addition, the survey will be promoted by snowball technique, or using social media, including Facebook, Twitter and WeChat.

Apart from the abovementioned data collection methods, potential participants will be recruited by survey service providers and promotions in mothers' groups in Hong Kong. In addition, research nurses or assistants will recruit participants in antenatal clinics or postnatal wards in public and private hospitals in Hong Kong, providing them with a link to the online questionnaire. To encourage participation, the first 500 participants in Hong Kong will be given a HK$50 coupon after completion.

Patient and Public Involvement

No patient involved.

Outcome measures

Four key outcome measures will be collected, namely fear associated with COVID-19 infection and adverse events, level of fear, depressive symptoms and childbirth experience.

1. Fear associated with COVID-19 infection and adverse events

Participants will be asked to indicate their level of fear of their family members or themselves of infecting COVID-19, the burden of childcare provision and restrictions related to social distancing and childbirth. On a scale of 0 to 10, a higher score means a higher level of fear, increased burden and restrictions.

2. Fear Scale

We adapted the eight-item Breast Cancer Fear Scale developed by Champion et al. (2004) for the present study.[18] The study instrument was originally developed to measure women's emotional responses to breast cancer. The Fear Scale was modified to assess the fear level on COVID-19 on 8 items, each rated on a 5-point Likert scale with "1" indicating "strongly disagree" and "5" indicating "strongly agree".[19] A higher total score indicates a higher fear level.

3. Depressive symptoms

The Patient Health Questionnaire-9 (PHQ-9) will be administered for assessing depressive symptoms.[20] It has been validated among pregnant women and is highly specific for identifying women with postpartum depression.[21 22] It comprises nine items, each rated on a 4-point Likert scale. In the scale, "0" indicates "not at all" and "3" indicates "nearly every day". A higher total score of each scale indicates a higher level of depression. A translated and validated Chinese version of the PHQ-9 will be used.[23 24]

4. Childbirth experience

Childbirth Experience Questionnaire (CEQ2) will be used to assess participants' childbirth experience [25] CEQ2 consists of 22 statements that assesses four domains of childbirth experience, i.e. own capacity, professional support, perceived safety, and participation.[25] 19 items adopt a 4-point Likert scale, with "1" indicating "totally agree" and "4" indicating "totally disagree", while the remaining three use a visual analogue scale (VAS). Higher scores indicate a better childbirth experience. CEQ2 was originally developed in English. It has been translated into traditional and simplified Chinese.

Covariates

In addition to the four key outcome measures, the following data will also be collected:

1. Socio-demographic information, including basic demographics, perceived social status, gestational status, and household size
2. Responses to pregnancy risk assessment questions, including height, body

weight, and physical and psychological health history

3. Participants' self-perception of their breastfeeding intention and current infant feeding practices
4. Participants' self-perception of their knowledge of COVID-19; whether they themselves or someone in their immediate social circle have been infected with COVID-19, their source of information, and plans for childbirth

Questionnaire

The questionnaire will be self-administered online to measure the impact of the COVID-19 pandemic on fear and childbirth experience in pregnant and postpartum women, and identify mothers' needs in times of a pandemic, appropriate preventive measures and pandemic response. The development, translation, validation and description of the questionnaire are discussed in the previous article[17].

The questionnaire consisted of 9 sections: (i) socio-demographic characteristics, (ii) pregnancy risk assessment, (iii) COVID-19 status, (iv) impact of the COVID-19 pandemic, (v) COVID-19 related knowledge, (vi) PHQ-9, (vii) lifestyle, (viii) fear and (ix) childbirth experience.

Planned analysis

Data will be exported from the corresponding institution licensed Qualtrics into files of Excel and transported and cleaned in Stata. Records with incomplete responses on any outcome measurements will be discarded. For each country, descriptive statistics will be used to describe the participants' characteristics, perceptions on the health impact of COVID-19, fear, depression, anxiety, childbirth experience and other measures. Cross-country data comparisons on outcomes will be made by univariable and multivariable regression models, with weighting adjustment with age of the corresponding population[26].

All analyses will be conducted using Stata version 16, a statistical software.[27] A 95% confidence interval and a *P*<.05 will be considered statistically significant.

