

# UNIVERSIDADE ESTADUAL DE CAMPINAS FACULDADE DE CIÊNCIAS MÉDICAS

### **RACHEL ESTEVES SOEIRO**

### SAÚDE SEXUAL E REPRODUTIVA DE ADOLESCENTES E MULHERES JOVENS EM SITUAÇÃO DE VULNERABILIDADE

## SEXUAL AND REPRODUCTIVE HEALTH OF VULNERABLE ADOLESCENTS AND YOUNG WOMEN

**CAMPINAS** 

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SEXUAL AND REPRODUCTIVE HEALTH OF VULNERABLE ADOLESCENTS AND YOUNG WOMEN

Tese apresentada ao Programa de Pós-Graduação em Tocoginecologia da Faculdade de Ciências Médicas da Universidade Estadual de Campinas como parte dos requisitos exigidos para a obtenção do título de Doutora em Ciências da Saúde, área de concentração Saúde Materna e Perinatal.

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- ORCID do autor: https://orcid.org/0000-0002-5308-424X

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# COMISSÃO EXAMINADORA DA TESE DE DOUTORADO RACHEL ESTEVES SOEIRO ORIENTADORA: PROFa. DRa. MARIA LAURA COSTA DO NASCIMENTO MEMBROS TITULARES: 1. PROFA. DRA. MARIA LAURA COSTA DO NASCIMENTO 2. PROFA. DRA. ELIANA MARTORANO AMARAL 3. PROFA. DRA. CASSIA RAQUEL TEATIN JULIATO 4. DRA. SUZANNE JACOB SERRUYA 5. DRA. VANESSA BRIZUELA

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### **EPÍGRAFE**

me levanto

sobre o sacrifício

de um milhão de mulheres que vieram antes

e penso

o que é que eu faço

para tornar essa montanha mais alta

para que as mulheres que vierem depois de mim

possam ver além

(Legado, Rupi Kaur)

### **RESUMO**

**Introdução**: A saúde sexual e reprodutiva (SSR) é um componente essencial da cobertura universal de saúde, sendo influenciada por fatores socioeconômicos. Globalmente, as mulheres têm um prejuízo no cuidado em SSR devido à pobreza, falta de acesso a cuidados de saúde e baixo nível educacional. Atualmente, mais de 40 milhões de mulheres foram obrigadas a se deslocarem devido a conflitos armados, violência generalizada ou violações de direitos humanos. A pandemia de COVID-19 também impactou nos frágeis serviços de SSR.

**Objetivo**: Descrever uma visão geral da SSR em contextos de emergência e humanitários.

**Métodos**: Foram realizados quatro estudos: 1) revisão sistemática para sintetizar as evidências disponíveis sobre os desafios de saúde sexual e reprodutiva vivenciados por adolescentes e mulheres jovens em todo o mundo 2) estudo transversal para descrever as principais questões de SSR entre adolescentes e mulheres jovens venezuelanas migrantes em Boa Vista, Brasil; 3) estudo transversal para descrever o manejo de higiene menstrual (MHM) entre adolescentes e mulheres jovens venezuelanas em Boa Vista, Brasil; 4) estudo qualitativo para compreender como as gestantes/puérperas vivenciaram a suspeita ou confirmação da infecção por COVID-19 e as consequências da pandemia para elas e suas famílias.

Resultados: Na revisão sistemática (estudo 1) foram incluídos 32 estudos, realizados em 13 países (nove em países africanos), e evidenciou que adolescentes e mulheres jovens tiveram desfechos ruins em SSR: contracepção não atendida, gravidez não planejada, falta de acesso e informações sobre SSR, casamentos infantis e altas taxas de violência sexual e de gênero. No estudo 2, a média etária foi de 17,7 anos e dois terços tinham menos de 20 anos. A maioria (84,3%) vivia em situação de rua, 54,3% relataram já ter tido pelo menos um parto anterior, 9,8% estavam grávidas no momento da entrevista e 30% delas não faziam pré-natal. A principal preocupação em SSR foi a contracepção (35,3%); no entanto, 75% das entrevistadas que procuraram o serviço de saúde não conseguiram o método de sua preferência e para 90,5% não foi oferecido nenhum outro método contraceptivo. No estudo 3 foram entrevistadas 142 adolescentes, com média etária de idade média de 17,7 anos, sendo que quase metade das participantes que menstruam (46,4%) não recebeu *kits* de higiene, 61%

não podiam lavar as mãos sempre que desejavam e a maioria (75,9%) não se sentia segura para usar o banheiro. Além disso, a menstruação foi frequentemente descrita com palavras negativas. Do estudo qualitativo (estudo 4), realizado antes da disponibilidade da vacina contra COVID-19, emergiram cinco grandes temas: assistência recebida pela mulher e bebê nos serviços médicos, impacto da pandemia de COVID-19, rede de apoio, problemas relacionados a consultas e exames de prénatal e lições aprendidas.

**Conclusões**: Embora haja um número crescente de estudos sobre SSR de adolescentes e mulheres jovens, os desafios de como alcançar essa população para pesquisas e intervenções direcionadas ainda precisam ser enfrentados, especialmente após o início da pandemia de COVID-19. Existe uma necessidade urgente de uma resposta multidisciplinar e abrangente, envolvendo múltiplos stakeholders como organizações governamentais e não governamentais e parceiros privados.

**Palavras-chave**: adolescente, jovens, migrante, saúde sexual e reprodutiva, COVID-19

### **ABSTRACT**

**Introduction:** Sexual and reproductive health (SRH) is an essential component of universal health coverage (UHC), being influenced by socioeconomic factors. Globally, women do not meet their SRH needs due to poverty, lack of access to health care, and low educational attainment. Currently, more than 40 million women have been displaced due to armed conflict, widespread violence, or human rights violations. The COVID-19 pandemic has also impacted fragile services.

**Objective:** To describe an overview of SRH in emergency and humanitarian contexts.

**Methods:** Four studies were conducted: 1) a systematic review to synthesize the available evidence on the sexual and reproductive health challenges experienced by adolescents and young women around the world 2) a cross-sectional study to describe the main SRH issues among Venezuelan migrant adolescents and young women in Boa Vista, Brazil; 3) a cross-sectional study to describe the management of menstrual hygiene (MHM) among Venezuelan adolescents and young women in Boa Vista, Brazil; 4) qualitative study to understand how pregnant women/puerperal women experienced the suspicion or confirmation of COVID-19 infection and the consequences of the pandemic for them and their families.

Results: The systematic review (study 1) included 32 studies, conducted in 13 countries (nine in African countries), and evidenced that adolescents and young women had poor SRH outcomes: unattended contraception, unplanned pregnancy, lack of access to and information about SRH, child marriages, and high rates of sexual and gender-based violence (SGBV). In study 2, the mean age was 17.7 years and two-thirds were under 20 years old. The majority (84.3%) lived on the streets, 54.3% reported having had at least one previous delivery, 9.8% were pregnant at the time of the interview and 30% of them did not receive prenatal care. The main concern in SRH was contraception (35.3%); however, 75% of the interviewees who sought the health service did not get the method of their preference and for 90.5% no other contraceptive method was offered. In study 3, 142 adolescents were interviewed, with a mean age of 17.7 years, and almost half of the participants who menstruate (46.4%) did not receive hygiene kits, 61% could not wash their hands whenever they wished and most (75.9%) did not feel safe to use the bathroom. In addition, menstruation was often described with negative words. From the qualitative study (study 4), performed before

the COVID-19 vaccine was available, five major themes emerged: assistance received by the woman and baby in medical services, impact of the COVID-19 pandemic, support network, problems related to prenatal appointments and exams, and lessons learned.

**Conclusions:** Although there are a growing number of studies on adolescents and young women's SRH, the challenges of how to reach this population for targeted research and interventions still need to be addressed, especially after the onset of the COVID-19 pandemic. There is an urgent need for a multidisciplinary and comprehensive response, involving multiple stakeholders such as governmental and non-governmental organizations and

**Keywords**: adolescent, young women, migrants, sexual and reproductive health, COVID-19

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### 1. INTRODUÇÃO

### 1.1 Saúde sexual e reprodutiva de adolescentes e mulheres jovens migrantes

Em 2022, o Alto Comissariado das Nações Unidas para os Refugiados (ACNUR) estimou que cerca de 100 milhões de pessoas em todo o mundo foram forçadas a fugir de suas casas devido a conflitos armados, perseguições, violência generalizada, eventos relacionados ao clima, falta de oportunidades econômicas ou violações de direitos humanos (1). Entre elas, quase 34 milhões são meninas adolescentes e mulheres em idade reprodutiva. (2)

Adolescentes e mulheres jovens (10-24 anos) são um grupo negligenciado em contextos humanitários (3) e suas necessidades de saúde sexual e reprodutiva (SSR) permanecem negligenciadas (4). Há dificuldade de acesso a serviços de saúde (distância, desconhecimento, barreira linguística), inaptidão para atender adolescentes, falta de insumos e equipamentos médicos, além de escassez de profissionais de saúde treinados. (3–6)

Adolescentes em contextos de crises humanitárias possuem maiores taxas de gestações não planejadas, devido à falta de acesso a contraceptivos; aborto inseguro; morbidade e mortalidade maternas; infecções sexualmente transmissíveis (ISTs), incluindo o vírus da imunodeficiência humana (HIV); e violência baseada em gênero, incluindo violência doméstica e sexual (4,5,7). Além disso, tem sido descrito que essa população possui conhecimento limitado ou errôneo sobre métodos contraceptivos, infecções sexualmente transmissíveis, menstruação e gestações. (8–12)

O manejo da higiene menstrual (MHM) também é desafio adicional para adolescentes e mulheres jovens em situação de migração. Há falta de produtos de higiene, inclusive absorventes higiênicos (descartáveis ou reutilizáveis), água e sabão; acesso inadequado a banheiros seguros, limpos e privativos (adolescentes referem ter medo de ir ao banheiro devido ao risco de violência sexual), impactando a saúde e a qualidade de vida dessa população. (12–15)

Devido à vulnerabilidade a que estão expostas (insegurança social, econômica e alimentar), adolescentes em situação de migração têm maiores taxas de casamento infantil (16–18), e sexo em troca de alimentação ou produtos de higiene, aumentando o risco de desfechos ruins em saúde sexual e reprodutiva.(3,19–21)

### 1.2 Saúde Sexual e Reprodutiva e os Objetivos de Desenvolvimento Sustentável

Em 2015, os 193 países-membros das Nações Unidas adotaram por unanimidade os Objetivos de Desenvolvimento Sustentável (ODS), um conjunto de 17 metas para acabar com a pobreza, proteger o planeta e garantir que até 2030 haja equilíbrio social, econômico e ambiental. (22)

Dentre essas metas estão: a diminuição da mortalidade materna (meta 3.1), acesso a serviços abrangentes de saúde sexual e reprodutiva (meta 3.7), a erradicação do casamento infantil e da mutilação genital feminina (meta 5.3), a igualdade de gênero (meta 5.5) e a implementação de políticas de migração (meta 10.7). (23)

A pandemia de COVID-19 aumentou o desafio de atingir essas metas, colocando em risco os já frágeis serviços de saúde sexual e reprodutiva em países de baixa e média renda e em contextos humanitários. (23,24)

### 1.3 O impacto da pandemia de COVID-19 na saúde sexual e reprodutiva

Estudos apontam para o impacto negativo da pandemia de COVID-19 na saúde sexual e reprodutiva (SSR) (24–27). A reorganização dos serviços de saúde para atendimento de pacientes suspeitos ou confirmados de COVID-19, interrupções de transporte, dificuldades financeiras, redução de suprimentos médicos e de recursos humanos levou à diminuição de acesso à serviços de SSR (24). O Fundo de População das Nações Unidas estimou que a pandemia dificultou o acesso, e consequentemente, a interrupção do uso de contraceptivos de cerca de 12 milhões de mulheres, resultando em até 2,7 milhões de gravidezes indesejadas (26). Em relação aos cuidados pré e pós-natais, muitos serviços reduziram ou cessaram os atendimentos presenciais (25) de modo que patologias como hipertensão gestacional ou problemas de saúde mental deixaram de ser diagnosticadas (27). Serviços específicos presenciais de atendimento a vítimas de violência de gênero, enquanto

atendimento remoto para vítimas de violência doméstica tiveram aumento durante a pandemia de COVID-19. (24,28)

Esses impactos nos serviços de SSR foram piores em países de baixa e média renda (24,28) nos quais já havia lacunas no atendimento saúde sexual e reprodutiva, principalmente para a população de adolescentes.

Um estudo de revisão sistemática identificou que nos países de baixa e média renda houve ruptura nos serviços de atenção à saúde materna, assim como de planejamento familiar, aumento de casamentos de adolescentes e aumento da violência doméstica e comunitária para meninas e adolescentes. (28)

Estudos que abordem o impacto da pandemia de COVID-19 em contextos de emergências humanitárias são raros de modo que pouco se sabe sobre o real impacto da pandemia em relação à saúde sexual e reprodutiva nesses contextos em que há escassez de serviços de SSR.

### 2. OBJETIVOS

### **2.1. Geral**

Descrever a Saúde Sexual e Reprodutiva de adolescentes e mulheres jovens em diferentes contextos de emergência e humanitários.

### 2.2 Específicos

- 2.2.1 Rever a literatura científica para compreender quais são os desafios em relação à Saúde Sexual e Reprodutiva (SSR) de adolescentes e mulheres jovens migrantes em todo o mundo.
- 2.2.2 Identificar as principais questões em SSR de adolescentes e mulheres jovens migrantes venezuelanas em Boa Vista, estado de Roraima, Brasil.
- 2.2.3 Fornecer uma visão geral das principais questões do manejo da higiene menstrual (MHM) que afetam adolescentes e mulheres jovens migrantes venezuelanas em Boa Vista, estado de Roraima, Brasil.

2.2.4 Relatar como as mulheres gestantes e puérperas experimentaram a suspeita/investigação e ou confirmação de infecção por COVID-19 e as consequências da pandemia para essas mulheres e as suas famílias.

### 3. MÉTODO

O objetivo específico 2.2.1 corresponde à uma revisão sistemática da literatura. Os objetivos específicos 2.2.2 e 2.2.3 correspondem a mesma metodologia (quantitativa), enquanto o objetivo específico 2.2.4 corresponde a outra metodologia (qualitativa). Desta forma as metodologias serão descritas separadamente.

### 3.1 Artigo 1: Revisão sistemática da literatura

### 3.1.1 Estratégia de busca e desenho do estudo

Nesta revisão sistemática de métodos mistos buscou-se relatar os resultados descritos em saúde sexual e reprodutiva para adolescentes e jovens mulheres migrantes. O número de registro na plataforma PROSPERO é CRD42023403907 (Anexo 1).

As bases de dados utilizadas para a busca foram: PUBMED, PUBMED PMC, EMBASE, BVS/LILACS, SCOPUS. A sintaxe foi: ((Adolescent OR Adolescents OR Adolescence OR Teens OR Teen OR Teenagers OR Teenager OR Youth OR Youths OR "Adolescents, Female" OR "Adolescent, Female" OR "Female Adolescent" OR "Female Adolescents") AND (((("Health Vulnerability") OR ("Sexual Vulnerability")) OR ((Sexual Health[MeSH Terms]) OR ("Sexual Health"[Title/Abstract] OR "Health, Sexual"[Title/Abstract]))) OR ((Reproductive Health[MeSH Terms]) OR ("Reproductive OR Reproductive"[Title/Abstract])))) Health"[Title/Abstract] "Health. AND (((Refugees[MeSH Terms]) OR (Refugees[Title/Abstract] OR Refugee[Title/Abstract] OR "Political Asylum Seekers"[Title/Abstract] "Asylum Seeker, Political"[Title/Abstract] OR "Asylum Seekers, Political"[Title/Abstract] OR "Political" Asylum Seeker"[Title/Abstract] OR "Seekers, Political Asylum"[Title/Abstract] OR "Political Refugees"[Title/Abstract] OR "Political Refugee"[Title/Abstract] OR "Refugee, Political"[Title/Abstract] OR "Refugees, Political"[Title/Abstract] OR "Asylum"

Seekers"[Title/Abstract] "Asylum Seeker"[Title/Abstract] OR OR "Seeker, Asylum"[Title/Abstract] OR "Seekers, Asylum"[Title/Abstract] OR "Displaced Persons"[Title/Abstract] OR "Displaced Person"[Title/Abstract] OR "Person, Displaced"[Title/Abstract] OR "Persons, Displaced"[Title/Abstract] OR "Internally Displaced Persons"[Title/Abstract] OR "Displaced Person, Internally"[Title/Abstract] "Displaced Persons, Internally"[Title/Abstract] OR "Internally Displaced Person"[Title/Abstract])) OR ((Transients and Migrants[MeSH Terms]) OR ("Transients and Migrants"[Title/Abstract] OR "Migrants and Transients"[Title/Abstract] OR Migrants[Title/Abstract] OR Migrant[Title/Abstract])))

### 3.1.2 Critérios de elegibilidade

Estudos quantitativos, qualitativos e de métodos mistos originais que investigaram os resultados de saúde sexual e reprodutiva na perspectiva das adolescentes e mulheres jovens (10-24 anos) migrantes (definido como mulheres deslocadas, refugiadas, requerentes de asilo ou deslocadas internos), publicado até 05 de janeiro de 2023, escritos em inglês, espanhol ou francês, foram incluídos.

### 3.1.3 Critérios de exclusão

Editoriais, artigos de opinião, carta aos editores, chamada para ações, comunicações breves, protocolos, diretrizes, capítulos de livros, estudos de caso, estudos retrospectivos, anais de congressos, boletins informativos e outras resenhas foram excluídos.

### 3.1.4 Avaliação crítica

Duas revisoras independentes realizaram a triagem inicial e a seleção dos estudos, considerando o título e resumo. Os conflitos foram abordados pela coordenadora do estudo. Os textos completos foram lidos avaliando a qualidade e a adequação.

Para avaliação da qualidade dos estudos incluídos, utilizou-se a versão "*Mixed Methods Appraisal Tool (MMAT)* 2018" (29). A MMTA é uma ferramenta que inclui critérios avaliativos de pesquisa em cinco categorias metodológicas: ensaios clínicos

randomizados e controlados quantitativos; estudos quantitativos não randomizados; estudos descritivos quantitativos; estudos qualitativos e estudos de métodos mistos. Esta ferramenta foi publicada pela primeira vez em 2009 e revisada e atualizada em 2018 (30,31). A versão MMAT 2018 está disponível e pode ser descarregada gratuitamente. Para orientar a análise dos estudos, existe um manual do utilizador com um algoritmo.(29)

A última versão (2018) inclui 2 perguntas de triagem e um total de 25 critérios, divididos em cinco categorias metodológicas de acordo com os desenhos de estudo: (a) qualitativos, (b) ensaios clínicos aleatórios, (c) não aleatórios, (d) estudos descritivos quantitativos e (e) métodos mistos. Para cada categoria, existem cinco critérios principais classificados em três opções de resposta: "sim" (o critério é cumprido), "não" (o critério não é cumprido) ou "não sei dizer" (não existe informação suficiente no documento para avaliar se o critério é cumprido ou não). Os estudos com métodos mistos devem ser avaliados em ambas as categorias, qualitativa e quantitativa, e depois reavaliados para a integração de estudos quantitativos e qualitativos. A avaliação final de cada estudo depende do número de critérios que foram cumpridos para cada categoria. (30,31).

### 3.1.5 Extração e Análise de Dados

Os dados de todos os artigos incluídos foram extraídos considerando-se autores e título, ano de publicação, local do estudo, tamanho da amostra, população do estudo, idade das participantes, principais objetivos, desenho do estudo e conclusões/recomendações. Cada estudo foi avaliado de acordo com suas categorias metodológicas. Estudos de métodos mistos foram avaliados como método misto, e tiveram os componentes qualitativos e quantitativos também avaliados.

A avaliação final de cada artigo dependeu do número de critérios cumpridos para cada categoria.

### 3.2 Artigos 2 e 3: Estudo transversal

O método descrito a seguir refere-se ao estudo transversal realizado no município de Boa Vista (Roraima) com adolescentes e jovens migrantes venezuelanas. Foram analisadas variáveis categóricas e variáveis numéricas

Tal estudo originou os artigos 2 e 3 desta Tese, apresentados nos resultados.

### 3.2.1 Desenho do estudo

Esse estudo fez parte de um estudo multicêntrico intitulado "Avaliação dos serviços de saúde sexual e reprodutiva para venezuelanos nas fronteiras venezuelanas com o Brasil e a Colômbia". Como o estudo inicial excluía pacientes menores de 18 anos de idade, foi realizada uma Ementa (aprovada pelo Comitê de Ética em Pesquisa) para a inclusão de pacientes migrantes venezuelanas entre 10 e 17 anos de idade.

Realizou-se um estudo transversal, descritivo.

### 3.2.2 Critérios de inclusão:

- Idade entre 10 e 24 anos de idade
- Migrante venezuelana
- Compreensão da língua espanhola

### 3.2.3 Critérios de exclusão:

- Não compreensão dos Termo de Assentimento Livre e Esclarecido (TALE)/ Termo de Consentimento Livre e Esclarecido (TCLE)
- Não autorização por parte do responsável (quando presente) das adolescentes menores de 18 anos

### 3.2.4 Instrumento de coleta dos dados

O questionário, elaborado para este estudo, foi adaptado e traduzido para o espanhol (língua nativa da Venezuela) do Pacote de Serviço Inicial Mínimo (PSIM) para a Saúde Sexual e Reprodutiva em Situações de Crise. Essa ferramenta é

baseada na revisão de 2018 do "Manual de Campo em Ambiente de Interagências sobre Saúde Reprodutiva em Contextos Humanitários" (32) desenvolvida pelo Grupo de Trabalho Interagências (IAWG) e estabelece os serviços prioritários em SSR que devem ser estabelecidos no início de uma crise humanitária, ampliados e mantidos a fim de garantir a equidade durante crises prolongadas visando a diminuição da morbimortalidade em SSR.

O questionário, elaborado em espanhol, incluiu questões de múltipla escolha sobre características sociodemográficas (idade, etnia, coabitação, anos de estudo, emprego, renda, local de residência e informações sobre migração), número de gestações e partos, incluindo gestação atual, acompanhamento pré-natal ou pós-parto e complicações obstétricas, outras questões de SSR (desejo e uso de anticoncepcionais além de outras questões ginecológicas), disponibilidade e acesso a serviços de SSR, incluindo a satisfação das usuárias desses serviços, acesso e qualidade dos *kits* de higiene, acesso e qualidade dos banheiros.

Foi também incluída no questionário a "Menstrual Practice Needs Scale" (MPNS)(33). Essa escala foi desenvolvida após uma revisão de literatura sobre práticas menstruais em mulheres de países de baixa e média renda e foi validada em uma pesquisa piloto em Uganda (34). Ela está disponível para download e pode ser adaptada para diferentes idades e contextos. Para o estudo ela foi traduzida do inglês para o espanhol.

Houve uma questão aberta sobre a experiência pessoal das adolescentes em relação à menstruação: "Como é menstruar para você?".

### 3.2.5 Local da pesquisa

As entrevistas foram realizadas na Rodoviária de Boa Vista (abrigo informal) e na Igreja de Santo Agostinho.

Desde 2019, a Operação Acolhida do exército brasileiro é responsável pelas centenas de venezuelanos sem documentos que vivem em barracas atrás da Rodoviária de Boa Vista, fornecendo alimentação três vezes ao dia, organizando a rotina diária local (filas para banheiros, chuveiros e lavanderia) e promovendo vacinação. Entre as barracas, há alguns pontos de água não potável. Em janeiro de

2021 (momento da pesquisa), havia 1.603 venezuelanos indocumentados morando nesse local, incluindo 71 meninas adolescentes (12-17 anos).

A Igreja de Santo Agostinho oferece gratuitamente alimentação, produtos de higiene, chuveiros e uma máquina de lavar roupa com o apoio do Fundo das Nações Unidas para a Infância (UNICEF) e da Cáritas Internacional.

### 3.2.6 Tamanho amostral

Foi realizada a seleção amostral por conveniência, convidando a participar todas as adolescentes que estavam morando nas barracas na Rodoviária de Boa Vista e todas as adolescentes que compareceram à Igreja de Santo Agostinho no período em que a pesquisa foi realizada.

### 3.2.7 Coleta de dados

A coleta de dados foi realizada entre 18 e 23 de janeiro de 2021 em Boa Vista, Roraima. A coleta de dados foi realizada pela autora desta tese, devido a sua experiência prévia com trabalho humanitário e por falar e compreender espanhol.

Um total de 167 adolescentes e jovens (entre 10 e 24 anos de idade, fluentes em espanhol e alfabetizadas) foram convidadas a participar do estudo no abrigo informal na Rodoviária ou na Igreja de Santo Agostinho, 153 (93,9%; entre 12 e 24 anos) concluíram o questionário. Dez adolescentes entre 10 e 11 anos não finalizaram o questionário e quatro adolescentes não puderam participar do estudo devido à recusa de suas mães. Um número de identificação pré-definido exclusivo foi atribuído a cada participante. Toda a comunicação foi realizada em espanhol e o questionário foi autorrespondido com uma duração média de 30 minutos.

### 3.2.8 Aspectos Éticos

Esse estudo foi aprovado pelo Comitê de Ética em Pesquisa (CEP) da Universidade Estadual de Campinas (CAAE: nº 20458219.0.0000.5404) (Anexo 2). Todas as participantes maiores de 18 anos assinaram o Termo de Consentimento Livre e Esclarecido (TCLE), assim como os responsáveis das adolescentes menores de 18 anos. Todas as participantes menores de 18 anos assinaram o Termo de Assentimento Livre e Esclarecido (TALE).

Para as adolescentes menores de 18 anos desacompanhadas, obtivemos a dispensa para a exigência de que um adulto responsável assinasse o TCLE. Como são consideradas como população vulnerável, as diretrizes e normas regulamentadoras brasileiras para pesquisas envolvendo seres humanos permitem a pesquisa sem a assinatura do TCLE pelo maior de idade legalmente responsável. No entanto, todas as adolescentes (menores de 18 anos de idade) assinaram o TALE e receberam a explicação antes da entrevista.

Também obtivemos autorização do Conselho Tutelar de Roraima para entrevistar as adolescentes. (Anexo 3)

Não houve compensação financeira para as participantes.

### 3.2.9 Análise dos dados

Foi realizada a distribuição simples para variáveis numéricas (usando médias e desvios padrão, intervalo, mediana e quartis).

Para a análise da questão aberta, as respostas foram agrupadas pela frequência das palavras mais usadas e analisadas por similaridade considerando uma palavra-chave, a partir disso, foi criada uma representação visual dos resultados.

### 3.3 Artigo 4: Estudo qualitativo

### 3.3.1 Desenho do estudo

Este estudo qualitativo foi uma análise secundária do estudo da Rede Brasileira de COVID-19 em Obstetrícia (REBRACO). A REBRACO foi um estudo multicêntrico com abordagens quantitativa e qualitativa, realizado em 15 maternidades brasileiras de referência que buscou compreender o impacto da COVID-19 durante a gestação, parto e puerpério na população brasileira.

A análise qualitativa, realizada antes da disponibilidade da vacina contra COVID-19 no Brasil, objetivou investigar a experiência de gestantes e puérperas que apresentaram suspeita/investigação ou diagnóstico confirmado de infecção por COVID-19 e a experiência de seus familiares em diferentes maternidades no Brasil durante a primeira e a segunda onda da pandemia no Brasil (de agosto de 2020 a março de 2021). Foram realizadas entrevistas em profundidade e os dados foram

submetidos a análises temáticas. O manuscrito foi escrito de acordo com a lista de verificação Consolidated Criteria for Reporting Qualitative Research (COREQ). (35)

### 3.3.2 Participantes do estudo

Os centros participantes foram de quatro das cinco macrorregiões brasileiras do país (Norte, Nordeste, Sudeste e Sul), de hospitais universitários e não universitários, públicos e privados.

A seleção amostral do estudo REBRACO foi por conveniência. De primeiro de fevereiro de 2020 a 28 de fevereiro de 2021, foram convidadas a participar do estudo todas as gestantes ou puérperas com idade entre 13 e 49 anos que frequentaram as maternidades dos centros participantes com sintomas de COVID-19 (apresentando pelo menos um dos seguintes sintomas febre, tosse, falta de ar, produção de escarro, congestão nasal ou conjuntival, dificuldade para engolir, dor de garganta, coriza, saturação de O2 <95%, sinais de cianose, batimento de asa de nariz e dispneia ou outros sintomas como diarreia, anosmia e disgeusia).

No momento da admissão, as mulheres elegíveis receberam explicação sobre o estudo e, em caso de concordância, assinaram o Termo de Consentimento Livre e Esclarecido (para mulheres maiores de 18 anos e responsáveis legais por mulheres menores de 18 anos) e o Termo de Assentimento (para mulheres menores de 18 anos). Elas também foram informadas de que poderiam ser contactadas posteriormente por telefone ou mensagem de *WhatsApp* para uma entrevista em profundidade.

O estudo principal REBRACO incluiu 729 mulheres. Para o estudo qualitativo, foram selecionadas aleatoriamente três mulheres maiores de 18 anos e uma menor de 18 anos de cada centro (n=60). A equipe de pesquisa entrou em contato com essas mulheres por telefonemas ou mensagens de *WhatsApp* relembrando-as do estudo REBRACO e as convidado a participar de uma entrevista em profundidade por telefone. No primeiro contato, o protocolo do estudo qualitativo foi explicado às mulheres e todas as questões foram respondidas. As mulheres puderam pensar e responder posteriormente por mensagem de *WhatsApp*, também puderam pedir mais informações, antes de agendar a entrevista.

Nos casos de recusa, as mulheres foram substituídas por outra (selecionadas aleatoriamente) do mesmo centro. Estabeleceu-se que seriam feitas três tentativas de contato com cada mulher em dias e horários diferentes antes de descartar o caso selecionado. Devido às recusas, a equipe de pesquisa entrou em contato com 136 mulheres. (Figura 1 do artigo) até atingir o método de amostragem por saturação. (35,36)

Também incluímos familiares ou parceiros próximos das mulheres, conforme indicado por elas durante a entrevista, para entender como a pandemia de COVID-19 impactou as famílias das gestantes/puérperas. Como as entrevistas dos familiares ou companheiros dependiam da indicação das mulheres, não foi considerado o tamanho amostral inicial.

### 3.3.3 Coleta dos dados

A coleta dos dados foi realizada remotamente por meio de ligações telefônicas no período de agosto de 2020 a março de 2021. O contato inicial foi feito por ligação telefônica ou mensagem de *WhatsApp* convidando as mulheres a participar do estudo. Quando a mulher concordava em participar, a entrevista era imediatamente realizada ou outro dia e horário eram agendados, de acordo com a conveniência da mulher.

Foram realizadas entrevistas semiestruturadas em profundidade por meio de perguntas abertas sobre a experiência da pandemia de COVID-19 relacionada ao tratamento e informações recebidas, período de quarentena, preocupações relacionadas ao autocuidado ou cuidados com o bebê e o impacto em suas vidas diárias. Outro questionário semiestruturado foi aplicado aos familiares próximos ou parceiros, abrangendo questões sobre o impacto do diagnóstico de COVID-19 na vida da mulher e da família, informações médicas recebidas e suas principais preocupações.

Para todas as mulheres entrevistadas, foi proposta uma segunda entrevista 60 dias após a primeira para acompanhamento após a suspeita/infecção por COVID-19. Para essa entrevista, foi elaborado um novo questionário com foco no período de recuperação e nos significados da COVID-19 em suas vidas.

As entrevistas foram realizadas pela autora dessa tese e uma pesquisadora social, ambas com experiência anterior em pesquisa qualitativa e formação específica para este estudo. Todas as entrevistas foram gravadas em áudio e transcritas na íntegra para análise dos dados.

No início da entrevista, as entrevistadoras recomendavam que os participantes estivessem em um local reservado, onde se sentissem à vontade para falar sobre os assuntos abordados. Ao final da entrevista, as entrevistadoras perguntavam aos participantes se gostariam de acrescentar alguma outra informação adicional.

### 3.3.4 Análises dos dados

Todas as entrevistas semiestruturadas foram gravadas em áudio, e, posteriormente, transcritas por meio do *Software Reshape*, e o texto obtido foi conferido com a gravação. Em seguida, os textos foram inseridos no programa NVivo V.12 para auxiliar na análise.

Com base nas recomendações de Braun e Clark (36), as transcrições foram lidas várias vezes e codificadas individualmente. As duas pesquisadoras inicialmente geraram códigos e, após discussão, definiram temas e subtemas, desenvolvendo conexões analíticas para a análise de conteúdo temática (37), construindo précategorias e depois categorias, utilizando conceitos da psicologia da saúde para interpretação.(38)

### 3.3.5 Aspectos éticos

A aprovação ética para o centro coordenador foi dada pelo Comitê de Ética em Pesquisa da Universidade Estadual de Campinas (Unicamp) e para cada centro participante obteve sua aprovação (CAAE: número 31590120.7.0000.5404, Anexo 4). O TCLE para as entrevistas semiestruturadas não foi assinado. Como as entrevistas foram realizadas por telefone e gravadas, o Comitê de Ética em Pesquisa autorizou que, após o processo de esclarecimento do Termo de Consentimento Livre e Esclarecido, caso a mulher/familiares aceitassem em participar, o aceite deveria ser registrado. Foi elaborado um TCLE específico para cada categoria de participante.

No momento da entrevista telefônica, foi lido o Termo de Consentimento Livre e Esclarecido antes da coleta de dados, todas as dúvidas dos participantes foram esclarecidas e os mesmos informados que poderiam interromper sua participação a qualquer momento sem prejuízos e também foi assegurado o sigilo de sua identidade. Os participantes foram questionados se concordavam em participar do estudo e se permitiam que a entrevista fosse gravada. O consentimento verbal foi gravado em áudio. Após a entrevista, uma cópia do consentimento informado foi enviada a cada um dos participantes por e-mail ou mensagem de texto/*WhatsApp*.

### 4. RESULTADOS

Os resultados do presente estudo serão apresentados a seguir no formato de artigos já publicados ou enviados a publicação.

- **4.1 Artigo 1:** Reported challenges in sexual and reproductive health for adolescent girls and young migrants
- **4.2 Artigo 2**: A neglected population: Sexual and reproductive issues among adolescent and young Venezuelan migrant women at the northwestern border of Brazil
- **4.2 Artigo 3:** Period poverty: menstrual health hygiene issues among adolescent and young Venezuelan migrant women at the northwestern border of Brazil
- **4.3 Artigo 4:** Listening to Pregnant Women and their families who Experienced a COVID-19 Infection before vaccination: A Qualitative Approach within a Multicenter Study in Brazil

# 4.1 Artigo 1: Reported challenges in sexual and reproductive health for adolescent girls and young migrants

Esse artigo responde ao primeiro objetivo específico, que pretendeu revisar a literatura científica para compreender quais são os desafios em relação à Saúde Sexual e Reprodutiva (SSR) de adolescentes e mulheres jovens migrantes em todo o mundo. Esse artigo foi submetido para a revista *Journal of Adolescent Health* e será apresentado a seguir.

Dear Dr. Costa,
Your submission entitled "Reported challenges in sexual and reproductive health for adolescent girls and young migrants" has been received by the Journal of Adolescent Health. Your manuscript has been assigned tracking number JAH-2023-00718. Please refer to this number when communicating with the editorial office about your paper.
You will be able to check on the progress of your paper by logging on to the Editorial System of the journal as an author. The URL is <a href="https://www.editorialmanager.com/jah/">https://www.editorialmanager.com/jah/</a> .
If you have not heard anything further regarding the status of your manuscript submission within 14 DAYS OF SUBMISSION, please check the EM site to make certain that you have not missed any communication from the editorial office.
Thank you for submitting your work to the Journal of Adolescent Health.
Kind regards,
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For further assistance, please visit our customer support site at <a href="http://help.elsevier.com/app/answers/list/pi/7923">http://help.elsevier.com/app/answers/list/pi/7923</a> . Here you can search for solutions on a range of topics, find answers to frequently asked questions and learn more about EM via interactive tutorials. You will also find our 24/7 support contact details should you need any further assistance from one of our customer support representatives.

Reported challenges in sexual and reproductive health for adolescent girls and young migrants

Rachel E Soeiro<sup>1</sup>, José Paulo de Siqueira Guida<sup>1</sup>, Juliana da-Costa-Santos<sup>1</sup>, Maria Laura COSTA<sup>1\*</sup>

<sup>1</sup> Department of Obstetrics and Gynecology, University of Campinas, Campinas/SP, Brazil

\*Corresponding Author

**Maria Laura Costa** 

**Department of Obstetrics and Gynecology** 

The University of Campinas

101 Alexander Fleming St; Campinas, SP, Brazil

mlaura@unicamp.br

### Abstract

Worldwide there are 42 million women and girls estimated to be forcibly displaced. Adolescent girls and young women (10-24 years old) are a neglected group in humanitarian settings and have their sexual and reproductive health (SRH) neglected. This systematic review aimed to describe the relevant outcomes of SRH for adolescent girls and young women in humanitarian settings.

We conducted a mixed-methods systematic review, six databases were searched (PUBMED, PUBMED PMC, EMBASE, BVS / LILACS, SCOPUS, WEB OF SCIENCE) focusing on migrant adolescents (10-24 years) and SRH outcomes. To evaluate the quality of studies the mixed-methods appraisal tool (MMAT) was used.

Results: Of 1290 studies screened by abstracts, 32 met the eligibility criteria: 15 were qualitative, 10 were quantitative and 7 were mixed-methods studies. Most of the studies were performed in the last 4 years, in African countries. They discussed the increased frequency of adolescent pregnancies, lack of contraceptive use and access, menstrual hygiene management (MHM), ignorance and stigma about sexually transmitted infections (STI) and HIV, a higher number of child early and forced marriage or partnership (CEFMP) and sexual and gender-based violence (SGBV), challenging to obtain SRH information/knowledge/access, and unmet SRH needs.

Conclusion: migration is a current issue, although there is a growing number of studies on adolescent girls' SRH in humanitarian settings, this population remain overlooked, and they have negative SRH outcomes. There is a need for targeting interventions on SRH.

Key words: sexual and reproductive health; adolescent; young women; knowledge; refugee; migrant; systematic review

### Implications and contribution

This systematic review describes the available evidence on SRH challenges experienced by adolescent girls and young women in humanitarian settings. Were analyzed 32 studies that evidenced poor outcomes in SRH and unmet needs.

Identifying those challenges can help humanitarian actors to address the SRH needs of these population groups.

### 1. Background

In 2022, the United Nations High Commissioner for Refugees (UNHCR) estimated that 100 million people were forcibly displaced worldwide due to conflict, violence, and weather-related events such as floods, storms, and cyclones (1). So far, accurate data on the number of displaced adolescent girls and young women must be collected. A report by the Internal Displacement Monitoring Center (IDMC) reported that almost 42 million displaced persons were women and girls, but there lack of data regarding information on adolescent girls (2). According to 2018 data, only 14% of the territories and countries where information on internally displaced people (IDP) is collected published information disaggregated by sex and age. (2)

This information is essential to determine specific needs about education, health, nutrition, and employment (2). The lack of demographic data about migrant adolescent girls reinforces this group as a neglected population worldwide.

Sexual and reproductive health (SRH) needs for migrant adolescent girls and young women (10–24 years old) in humanitarian settings remain unmet (3). They lack access to SRH services and contraceptives, consequently, this group is more vulnerable to unplanned pregnancies, sexually transmitted infections, including HIV, higher maternal morbidity and mortality, and gender-based violence, including domestic and sexual violence. (3,4)

About 60% of maternal mortality or childbirth among adolescent girls happen in conflict or disaster contexts (5). According to the United Nations Funds for Population (UNFPA) report, in 2015, 15 million adolescent girls aged 15 to 19 gave birth, and 87% (13.050.000) of them lacked access to contraceptives. (6)

Some studies have described the inequalities regarding SRH for migrant adolescents and young women, due to differences in needs, language, difficulty obtaining contraception, fees, waiting times, travel distances, and the insufficiency of specific programs for this population (7–10), leading to higher taxes for repeated abortion, lower antenatal care (ANC) attendance, more postpartum complications such as perinatal mortality, fetal death and stillbirth, unsafe abortions, higher risk of HIV and sexual violence. (4,11,12)

Although the discussion on the SRH needs for this group has been gaining attention globally in the last years, there is scarce information on the difficulties and challenges they must deal with. Enhancing the evidence on the challenges migrant adolescents and young women face in humanitarian settings can help the research community and humanitarian actors to identify better ways to address the SRH needs of these population groups. This systematic review aims to synthesize the available evidence on the sexual and reproductive health challenges experienced among migrant and displaced girls and young women worldwide.

### 2. Methods

### 2.1 Search strategy and study design

This mixed-methods systematic review was conducted according to Sandelowski et al (13) and followed the three steps: segregated (qualitative and quantitative studies were analyzed separately), integrated (the differences between qualitative and quantitative studies were minimized), and contingent (addressing the same research questions).

We also followed the reporting guidelines as described in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (14) statement and used the "Mixed Methods Appraisal Tool (MMAT) version 2018" (15) for the studies' evaluation.

The MMTA is a tool which includes research evaluative criteria for quantitative, qualitative, and mixed-method studies. This tool was first published in 2009 and revised and upgraded in 2018 (16,17). The MMAT 2018 version is available and can be freely downloaded. To guide the studies analyses in there is a user manual with an algorithm. (15)

The latest version (2018) includes 2 screening questions and a total of 25 criteria, divided into five methodological categories of study designs: (a) qualitative, (b) randomized controlled trials, (c) nonrandomized, (d) quantitative descriptive studies and (e) mixed methods. For each category, there are five core criteria rated in three response options: "yes" (the criterion is met), "no" (the criterion is not met) or "can't tell" (there is not enough information in the paper to evaluate if the criterion is met or not). Mixed-method studies must be assessed in both, qualitative and quantitative

categories and then reevaluated into the integration of quantitative and qualitative studies. (16,17)

This review is registered in the PROSPERO platform, under the registration number CRD42023403907.

Our research question was "Which is the available evidence on sexual and reproductive health among migrant girls and young women?".

The search strategy was built with the guidance of an information specialist. The chosen research terms and its variations, including Medical Subject Headings (MeSH) (18), were combined according to each database requirements and specifications.

The databases used for searching were: PUBMED, PUBMED PMC, EMBASE, BVS / LILACS, SCOPUS, WEB OF SCIENCE. The syntax were: ((Adolescent OR Adolescents OR Adolescence OR Teens OR Teen OR Teenagers OR Teenager OR Youth OR Youths OR "Adolescents, Female" OR "Adolescent, Female" OR "Female Adolescent" OR "Female Adolescents") AND (((("Health Vulnerability") OR ("Sexual Vulnerability")) OR ((Sexual Health[MeSH Terms]) OR ("Sexual Health"[Title/Abstract] OR "Health, Sexual"[Title/Abstract]))) OR ((Reproductive Health[MeSH Terms]) OR ("Reproductive Health"[Title/Abstract] OR "Health, Reproductive"[Title/Abstract])))) OR AND (((Refugees[MeSH Terms1) (Refugees[Title/Abstract] OR Refugee[Title/Abstract] OR "Political Asylum Seekers"[Title/Abstract] OR "Asylum Seeker, Political"[Title/Abstract] OR "Asylum Seekers, Political"[Title/Abstract] OR "Political Asylum Seeker"[Title/Abstract] OR "Seekers, Political Asylum"[Title/Abstract] OR "Political Refugees"[Title/Abstract] OR "Political Refugee"[Title/Abstract] OR "Refugee, Political"[Title/Abstract] OR "Refugees, Political"[Title/Abstract] OR "Asylum" Seekers"[Title/Abstract] "Asylum Seeker"[Title/Abstract] OR OR "Seeker, Asylum"[Title/Abstract] OR "Seekers, Asylum"[Title/Abstract] OR "Displaced Persons"[Title/Abstract] "Displaced Person"[Title/Abstract] OR OR Displaced"[Title/Abstract] OR "Persons, Displaced"[Title/Abstract] OR "Internally Displaced Persons"[Title/Abstract] OR "Displaced Person, Internally"[Title/Abstract] Internally"[Title/Abstract] OR OR "Displaced Persons, "Internally Person"[Title/Abstract])) OR ((Transients and Migrants[MeSH Terms]) OR ("Transients and Migrants"[Title/Abstract] OR "Migrants and Transients"[Title/Abstract] OR Migrants[Title/Abstract] OR Migrant[Title/Abstract])))

### 2.2 Eligibility criteria

Original quantitative and qualitative studies which investigated sexual and reproductive health outcomes from the perspective of migrant (defined as displaced women such as refugees, asylum seekers or internally displaced people) adolescent girls and young women (10-24 years old), published until January 05, 2023, written in English, Spanish or French, were included.

### 2.3 Exclusion criteria

Editorials, opinion articles, letter to editors, call for actions, short reports, brief communications, protocols guidelines, book chapters, case studies, retrospectives studies, congress annals, newsletters, and other reviews were excluded.

Figure 1 shows the process of the review according to the PRISMA guidelines. (19)

### 2.4 Critical appraisal

The search fields were title and abstract. The Rayyan Systematic Review Tool (20) was used for the initial screening of abstracts and titles.

Two independent reviewers performed the initial blind screening and selection of studies, considering the title and abstract. Conflicts of selection were approached by the study coordinator.

The full texts were read assessing quality and appropriateness.

To evaluate the quality of the included studies, the "Mixed Methods Appraisal Tool (MMAT) version 2018" (15) was used. The MMAT user manual instructs to provide the analysis with a detailed presentation of each one of the five core criteria, according to the study category. (16)

### 2.5 Data Extraction and Analysis

Data from all included articles were extracted following the headlines: authors and title, year, study setting, sample size, study population, age of participants, main objectives, study design and conclusions/recommendations. Each study was evaluated under its methodological categories. As each category has five

items, we considered 20% for each item, scoring a total of 100%. Mixed-methods studies were evaluated as mixed-method, and qualitative and quantitative components were evaluated independently on their corresponding quality criteria. All articles were given a final quality score. (Table 1)

### 3. Results

### 3.1 Overview of the studies

Among 1290 studies screened by abstracts, 32 met the eligibility criteria; 15 were qualitative studies (21,22,31–34,23–30), 10 were quantitative (9,35–43) and 7 were mixed-methods studies (44–50).

More than 50% (17 studies) were published between 2021 and 2022 (9,22,43,46,49–51,24,27,29,31,33,34,41,42), 12 studies were published between 2017 and 2020 (21,25,45,47,26,28,32,35,36,38–40), one was published in 2013(30) and two in 2010 (44,48).