DISCUSSION

Regardless of the rising number of confirmed COVID-19 cases, our understanding of the pandemic's impact on fear and childbirth experience of pregnant women and new mothers remains limited. Our study will explore this gap on an international scale. The inclusion of both participants who are currently pregnant and those who have recently given birth would allow us to explore the impact of the pandemic on women at different stages of pregnancy and with different childbirth experience. The results could provide important information on (1) the health-related impact of the pandemic and pandemic response on pregnant women and new mothers, and (2) the unique needs of this vulnerable population group under different pandemic restrictions, hence informing intervention and healthcare policy in perinatal care. Moreover, the large sample size in each country will enable us to conduct significant subgroup analysis and may inform international and local policy and strategy on COVID-19 and future pandemic response.

Maternal mental health problems have a significant impact on women and child health. Studies show that maternal mental health problems, including antenatal depressive symptoms,[28 29] anxiety[30] and increased stress level[31] were associated with increased risk of perinatal complications or adverse outcomes. These problems would also affect child health outcomes. Studies show that maternal depression was associated with delayed child development[32] while high stress level during pregnancy was associated with children's emotional and behavioral problems.[33] Therefore, this study would inform healthcare providers of the mental health needs of pregnant women and new mothers.

The international design, additionally, allows comparisons across different cultures, levels of pandemic severity and policy responses to the pandemic. As policies often change rapidly in response to the changing level of pandemic severity, results from this

study could provide valuable insights for healthcare professionals to adjust the intervention and care strategies for pregnant women and new mothers accordingly. It would also strengthen future epidemic or pandemic response.

The survey website specifically developed for this study may increase the accessibility of the study. Since the website can be easily navigated on all devices and the number of smartphone users in the participating countries is high - ranging from 31.83 million to 882 million,[34] accounting for about 60% -95% of the population - we should be able to reach our target population group effectively. Limited generalizability is one of the limitations of the study. The participants in China and Canada stated the provinces they live in, which will allow us to examine the association between the number of cases and the proposed outcome.

Despite the strengths of the study, the cross-sectional design might limit the extent to which the results might be comparable for countries at vastly different stages of pandemic or pandemic response during survey administration. Additionally, the comparability of the impact in different countries may be limited by the differences not just in the severity and public health measures, but also in the healthcare system, particularly antenatal and postnatal care. With voluntary participation, the responses collected may be susceptible to self-selection bias. In addition, the survey is conducted online. Women with limited internet access and a very low level of digital literacy may not be able to participate in this study.

In summary, this study will represent an international survey on the impact of the COVID-19 pandemic on pregnant women and new mothers. It will further our understanding on how the pandemic and various public health measures impact the fear and mental health status during pregnancy and the postpartum period, and the childbirth experience of women. Consequently, the findings will help us better understand the impact of COVID-19 in comparison to other countries in this population

group. The implications of these findings will inform policy makers and healthcare professionals of the needs, enabling them to better support this vulnerable group during the pandemic locally and globally.

ETHICS AND DISSEMINATION

The study has been reviewed and approved by the Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster (UW 20-490). Participation is entirely voluntary and online informed consent will be obtained from all participants. Ethical and R&D approvals have been sought and obtained in each country involved in the study, where local ethics approval is needed. Subjects will be given information online and with informed consent through the completion of the survey. Only those who agree to participate in the study will start completing the survey. Respondents can withdraw from the study any time during the data collection process without any consequences. All information will be kept confidential, and results will be reported in aggregated form. No personal identifiable information will be collected in order to maintain the anonymity of the participants.

The research findings will be disseminated through a strategic method. The dissemination plan will include various forms of media to reach out to a wide range of stakeholder groups and individuals at the local, national, and international levels. This will inevitably include the use of academic media (i.e., peer-reviewed journal articles, national and international conference presentations), social media (i.e., Facebook, Instagram, Twitter, LinkedIn), print media (i.e., newspaper), broadcast media (i.e., radio, television) and community engagement activities such as community forums or stakeholder meetings to widen our reach of dissemination.

Authors' Contribution

KL and RK drafted the manuscript. KL is the principal investigator of the study and is responsible for conducting the study overall. KL, DF, EC, JW and MT conceived the study.

KL, RK, HF, JW, EC, DF, MT, NS, HN contributed to the design of the study. JL, YH, YO and RK collected the data. All authors contributed to the data acquisition, critically appraised and approved the manuscript, and assume responsibility for the contents of the manuscript.

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Competing Interest

None declared.

Ethics approval

The study was approved by the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (UW 20-490). Participants will be informed about the study via the Qualtrics cover sheet. Informed consent will be implied through the completion of the survey.

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