There were 20 studies with only female participants (9,22,35,36,38,40–43,49,50,23–26,29,30,33,34) and 12 studies had female and male participants (21,28,51,31,32,34,39,44,46–48). Seven studies included adults as well (adolescent parents, non-governmental organizations workers, and health workers) (21–23,26,32,46,50) regarding their opinion of the adolescent's SRH issues.

Most of the studies were performed in African countries: nine in Uganda (25,34,35,39–41,45,46,51), four in Nigeria (29,42,47,48), two in Ethiopia (32,33), one in Egypt (23), one in Ghana (36), and one in Rwanda (31)), three studies were from Thailand (21,28,44), three from Lebanon (22,26,27), one from Iraq (37), two from Bangladesh (49,50), one from Jordan (24), two from Brazil (9,43), one from Australia (30) and one study was performed in two different countries (Thailand and Ethiopia) (38).

### 3.2 Adolescent Pregnancy

Four studies reported specifically on adolescent pregnancy: two of them were quantitative (33,41) and the other two were qualitative (21,30).

The two qualitative studies (21,30) interviewed specific pregnant women. Asnong et al (21) reported three adolescents were forced to marry after getting

pregnant, and only two pregnant adolescents over a total of 20, reported they stopped contraception intending to get pregnant. In both qualitative studies, all the adolescents quit school: some of them were too ashamed to continue studying, others were expelled, and others due to motherhood responsibilities.

The adolescents also complained about social isolation due to the burden of taking care of a child and all the household tasks.

The two quantitative studies reported a pregnancy prevalence of 21,7 (41) and 23% (33). Bol et al (33) described poor SRH knowledge (40%), low prevalence of contraceptive use (6,5%), and low educational status (42% with no formal education). The pregnancy rates among adolescent girls with no formal education were 3.4 times higher compared with girls who attended secondary school and above.

Malama et al (41) reported adolescents with children were twice as likely to experience food insecurity and depressive symptoms.

All studies reported financial difficulties, including the married ones, and few of the pregnant unmarried adolescents had received family support.

## 3.3 Contraceptive use and access

Four studies reported on contraceptive use and access, three quantitative (35,36,42) and one mixed methods (48).

All the studies reported very low use of contraceptives (lower than 9% for the quantitative studies (35,36,42) and 32% for the mixed-method study (48)).

The reasons reported for not using contraceptives were difficulties accessing health services or lack of information about health services: Ganle (36) reported 39% of adolescent's girls who heard about contraception did not know where they could get it, and Okanlawon (48) reported 60%; fear of side effects (39-80%); cultural beliefs (11-17%); and partner prohibition (16-40%).

The studies also reported misinformation regarding contraception: Okanlawon (48) described a belief that adolescents will become infertile after contraception use, and 84% of the adolescent girls in the Ganle (36) study believed that the women who use contraceptives become promiscuous.

# 3.4 Menstrual hygiene management (MHM)

Five studies reported on MHM, two quantitative (38,43), one qualitative (25) and two mixed methods (49,50). All of them described a poor MHM.

The studies reported there was no private toilet for the majority of the adolescent girls to use (85-93%) (38,49) and there is a lack of MHM products such as hygienic pads (disposable or reusable), soap and clean water (55-83%) (38,43,49). There is no proper place to wash or dry the disposable pads (65%). (43,49)

The adolescent girls reported feeling embarrassed during menstruation (50-60%) (25,43,49) and missing school because of MHM issues. (25)

The study performed in the Rohingya camp reported that 72% of adolescent girls were not allowed to go out during the menstruation period and 88% were not allowed to cook. (49)

The studies also reported that adolescent girls referred that the toilets in the IDP camps are distant, and they are afraid to go to the toilet because of the risk of sexual violence (55-65%). (25,43,49)

### 3.5 Sexually transmitted infections (STI) and HIV

Two studies reported on STI (39) and HIV (34). Both described there is a stigma on taking these tests.

The study on STIs (39) described 74% had never been tested for STIs and more than half of the adolescents (56%) were unaware of the STI testing services. Among those tested, 16% did not know to inform the test results. The STIs reported by the adolescents were: 10% more than two STIs, 15% herpes, 9% gonorrhea, and 6% syphilis. There was no information regarding HIV.

Among the adolescent girls and young women (AGYW), the stigma on STI testing was associated with lower contraceptive use and food insecurity. (39)

The HIV study evidenced the barriers to HIV testing and prevention are the cost of transportation to HIV testing services, language barriers, lack of private spaces to do the self-test, medical mistrust, and inequitable gender norms. (34)

# 3.6 Child early and forced marriage or partnership (CEFMP)

Four studies one quantitative (37), two qualitative (23,26) and one mixed methods (46) reported on CEFMP (formal marriage or an informal union, before reaching the age of 18) (52). For all of them, there was an association between social and financial insecurity and early marriage.

Adolescent marriage was associated with negative SRH outcomes such as lack of family planning, unplanned pregnancies, and disruption of schooling (23,26,37,46). Elnakib et al (23) described adolescent girls' isolation after marriage and difficulties with their baby birth registration.

Goers et al (37) described that 38% of the adolescent girls (10-19) were married. The risk of marriage before 18 years old was 6.2 times higher for girls than boys. Only 6% of the married or engaged refugee adolescent girls were in school. The influencing factors in marriage decisions were displacement (12%), money/resources (21%) and war/conflict (29%).

In the Loutet et al (46) study, 75% of adolescents were married, and 57% had primary-level education or lower. CEFMP was associated with forced pregnancy (50%), forced abortion (45%), missed school due to sexual violence (95%) and survival sex work (64%).

Contrary to the other three studies, Knox et al (26) results evidenced that not all child pregnancies were forced. Some adolescents reported having chosen marriage. Nevertheless, all of them reported financial insecurity.

### 3.7 Sexual and gender-based violence (SGBV)

Two studies reported SGBV as the main outcome. In a quantitative study, Logie et al (40) evidenced that over half of the participants (54%) reported intimate partner violence (IPV) in the last 12 months (55% reported polyvictimization: physical, sexual, and control violence). IPV polyvictimization was associated with depressive symptoms (90%), and food insecurity (94%).

In a qualitative study, Logie et al (51) explored the refugee adolescent wellbeing factors and SGBV was associated with poverty, food insecurity, and unemployment, leading to CEFMP and transactional sex. The study also described how deforestation exacerbated sexual violence, as the AGYW must go further to collect water and firewood.

## 3.8 SRH information/knowledge/access

Seven studies reported on SRH information, knowledge, and access: five qualitative (22,24,27,28,31) and two mixed methods (44,45). Overall, there is a lack of SRH information and misconceptions and an unsatisfactory number of SRH services.

Family members, mostly mothers, were described in three studies as the trustable person to obtain SRH information. (22,27,45)

Schools were also described as a place to obtain SRH information, although most of the adolescent girls do not attend school. (28,31,32,45)

Regarding SRH knowledge, Ivavona et al (45) reported that 16% of the adolescent did not know about STIs and 52% were able to mention only one STI; 14% had no knowledge of contraception, 44% knew one method and 15% knew three or more methods.

Benner et al (44) identified 66% of adolescent girls did not know if it was possible to get pregnant after the first sexual intercourse, 68% did not know if women can take contraceptive pills daily, 59% did not know if condoms can be used during sex, and 45% did not know if it is OK for a boy to sometimes force a girl to have sex if he loves her.

Meyer et al (31) described the decrease in SRH information sessions and SRH services after the onset of the COVID-19 pandemic; the adolescents complained of unplanned pregnancies due to the contraception disruptions and about the suspension of the SRH activities from local Non-Governmental Organizations (NGOs).

All studies highlighted the need for shaping programs by sex and age to address SRH information and recommended empowering adolescent mothers as agents of SRH evidence-based information.

# 3.9 Overview of the main SRH needs

Four studies, two qualitative (29,32), one quantitative (9) and one mixed methods (47) reported an overview of SRH information, needs, access to, and outcomes.

All of them evidence poor SRH outcomes as limited access to family planning, unsafe sex, early marriages, pregnancy complications and low knowledge and access to SRH services.

Soeiro et al (9) reported among pregnant adolescent girls and young women, 33% were not attending ANC, and the reasons were not knowing where to go (40%), difficulty reaching the health center (20%) and not having personal documents (20%). The main self-reported SRH concerns were contraception (35%), and 75% of the adolescents who went to a health center did not get contraception.

In the Odo et al (47) study, 98% of adolescent girls described sex education as important and they agreed to the main SRH problems were teenage pregnancy (72%), early marriage (76%), menstrual problems (70%), and maternal mortality (80%).

Marlow et al (29) also demonstrates that food insecurity in the IDP camp has driven adolescent girls to sex in exchange for goods or into forced marriages.

All articles highlighted the need for specific SRH services for IDP, refugees or migrant AGYW.

#### 4 Discussion

This review aimed to describe the relevant outcomes of SRH for adolescent girls and young women in humanitarian settings.

Specific studies targeting SRH of adolescent migrants (10-24 years old) are recent, with a significant increase since 2021. A possible explanation for this increment could be that adolescent health is comprised of the 2030 Sustainable Development Goals (53) described in several targets: target 3.1 aims to decrease maternal mortality, target 3.7 aims to ensure comprehensive SRH services, 5.3 aims to eliminate CEFMP and female genital mutilations, 5.5 aims to ensure gender equality, and target 10. 7 aims to implement migration policies. (53)

All the subjects of the SDG targets mentioned above were described in the evaluated studies and evidenced that adolescent girls and young women in humanitarian settings have negative outcomes in SRH and remain a neglected population.

The CEFMP has been described in other countries as a cultural and societal pattern (54). Nevertheless, in humanitarian settings, the situation of insecurity, increased poverty, and often loss of family members leads girls more frequently to CEFMP (23,37,46). Recommendations on how to address it do not include emergency settings. (55,56)

CEFMP is also linked to adolescent pregnancies (4,54), as well as lack of contraception (57). Pregnancy and childbirth complications are one of the leading causes of death among 15- to 19-year-old girls worldwide (4,57). Studies in this review showed a high prevalence of adolescent pregnancies, frequently unplanned (21,30,33,41), but most of them did not discuss those pregnant adolescent's morbidity and mortality rate in the study settings. As there is a lack of health services and proper data systems records in humanitarian settings, probably the impact of those pregnancies remains underestimated. (58)

The global increase of STIs among adolescents has been described for boys and girls, however, the prevalence is higher among adolescent girls (59). New HIV infections are also higher among adolescent girls (59). Logie et al (34,39) identified barriers to HIV and STI tests and stigma for refugee adolescent girls living in Kampala (Uganda), so these numbers may be even greater for refugee AGYW.

Despite studies have shown the disruptions of SRH services since the COVID-19 pandemic onset (60,61), only one study analyzed this impact on the adolescent girls' SRH (31).

Most of the studies also did recommendations on specific SRH programs and health services for adolescents in humanitarian settings. Notwithstanding the increase in the number of studies on this subject, specific interventions targeting SRH for adolescent girls are still low. A systematic review (62) published in 2019 identified only nine SRH interventions for adolescents and youth in armed conflict settings, only one study was published before 2012 (in 2006), and the majority were implemented in African countries, one in Colombia and one in Pakistan, evidencing the need for global SRH interventions targeting AGYW.

There is a growing interest in the sexual and reproductive health of migrant adolescent girls and young women, including some systematic reviews (3,58,62).

Nevertheless, as far as we know, this is the first systematic methodological review, evidencing the relevant outcomes in SRH for this population.

### 5 Limitations

We only included studies with adolescent girls from 10 - 24 years old, and we may have missed data from studies which included all women of reproductive age.

### Conclusions

The ongoing world crises have been increasing migration, as well as all the risks for adolescent girls' health. Although there is a growing number of studies on adolescent girls' SRH in humanitarian settings, there are still limited interventions to address this issue.

Next studies should be on interventions targeting adolescent girls.

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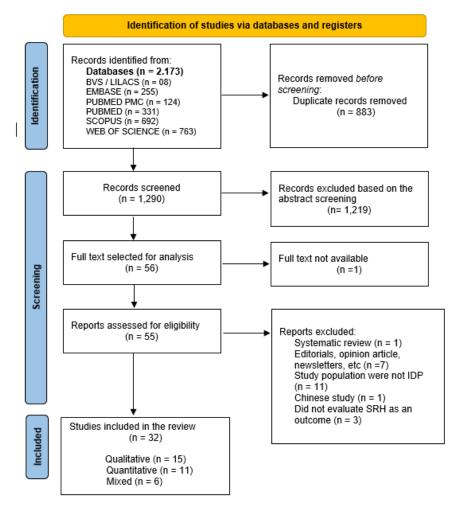


Figure 1 PRISMA 2020 flow diagram: process of the integrative review

Table	1: Study character	ristics							
	Author/Title	Year	Study Setting	Sample Size	Study Population	Age of participants	Main Objectives	Study Design	53 Conclusions/ recommendations
1	Asnong C. et al  Adolescents' perceptions and experiences of pregnancy in refugee and migrant communities on the Thailand- Myanmar border: a qualitative study	2018	Two refugee camps (Thailand/ Myanmar border)	Total sample: 40 participants (20 pregnant adolescents, 3 husbands of pregnant adolescents, 6 adolescent boys, 6 non-pregnant adolescent girls, 5 locally trained ANC staff members)	Migrants and refugee pregnant adolescents' girls attending ANC and non pregnant adolescents' girls	13-19	Explore adolescent pregnancy including the experienc e, consequen ces, family, and communit y support, and SRH knowledg e on two refugee camps	Qualitative Cross- sectional FGDs and individual interviews	Adolescents refer to pregnancy as a challenging life event.  It is necessary to provide comprehensive adolescent friendly SRH services and education to the refugee and migrant communities on the Thailand-Myanmar border.
2	Bakesiima R. et al  Modern contraceptive use among female refugee adolescents in northern Uganda: prevalence and associated factors	2020	Palabek refugee settlement (Northern Uganda)	839 adolescent girls	Sexually active female refugees	15-19	Establish the prevalenc e and associated factors with modern contracept ive use among female refugee adolescent s in Uganda	Quantitative Cross- sectional Questionnai re	Modern contraceptive use was less than 10% among refugee adolescents, putting them at pregnancy risk and its consequences during adolescence. The main reasons for not using modern contraceptives were partner prohibition, fear of side effects, and lack of knowledge.  This evidence an urgent need for access to quality SRH services and for SRH counselling to empower adolescent girls in refugee settings.

3	Benner M. T., et	2010	Two	416 (222	Young	15 - 24	Assess	Quantitative	There is a lack of sexual
	al		refugee	adolescent	Burmese	years	young	and	health information and SRH
			camps	boys and	refugee's	-	Burmese	Qualitative	services. There is a need for
	Reproductive		(Thailand)	194	Total good		refugee's	Cross-	specific policies.
	health and		(Thanana)	adolescent			reproducti	sectional	specific policies.
	1:4 £1:£ £						ve health	Self-	
	quality of life of			girls)			ve nealth		
	young Burmese						issues and	responded	
	refugees in						quality of	questionnair	
	Thailand						life	e	
								Semi-	
								structured	
								questionnair	
								es	
			1	i	1	l	1	l	

4	Bol K. N. et al  Pregnancy among adolescent girls in humanitarian settings: a case in refugee camp of Gambella regional state, community- based cross- sectional study, Southwest Ethiopia, 2021	2021	Nguenyyiel Refugee Camp (Gambella region, Southwest Ethiopia)	414 (adolescent girls)	Adolescent girls living in the Nguenyyiel Refugee Camp for at least 6 months before the data collection	1019	Determine the prevalenc e of pregnancy among adolescent girls and associated factors in a Refugee Camp, in the Southwest of Ethiopia	Quantitative Cross- sectional Questionnai re HCG pregnancy test	There is a high prevalence of pregnancy among refugee adolescent girls in the Nguenyyiel Refugee Camp, most among late-stage, illiterate, and those adolescents living without a biological family. It is necessary to provide comprehensive adolescentfriendly SRH services and education. Future researchers should address other important points such as unmet family planning needs and unwanted pregnancy and use a mixed approach (qualitative and quantitative study).
5	El Ayoubi L. L, et al  Sexual and Reproductive Health Information and Experiences Among Syrian Refugee Adolescent Girls in Lebanon	2021	Lebanon's Bekaa governorate	There is no description of the total number of participants: 3 FG with unmarried adolescent girls (5-7 participants/ FG), 11 IDIs with married adolescent girls, and 2 FG with mothers of 11- to 14-year-old adolescent girls (4-8 participants/ FG)	Married and unmarried Syrian refugee adolescent girls	14-20	Understan d what SRH informatio n Syrian refugee adolescent girls receive and from which sources	Qualitative Cross- sectional FGDs and individual in-depth interviews (IDI)	There are misconceptions regarding SRH information. The preferred source of information of the married and unmarried adolescent girls was their mothers, followed by schools' and NGO's SRH sessions, and their peers. The SRH programs for refugee adolescent girls should engage their mothers improving their SRH knowledge and communication skills.

6	Elnakib S., et al  Drivers and consequences of child marriage in a context of protracted displacement: a qualitative study among Syrian refugees in Egypt	2021	Giza, Damietta, and Qalyubia (Egypt)	72 (27 married and unmarried adolescent girls, 14 adolescent girls' mothers, 3 adolescent girls' fathers, 9 Community Leaders, 6 Health Providers, 11 Humanitaria ns, 2 Legal experts)	Married and unmarried Syrian refugee adolescent girls	1019	Understan d the drivers of child marriage in a displacem ent context and how this affects the Syrian refugees girl's wellbeing	Qualitative Cross- sectional FGDs and individual in-depth interviews (IDI)	The study provides an overview of the marriage of adolescent Syrian refugee girls living in Egypt. The interventions should focus not only on the prevention of child marriage but also on mitigating their impacts.
7	Risky sexual behavior and contraceptive use in contexts of displacement: insights from a cross-sectional survey of female adolescent refugees in Ghana	2019	Budumbura m refugee camp (Ghana)	242 (adolescent girls)	Refugee adolescent girls	14-19	Assess contracept ive use and sexual behavior among female adolescent refugees in Ghana	Quantitative Cross- sectional Structured questionnair e	The use of modern contraceptives, their knowledge and access to them among refugee adolescent girls are very low.
8	Ghandour R., et al  Coming of age: a qualitative study of adolescent girls' menstrual preparedness in Palestinian refugee camps in the West Bank and Jordan	2022	Palestinian refugee camps in the West Bank and Jordan	232 (adolescent girls)	Palestinian refugee adolescent girls	14–21	Understan d how Palestinia n adolescent girls were prepared for menstruati on and the main factors influencin g their preparedn ess.	Qualitative Cross- sectional FGDs and individual in-depth interviews (IDI)	There is a need for evidence-based interventions regarding SRH (of refugee adolescent girls to address these disparities.

9 Goers M. et al  Child marriage among displaced populations — a 2019 study is Kurdistan Region of Iraq	1	Governorate s of Sulaimani, Erbil, Dohuk (Kurdistan Region of Iraq)	3040 (AGYW)	Host, internally displaced (IDP) and refugee adolescent girls from KRI	1024	Describe child marriage prevalenc e, influences , and beliefs among displaced population s in the Kurdistan Region of Iraq (KRI)	Quantitative Cross- sectional Survey	IDP adolescent girls have an increased risk for child marriage than refugee and host adolescent girls in KRI.
A cross- sectional mixe methods study of sexual and reproductive health knowledge, experiences, a access to services among refuge adolescent girl in the Nakival- refugee settlement, Uganda	d- nd e s	Nakivale refugee settlement (Isingiro District, Southwest Uganda)	260 (adolescent girls)	Refugee adolescent girls	13-19	Provide an overview of SRH experienc es, knowledg e, and access to services among adolescent refugee girls in a humanitar ian setting in Uganda.	Quantitative and Qualitative Cross-sectional Questionnai re Semi-structured questionnair es and individual in-depth interviews (IDI)	Refugee adolescent girls in humanitarian settings have limited access to SRH services and SRH knowledge. The schools and the parents are their main sources of SRH information.  A multi-sectoral approach is needed for SRH education and access to SRH services for adolescents. It is also important to offer comprehensive care to sexual violence victims.

11	Kågesten A.E., et al  Transitions into puberty and access to sexual and reproductive health information in two humanitarian settings: cross-sectional survey of very young adolescents from Somalia and Myanmar	2017	Thailand- Myanmar border and Kobe refugee camp (Ethiopia)	406 Somali VYA girls 399 VYA girls from Myanmar	Refugee adolescent girls from Somalia and from Myanmar	1014	Describes the characteri stics of very young adolescent s (VYA) in two humanitar ian settings, regarding transitions into puberty, MHM, and access to SRH informatio n	Quantitative Cross- sectional Structured questionnair e	There is a lack of SRH information and supplies for MHM in these two humanitarian settings. VYA's parents are their main source of SRH information. SRH interventions involving parents and educational centers may have encouraging results on the VYA pubertal and sexual development.
12	Kemigisha E., et al  A Qualitative Study Exploring Menstruation Experiences and Practices among Adolescent Girls Living in the Nakivale Refugee Settlement, Uganda	2020	Nakivale refugee settlement (Isingiro District, Southwest Uganda)	28 (adolescent girls)	Refugee adolescent girls	13-19	Describe the context and challenges faced by adolescent refugee girls during migration and their stay at the refugee settlement in Uganda and address the knowledg e gap	Qualitative Cross- sectional FGDs and interviews	Refugee adolescent girls in humanitarian settings have poor menstrual health management (MHM). It is mandatory to provide timely and evidence-based information. Family and school have an important role in this process.

13	Knox S. E. M.  How they see it: young women's views on early marriage in a post-conflict setting	2017	Nahr el Bared Palestinian refugee camp (North Lebanon)	37 adolescent girls, 5 adolescent girls' mothers and 12 NGO workers	Refugee girls from and residing in Nahr el Bared, married engaged to Palestinian refugee men from and residing in Nahr el Bared		Explore the views and experienc es of early marriage among married and engaged refugee adolescent girls	Qualitative Cross- sectional FGDs and individual in-depth interviews (IDI)	The refugee adolescent girls residing in Nahr el Bared do not feel forced to marry and did not see themselves as victims. Early marriage was related to insecurity, isolation and loss of friendships and peers. There is a lack of information and misinformation regarding SRH. Any intervention in early marriage must include the community and bring adolescent girls together providing access to courses, leadership, and civic engagement.
14	Korri R. et al  Sexual and reproductive health of Syrian refugee adolescent girls: a qualitative study using focus group discussions in an urban setting in Lebanon	2021	Bourj Hammoud (Urban setting in Lebanon)	40 (adolescent girls)	Married and unmarried Kurdish and Arab Syrian refugee adolescent girls	13-17	Explore the SRH perception s and experienc es of Syrian refugee adolescent girls living in an urban setting in Lebanon.	Qualitative Cross- sectional FGDs	There is a need for solid information about SRH issues, through accessible programs adolescents and additionally, encouraging the role of mothers perceived as trusted and accessible sources of information.
15	Lee C., et al  Sexual and reproductive health needs and risks of very young adolescent refugees and migrants from Myanmar living in Thailand	2017	Mae Sot (Myanmar- Thailand border) and Mae La Refugee camp (Thailand)	180 participants (88 adolescent boys, 88 adolescent girls, 4 adolescent parents)	Refugee adolescent girls	1016	Understan d the SRH needs and risks of VYA in two humanitar ian settings	Qualitative Cross- sectional FGDs (community mapping and photos)	There is a lack of SRH information. Schools, youth centers and religious institutions were identified as trustable places to obtain information.  There is a need for youth-directed programs and policies, involving peerpeer communication.

16	Sexually transmitted infection testing awareness, uptake and diagnosis among urban refugee and displaced youth living in informal settlements in Kampala, Uganda: a cross-sectional study	2019	5 informal settlements in Kampala (Uganda)	445 (112 young men and 333 young women)	Youth self- identified as IDP or refugee	16–24	Explore factors associated with the STI services awareness, testing and diagnosis among urban refugees and displaced youth in Kampala, Uganda.	Quantitative Cross- sectional Survey	The SRH stigma among urban refugee young women was associated with lower STI services awareness, testing uptake and diagnosis. Strategies tailored by gender and age can be promising for STI prevention
17	Logie C. H., et al  Social ecological factors associated with experiencing violence among urban refugee and displaced adolescent girls and young women in informal settlements in Kampala, Uganda: a cross-sectional study	2019	5 informal settlements in Kampala (Uganda)	333 (adolescent girls)	Adolescent girls and young women (AGYW) self- identified as IDP or refugee	16–24	Determine the prevalenc e of experienc e violence among urban refugees and displaced AGYW and the sociodemograp hic and social-ecological factors associated .	Quantitative Cross- sectional Survey	The study provides information regarding the prevalence and correlates of young adulthood violence and recent intimate partner violence among urban refugee AGYW. There are a need for comprehensive interventions addressing economic and cultural gender-based inequities. Next studies should explore digital health technology use among urban refugee AGYW and its associations with risk for SGBV as well as its potential use in SGBV prevention.

18	Logie C. H., et al  Exploring resource scarcity and contextual influences on wellbeing among young refugees in Bidi Bidi refugee settlement, Uganda: findings from a qualitative study	2021	Bidi Bidi refugee settlement (Uganda)	48 (24 men; 24 women)	Refugee or displaced adolescent and youth	16–24	Address knowledg e gaps regarding Sexual and Gender-Based Violence (SGBV) risks among refugee adolescent s and youth. The secondary aim (due to the emergenc e of COVID-19 during the study) was to explore experienc es and perspectives toward COVID-19 among this population .	Qualitative Cross- sectional FGDs and individual in-depth interviews (IDI)	Contextual factors affect refugee adolescents' and youth's well-being. The social-ecological model for SGBV among adolescent girls in humanitarian settings can be extended considering resource scarcity (water, food, firewood) and ecological contexts such as deforestation.  Strategies to address SGBV should be gender and age tailored.
19	Logie C. H., et al  The role of context in shaping HIV testing and prevention engagement among urban refugee and displaced adolescents and youth in Kampala, Uganda: findings from a qualitative study	2021	Kampala's informal settlements (Uganda)	44 (17 young men, 27 young women from Democratic Republic of Congo, Rwanda, Burundi and Sudan)	Refugee or displaced adolescent and youth	16–24	Understan d experienc es and access to HIV testing and prevention among urban refugee/di splaced youth in Kampala.	Qualitative Cross- sectional FGDs	The barriers to HIV testing and prevention were transportation costs to clinics, lack of private spaces due to overcrowded living conditions, low literacy, and language barriers. Symbolic contexts were medical mistrust and inequitable gender norms. The interventions should include religious leaders to offer contextually relevant services and gender transformative approaches.

20	Loutet M. G., et al  Sexual and reproductive health factors associated with child, early and forced marriage and partnerships among refugee youth in a humanitarian setting in Uganda: Mixed methods findings	2022	Bidi Bidi refugee settlement (Uganda)	In-depth interviews were conducted among 12 youth (boys and girls) and 8 elders aged 55+ years old who were sexual violence survivors, eight healthcare providers working in Bidi Bidi 48 youth participated in FGDs 120 youth answered the questionnair es	Refugee or displaced adolescent and youth	16–24	Address the gaps in the prevalenc e and health outcomes of the child, early and forced marriage (CEFMP) in humanitar ian settings	Quantitative and Qualitative Cross-sectional Questionnai re FGDs and individual in-depth interviews (IDI)	CEFMP is common among youth in humanitarian settings and is influenced by poverty and education, impacting the reproductive outcomes among young refugee women. There is a need for context-specific interventions to address CEFMP
21	Malama K., et al  Factors associated with motherhood among urban refugee adolescent girls and young women in informal settlements in Kampala, Uganda	2022	5 informal settlements in Kampala (Uganda)	333 (adolescent girls)	Refugee or displaced adolescent girls and young women	16–24	Address the knowledg e gap around the factors associated with motherho od among AGYW living in informal settlement s.	Quantitative Cross- sectional Survey	Motherhood among refugee AGYW was associated with food insecurity, depressive symptoms and recent contraceptive uptake. It is recommended an SRH and mental health integrated service as well as resource insecurity initiatives in the community.

22	Marlow H. M., et al  The Sexual and Reproductive Health Context of an Internally Displaced Persons' Camp in Northeastern Nigeria: Narratives of Girls and Young Women	2022	IDP camp in Northeaster n Nigeria	25 (adolescent girls)	Single and married IDP adolescent girls and young women	15–24	Understan d SRH AGYW's experienc es as unwanted pregnancy , abortion, contracept ion, sexually transmitte d infections (STIs), genderbased violence (GBV), and forced marriage.	Qualitative Cross- sectional FGDs and individual in-depth interviews (IDI)	IDP adolescent girls and young women have poor SRH outcomes including unwanted pregnancies, STIs, GBV, and unsafe abortion. Due to the ongoing violence, food insecurity and lack of resources, AGYW are forced into sexual relationships and early marriages. Despite some SRH services available, AGYWs do not access them due to shame and stigma. To improve poor SSR outcomes, it is necessary to provide integrated services that address the drivers of early sex and forced marriage.
23	Marlow H. M., et al  Contraceptive use, menstrual resumption, and experience of pregnancy and birth among girls and young women in an internally displaced persons camp in Northeastern Nigeria	2022	IDP camp in Northeaster n Nigeria	480 (adolescent girls)	Displaced adolescent girls and young women	15–24	Examine the relationshi ps between contracept ive use, menstrual resumptio n, and pregnancy and birth experienc es of AGYW in an IDP camp	Quantitative Cross- sectional Survey	Contraceptive services have yet to reach many AGYW in the IDP camps in Northeastern Nigeria.
24	McMichael C.  Unplanned but not unwanted? Teen pregnancy and parenthood among young people with refugee backgrounds	2013	Settlements in Victoria (Australia)	9 adolescent girls	Pregnant African- born young women with refugee background s	1119	Examines the ways adolescent girls with refugee backgroun ds negotiate teen pregnancy and the challenges of early settlement	Qualitative Longitudina 1 (4 years) Field notes, open-ended survey questions and interviews	All adolescent reported an unplanned pregnancy, for someone the pregnancies it was unwanted. All of them quit the school, most of them reported they receive family support.  It is fundamental provide SRH education on the settlements, and for pregnant adolescent, programs should support them to return to school, work and ensure access to adequate housing.

25	Meyer, K., et al Understanding the Sexual and Reproductive Health Experiences of Refugee and Host Community Adolescents and Youth in Rwanda During COVID-19: Needs, Barriers, and Opportunities	2022	Mahama Refugee Camp (Rwanda)	517 (adolescent girls and boys)	Refugee adolescent and youth	1024	Understan d the reasons for accessing SRH informatio n and services by adolescent s and youth refugees.	Qualitative Cross- sectional FGDs and adolescents and youth refugees' stories	Difficulties accessing SRH information and services (including stigmatization among service providers) were reported by adolescents and youth. There is a need to increase specific SRH services prioritization for adolescents and youth in humanitarian settings.
26	Odo A.N., et al  Sexual and Reproductive Health Needs and Problems of Internally Displaced Adolescents (IDAs) in Borno State, Nigeria: A Mixed Method Approach	2020	IDP camps in Borno State (Nigeria)	396 (220 adolescent boys and 176 adolescent women)	ID adolescent and youth	1024	Identify the ID adolescent s and youth SRH needs and problems and the strategies for improving their SRH.	Quantitative and Qualitative Cross- sectional Questionnai re FGDs	SRH problems such as pregnancy complications, adolescent pregnancy, early sex experimentation, unsafe sex, maternal mortality, STIs, sexual harassment, genital fistulas, abortion and its complications were reported by internally displaced adolescents and youth. Youth-friendly SRH services were reported as a possibility to address SSR needs and problems.
27	Okanlawon K., et al  Contraceptive Use: Knowledge, Perceptions and Attitudes of Refugee Youths in Oru Refugee Camp, Nigeria	2010	Oru refugee camp (Nigeria)	280 youth (116 girls and boys)	Refugee AGYW	1024	Examines the perception s, beliefs, knowledg e, and attitudes of refugee adolescent s and youths toward contracept ive use and the access to them.	Quantitative and Qualitative Cross-sectional Self-responded questionnair e FGDs and individual in-depth interviews (IDI)	There was a misinformation about contraceptives, perceived as a dangerous for women's health, and a difficult to accesses contraceptives.  The low contraception use resulted on a large number of unintended pregnancies and poor reproductive health outcomes.  The AGYW reported to engage in transactional sex and prostitution, highlighting their vulnerability and the need for specific policies for this population.

28	Ortiz- Echevarria L., et al  Understanding the unique experiences, perspectives and sexual and reproductive health needs of very young adolescents: Somali refugees in Ethiopia	2017	Kobe refugee camp (Ethiopia)	126 (32 adults: adolescents' parents) and 94 adolescents (46 girls and 48 boys)	Somali refugee very young adolescents (VYA)	1016	Understan d the realities of very young adolescent s (VYAs) in Kobe refugee camp, and their health needs, expectations, and goals.	Qualitative Cross- sectional FGDs	VYA girls in Kobe refugee camp are at increased risk of poor SRH outcomes due to inequitable relations between boys and girls, risk of physical and sexual violence, early marriage and harmful traditional practices. The next programs should reinforce positive behaviors for VYA improving SRH.
29	Pandit K., et al  Constraints and current practices of menstrual hygiene among Rohingya adolescent girls	2022	Kutupalong refugee camp (Cox's Bazar, Bangladesh)	101 (adolescent girls)	Rohingya adolescent girls	1318	Assess the MHM practices and constraint s among adolescent girls in the Rohingya camps in Banglades h	Quantitative and Qualitative Cross-sectional Semi-structured questionnair e FGDs	The Rohingya adolescent girls, have low premenstrual knowledge, face challenges regarding MHM as lack of disposable pads and inadequate toilets, exposing them to higher risk of sexual violence and live in limited supportive environments.

30	Rakhshanda S., et al  Knowledge and practice regarding menstrual hygiene management among the Rohingya refugee adolescent girls in Cox's Bazar, Bangladesh: a mixed method study	2021	Rohyngya refugee camp ( Cox's Bazar, Bangladesh)	340 adolescent girls (340 questionnair es and 7 IDI) 14 adolescents' mothers (2 FGD)	Rohingya adolescent girls	1418	Understan d the knowledg e, practice and associated factors regarding MHM among adolescent girls in Rohingya refugee camps	Qualitative Cross- sectional Structured questionnair e Individual in-depth interviews (IDI)	The adolescents have not enough knowledge on menstruation and have not enough disposable pads. Distance to reach toilet, soap availability and sociocultural norms determines the cleanliness and frequency of change of pads.  There is a need for specific female's toilets near to the homestead, with clean water and soap, available and affordable sanitary pads and MHM counselling.
31	Soeiro R.E., et al  Period poverty: menstrual health hygiene issues among adolescent and young Venezuelan migrant women at the northwestern border of Brazil	2021	Boa Vista (Roraima State, Brasil)	153 (adolescent girls)	Venezuelan migrant AGYW	1024	Provide an overview of the main MHM issues among Venezuela n migrant AGYW in Boa Vista, Roraima, Brazil	Quantitative Cross- sectional Self- responded questionnair e	The Venezuelan migrant AGYW have their MHM needs neglected and they were more affected due to the COVID-19 pandemic. Efforts to address the MHM needs to be on collaboration NGO's, UNHCR shelters and the Brazilian Government.

32	Soeiro R.E., et al  A neglected population: Sexual and reproductive issues among adolescent and young Venezuelan migrant women at the northwestern border of Brazil	2021	Boa Vista (Roraima State, Brasil)	153 (adolescent girls)	Venezuelan migrant AGYW	1024	Describe an overview of the main SRH issues affecting migrant Venezuela n AGYW in Boa Vista, Brazil.	Quantitative Cross- sectional Self- responded questionnair e	The migrant Venezuelan AGYW in Boa Vista have their SRH needs neglected, and due to the COVID-19 pandemic they might be more affected. Efforts to address SRH for this population should be on a coordinate and comprehensive response among the Brazilian healthcare network and NGO's.
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**Table 2: Evaluation of included Studies** 

Qualitative studies	1.1	1.2	1.3	1.4	1.5
Asnong C. et al, 2018	Y	Y	N	Y	Y
Bol K. N. et al, 2021	Y	Y	Y	Y	Y
El Ayoubi L. L, et al, 2021	Y	Y	Y	Y	N
Elnakib S., et al, 2021	Y	Y	Y	N	N
Ghandour R., et al, 2021	Y	Y	Y	Y	Y
Kemigisha E. et al, 2020	Y	Y	Y	N	N
Knox S.E.M., 2017	Y	Y	N	Y	Y
Korri r. et al, 2021	Y	Y	Y	Y	Y
Lee C. et al, 2017	Y	Y	Y	N	Y
Logie C. H. et al, 2020	Y	N	Y	Y	Y
Logie C. H. et al, 2021	Y	Y	Y	N	Y
Marlow H.M., et al, 2022	Y	Y	Y	Y	Y
McMichael C., 2013	Y	N	Y	Y	Y
Meyer, K., et al, 2022	Y	Y	Y	Y	Y
Ortiz-Echevarria L., et al, 2017	N	Y	Y	Y	Y
, ,					
Quantitative descriptive					
studies	4.1	4.2	4.3	4.4	4.5
Bakesiima R., et al, 2020	Y	Y	Y	Y	Y
Goers M., et al, 2022	Y	N	N	N	Y
Ganle J.K., et al, 2019	Y	Y	Y	Y	Y
Kågesten A.E., et al, 2017	Y	Y	Y	Y	Y
Logie C. H., et al, 2019	Y	Y	Y	N	Y
Logie C. H., et al, 2019	Y	Y	Y	N	Y
Malama k., et al, 2022	Y	Y	Y	N	Y
Marlow H.M., et al, 2022	Y	Y	N	Y	N
Soeiro R.E. et al, 2021	Y	Y	Y	N	Y
Soeiro R.E. et al, 2021	Y	Y	Y	N	Y
Mixed methods studies	5.1	5.2	5.3	5.4	5.5
Benner M. T., et al, 2010	N	N	Y	N	Y
Ivanova O., et al, 2019					
	Y	Y	Y	Y	Y
Loutet M. G. et al, 2022	N	Y	Y	Y	Y
Odo A.N., et al, 2020	Y	Y	Y	Y	Y

Okanlawon K, et al, 2010	N	N	Y	Y	Y
Pandit K., et al, 2022	N	Y	N	Y	Y
Rakhshanda S., et al	Y	Y	Y	Y	Y

# 4.2 Artigo 2: A neglected population: Sexual and reproductive issues among adolescent and young Venezuelan migrant women at the northwestern border of Brazil

Esse artigo responde ao segundo objetivo específico, que pretendeu identificar as principais questões em SSR de adolescentes e mulheres jovens migrantes venezuelanas em Boa Vista, estado de Roraima, Brasil. Foi publicado na revista *International Journal of Gynecology and Obstetrics*, e será apresentado a seguir.

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#### CLINICAL ARTICLE

Gynecology



# A neglected population: Sexual and reproductive issues among adolescent and young Venezuelan migrant women at the northwestern border of Brazil

Rachel E. Soeiro | Leila Rocha | Fernanda G. Surita | Luis Bahamondes | Maria L. Costa

Department of Obstetrics and Gynecology, University of Campinas Faculty of Medical Sciences, Campinas, SP, Brazil

#### Correspondence

Maria Laura Costa, Department of Obstetrics and Gynecology, The University of Campinas, 101 Alexander Fleming St; Campinas, SP, Brazil. Email: mlaura@unicamp.br

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#### Abstract

**Objective:** Adolescent and young women (10–24 years old) are a neglected group in humanitarian settings and their sexual and reproductive health (SRH) needs are habitually ignored. Our study aims to assess main SRH issues affecting migrant Venezuelan adolescents and young women in Boa Vista, Roraima at the northwestern border of Venezuela-Brazil.

**Methods:** A cross-sectional study with a self-responded questionnaire with information about SRH was conducted in 153 Venezuelan adolescent and young migrant women at Boa Vista, from January 18 to 23, 2021. A descriptive analysis was performed.

Results: Mean age was 17.7 years and two-thirds were under 20 years old. The majority (84%) were living on the streets. Most of them (54%) reported that they had at least one previous childbirth, 10% were pregnant at the time of the interview, 30% of them were not attending prenatal care. The main SRH concern was contraception (35%); however, 75% of those interviewed who went to a healthcare service were unable to obtain the method of their choice and for 91% no other contraceptive was offered.

**Conclusion:** Migrant Venezuelan adolescents and young women in Boa Vista have their SRH needs overlooked. Efforts to address these SRH needs, especially during the pandemic, require urgent attention.

#### KEYWORDS

adolescents, Brazil, migrant, sexual and reproductive health, Venezuela

#### 1 | INTRODUCTION

In the year 2020, the United Nations High Commissioner for Refugees (UNHCR) estimated that at least 79.5 million people around the world had been forced to flee their homes. Among them, nearly 34 million are adolescent girls and women of reproductive age. Adolescent girls and young women (10–24 years old) are a neglected group in humanitarian settings and their sexual and reproductive health (SRH) needs

remain neglected. <sup>4</sup> They have poor SRH outcomes because of reduced access to healthcare services and providers, services not being adequate for adolescents, lack of health supplies, and scarcity of trained healthcare workers. <sup>3-5</sup> Adolescents in contexts of humanitarian crises are more vulnerable to unplanned pregnancies because of lack of access to SRH services and contraceptives, sexually transmitted infections, including HIV, maternal morbidity and mortality, and genderbased violence including domestic and sexual violence. <sup>4,6</sup>

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One systematic review on SRH in nine African countries demonstrated that 60%–91% of displaced adolescent girls and young adults found it difficult to obtain contraceptives.<sup>4</sup> In Colombia, a study showed that the percentage of migrant Venezuelans attending for contraception was up to four times lower than in the host community.<sup>7</sup>

The World Health Organization defines adolescence as the population between the ages of 10 and 19 years<sup>8</sup>; however, research concerning adolescents is often extended to include individuals aged up to 24 years, defined as young adults or youth.<sup>3,4</sup> It was also reported that refugee and migrant adolescents have misconceptions about contraceptive methods and are unaware about sexually transmitted infections, including HIV. They are also victims of physical, psychological, and sexual violence in refugee camps and shelters and have a high rate of unplanned pregnancies.<sup>4</sup>

Since 2014, Venezuela has been facing a complex economic situation and the country is collapsing with a hyperinflation of 10 000% and a shortage of basic food and medical supplies. 9 This crisis has led to the largest displacement in the recent history of Latin American and Caribbean countries. According to the UNHCR, there are approximately 5.4 million refugees and migrants from Venezuela, including an estimated 1 million with irregular status. 1 It is estimated that over 289 000 Venezuelans migrated to Brazil between 2017 and 2019. $^{10}$  In Brazil, the main entry point for migrants coming from Venezuela is the state of Roraima (at the northwestern border). where approximately 10 000 Venezuelans are estimated to be living in the city of Boa Vista (the state capital), representing around 10% of the local population<sup>11</sup> and in Pacaraima, a small city with 17 000 inhabitants located exactly at the border between both countries. The UNHCR, the Brazilian government, and the Brazilian army have established 11 shelters in Boa Vista, hosting almost 4400 Venezuelans and two shelters in Pacaraima.1

Since March 2020, because of the severe acute respiratory syndrome coronavirus 2 (coronavirus disease 2019 [COVID-19]) pandemic, the Brazilian border has been closed. <sup>12</sup> Nevertheless, informal news reported that Venezuelan migrants continue to cross the border using alternative routes because the border does not have any physical or natural barrier. <sup>10,11,13</sup> The International Organization for Migration estimates that there are 1603 Venezuelans living in tents behind Boa Vista's bus station, including 71 female adolescents (12–17 years old). <sup>13</sup> Data on the Venezuelan migrant adolescents' needs, including SRH, are scarce and fragmented. <sup>3,5</sup> With the paucity of data, our aim was to provide an overview of the main SRH issues affecting migrant Venezuelan adolescents and young women in Boa Vista, Brazil. The results should contribute to the limited knowledge about SRH needs in this humanitarian crisis in this specific group of women.

#### 2 | MATERIALS AND METHODS

A cross-sectional study was conducted with the use of a selfresponded questionnaire among Venezuelan adolescent and young migrants enrolled at Boa Vista city (state of Roraima). The Ethics Committee of the University of Campinas, Brazil, approved the study protocol and all participants signed an informed consent or assent form before being interviewed (IRB no. 20458219.0.0000.5404).

For the unaccompanied under-aged adolescents (below 18 years), we obtained a waiver for the requirement that a responsible adult signs the informed consent form. As they are considered a vulnerable population, with significant prevalence of violence inside their households, Brazilian guidelines and regulatory norms for research involving humans<sup>14</sup> allow the research without the consent being signed by the legally responsible adult, as this could impose an additional risk for the adolescents when answering questions on SRH issues. Nevertheless, all included adolescents (below 18 years of age) have signed the informed assent and had the research adequately explained before the interview. We also obtained authorization from the UNHCR and from the State Underage Guardianship Council (*Roraima's Conselho Tutelar*) to interview adolescents.

The questionnaire, designed for this study, was adapted and translated into Spanish from the Minimum Initial Service Package readiness assessment tools from the Inter-Agency Working Group on Reproductive Health. It included multiple-choice questions on sociodemographic characteristics (age, ethnicity, cohabitation status, years of schooling, employment, income, place of residence, and migration information), number of pregnancies and childbirth, including current pregnancy status, prenatal or postnatal care and complications, other SRH issues (contraceptive desire and use, and other gynecologic issues), and availability of and access to SRH services, including user satisfaction.

The study was conducted in Boa Vista, Roraima, a Brazilian state located in northwestern Brazil that shares borders with Venezuela and Guiana. Boa Vista, the capital, has 430 000 inhabitants. Regarding the Brazilian healthcare system, according to the country's constitution, the National Health System (Sistema Único de Saúde) should provide universal coverage, and health care is considered an obligation of the state and the right of all individuals (nationals, residents, and migrants, including non-legally documented persons).<sup>16</sup> The National Health System offers from primary to specialized care, including the provision of prescribed medication that is in accordance with a list of essential drugs, and contraceptives (medroxyprogesterone injection, norethisterone enanthate/ estradiol valerate injectable, oral combined pill). However, the only long-acting reversible contraceptive method available at the public health institutions is the TCu380A intrauterine system. 16 In Boa Vista, there is only one public maternity hospital, providing inpatient healthcare in Obstetrics and Gynecology, it is 50 minutes away by foot from the tents to the bus station.

There are 34 primary-care health centers and each one is responsible for approximately 13 000 inhabitants, providing outpatient care in prenatal care, postnatal care, family planning, pediatrics, and communicable and non-communicable diseases. There are also the community health workers who go into the community to search for patients with any medical condition and refer them to the health centers. Since the beginning of the COVID-19 pandemic, they have

been struggling with COVID-19 management; prenatal care continues, but access for others medical issues is reduced and the community health workers cannot go into the community.

There are few non-governmental organizations, such as the International Organization for Migration and Doctors Without Borders (Médecins Sans Frontières), which provide a few consultations a week for the general population. There is no specific service for adolescents and young women. In Brazil, there are also private clinics and private hospitals, but they are not affordable for 95% of Roraima's population.<sup>17</sup>

Because of the COVID-19 pandemic, the research team was not authorized to enter in 9 of the 11 operating UNHCR shelters. as initially agreed. When the research team arrived at Boa Vista. the only places where interviews could be performed were the Boa Vista bus station (an informal shelter) and the St. Agostinho Church. Since 2019, hundreds of Venezuelans have been living in tents behind the Boa Vista bus station. The Brazilian army is responsible for providing food three times a day and organizing the daily routine there. One place is used as a restroom, with toilets and showers, and one point is adapted for laundry: people need to queue for use. Among the tents, there are some non-potable water points. In January 2021, there were 1603 Venezuelans non-legally documented living in there, including 71 adolescent girls (12-17 years old). 13 The St. Agostinho Church offers free food, goods, showers, and a laundry machine from a non-government program supported by the United Nations Children's Fund (UNICEF) and Caritas International.

A team of two female postgraduate students performed the data collection between January 18 and 23, 2021 in Boa Vista. Adolescents and young women between 10 and 24 years old (fluent in Spanish and literate) were approached at the informal shelter or the St. Agostinho Church and invited to participate in the study. All the communication was conducted in Spanish and the questionnaire was self-responded with an average duration of 30 minutes. We invited 167 adolescents and young women to participate and 153 (93.9%; age range 12-24 years) completed the questionnaire. Ten adolescents between 10 and 11 years old did not finish the questionnaire and four adolescents were unable to answer the questionnaire because of their mothers' refusal. A unique pre-defined identification number was attributed to each woman. Participants did not receive financial compensation. For data analysis, the simple distribution was initially performed for numeric variables (using means and standard deviations, range, median, and quartiles).

#### 3 | RESULTS

We interviewed 153 individuals, the mean ( $\pm$  standard deviations) age was of 17.7 ( $\pm$  3.6) years and two-thirds were between 12 and 19 years old. Among the below 18 years old group (81 adolescents), there were 28 (35%) unaccompanied (Table 2). The majority (84%) were living in the tents behind the bus station (Table 1)

TABLE 1 Sociodemographic characteristics of the migrant Venezuelan adolescents and young women interviewed at the Brazilian-Venezuelan border, 2021<sup>a</sup>

Characteristics of the adolescent/ young		
women (n = 153)	n	%
Age, y		
10-19	94	61
20-24	59	39
Ethnicity		
White	39	26
Biracial	62	40
Black	28	18
Asian	24	16
Cohabitation status		
Living with a partner	68	44
Without a partner	85	56
Schooling $(n = 150)^{b,c}$		
Did not finish primary school	2	1
0-4 years	52	35
5-9 years	77	51
10 or more years	19	13

<sup>&</sup>lt;sup>a</sup>Multiple choice questions.

and for most of them (81.1%) the main source of income since their arrival was through donations. The migration conditions are presented in Table 2. The majority (81%) migrated to Brazil within the 6 months before the interview, the main reason for migration was lack of economic opportunities (72%) and only 12% had attended some years of schooling in Venezuela. Despite most of the adolescents and young women having migrated with three or more people (68%), more than one-third from the underage group had migrated without any relatives, 66 adolescents and young women (44%) had children living with them in Brazil and 11% left at least one child in Venezuela.

Eighty-three adolescents and young women (54%) reported that they had at least one previous childbirth, 12 (15%) referred to having given birth after arriving in Boa Vista (Table 3). The majority (83%) reported that they attended prenatal care. Of the 12 youth who gave birth after arriving in Boa Vista, half attended postnatal care; but 50% of them reported that healthcare professionals failed to offer contraception following childbirth.

Regarding the current obstetrical conditions (Table 4), at the time of the interview, 15 (10%) were pregnant and two-thirds of them were attending prenatal care. Concerning the quality of prenatal care, not all the visits followed the recommended standard care, <sup>18</sup> 40% did not have a blood or urine test requested, only one-third had an ultrasound performed and more than half had not been informed about any alarm signs during pregnancy. For the one-third who were not attending prenatal care, 40% reported

<sup>&</sup>lt;sup>b</sup>Three adolescents and young women did not answer this question.

<sup>&</sup>lt;sup>c</sup>Two adolescents and young women did not answer this question.



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TABLE 2 Migration conditions of the migrant Venezuelan adolescents and young women interviewed at the Brazilian-Venezuelan border, 2021

Migration conditions	N	%
Period of time in Brazil (n = 153)		
Less than 1 month	64	42
1-6 months	60	39
6 months to 1 year	7	5
More than 1 year	12	8
Do not remember	10	6
Main reasons for migrating $(n = 153)$		
Lack of economic opportunities	110	72
Insecurity	10	6
Hunger	7	5
Corruption	5	3
Social violence	3	2
Do not know	18	12
Number of people who migrated with the $(n = 153)$	e adolescent/yo	ung women
1	24	16
2	24	16
3	22	14.
4 or more	82	53
Do not remember	5	1
People who migrated with the adolescen	nt/young womer	$(n = 153)^a$
Partner	62	20
Son/daughter	58	18
Parents	71	23.8
Brothers/sisters	75	24.0
Other	46	15
Adolescent younger than 18 years old un	naccompanied? (	n = 81)
Yes	28	35
No	53	65
Children living with the adolescent/youn $(n = 151)^b$	ng women in Bra	zil
Yes	67	44
No	84	56
Number of children living with the adole Brazil ( $n = 66$ ) <sup>c</sup>	scent/young wo	men in
1	37	56
2	23	35
3	5	8
4	1	1
Age of children living in Brazil $(n = 66)^{c}$		
Under 12 months	20	30
12 months to 6 years old	39	59
Older than 6 years old	7	11
	450)	
Employment status before migrating ( $n =$	= 153)	
Employment status before migrating ( $n = $ Formal job	= 153) 39	25

(Continues)

TABLE 2 (Continued)

Migration conditions	N	%	
Housewife or did not work	88	58	
Student	18	12	

<sup>&</sup>lt;sup>a</sup> More than one alternative was possible.

TABLE 3 Obstetrical background and conditions since arrival in Brazil of the Venezuelan adolescents and young women interviewed at the Brazilian-Venezuelan border, 2021

interviewed at the Brazilian-vene	zuelan border	, 2021
	N	%
Parity (n = 153)		
0	70	46
1	40	48
2	25	30
3	13	16
4 or more	5	6
Since you arrived in Brazil, have y	ou given birth?	(n = 83)
Yes	12	15
No	71	85
Did you attend postnatal care? (n	= 12)	
Yes	6	50
No	6	50
If you attended postnatal care, we contraception use? $(n = 6)$	ere you counse	led on
Yes	3	50
No	2	33
Do not know	1	17
Why did you not attend postnata	l care? $(n = 6)$	
I did not feel the need	2	33
I did not know where to go	2	33
I did not have time	1	17
No answer	1	17

that they did not know where to go and 20% did not have documents (although documents are not necessary to access Brazilian health care). From the 15 pregnant adolescents, four of them (27%) reported having health complications, but three out of the four did not seek medical care.

We further questioned the participants about their main SRH concerns (Table 5), and nearly half reported that contraceptive use was their reason to seek the healthcare system; however, 75% of them reported that they were unable to obtain the contraceptive method of their choice and the majority (90.5%) were not offered another contraceptive. Subdermal contraceptive implant and hormonal intrauterine systems (provided by Venezuelan public health care), both not available in the Brazilian public health care, were

 $<sup>^{\</sup>rm b}$  Two adolescents did not answer this question

<sup>&</sup>lt;sup>c</sup> One adolescent did not answer this question

TABLE 4 Current obstetrical conditions of the Venezuelan adolescents and young women interviewed at the Brazilian-Venezuelan border. 2021

	N	%
Are you pregnant? (n = 153)		
Yes	15	10
No	132	86
I don't know	6	4
Do you already know where you are going	to give birt	h? (n = 15)
Women's Reference State Center	1	7
Maternity hospital	6	40
Non Governmental (NGO) Clinic <sup>a</sup>	1	7
Don't know	7	46
During ANC visits, did you have your weigl	ht measured	i? (n = 10)
Yes	7	70.0
No	3	30.0
During ANC visits, did you have your blood (n = 10)	d pressure n	neasured?
Yes	8	80.0
No	2	20.0
During ANC visits, did you have your belly	measured?	(n = 10)
Yes	7	70.0
No	3	30.0
During ANC visits, did you have an urin tes	t collected?	? (n = 10)
Yes	6	60.0
No	4	40.0
During ANC visits, did you have a blood te	st requeste	d? (n = 10)
Yes	6	60.0
No	4	40.0
During ANC visits, did you have an ultraso	und perforn	ned? (n = 10)
Yes	3	30.0
No	7	70.0
During ANC visits, were you informed abo	ut warning:	signs? (n = 10
Yes	3	30.0
No	7	70.0
Why haven't you attended ANC? (n = 5)		
I don't know where to go	2	40.0
It's difficult to reach the health centre	1	20.0
I don't have time	1	20.0
I have no documents	1	20.0

<sup>&</sup>lt;sup>a</sup> There are NGO's running a primary care clinics for the Venezuelan migrants but they don't delivery babies.

requested by 50% of the adolescents seeking contraceptives. Half of the adolescents (50.3%) reported that they were satisfied with the attention received at the healthcare unit. In addition, one-third (30%) of those interviewed reported a history of violence (as victims); however, only 10 (21.7%) had reported the violence to any authority (Table 5).

#### 4 | DISCUSSION

Our study shows that life conditions of the Venezuelan migrant youth in Boa Vista are extremely concerning. Most of them are living on the streets (tents), without documents, with unmet SRH needs including contraceptive provision and insufficient healthcare during prenatal, childbirth and postnatal care. Their situation has been aggravated by the COVID-19 pandemic, when the current evaluation was conducted, with the closing of the Brazilian borders and the collapse of the health system in Brazil. At the time this study was prepared, Brazil had reported more than 371 678 deaths due to COVID-19.

Half of those interviewed had already had a previous childbirth. Higher rates of unplanned pregnancies among refugees and migrants are reported, <sup>3-5</sup> and adolescents are at great risk of complications in unplanned pregnancies.

One of the main concerns observed was that, despite the universal health care offered in Brazil, close to one-third of those interviewed were not attending prenatal care or presented issues with quality of care These results can be explained by the fact that adolescents usually start prenatal care late, because of not recognizing signs of pregnancy and fear of prejudice from family or medical services.<sup>2,21</sup> Poor prenatal care provision in primary care for pregnant women in general has been previously reported in other Brazilian cities, 21 indicating that it is necessary to reinforce prenatal care protocols to healthcare providers and develop a specialized care system for pregnant adolescents, principally migrants. For most of these migrant adolescents there is also the fact they are living in Brazil for only a few months, most of them are still living in the tents behind the bus station, under the supervision of the Brazilian army, trying to obtain documents and find a better place to live. Therefore, it is likely that they have a lack of familiarity with the healthcare system. without knowing the localization of healthcare centers, what kind of health care is provided and the fact that they have the right to receive medical care even without documents, according to Brazilian

Postnatal care was also a challenge. Most guidelines recommend at least three visits after childbirth and care should be an ongoing process with individualized comprehensive care until 12 weeks, including evaluation about postpartum complications, mental health issues, family planning, and breastfeeding. Studies have shown that almost 40% of women do not attend postnatal care cever, among adolescents in low-income countries these figures are even higher and are worst for migrants, reaching a loss to follow up of 76%. To the migrant adolescents, at least one postnatal care visit should be attempted, to provide guidance on contraception and evaluate any possible additional clinical risk for mothers and babies, and assuring childhood vaccination.

The results found in this study are in agreement with figures reported in other studies carried out with adolescents and young women in other humanitarian settings: lack of information in SRH, difficult to obtain contraception, and the insufficiency of specific programs for this population.<sup>3-6</sup>



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TABLE 5 Sexual and reproductive health issues and healthcare assessment in migrant Venezuelan adolescents and young women at the Brazilian-Venezuelan border, 2021

	N	%
Main self-reported SRH concerns (n = 153)		
Access to contraception	54	35
Prenatal or postnatal care	14	9
Gynecologic condition (e.g. menstrual disturbances, pelvic pain, vaginal discharge	21	14
Sexually transmitted infection	13	9
Sexual violence	5	3
Want to get pregnant	3	2
Do not have	43	28
Adolescent/young women consulted for SRH iss	ue (n = 152)	)
Yes	67	44
No	85	56
Reasons for consultation ( $n = 67$ )		
Contraception	28	42
Prenatal care	17	25
Gynecologic problem	4	8
Sexual violence	1	2
Other	16	23
Did you get the contraception you wanted? ( $n =$	28)	
Yes	7	25
No	21	75
What did you want as contraception? $(n = 28)$		
TCu380A	3	11
IUS	3	11
Contraceptive implant	11	39
Contraceptive injection	7	25
Oral contraceptive	3	11
Sterilization	1	3
Are you satisfied with the attention you received unit? $(n = 153)$	d at the heal	thcare
Satisfied	77	50
Partially satisfied	26	17
Dissatisfied	10	7
Do not know	40	26
For those who stated that they were dissatisfied satisfied, what was the reason? $(n = 36)$	or partially	
Many people attending the unit	3	8
Did not like the care received	7	19
Long waiting time	1	3
Language barrier	1	3
Others	4	11
Would rather not answer	20	56
What organizations do you know that provide SF $(n = 153)$	RH services	?
	46	30

(Continues)

TABLE 5 (Continued)

	N	%
Women's Reference State Center	14	9
Maternity hospital	23	15
Other service	3	2
Do not know any	67	44
Travel time from respondent's place of resident unit providing SRH services $(n = 111)^a$	ce to the heal	thcare
Less than 10 min	22	20
10-20 min	19	17
20-30 min	14	13
30 min or more	6	5
Do not know	50	45
Have you ever attended a program specifically $(n = 152)^{b}$	for young pe	ople?
Yes	11	7
No	141	93
Have you ever been a victim of sexual or physi	cal violence? (	n = 153)
Yes	46	30
No	107	70
Did you report to any authority? $(n = 45)$		
Yes	10	22
No	35	78
Did they receive you well? $(n = 10)$		
Yes	9	90
No	1	10

 $Abbreviations: \ IUS, intrauterine\ system; SRH,\ sexual\ and\ reproductive\ health; TCu380A,\ copper-bearing\ intrauterine\ system.$ 

Regarding SRH needs, migrant adolescents have a limited knowledge on such issues, facing difficulties in accessing age-appropriate and scientifically accurate SRH information and sex education. Healthcare professionals in humanitarian settings should be trained to provide information and provision of good-quality SRH, including specific services for adolescents and youths. 5,25

Our findings on the high frequency of physical and/or sexual violence, usually not even reported to authorities, corroborates other studies in refugee camps that describe a prevalence for physical and sexual violence higher than 50%, which provokes psychological suffering and, in many cases, leads to unplanned pregnancy. <sup>4,6</sup> To address gender-based violence issues a planned intervention with female and male adolescents, healthcare providers, social services, and humanitarian agencies is necessary. <sup>3,25</sup> Migrant adolescents and youths are a neglected group of migrants and remain understudied and underserved. Prioritizing SHR can avoid unplanned pregnancies, reduce maternal morbidities and mortalities, improve health outcomes, and decrease these individuals' vulnerability to gender-based violence. <sup>6,25</sup>

<sup>&</sup>lt;sup>a</sup>42 adolescents and young women did not answer this question.

<sup>&</sup>lt;sup>b</sup>1 adolescent did not answer this question.

In line with our findings, the Venezuelan women who migrated to Colombia also have unmet SRH needs that have been exacerbated during the COVID-19 pandemic, despite the implementation of the Minimum Initial Service Package in SRH by the Colombian Ministry of Health and Pan American Health Organization focused on migrants in cities on the Colombia-Venezuela border.<sup>7</sup>

Our study has a few limitations. Due to the COVID-19 pandemic it has not been possible to have access to the UNHCR shelters, consequently the results are almost entirely from migrants living on the streets. As we use a self-responded questionnaire, we could not enroll adolescents between 10 and 11 years old because they did not complete the questionnaires. However, the strengths of our study include the fact that it is the first to provide an overview of the status of SRH issues and concerns among Venezuelan adolescent migrants.

In conclusion, the migrant Venezuelan adolescents and young adults in Boa Vista have their SRH needs overlooked and because of the COVID-19 pandemic they might be more affected because primary health care is overcrowded by COVID-19 patients and there is reduced access for other health issues such as contraception and gynecologic follow-up visits. Efforts to address the SRH needs of this population require urgent attention. In spite of the pandemic, it is necessary to have a coordinated effort among the governmental healthcare network and non-governmental and international organizations to guarantee a comprehensive response.

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#### CONFLICTS OF INTEREST

The authors have no conflicts of interest.

#### **AUTHOR CONTRIBUTIONS**

RES, LB, and MLC had the initial idea for the study. RES and LR were responsible for data collection. RES, FGS, LB, and MLC were responsible for planning the analysis and interpretation of data. RES wrote the first draft of the paper. All authors read and approved the final manuscript.

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## 4.2 Artigo 3: Period poverty: menstrual health hygiene issues among adolescent and young Venezuelan migrant women at the northwestern border of Brazil

Esse artigo responde ao terceiro objetivo específico, que pretendeu fornecer uma visão geral das principais questões do manejo da higiene menstrual (MHM) que afetam as adolescentes e mulheres jovens migrantes venezuelanas em Boa Vista, estado de Roraima, Brasil. Foi publicado na revista *Reproductive Health*, e será apresentado a seguir.

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RESEARCH Open Access

# Period poverty: menstrual health hygiene issues among adolescent and young Venezuelan migrant women at the northwestern border of Brazil

Rachel E. Soeiro, Leila Rocha, Fernanda G. Surita, Luis Bahamondes and Maria L. Costa o

#### Abstract

**Background:** Adolescent and young women (10–24 years old) are habitually a neglected group in humanitarian settings. Menstrual hygiene management (MHM) is an unmet aspect of sexual and reproductive health (SRH) and an additional challenge if lack of hygiene products, inadequate access to safe, clean, and private toilets identified as period poverty. Our objective was to provide an overview of the main MHM issues affecting Venezuelan migrant adolescents and young women in the north-western border of Venezuela-Brazil.

**Method:** A cross-sectional study was conducted, early in 2021, with the use of a self-responded questionnaire, in Spanish, adapted from the Menstrual Practice Needs Scale (MPNS-36). All identified adolescents and young women aged between 12 and 24 years old were invited to participate (convenience sample-167 women). Women with complete questionnaires and who menstruate were included. Information on access to and quality of hygiene kits and toilets were retrieved, and a descriptive analysis performed, with an evaluation of frequencies for categorical variables (n, %) and mean (±SD-standard deviation) for continuous variables. In addition to the open-ended questions, we included one open question about their personal experience with menstruation.

**Results:** According to official reports, at the moment of the interviews, there were 1.603 Venezuelans living on the streets in Boa Vista. A total of 167 young women were invited, and 142 further included, mean age was 17.7 years, almost half of the participants who menstruate (46.4%) did not receive any hygiene kits, 61% were not able to wash their hands whenever they wanted, and the majority (75.9%) did not feel safe to use the toilets. Further, menstruation was often described with negative words.

**Conclusions:** Migrant Venezuelan adolescents and young women have their MHM needs overlooked, with evident period poverty, and require urgent attention. It is necessary to assure appropriate menstrual materials, education, and sanitation facilities, working in partnership among governmental and non-governmental organizations to guarantee menstrual dignity to these young women.

\*Correspondence: mlaura@unicamp.br Department of Obstetrics and Gynecology, Faculty of Medical Sciences, The University of Campinas, 101 Alexander Fleming St, Campinas, SP, Brazil



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#### Abstract

**Contexto:** Adolescentes e mulheres jovens (10–24 anos) são frequentemente negligenciadas em contextos humanitários. O manejo da higiene menstrual (MHM) é um aspecto ignorado em saúde sexual e reprodutiva (SSR) e um desafio adicional é a pobreza menstrual: falta de produtos de higiene pessoal, acesso inadequado a banheiros seguros, limpos e privados. Nosso objetivo foi fornecer uma visão geral das principais questões no MHM que afetam adolescentes e mulheres jovens imigrantes venezuelanas na fronteira da Venezuela com o Brasil.

**Método:** Foi realizado um estudo transversal no qual aplicou-se um questionário autorrespondido, em espanhol, adaptado da "Menstrual Practice Needs Scale" (MPNS-36) em janeiro de 2021, 167 adolescentes e mulheres jovens com idades entre 12 e 24 anos foram convidadas a participar, 142 responderam ao questionário. Os dados obtidos foram inseridos em um Banco de Dados elaborado para o estudo, no programa Excel para Windows e analisados no software SPSS. Foi realizada análise descritiva dos dados, com avaliação de frequências para variáveis categóricas (n, %) e média (±DP-desvio padrão) para variáveis contínuas. Recuperamos as informações de acesso e qualidade dos kits de higiene e realizamos uma análise descritiva. Além das questões de múltipla escolha, incluímos uma questão aberta: "Como é a menstruação para você?".

**Resultados:** Segundo informações oficiais, no momento das entrevistas, havia 1.603 venezuelanos vivendo nas ruas de Boa Vista. Foram entrevistadas 142 adolescentes, com média de idade de 17,7 anos, quase metade das participantes que menstruavam (46,4%) não receberam kit de higiene, 61% não conseguiam lavar as mãos quando desejassem e a maioria (75,9%) não se sentia segura para usar o banheiro. Além disso, a menstruação foi frequentemente descrita com palavras negativas.

**Conclusões:** Adolescentes e mulheres jovens imigrantes venezuelanas têm suas necessidades no MHM negligenciadas, com evidente pobreza menstrual, e requerem atenção urgente. É necessário garantir absorventes, educação e saneamento básico, trabalhando em parceria entre organizações governamentais e não governamentais para garantir a dignidade menstrual a essas jovens.

#### Plain language summary

Adolescent and young women (10–24 years old) are habitually a neglected group in humanitarian settings (situations of forced displacement, armed conflict, or natural disaster) and, in those contexts, they hardly have access to hygienic menstrual products, safe toilets, or water. This study provides an overview of the menstrual hygiene management issues among Venezuelan adolescents and young migrants living in the northwestern Brazilian border. We found almost half of the participants who menstruate (46.4%) did not receive any hygiene kits, 61% were not able to wash their hands whenever they wanted, and the majority (75.9%) did not feel safe to use the toilets evidencing the period poverty (lack of menstrual supplies, private toilets, sanitation conditions, and education) that affects the wellbeing of these women, especially during humanitarian crisis. Knowing about the Venezuelan adolescent migrant's menstrual health management issues may help other humanitarian settings to discuss and address those needs, reducing the physical, psychological, and social consequences of menstrual poverty.

Keywords: Adolescent/young women, Menstrual health, Period poverty, Migrant, Venezuela, Brazil

#### Background

It is estimated that there are at least 79.5 million people worldwide who have left their homes due to armed conflict, persecution, generalized violence, lack of economic opportunities, or human rights violations [1]. Around half of them are adolescent girls and women of reproductive age [1, 2]. The World Health Organization (WHO) defines adolescents as the group aged from 10 to 19 years old [3]. Nevertheless, research concerning adolescents is often extended to include individuals until 24 years old, defined as young adults or Youth, in agreement with contemporary patterns of adolescent growth [4].

Adolescent girls and young women are a neglected group in humanitarian settings [5] and their sexual and reproductive health (SRH) issues are habitually neglected [6]. They have limited knowledge about contraceptive methods, sexually transmitted infections (STIs), and are more vulnerable to unplanned pregnancies, leading to increased rates of unsafe abortion, maternal morbidity, and mortality. Gender-based, domestic, and sexual violence is also a key concern among this group [6, 7]. Issues considered trivial in other contexts, are of relevance in vulnerable populations, with important impact on individual wellbeing

and healthcare. Menstrual hygiene management (MHM) is an unmet aspect of SRH and can be an additional challenge for displaced adolescents and young women, due to a period poverty: lack of hygiene products, inadequate access to safe, clean, and private toilets that all of them impacting in their health and wellbeing [8–10]

In Latin America, the Venezuelan economic crisis during the last 5 years, led that almost 5.4 million Venezuelans leave the country [11], and it is considered the largest displacement in the history of the region [1, 12]. It was estimated that since 2017 over 455,000 Venezuelans have arrived in Brazil, and of these, about 40,000 currently reside in the city of Boa Vista (the state capital, near to Venezuelan border), representing around 10% of the local population [12, 13]. The Brazilian Government, in collaboration with the United Nation High Commissioner for Refugee (UNHCR), built 13 shelters in the state hosting at early May 2021, 7,175 Venezuelans as transit location waiting for a definitive resettlement in other parts of the country [14].

Due to the SARS-CoV-2 (COVID-19) pandemic, since March 2020, the Brazilian border with Venezuela was closed [15]; nevertheless, the Venezuelans continue to cross the border through alternative routes [16, 17]. The International Organization for Migration (IOM) reported around 1603 Venezuelans living in tents behind the Roraima's bus station, including 84 female adolescents (12–17 years old) [16]. Further, MHM is an important issue for migrant women worldwide [4]. Due to the scarce information regarding Venezuelan migrant adolescents about MHM, our aim was to provide an overview of the main MHM issues affecting migrant Venezuelan adolescents and young women in Boa Vista, Roraima, Brazil.

#### Methods

#### Study design and study tools

A cross-sectional study was conducted, with the use of a self-responded questionnaire, designed for this study, adapted, and translated into Spanish (the native language of the Venezuelan) from the Menstrual Practice Needs Scale (MPNS-36) [18]. This scale was developed after a literature review about menstrual practices in low-and middle-income countries and was assessed in a pilot survey in Uganda. It is available for download and can be further adapted for different ages and contexts [18, 19]. The questionnaire used in the current study included one open question about menstruation and multiple-choice questions on sociodemographic characteristics (age, ethnicity, cohabitation status, years of schooling, employment, income, place of residence, and migration

information), access to and quality of hygiene kits, and toilets. A unique pre-defined identification to each adolescent and young woman was attributed, respecting data confidentiality.

#### Study participants and sampling

Since 2019, there are hundreds of Venezuelans living in tents behind the Boa Vista bus station. The Brazilian army is responsible for organizing the daily routine at the place, providing food, vaccines, and some hygiene kits. In this place, there are limited non-potable water points among the tents, one place used as restroom, with toilets and showers, and one point adapted for laundry. It is estimated that 1603 Venezuelans non-legally documented are living in that place, including 84 adolescent girls (12–17 years old) [16].

A sample was selected from Venezuelan adolescents and young women living in tents behind the Boa Vista bus station, however those living in UNHCR shelters or in informal non-UN settlements in Boa Vista who attended the St. Agostinho church, a location that provides food and other essential items that migrant needed including hygiene kits under a program managed by UNICEF and CARITAS International, were also included.

A total of 167 adolescents and young women were invited to participate, 153 completed the questionnaire and 142 reported menstruation.

#### Data collection

The study was conducted in Boa Vista, capital of Roraima state. Due to the epidemiological condition of the Covid-19 pandemic, the research team was not authorized to enter the UNHCR shelters, as initially established and the only allowed places to perform the interviews were informal shelters. The largest one, located at the Boa Vista bus station and at the St. Agostinho church.

Two female healthcare providers (one physician and one nurse) were responsible for the data collection between 18 and 23 January 2021. The team identified young women between 10 and 24 years old (fluent in Spanish and literate) at the informal shelter or the St. Agostinho church and further invited them to participate in the study. A self-responded questionnaire was applied with an average duration of 30 min. Participants did not receive financial compensation.

#### Statistical analysis

A descriptive analysis was performed, the simple distribution was initially performed for numeric variables (using frequency, means, and standard deviations (SD), range, median, and quartiles). There was one open question in the questionnaire, on the women's personal experience/feeling about menstruation, as: "How is menstruation for you?" The answers were grouped by the frequency of the most used words and analyzed by similarity considering a keyword, from that, a visual representation of the results was created.

#### **Ethical issues**

The study protocol was approved by the Ethics Committee of the University of Campinas, Brazil and all participants signed an informed consent or assent form prior to being interviewed (IRB no. 20458219.0.0000.5404).

For the unaccompanied girls under 18 years of age, a waiver for the need that a responsible adult signed the informed consent form was obtained. The Brazilian regulation for research involving human beings [20] only accepted research without the consent signed for the legal responsible, in case of vulnerable populations [20], understanding that it could add an additional risk for the adolescents when considering questions on SRH issues. Nevertheless, all included young women have signed an assent form and were exhaustively elucidated about the research. The UNHCR and the Roraima State Underage Guardianship Council (Roraima's Conselho Tutelar) also authorized the study prior to its implementation.

#### Results

A total of 167 adolescents and young women were invited to participate, 142 (12-24 years old; 85.0%) completed the questionnaire; the age (mean  $\pm$  SD) was 17.7 ( $\pm$  3.6). Ten adolescents aged 10-11 years old were excluded because they did not adequately respond, filling out all alternatives in every question, invalidating their analysis and other four (under 18 years old), 11 adolescents were excluded because they reported that they had not yet had menarche and other four (under 18 years old), were also excluded because they were deprived of authorization by their mothers to participate in the study due to the topic related to sexual and reproductive health issues, including menstruation. In relation to housing conditions, the majority (84.5%) was living on the tents behind the Roraima's bus station, and for most of them (80%) the main source of income since they arrived in Brazil, was donations (Table 1).

A half of the interviewed females (50%) who menstruate did not receive any hygiene kit since they arrived at Boa Vista (Table 2). In addition, among those who received disposable pads (45%), little more than a half (53.6%) reported that the pads' material was rarely or never comfortable and there were not distributed in sufficient quantity (33.3%) (Fig. 1). No menstrual caps were distributed in this population.

**Table 1** Sociodemographic characteristics of the migrant Venezuelan adolescents and young women interviewed at the Brazilian-Venezuelan border (n = 142), 2021<sup>a</sup>

Characteristics of the adolescent (n = 142)	N	(%)
Age (years)		
10–19	83	58.4
20-24	59	41.6
Adolescent younger than 18 years old unaccompa	anied?b (n = 81	1)
Yes	28	34.6
No	53	65.4
Race $(n = 142)$		
White	34	23.9
Biracial	60	42.3
Black	24	16.9
Asian	24	16.9
Schooling $(n = 142)^c$		
0–4 years	46	32.4
5–10 years	77	54.2
11 or more years	19	13.4
Main reasons for migrating (n = 142)		
Lack of economic opportunities	101	71.1
Insecurity	12	8.5
Hunger	7	4.9
Corruption	5	3.5
Don't know	17	12.0

<sup>&</sup>lt;sup>a</sup> Multiple choice questions. Were included all the adolescents and young women who menstruate

Concerning the sociocultural concepts about menstruation, one third of the interviewed females do not feel comfortable about carrying pads with them and almost all of them (93.2%) in a certain way were concerned that someone could see the pads in the place where they were disposed (Fig. 1).

Although the majority (88%) reported they had access to a toilet for changing pads, these places do not offer adequate sanitation conditions, 61% were not able to wash their hands whenever they wanted and did not feel safe to use the toilets. Most of the interviewed women reported, at least sometimes, they were afraid to be harmed by someone (75.9%) or by an animal or insect (82%) (Fig. 2).

Regarding the open question ("How is menstruation to you?"), 28 participants (19.7%) did not respond it. Among those who responded, almost a quarter said they did not know, for the others in general the responses about menstruation were often described

b In Brazil the legal majority is from the age of 18 years old

<sup>&</sup>lt;sup>c</sup> Completed years at school. In South American countries, 0–4 years at school, means they did not finish primary school, 5–9 years means they completed primary school and 10 or more years means they studied until secondary school or more. At the moment of the interview, none of the adolescents was studying

**Table 2** Access to hygiene kits by migrant Venezuelan adolescents and young women interviewed at the Brazilian-Venezuelan border (n = 153), 2021

Since arriving at Boa Vista, which items of hygiene have you received?(n = 153)	N	%
Disposable sanitary pads	69	45.1
Others hygiene items (soap, shampoo, toothpaste, tooth brush)	2	1.3
None	71	46.4
Haven't had menarch yet	11	7.2
How were hygiene items distributed? (n = 153)		
International Organization for Migration (IOM)	8	5.2
United Nations Population Fund (UNPF)	5	3.3
Caritas	6	3.9
Brazilian army	8	5.2
Other	6	3.9
Don't know	37	24.2
Didn't receive	72	47.1
Haven't had menarch yet	11	7.2
Where were the kits distribute? $(n = 153)$		
Bus station shelter	46	30.1
Caritas Unit	6	3.9
Other	19	12.4
Didn't receive	71	46.4
Haven't had menarch yet	11	7.2

<sup>&</sup>lt;sup>a</sup> Were included all the adolescents and young women who menstruate

with negative words as horrible, terrible, bad, or painful. Figure 3 shows the grouping of words in their meanings according to the frequencies in which they appeared.

#### Discussion

Menstrual poverty among the Venezuelan migrant youth in Boa Vista, Brazil was evident: lack of access to adequate menstrual hygiene products, sanitation conditions and toilets.

Less than a half of the interviewed adolescents and young women had received menstrual materials (disposable pads), and for those, one-third reported that the quantity distributed was not enough for a month period. Further, menstrual caps were not allowed in this group of young women. The literature showed that in the lack of appropriate materials, the adolescents and young women handle menstruation with methods that could be unhygienic as reusable old cloth, tissue paper, leaves, wool pieces, or cotton [10, 21, 22]; this could cause discomfort, irritation, and potentially increase the risk of reproductive tract infections (RTI) [22, 23]. In the year 2014, the United Nations Educational, Scientific and Cultural Organization (UNESCO) reported that 1 out of every 10-menstruating youth miss school during their menstrual cycle due to lack of access to menstrual products and resources. Further, in many developing countries

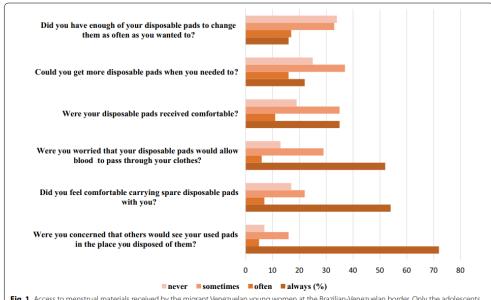


Fig. 1 Access to menstrual materials received by the migrant Venezuelan young women at the Brazilian-Venezuelan border. Only the adolescents and young women who received disposable pads answered this section (n = 69)

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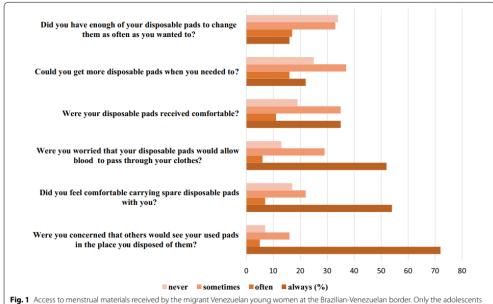
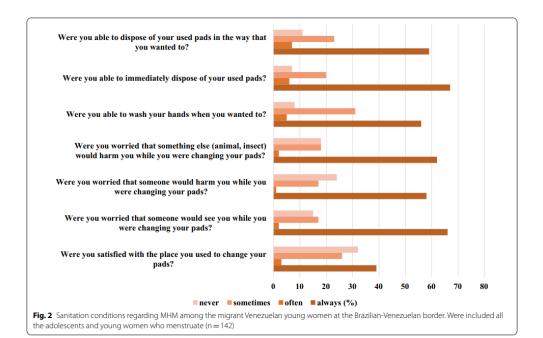


Fig. 1 Access to menstrual materials received by the migrant Venezuelan young women at the Brazilian-Venezuelan border. Only the adolescent and young women who received disposable pads answered this section (n=69)



many schools do not have sufficient toilets and when exist they were without adequate privacy and in many cases, they provided poor water, sanitation and hygiene infrastructure [24]. If this situation was described in set-

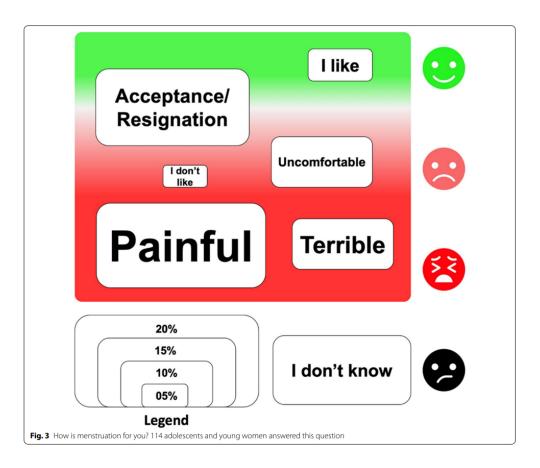
infrastructure [24]. If this situation was described in settings not under humanitarian crisis it is possible to imagine what happens among females living almost on the streets as occurred with the interviewed females.

In addition, it was described that those adolescents and young women in humanitarian settings can suffer sexual exploitation trying to manage their MHM needs [10, 22]. In our study, we observed that the majority of females reported fear and anxiety of leakage of bleeding through the clothes which was also reported in other humanitarian contexts causing psychological and social effects as harassment, isolation, and absenteeism at school [9, 10, 25].

Regarding the access to private toilets and sanitation infrastructure, not all the interviewed youth were able to use the toilets and the majority were unable to wash their hands, acknowledging the negligence already reported previously in MHM in emergency settings [8–10]. The absence of adequate sanitation facilities can increase the risk of sexual violence [22, 26] which was related as a fear by the majority of adolescents and young women in our study.

A stigma or taboo about menstruation in this group of migrants is clear, including the finding of mothers who have deprived their daughters to participate in this research, highlighting the characteristics of this transgenerational taboo, which contributes to the persistence of menstrual poverty [27]. Almost 30% of them did not answer the questions or answered that they did not know what menstruation for them is; moreover, for the others, menstruation was associated either with negative feelings or resignation. This has been described in other studies regardless the nationality, religious, or cultural beliefs [9, 10, 22-25], underlying the needs of education on menstrual and reproductive health with the youth and the communities, so that everyone, including men, would be knowledgeable and comfortable in discussing MHM issues [10, 22, 27].

The interviewed females reported a shortage of menstrual supplies, private toilets, sanitation conditions, and comprehensive information. This situation has been published previously in studies with adolescents and young women in other humanitarian contexts including in lowand middle-income countries; with socio-psychological impacts in quality of life and in reproductive health of this population [22–24, 26]. Regarding the reality in Boa Vista, so far, the Brazilian government does not have a



policy to address period poverty. On the latest October 07th, Jair Bolsonaro, Brazilian president vetoed a bill that provided for the distribution of sanitary pads to vulnerable populations. [28]

An international effort to alert and educate about this condition was created by the Alliance for Period Supplies: Period Poverty Awareness Week which took place on the last week of May (24–30) 2021 [29]. This initiative is very important to raise society' awareness, prompting to pressure governments to develop an educational policy that demystifies menstruation and ensures hygiene kits for adolescents, as has been done in Canada, Australia and New Zealand [30].

In humanitarian settings, the presence of other actors as NGO's, working in collaboration with governments and community leaders is also very important to educate,

advocate, provide adequate sanitation installations and assure access to hygiene kits [31].

This study has some limitations. Due to the COVID-19 pandemic it was not possible to have access to the UNCHR shelters, as initially agreed, consequently the results are almost only from migrants living on the streets. Since a self-responded questionnaire was used, adolescents between 10 and 11 years old were excluded because they did not complete the questionnaires adequately. Also, focus group discussions could be more appropriate to enable more data from the younger adolescents. However, the study strength is that, as far as we know, it is the first report which provides an overview of the status of MHM issues among Venezuelan adolescent migrants.

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#### Conclusions

In conclusion, the migrant Venezuelan adolescents and young women in Boa Vista have their MHM needs overlooked and due to the COVID-19 pandemic they might be more affected since they are living in precarious conditions. Efforts to address the MHM needs from this population require urgent attention.

Despite the COVID-19 pandemic, it is necessary to strengthen the collaboration among NGO's which are already working in Boa Vista, UNHCR shelters, the Brazilian army and local leaders discussing menstrual health, offering menstrual and hygiene kits, building adequate sanitation with proper water and specific toilets for women and advocating a government policy to address period poverty, in order to guarantee a menstrual dignity to this neglected population.

#### Abbreviations

IOM: International Organization for Migration; IRB: Institutional Review Board; MHM: Menstrual hygiene management; MPNS-36: Menstrual Practice Needs Scale; SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2; SRH: Sexual and reproductive health; STI: Sexually transmitted infections; UNESCO: United Nations Educational, Scientific and Cultural Organization; UNHCR: United Nation High Commissioner for Refugee; WHO: World Health Organization.

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#### Authors' contributions

RES, LB and MLC had the initial idea for the study. RES and LR were responsible for data collection. RES, FGS, LB and MLC were responsible for planning the analysis and interpretation of data. RES wrote the first draft of the paper. All authors read and approved the final manuscript.

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#### Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

#### Declarations

#### Ethics approval and consent to participate

The study received ethical approval from the Ethics Committee of the University of Campinas, Brazil and all participants signed an informed consent or assent form prior to being interviewed (IRB no. 20458219.0.0000.5404).

#### Consent for publication

Not applicat

#### Competing interests

authors declare that they have no competing interests.

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## 4.3 Artigo 4: Listening to Pregnant Women and their families who Experienced a COVID-19 Infection before vaccination: A Qualitative Approach within a Multicenter Study in Brazil

Esse artigo responde ao terceiro objetivo específico, que pretendeu relatar como as mulheres gestantes e puérperas experimentaram a suspeita/investigação e ou confirmação de infecção por COVID-19 e as consequências da pandemia para essas mulheres e as suas famílias. Foi submetido para a revista *Midwifery* e será apresentado a seguir.

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#### **ORIGINAL RESEARCH**

Listening to Pregnant Women and their families who Experienced a COVID-19 Infection before vaccination: A Qualitative Approach within a Multicenter Study in Brazil

Rachel E SOEIRO<sup>1</sup>, Renato T SOUZA<sup>1\*</sup>, Silvana F BENTO<sup>1</sup>, Jose G CECATTI<sup>1</sup>, Fernanda G SURITA<sup>1</sup>, Juliana Vasconcellos FREITAS-JESUS<sup>1</sup>, Rodolfo C PACAGNELLA<sup>1</sup>, Carolina C RIBEIRO-DO-VALLE<sup>1</sup>, Adriana G LUZ<sup>1</sup>, Giuliane J LAJOS<sup>1</sup>, Guilherme M NOBREGA<sup>1</sup>, Thayna B GRIGGIO<sup>1</sup>, Charles M CHARLES<sup>1</sup>, Carla SILVEIRA<sup>1</sup>, Maria J MIELE<sup>1</sup>, Ricardo P TEDESCO<sup>2</sup>, Karayna G FERNANDES<sup>2</sup>, Sérgio HA MARTINS-COSTA<sup>3</sup>, Frederico JA PERET<sup>4</sup>, Francisco E FEITOSA<sup>5</sup>, Evelyn TRAINA<sup>6</sup>, Edson V CUNHA FILHO<sup>7</sup>, Janete VETTORAZZI<sup>3,7</sup>, Samira M HADDAD<sup>8</sup>, Carla B ANDREUCCI<sup>9</sup>, José P GUIDA<sup>10</sup>, Mario D CORREA JUNIOR<sup>11</sup>, Marcos AB

DIAS<sup>12</sup>, Leandro G OLIVEIRA<sup>13</sup>, Elias F MELO JUNIOR<sup>14</sup>, Marília GQ DA LUZ<sup>15</sup>, and Maria Laura COSTA<sup>1</sup>, for the REBRACO Study Group#

- <sup>1</sup> Department of Obstetrics and Gynecology, University of Campinas, Campinas/SP, Brazil
- <sup>2</sup> Jundiaí School of Medicine HU/FMJ, Jundiaí/SP, Brazil
- <sup>3</sup> Clinics Hospital of Porto Alegre, Porto Alegre/RS, Brazil
- <sup>4</sup> UNIMED Maternity UNIMED/BH, Belo Horizonte/MG, Brazil
- <sup>5</sup> Federal University of Ceará MEAC/UFC, Fortaleza/CE, Brazil
- <sup>6</sup> Federal University of São Paulo UNIFESP/EPM, São Paulo/SP, Brazil
- <sup>7</sup> Moinhos de Vento Hospital HMV, Porto Alegre/RS, Brazil
- 8 Jorge Rossmann Regional Hospital Sócrates Guanaes Institute, Itanhaém/SP, Brazil
- <sup>9</sup> Federal University of São Carlos/UFSCAR, São Carlos/SP, Brazil
- <sup>10</sup> Sumaré State Hospital HES, Sumaré/SP, Brazil
- <sup>11</sup> Federal University of Minas Gerais HC/UFMG, Belo Horizonte/MG, Brazil
- <sup>12</sup> Fernandes Figueira Institute IFF/Fiocruz, Rio de Janeiro/RJ, Brazil
- <sup>13</sup> São Paulo State University School of Medicine, Botucatu/SP, Brazil
- <sup>14</sup> Federal University of Pernambuco HC/UFPE, Recife/PE, Brazil
- 15 Santa Casa de Misericórdia of Pará, Belém/PA, Brazil

#The full list of participants of the **REBRACO study group** is provided in the acknowledgements

Short title: Learning With Pregnant Women Who Experienced a Suspected COVID-19 Infection.

#### \*Corresponding Author

Renato T Souza

Department of Obstetrics and Gynecology

The University of Campinas

101 Alexander Fleming St; Campinas, SP, Brazil

rtsouza@unicamp.br

#### Abstract

Background: Pregnant and postpartum women infected by COVID-19 are at increased risk of adverse outcomes, including negative effects on their mental health. Brazilian maternal mortality rate due to COVID-19 is 2.5 times higher than overall mortality rates. This study aimed to understand how pregnant/postpartum women experienced the COVID-19 suspicion/investigation or confirmed infection in different Brazilian cities, the pandemic's consequences to women and their families, and their needs to improve maternal health services during public health emergencies. Methods: We conducted a qualitative study with 27 women with COVID-19 and 6 of their family members, as part of a multicenter study among 15 maternity hospitals in Brazil. We applied in-depth interviews through telephone calls when women received the diagnostic or had a suspect infection and after 60 days. Another semi-structured interview was applied to their close family members. The interviews were considered through thematic analysis. Results: Five major themes emerged from the interview: (1) assistance received by the woman and baby in the medical services, (2) COVID-19 pandemic impact, (3) support network, (4) problems related to antenatal visits and exams, (5) lessons learned. Conclusion: The COVID-19 pandemic still impacts the lives of pregnant women. Before the COVID-19 vaccine was available, these impacts were even greater due to fear of death, hospitalizations, quarantine, loss of family members, and financial impact causing physical, psychological, and socioeconomic repercussions on the lives of these women. There is an urgent need for multidisciplinary and comprehensive care, addressing specific information about the risk of COVID-19 in pregnancy, symptoms that may persist after COVID-19 infection, and adequate psychosocial support.

Key words: pregnant women, COVID-19 pandemic, experience

#### Introduction

Since March 2020, the world has faced a Public Health Emergency due to the coronavirus pandemic (COVID-19). (1) Brazil was one of the most affected countries in total numbers of deaths due to COVID-19 (1), most likely as a consequence of combined factors: its great extension (the fifth largest country worldwide), huge socioeconomical inequities and political crisis, with insufficient government measures. (2,3)

Studies have shown that pregnant and postpartum women with COVID-19 are at increased risk of adverse outcomes (4–6), with significant increment of anxiety, depression and fear, negatively affecting their mental health (4–6). Brazilian maternal mortality rate due to COVID-19 is 2.5 times higher than overall mortality rates, with impact of delayed care, including lack of access to health services, hospitalization in ICUs and intubation (7–9). Women with underlying comorbidities, such as obesity, diabetes, chronic hypertension prior to COVID-19 infection are at increased risk (10), and, although adverse outcomes such as anemia, preeclampsia, small for gestational age and stillbirth have been previously described for teenage/young women's pregnancies (11,12), scarce studies have analyzed the effects of COVID-19 infection among this relevant subgroup.

A study performed in India (13) comparing the first and second COVID-19 waves, before COVID-19 vaccine availability in the country, evidenced a higher number of moderate to severe disease and maternal deaths during the second wave of the pandemic, as well as a higher incidence of severe oligohydramnios and cesarean section.

Some studies (14,15) accessed pregnant women's well-being and psychological status, during the COVID-19 pandemic demonstrating that they have high levels of mental health diseases (anxiety, stress, and depression) and factors such as increased social support are protective for pregnant women. (14–16)

Among many unanswered questions about the COVID-19 infection in pregnant/postpartum women, we know even less about those women's experiences during the quarantine and infection periods and their consequences, especially for those who were infected in the first year of the pandemic, when the vaccination as a preventive intervention was not yet available.

Since the beginning of the pandemic, the Brazilian Network of Studies in Reproductive and Perinatal Health (a collaborative initiative comprised of more than 30 institutions that has been conducting multicentric studies on maternal and perinatal health for over 10 years) (13) settled a collaborative multicenter investigation, called REBRACO (Brazilian network of COVID-19 during pregnancy, in Portuguese: REde BRAsileira em estudos do COVID-19 em Obstetrícia). The purpose of the REBRACO study was to evaluate several conditions associated with SARS-CoV-2 infection during pregnancy and postpartum considering clinical, epidemiological and laboratory aspects, along with a quantitative and qualitative assessment on how women and healthcare professionals experienced this situation, to describe maternal and perinatal outcomes and collect relevant information to provide quick responses and proper organization of health services to face the COVID-19 pandemic (14,15)

There are a few qualitative studies regarding pregnant women's COVID-19 pandemic experiences (6,13), and, as far as we know, none including women's families.

The present analysis is on the qualitative approach within REBRACO study and aimed to report relevant information in different maternity hospitals in Brazil, to understand how pregnant/postpartum women experienced the COVID-19 suspicion/investigation or confirmed infection, the pandemic's consequences to women and their families.

#### Materials and methods

#### Study design

This qualitative study was part of the multicenter study REBRACO with quantitative (a cross-sectional study, a cohort study, an ecological study, qualitative approaches, and a crisis management committee in the COVID-19 Research Network) carried out in 15 Brazilian referral maternity hospitals (14).

As at the beginning of the pandemic, the COVID-19 prevalence and incidence for pregnant women were unknown, the sample size for the REBRACO study was stipulated by convenience: all pregnant or postpartum women who met the inclusion criteria (presented at maternity hospitals with flu-like symptoms or COVID-19 test positive) were invited to participate on the study.

After they signed the informed consent were collected sociodemographic data, medical history, and telephone numbers. It was also informed that they would be further contacted for a telephone interview.

In this paper, we focused on investigating the experience of pregnant/postpartum women who presented COVID-19 suspicion/investigation or confirmed infection and their families' experience in different maternity hospitals in Brazil during the first and second wave of the pandemic in Brazil (from August 2020 to March 2021).

We conducted in-depth interviews and we thematically analyzed data, building categories. The manuscript was written according to the COREQ checklist. (15)

#### Study participants, recruitment and setting

The participating centers were from four of the five Brazilian macro-regions of the country (North, Northeast, Southeast, and South) from university and nonuniversity hospitals, and from both public and private sectors.

From 1st February 2020 to 28 February 2021, all pregnant or postpartum women aged between 13-49 years and with COVID-19 symptoms (presenting at least one of the following symptoms fever, cough, shortness of breath, sputum production, nasal or conjunctival congestion, difficulty swallowing, sore throat, runny nose, O2 saturation <95%, signs of cyanosis, flapping of the nose and dyspnea or other symptoms such as diarrhea, anosmia, and dysgeusia) who attended the maternity services at the participating centers were invited to participate in the Rebraco study.

At admission eligible women received an explanation about the study and, in case of agreement, they signed the Informed Consent Form (for women older than 18

years old and legally responsible for women under 18 years old) and the Assent Form (for women under 18 years old).

They were also informed they could be contacted later by phone or *WhatsApp* message for an in-depth interview.

The REBRACO study included 729 women, for the main study. For the current qualitative study, three women over 18 years old and one woman below 18 years old from each center were randomly selected (n=60). The research team further contacted those women by phone calls or WhatsApp messages asking if they agreed to participate in an in-deep interview by phone. At the first contact, the study protocol was explained to the women and all the questions were answered. The women could think about and answer later by WhatsApp message if they agreed to participate, they could also ask for further information, before scheduling the interview.

In case of refusal, the women were replaced by another one (randomly selected) from the same center. Due to the refusals, the research team reached out to 136 women. (Figure 1) until achieving the saturation sampling method. (15)

We also included the women's close family members or partners, as indicated by them during the interview, to understand how the COVID-19 pandemic impacted the pregnant women's families. As the family members or partners' interviews depended on the women's indication, there was no initial sample size considered.

We collected data remotely through telephone calls from August 2020 to March 2021. The initial contact was made by phone call or WhatsApp message inviting the women to participate in the study. It was established that three attempts would be made to contact each woman on different days and times before discarding the selected case.

#### Data collection

We applied in-depth semi-structured interviews through open-ended questions about their COVID-19 pandemic experience related to treatment and information received, quarantine period, concerns related to self-care or baby care and the impact in their daily lives. Another in-depth semi-structured guide was applied to their close family members or partners encompassing questions about the impact of the COVID-19 diagnosis in the women's lives, family, the medical information received and their

major concerns. For all the women, a second interview 60 days after the first one was also proposed to follow up the women after the COVID-19 suspicion/infection. For that interview, a new questionary was designed with a focus on the recovery period and meanings of the COVID-19 in their lives. All the interviews were audio-recorded and transcribed *verbatim* for data analysis.

At the beginning of the interview, the interviewer recommended that the participants should be in a private place where they would feel comfortable talking about the subjects approached. At the end of the interview, the interviewer asked the participants if they would like to add any other additional information. There were two interviewers for this study, a medical doctor and a social researcher with previous experience with qualitative research and specific training towards this study.

The first interviews with women and family members lasted from 10 to 58 minutes.

#### **Data Analyses**

All semi-structured interviews were recorded on audio, subsequently, recordings were transcribed through Reshape Software, and the text obtained was checked with the recording. Then texts were inserted into the NVivo V.12 computer program to help with the analysis.

Based on Braun and Clark's (16) recommendations the transcriptions have been read several times and individually codified. Two researchers initially generated codes and after discussion defined themes, and subthemes, developing analytical connections for the thematic content analysis (17), concepts from health psychology were used for interpretation. Health psychology (18) considers not only biological, social, and psychological factors that may influence the health-disease process and physical and emotional well-being but also the physical and psychosocial environment, the sociocultural support systems, and the political systems that influence health and health care, including risks and protective factors. Therefore, for the thematic analysis, health psychology aspects (psychological distress, physical consequences of COVID-19 infections, social impact of the pandemic) were considered in the interpretation of the feelings and behaviors described by the women and their families.

#### **Ethical issues**

The research followed the determinations of the Helsinki Declaration, as well as the norms that regulate the research involving human beings in Brazil. Ethical approval for the coordinating center was given by the Institutional Review Board of the State University of Campinas (Unicamp) and for each participating center was obtained (Letter of Approval number 31590120.7.0000.5404). The informed consent was not signed. Since the interviews were conducted by telephone and recorded, the Institutional Review Board authorized that after the process of obtaining the informed consent, if woman/family members accepted to participate, their acceptance should be recorded. A specific informed consent was prepared for each category of participants (women/ family members and adolescents and their parents).

At the time of the telephone interview, the informed consent was read before data collection, all questions from the participants were elucidated and they were informed they could interrupt their participation at any time without consequences and they were also assured their identity would be kept confidential. The participants were asked if they agreed to participate in the study and if they allowed the interview to be recorded. The verbal consent was audio-recorded. After the interview, a copy of the informed consent was sent to each of the participants by e-mail or text message/WhatsApp.

#### **Psychology support**

There was a psychology referral system from each center, in cases where the research team noticed that women or their families presented concerning symptoms of emotional distress during the interviews, or if requested by them.

One woman was referred to psychology support.

#### Results

We interviewed 27 women and 6 family members. Table 1 shows the sociodemographic characteristics of the pregnant women. Women included were 18

years old or more. From an initial list of eligible women, we tried contact with other 109 women before reaching saturation with the last interview, most of them never answered the phone or messages. In the second interview, 60 days after the first one, four women participated, the others did not answer their phones neither the WhatsApp messages. The second interviews lasted from 6 to 12 minutes. Figure 1 represents the process of selecting participants, 11 participating women indicated close family members or partners. We used the same approach detailed above and after three attempts, six people accepted to participate.

Five major themes emerged from the analyses: assistance received by the woman and newborn in the medical services (outpatient care, emergency room, hospitalization, childbirth, and neonatal care), COVID-19 pandemic impact, support network, problems related to antenatal visits and exams, and lessons learned. Figure 2 demonstrates the process of thematic content analysis.

### 1. Perspective on the assistance received by the woman and newborn in the medical services

In this category, two subcategories were defined regarding the access and medical care received in outpatient care, emergency room, hospitalization, childbirth, and neonatal care.

#### 1a. COVID-19 infection misdiagnosis

Most women reported that they searched care, but the symptoms of COVID-19 were mistaken by pregnancy symptoms, mainly for the ones with a high-risk pregnancy. In addition, in the first months of the pandemic, most services did not perform confirmatory COVID-19 tests (in many settings there were restrictions and only cases admitted or severe, were tested). Their perception was that the delay in diagnosis had an impact on both, their health and their baby's health, leading to the worst outcomes. This is because some of them were only hospitalized when the disease symptoms were very advanced, and therefore needed ICU admission.

"... I'm short of breath and I'm feeling like I can't breathe... "Ah, but it's normal because you're pregnant...", but I was twenty-two weeks yet, I didn't have a giant belly of end of pregnancy". (Interview 2)

"Actually, the first test was negative, I was calm. my husband was hospitalized [and intubated] and his was positive. ... The shortness of breath started to increase; I thought it was just because of the pregnancy. ... the days went by, the shortness of breath increased... [my friend] took me to the hospital and I was hospitalized [in the ICU] and in the next morning I was intubated". (Interview 7)

"I went several times to the hospital. Since I was about almost eight months pregnant, they said it was back pain and it was normal from pregnancy. [...]. So, they sent me home, with painkillers". [...]

When I arrived [after several medical consultations], the doctor suspected it was Covid [...] I couldn't speak anymore. I couldn't breathe on my own anymore. Then they put me the oxygen and sent me to the hospital [...] I was in a serious condition". (Interview 11)

#### 1b. Feelings regarding hospitalization, childbirth, and the newborn

The situation the women experienced during initial evaluation and hospitalization (in the beginning of pandemic) as to the lack of adequate care, fear of contamination from health workers and lack of information and guidance about COVID-19 made them feel insecure and distressed with their health, afraid of dying or of adverse outcomes on the fetus and also worried about the other children they left at home.

"What was on my head? I said: "wow, I am going to die". Because we are seeing it on television. Everyone is dying because of this disease. Then I said, now that's it, one more, I am going to die too, I was pregnant with high blood pressure, I said now I'm going to die too, we get scared, frightened". (Interview 3)

"I was very [emotional]. Every time I thought about it, the more I thought about them [their children], the worse I got [in health]. ... every time I heard from them or had news about them, I got worse. Ah, I thought I would not be able to go back and see my children again". (Interview 11)

Regarding childbirth and neonatal care, some women were intubated prior to or during delivery and when they resumed consciousness, they realized that the baby was no longer there. Other women reported that as the baby was premature, they had no contact with the baby who was immediately taken to the Neonatal Intensive Care Unit (NICU). The husband of one of them died during the period she was intubated; she received the information when she woke up along with the one that her baby had been born (Figure 3).

"... on the third day that I was intubated, they took the baby out, because he was in fetal distress, they said he was at risk, he and I. Then they took the baby and when I woke up it was a shock! I woke up still unable to speak, I was very weak, and I put my hand on my belly and said where is my baby? I thought where is my baby? Then I started crying, desperate, and then they increased the oxygen, I got nervous, and my oxygenation dropped again. They put me on oxygen, increased it and told me "If you don't stay calm, we'll intubate you again...". (Interview 11)

"... crying every day at home, I could see the baby [after 22 days] who was already very fat, she had changed so much, I cried and said, 'my daughter will not recognize me'. She will not know who I am". (Interview 8)

#### 2. COVID-19 pandemic impact

Among the women's answers, we observe that the COVID-19 pandemic has affected their lives in different ways. Some of them had severe symptoms, others had suffered from fear and social isolation, others had financial losses and other had family member losses. Figure 3 shows an example of how COVID-19 infection has affected one pregnant women's life and all her family.

In this category, three subcategories were defined, emotional distress due to the COVID-19 infection, financial impact, and post-COVID-19 symptoms.

#### 2.a Emotional distress due to COVID-19

The women reported several feelings regarding the COVID-19 infection/suspicion period. They mentioned the difficulty of being alone and without communication during hospitalization time and experienced prejudice or fear of contamination from health workers, family members, neighbors, and friends reported by the women due to being diagnosed with COVID-19.

Regarding the fear/prejudice from the health workers, some women reported they suffered a lot with the treatment received, mainly when they were hospitalized. Some of them said they were outraged by the disrespectful treatment received, other told the health workers had avoided any kind of contact with them worsening their physical and emotional status.

"The nurse didn't want to pick me up, lift me up... He was afraid of contaminating himself. ... they did not want to touch me." (Interview 17)

"I felt that no one wanted to have contact with me [...] I felt like an "ET" [...]. I felt [they were] afraid of the disease, I felt it. I perfectly understood what was happening, they had to protect the other patients." (Interview 4)

Nine women reported that they suffered with the fear felt from their family members and people they knew.

"... Some people were afraid of contamination, even my brother, [...], he did not even want to have contact with my children or my husband, because he was afraid..." (Interview 11)

"People from my street [had prejudice] yes. I was on a sidewalk, they went to another, I called, and they answered from afar." (Interview 13)

Experiencing quarantine during the infection was considered very difficult for some women. They reported concern about contaminating their families and found it difficult to not have contact with family (mainly their children) and other people.

"... my other son is nine years old, and I couldn't be with him. ... I talked to him through the window. My son practically sleeps with me... I was very, very sad and worried because I could transmit [the COVID-19 to the family]." (Interview 1)

"... it was terrible because staying for 15 days at home and not being able to go out is terrible. I slept, ... I was very stressed about being locked in the house." (Interview 22)

One woman on the second interview mentioned that people at work judged and blamed her for getting COVID-19. She also mentioned that when she got infected, her boss wanted her to go to work anyway, and when she returned to work after the COVID-19 infection, her role at the company had changed.

"People judged me, they said I got it (COVID-19) because I went out, ... in fact, I had contact with people at work who got COVID [...] In fact, people tried to blame me because I left (the work during the quarantine period), [...] on the day I got COVID-19. I warned (my boss) that I would not come back from lunch, she wanted me to work anyway [...] when I returned (after the quarantine period) my activities had completely changed, [...] now I think when I return from maternity leave, they are going to fire me..." (Second interview 16)

Some women reported the experience of having lost important pregnancy moments and.

"I am really upset because I could not take pregnancy pictures, I could not do the baby shower, I could not introduce my daughter to the family, [...]. Looking back is very sad..." (Second interview 5)

#### 2.b Financial impact

The women who had paid activities before the pandemic referred financial loss that negatively affected their lives. Those who worked on their own had an even larger decrease in their salaries.

"...When I found out I was pregnant, I was put on leave from my work [...] we had a financial impact. We had to cut off everything that was not essential in April, May, June and July. [...] Then, in July, we couldn't do it anymore, [...]even the supermarket (it was not possible) to buy everything we needed. We went through this change." (Interview 4)

"Mainly financial impact, because I work on my own and I had to stop working [due to social isolation]." (Interview 21)

#### 2.c Post-COVID-19 symptoms

Eight women reported some symptoms after COVID-19 infection (post recovery from acute infection), but they also referred comorbidities and could not affirm if the symptoms were due to COVID-19 or some comorbidity they had previously. At that moment the information regarding post-COVID-19 symptoms were scarce.

"After you get the coronavirus, it takes six months to get back to normal. Sometimes I feel a strong headache, body ache, but I also have high blood pressure, it could be due to high blood pressure, I take controlled drugs, but I don't know if it is from the coronavirus, I became a bit forgetful about things". (Interview 11)

"I still have pain, [...] the disease affected me a little bit more." (Interview 2)

"I don't know if it is from the COVID-19, but I definitely know it is from the pandemic, let's say, knee pain, joint pain, lack of energy, weight gain, all this due to the pandemic [...] the doctor said it's probably due to the pandemic." (Second interview 5)

The psychological impacts of COVID-19 it was also reported.

"I felt like the floor was falling out from under me"; " It was a disaster in my life" (the death of her husband from COVID-19 at the same time she was intubated with SarsCov-2). (Second interview 7- Figure 3)

#### 3. Support network

The women reported having received different ways of support: partners, family members, friends and peer support groups. They described how the support received had a positive impact on their pregnancies during the pandemic.

"I received help from my mother. She helped me to stay at home, cleaned my house, cooked food, and did everything that I needed..." (Interview 18)

"He (the husband) was really concerned about me. [...] He did not step away from me. He took care of me all the time, if it was not for him, I would not have been able to overcome the COVID-19 infection." (Interview 21)

"... I talked with other mothers because we had a group (WhatsApp) of mothers, [...] we talked to each other about the symptoms, information [...]. So, for me, it was calmer afterwards, because of that." (Interview 23)

#### 4. Problems related to antenatal visits and exams

Some women reported they were afraid to get the COVID-19 virus and did not attend their antenatal consultations, but most of them still kept going to the appointments. Other women told the primary care center was closed due to the pandemic.

"[I thought] a lot [about not showing up] because I could get the virus at the doctor's appointments. I stopped going to antenatal consultations in the last 3 months..." (Interview 21)

"[I] had a lot [of difficulty to get an appointment] at the beginning of the pregnancy, [...] they [Primary care center] were not offering care..." (Interview 21)

#### 5. Lessons learned

After the COVID-19 symptoms or confirmed infection, the women reported different lessons learned which did not appear in the first interview: to be more careful about their health and follow the guidelines regarding COVID-19, to consider other people and try avoiding contamination, to avoid procrastinating about things they need and want to do in the future.

"... it served as a warning for us to open our eyes, to be more careful about where we go, to really take care [,..]not to go to a very crowded place, to stay indoors, these things." (Second interview 16)

"...it was a very big learning experience, seeing other mothers going through the same as myself [...] there was a lot of people who got COVID-19, people who were hospitalized, so I think I learned a lot with this ... I have started to think about the others, because there is my father-in-law, my mother-in-law, there is my son who is

young, so we have to follow all the protocols, wash our hands, use sanitizer..." (Second interview 1)

#### Family perception

The close family members/partners interviewed reported they had a very difficult time during the pregnant women's COVID-19 suspicion/infection. All the partners reported having felt fear and anxiety for the women and babies' lives, and as was reported by the women, they also mentioned the family support received was very important during the women's COVID-19 infection/hospitalization.

One of the interviewed family members reported his brother passed away from COVID-19 at the same her sister-in-law was intubated in ICU, and she had to take care of her two nephews who were at home, waiting for their parents. Figure 3 shows some phrases expressing the feelings described by her.

"... I was taken by surprise because she was hospitalized during the night... and in the other day... I found out that she had delivered... [...] This was far from the worst of all." (Family member 4)

"... Some friends helped a lot, [...] And the family members of both my family and hers.
[...] so, the family was fundamenta.!" (Family member 4)

"Oh, it was very bad for me, [...] she was hospitalized, [...], what I felt was fear." (Family member 5)

#### **Discussion**

Our study evidences that the COVID-19 pandemic has affected the lives of pregnant/postpartum women, their babies and families from antenatal care to post-COVID-19 symptoms, including families' losses and financial difficulties in the first year of the pandemic. All the interviews were done before the availability of the COVID-19

vaccine, at that moment Brazil was facing an increase in the daily number of hospitalizations and deaths due to COVID-19 infection, and at the same time as, in several states, only essential services were working impacting psychological and financially those pregnant women's life.

The perception of the delay on medical care reported by some women at the beginning of the pandemic, could be explained by the uncertainties related to COVID-19 diagnosis and clinical management, the shortage of diagnostic tests or to false-negative results leading to worst outcomes (3,9). Studies have described ICU admissions, severe perinatal morbidity or preterm delivery in COVID-19 infected pregnant women due to scarcity of trained health workers misdiagnosis or false-negatives tests.(19–21)

Among women who had Severe or Critical Illness, the fear of dying and the feeling of having missed their delivery due to their clinical status (intubation) was reported by all of them. An association between patients with severe acute respiratory distress syndrome and increased risk of medically indicated preterm birth has already been described (22). The critical situation those women have faced can lead to Depression, Anxiety and Post Traumatic Stress Disorder (PTSD) and should be addressed to avoid complications in the post-partum period. (23,24)

In both, first and second interviews, there were symptoms related to post-COVID-19 syndrome reported, nevertheless, they were not properly diagnosed. So far, post-COVID-19 syndrome has been described with different clinical manifestations, like fatigue, dyspnea, pain, dizziness, headache, cognitive impairment, depression, anxiety, post-traumatic symptoms, causing a decrease in quality of life, leading to an increase in suicide risk. (25,26).

Some women associated how they felt to a prejudice from part of health workers. This could be explained as a fear of contamination from the health workers because at the beginning of the pandemic, in many Brazilian cities, there was a clear lack of trainings and of available individual protection equipment (3). This treatment received at the hospital could cause even more stress leading to depression and anxiety to those women, who were already concerned about themselves and their babies' health. Studies have shown that pregnant women infected by COVID-19 are at increased risk to develop anxiety and depression. (6,27)

Although most of pregnant women kept going to their antenatal consultations, there were some reports about not attending antenatal care due to fear or because the primary health care had cancelled it during the pandemic. Those different answers could be a consequence of the inequities in Brazil, the cities far from capitals had reduced access to health care (2), disruption on maternal health care services have been described in other low and middle- income countries as well.(21,28)

It is important to observe that the feelings regarding the incertitude of the COVID-19 pandemic, problems related to work, grieving for missing pregnancy milestones or for family losses remained and came up in the second interview, those feelings added to post COVID-19 syndrome, that was previously described (6,23) and need to be addressed to avoid the long-term burden in those women's mental health.

In the second interview, we could understand that the lessons learned described in the interviews, were related to the coping strategies. All women acknowledged the family members' support as a protector factor. This was also considered by the close relatives/partners. The family member's support even through WhatsApp calls were described as an important coping mechanism for pregnant women during the pandemic. (23)

Our study has a limitation that we could not enroll the adolescents under 18 years old, our list had 9 adolescents, but they never answered the telephone or WhatsApp messages. The finding of the increased refusal of adolescents in participating needs to be further addressed and should be considered as a limitation for understanding the impact of the pandemic on their lives. Future studies must focus on different communication skills to capture such experiences among young and adolescent women. However, the strengths of our study include the fact that we could interview the same women at two different moments, and we could also interview their close family members/partners to enable an overview of the pandemic impact on their lives.

#### Conclusion

The COVID-19 pandemic impacted the lives of pregnant women in a very diverse range of complications. Before the COVID-19 vaccine was available, the misinformation, the overload of health services and the unknown involving the COVID-

19 infection consequences impacted all women's lives we interviewed: physical and psychological sequels, loss of family members, and socioeconomic impact. There is a need for multidisciplinary and comprehensive care, addressing specific care in social and psychological support for those affected by COVID-19 in pregnancy.

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### Declaration of interests

The author(s) report(s) no conflict of interest.

### **Contributors**

MLC, RTS, RCP and JGC developed the concept of the primary study. The other members from the coordinating center including SBF, CCRV, AGL, GJL, LGB, FGS, and post-graduate students RES, GMN, TBG, CMC, MJM, JPG worked to implement the study. Then the idea of increasing the initiative to a network for a multicenter study arose and RPT, KGF, SMC, FJP, FEF, RM, ET, EVCF, JV, SMH, CBA, MDCJ, MABD, LGO, EFMJ, CASM and MGOL were invited and contributed with information for building the proposal. All of them read and agreed on the final version of the manuscript. SFB conducted the analysis. RES wrote the manuscript which was revised and approved by all co-authors.

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Table1: Sociodemographic characteristics of the pregnant women

Number	Ag e	Scholars hip	Ethnici ty	Marital Status	Number of Pregnan cies		Hospitalizat ion	ICU	Regi on*
1	38	High School	Non- white	Married	2	Yes	Yes	No	
2	45	High School	White	Cohabitatio n	3	Yes	No	No	4
3	22	Elementa ry	Non- white	Cohabitatio n	1	No	Yes	Yes	4
4	33	Higher education	White	Married	2	Yes	No	No	3
5	40	Higher education	White	Married	1	Yes	No	No	4
6	29	High School	Non- white	Single	1	No	Yes	No	4
7	35	High School	Non- white	Widow	3	Yes	Yes	Yes	3
8	38	High School	Non- white	Married	2	Yes	Yes	Yes	1

9	36	Elementa ry	White	Married	1	Yes	No	No	4
10	24	High School	Non- white	Married	1	Yes	No	No	4
11	36	Elementa ry	Non- white	Married	7	Yes	Yes	Yes	4
12	33	High School	Non- white	Married	2	Yes	Yes	No	4
13	NI**	Elementa ry	Non- white	Cohabitatio n	3	Yes	No	Yes	4
14	24	Higher education	White	Single	1	Yes	No	No	4
15	48	Higher education	White	Cohabitatio n	1	Yes	No	No	3
16	34	Higher education	White	Single	1	Yes	Yes	No	4
17	20	High School	Non- white	Married	1	Yes	Yes	No	2
18	25	High School	White	Married	4	Yes	No	No	4
19	39	High School	Non- white	Single	1	Yes	Yes	No	3
20	39	High School	Non- white	Married	2	Yes	Yes	No	4
21	NI	High School	Non- white	Cohabitatio n	1	No	No	No	3

22	20	High School	White	Cohabitation	1	No	No	No	4
23	37	High School	Non- white	Cohabitation	2	Yes	Yes	Yes	2
24	21	High School	Non- white	Cohabitation	1	No	Yes	No	2
25	24	High School	NI	Married	2	Yes	No	No	3
26	22	High School	Non- white	Cohabitatio n	3	3 No	No	No	2
27	24	Higher education	Non- white	Married	1	No	No	No	4

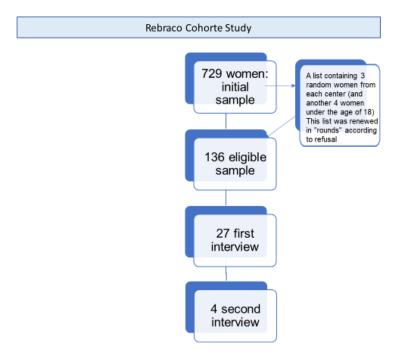
<sup>\*1.</sup> North

\*NI: Not informed

<sup>2.</sup> Northeast

<sup>3.</sup> South

<sup>4.</sup> Southeast



\*In total there were carried out 549 attempts to contact the 136 women until the final outcome (interviewed, lost, refusal, etc.)

Figure 1: Study participants selection\*

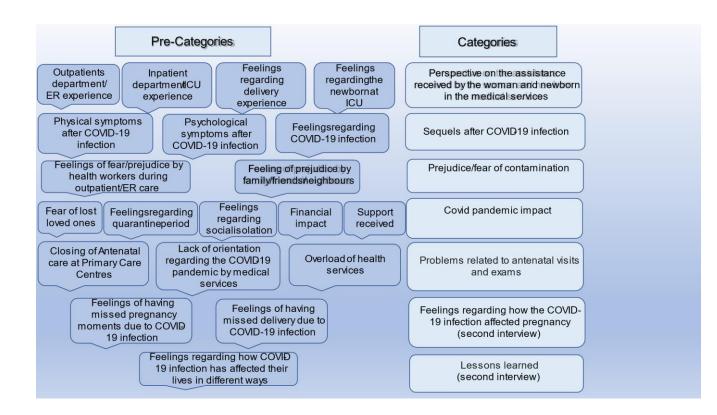


Figure 2: The process of thematic content analysis (n=27)

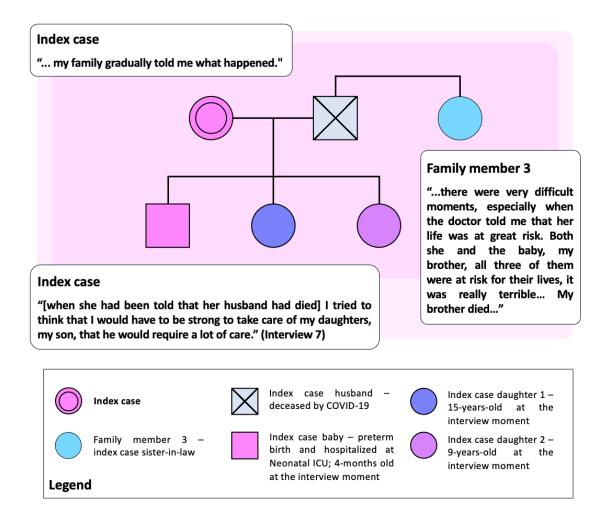


Figure 3: An example of how COVID-19 infection has affected patients and their families

This figure represents a selected interview from a pregnant woman who got COVID-19 at the same time as her husband. Both were hospitalized, and he died. When she woke up from intubation, she realized a C-section had been performed, the baby was in NICU, and she was told her husband had died. Her sister-in-law, who also participated in this study as a family member, stayed at home taking care of the other two children.

# 5. DISCUSSÃO

Como parte da discussão dessa tese, apresentamos um artigo (comunicação breve/ "Brief Communication"), discutindo os desafios para inclusão de adolescentes em pesquisas em saúde materna e reprodutiva. Esse artigo foi publicado na revista *International Journal of Gynecology and Obstetrics*, e será apresentado a seguir.

# 5.1 Artigo 5 The challenge to include adolescent girls and young women in maternal and reproductive health research

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### **BRIEF COMMUNICATION**

Gynecology



# The challenge to include adolescent girls and young women in maternal and reproductive health research

Rachel E. Soeiro<sup>1</sup> | Renato T. Souza<sup>1</sup> | Renan M. Nakamura<sup>1</sup> | Silvana F. Bento<sup>1</sup> | Fernanda G. Surita<sup>1</sup> | Jose G. Cecatti<sup>1</sup> | Roseli Nomura<sup>2</sup> | Maria L. Costa<sup>1</sup>

Maria L. Costa, Department of Obstetrics and Gynecology, The University of Campinas, 101 Alexander Fleming St; Campinas, SP, Brazil. Email: mlaura@unicamp.br

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### **Synopsis**

The contents of this page will be used as part of issue TOC only. It will not be published as part of main article.

Including adolescent girls and young women in maternal and reproductive health research is challenging.

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<sup>&</sup>lt;sup>1</sup>Department of Obstetrics and Gynecology, University of Campinas Faculty of Medical Sciences, Campinas, Brazil

<sup>&</sup>lt;sup>2</sup>Department of Obstetrics, Paulista School of Medicine, Federal University of São Paulo, São Paulo, Brazil

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# The challenge to include adolescent girls and young women in maternal and reproductive health research

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Maria L. Costa, Department of Obstetrics and Gynecology, The University of Campinas, 101 Alexander Fleming St; Campinas, SP, Brazil. Email: mlaura@unicamp.br

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Keywords: adolescents, Brazil, maternal health, research, sexual and reproductive health, young women

According to the United Nations (UN), in 2021 there were almost one billion adolescent and young women (from 10 to 24 years old) in the world, with almost 90% living in low- and middle-income countries (LMICs).1 These women usually have difficulty accessing or experience unmet demand for family planning, frequently leading to unplanned pregnancies and an increased risk of adverse maternal and perinatal outcomes.2 This can limit education, work opportunities, and earnings.<sup>2</sup> Since March 2020, the COVID-19 pandemic has caused significant mortality and morbidity worldwide. In previous epidemic outbreaks, adolescent girls and young women living in LMICs have faced increased vulnerability to gender-based violence, early marriages, and unintended pregnancy.3 To date there have been few studies demonstrating the real impact of the COVID-19 pandemic on this specific population.

Brazil was one of the countries most affected by the pandemic, with high maternal mortality ratios. National research studies on the impact of the COVID-19 pandemic among pregnant women have been implemented in the last 2 years; however, enrolling adolescents and young women has been challenging. Among these studies, two collaborative multicentric studies were implemented to evaluate several conditions associated with SARS-CoV-2 infection during pregnancy and the postpartum period, considering clinical, epidemiological, and laboratory aspects, along with quantitative and qualitative research on how women experienced this situation, and also the prevalence of maternal anxiety. For both studies participants agreed and signed an informed consent form.<sup>4,5</sup>

In the qualitative study (Figure 1), 152 adolescents/young women were randomly selected from a cohort of symptomatic cases, and only 10 young women (18-24 years old) agreed to be further interviewed. In the maternal anxiety study (Figure 1), the group of young women had reported less knowledge about COVID-19 infection than the older women. These results demonstrate the challenge of engaging adolescents/young women in research and emphasizing the need for targeted communication in health education. Studies have shown the importance of involving family and community in adolescents' health interventions and the importance of engaging youth as 'co-actors' in the research process.2

Research into adolescents'/young women's maternal and reproductive health is necessary to support the improvement in public policies for this group. The lessons learned from the two Brazilian research experiences should enable future improvement in communication and planning studies that can better engage adolescents/ young women in maternal and reproductive health research.

### **AUTHOR CONTRIBUTIONS**

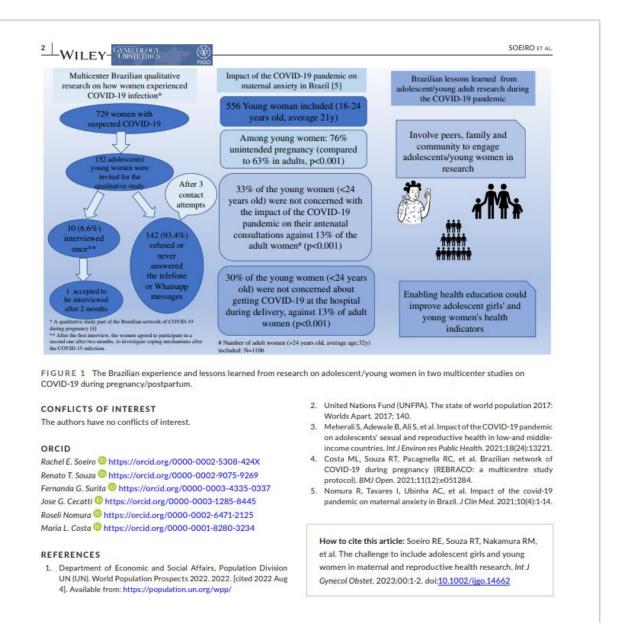
Maria L. Costa, Renato T. Souza, Renato T. Souza, and Roseli Nomura are the coordinators of both studies and proposed the analysis. Rachel E. Soeiro and SFB collected data for the qualitative study: Roseli Nomura and Renan M. Nakamura collected and analyzed data for the quantitative study. Rachel E. Soeiro wrote the first draft of the paper. All authors reviewed and approved the final manuscript.

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<sup>&</sup>lt;sup>1</sup>Department of Obstetrics and Gynecology, University of Campinas Faculty of Medical Sciences, Campinas, Brazil

<sup>&</sup>lt;sup>2</sup>Department of Obstetrics, Paulista School of Medicine, Federal University of São Paulo, São Paulo, Brazil



### 5.2 A Saúde Sexual e Reprodutiva enquanto direito

A pandemia de COVID-19 evidenciou as iniquidades em SSR já existentes entre os países de baixa e média renda: falta de políticas públicas para garantir o acesso igualitário, ausência de serviços de SSR específicos para adolescentes e jovens e violação de direitos sexuais e reprodutivos (39,40). Ademais, emergências humanitárias e climáticas são mais prevalentes nesses países. (40)

Anualmente, mais de 30 milhões de mulheres não dão à luz em um serviço de saúde, mais de 45 milhões têm cuidados pré-natais inadequados ou inexistentes e mais de 200 milhões de mulheres gostariam de evitar a gravidez, mas não têm acesso à contracepção moderna. Além disso, uma em cada três mulheres experimenta

violência por parceiro íntimo ou violência sexual sem parceiro em algum momento de suas vidas. (41)

Os estudos apresentados nesta tese corroboram com os dados acima, as adolescentes venezuelanas relataram falta de acesso à contracepção, cuidados prénatais inadequados e pobreza menstrual. As mulheres jovens e adultas no estudo multicêntrico REBRACO, relataram que, em alguns municípios as consultas de prénatal foram suspensas e, para as mulheres que foram hospitalizadas com COVID-19 grave as questões de saúde mental após a internação por COVID-19, na maioria dos casos, não foram endereçadas.

As metas de desenvolvimento sustentável da ONU para 2030 (22) colocam o direito à saúde sexual e reprodutiva de forma abrangente (contracepção, saúde materna e neonatal e HIV / AIDS) assim como a equidade de gênero e redução da violência contra a mulher em todas as suas formas. Contudo, a pandemia de COVID-19 desacelerou os avanços para a obtenção dessas metas. (42)

A SSR e os direitos sexuais e reprodutivos são essenciais para o desenvolvimento sustentável com impacto na saúde materna, neonatal, infantil e adolescente. Estudos sugerem programas de SSR abrangentes, incluindo não apenas serviços de planejamento familiar, saúde materna e neonatal e prevenção e tratamento do HIV / AIDS, mas também prevenção, detecção e aconselhamento para a violência baseada no gênero; detecção e tratamento da infertilidade e câncer cervical; assistência ao aborto seguro e educação sexual integral e específica para adolescentes. (40,41,142)

Iniciei o doutorado em março de 2020, concomitantemente ao anúncio da pandemia de COVID-19. O planejamento inicial era realizar um levantamento sobre a situação de saúde sexual e reprodutiva das adolescentes migrantes venezuelanas em Boa Vista (estudos 2 e 3), e após, realizar um estudo de intervenção. Quando o CEP aprovou a emenda para a pesquisa com as adolescentes migrantes venezuelanas em Boa Vista, as viagens haviam sido suspensas. Nesse momento, o estudo REBRACO havia iniciado e comecei a participar da parte qualitativa desse estudo. O foco era que eu entrevistasse as adolescentes, no entanto, ou as adolescentes não respondiam às mensagens por *WhatsApp*, ou se recusavam a participar do estudo, de modo que no estudo 5, só obtivemos participantes maiores de 18 anos.

Em novembro de 2020 houve a liberação da UNICAMP para viagens de campo e, agendamos a viagem para Boa Vista para entrevistar as adolescentes venezuelanas. Na semana da entrevista, já havia um aumento de casos de COVID-19, principalmente no estado do Amazonas, e, apesar da pactuação prévia para a realização das entrevistas, foi necessária uma nova pactuação com a Operação Acolhida quando chegamos em Boa Vista.

Realizar as entrevistas das adolescentes migrantes venezuelanas foi bastante difícil. Todas relataram uma piora no acesso aos serviços de saúde sexual e reprodutiva (inclusive acompanhamento pré-natal), uma vez que a maioria das organizações humanitárias que estavam em Boa Vista haviam enviado as equipes para o estado do Amazonas devido ao aumento dos casos de COVID-19.

Enquanto médica, com experiência no atendimento à população deslocada interna em países africanos, escutar as entrevistas das adolescentes no lugar de pesquisadora sem poder prestar assistência foi bastante difícil e, devido à pandemia de COVID-19, também não foi possível realizar o projeto de intervenção.

Assim como as incertezas e mudanças repentinas de planejamento presentes no cotidiano do trabalho humanitário, o planejamento inicial do meu doutorado também teve de ser modificado e adaptado.

Apesar da mudança de delineamento devido à pandemia de COVID-19, obtive um grande aprendizado, participando de estudos multicêntricos e aprimorando meus conhecimentos em pesquisa quantitativa e qualitativa, sempre com um grande apoio da minha orientadora que generosamente ampliou o caminho das possibilidades dentro do fascinante universo da pesquisa.

# 6. CONCLUSÕES

Objetivo específico 1: Rever a literatura científica para compreender à Saúde Sexual e Reprodutiva (SSR) de adolescentes e mulheres jovens migrantes em todo o mundo.

A SSR de adolescentes e mulheres jovens em contextos de crise humanitária é negligenciada. Apesar do número crescente de estudos com essa população (foram analisados 32 estudos, a maioria publicado entre 2020 e 2022), projetos de intervenção são raros. Há dificuldade de acesso a contraceptivos com maior risco de gestações não planejadas, casamento infantil e violência sexual e baseada no gênero (SGBV). A identificação destes desafios pode auxiliar os atores humanitários e pesquisadores a desenvolver ações de intervenção específicas para essa população.

Objetivo específico 2: Identificar as principais questões em SSR de adolescentes e mulheres jovens migrantes venezuelanas em Boa Vista, estado de Roraima, Brasil.

Dentre as 153 adolescentes e mulheres jovens migrantes venezuelanas entrevistadas em Boa Vista, RR (idade média de 17,7 anos), mais da metade já havia tido pelo menos uma gestação e 35% das adolescentes menores de 18 anos migraram sem seus responsáveis legais. Houve dificuldade de acesso aos serviços de saúde sexual e reprodutiva, as necessidades por contracepção não foram atendidas e o prénatal realizado foi insuficiente. Apesar da sobrecarga dos serviços de saúde em Boa Vista, pelo aumento do fluxo migratório e pela pandemia de COVID-19, é necessária uma resposta multisetorial com esforços governamentais e não governamentais a fim de endereçar as questões relacionadas à SSR dessa população.

Objetivo específico 3: Fornecer uma visão geral das principais questões do manejo da higiene menstrual (MHM) que afetam adolescentes e mulheres jovens migrantes venezuelanas em Boa Vista, estado de Roraima, Brasil.

As 142 adolescentes e jovens mulheres migrantes venezuelanas em Boa Vista que já tiveram a menarca têm as suas necessidades de MHM ignoradas vivenciando a falta de absorventes higiênicos (50% delas nunca recebeu absorventes higiênicos),

e de água e sabão para higiene das mãos (60%), além do medo de agressão ao utilizar os banheiros (80%). A menstruação foi associada a sentimentos negativos para a maioria. Apesar da crescente discussão sobre pobreza menstrual, em contextos humanitários ações para o enfrentamento dessa realidade ainda são escassas.

Objetivo específico 4: Relatar como as mulheres gestantes e puérperas experimentaram a suspeita/investigação e ou confirmação de infecção por COVID-19 e as consequências da pandemia para essas mulheres e as suas famílias.

A pandemia COVID-19 afetou a vida das gestantes e puérperas com uma gama diversificada de complicações. Antes da vacina contra a COVID-19 estar disponível, a desinformação, a sobrecarga dos serviços de saúde e o desconhecimento dos profissionais de saúde impactaram as vidas das mulheres que entrevistamos através de sequelas físicas e psicológicas, perda de membros da família, e questões socioeconômicas.

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# 8. ANEXOS

# **Anexo 1 Registro PROSPERO**



### Anexo 2 Aprovação dos estudos 2 e 3



### UNICAMP - CAMPUS CAMPINAS



#### PARECER CONSUBSTANCIADO DO CEP

#### DADOS DA EMENDA

Título da Pesquisa: AVALIAÇÃO DOS SERVIÇOS DE SAÚDE SEXUAL E REPRODUTIVA PARA

VENEZUELANOS NAS FRONTEIRAS VENEZUELANAS COM O BRASIL E A

COLÔMBIA, 2019

Pesquisador: Luis Guillermo Bahamondes

Área Temática: Versão: 3

CAAE: 20458219.0.0000.5404

Instituição Proponente: CEMICAMP - CENTRO DE PESQUISAS EM SAUDE REPRODUTIVA DE

Patrocinador Principal: Financiamento Próprio

#### DADOS DO PARECER

Número do Parecer: 3.856.056

#### Apresentação do Projeto:

Visão global: Esta proposta se concentra na Fase 1 desta pesquisa. O objetivo é avaliar a disponibilidade de serviços de SSR, bem como a resposta da SSR às mulheres venezuelanas na fronteira da Venezuela com o Brasil e a Colômbia. Ele consistirá de: 1a. entrevistas com informantes-chave e 1.b. avaliações de instalações de saúde. As entrevistas com informantes-chave girarão em torno da avaliação da disponibilidade do Pacote de Serviço Inicial Mínimo (PSIM) (14) para a SSR nos principais pontos de entrada na fronteira no Brasil (um ponto) e na Colômbia (dois pontos), com os principais interessados, ministérios da saúde e agências parceiras de implementação, agências da ONU, bem como informantes-chave nos mesmos pontos de entrada do lado venezuelano. As avaliações dos serviços de saúde serão realizadas com gestores de programas, médicos e/ou enfermeiros em centros identificados. Eles enfatizarão, especificamente, a avaliação do lado da oferta da PSIM quanto à disponibilidade de suprimentos, equipamentos, medicamentos e infraestrutura (com um foco específico na disponibilidade dos kits de saúde reprodutiva).

#### Objetivo da Pesquisa:

Objetivo Primário:

Até onde sabemos, existem dados limitados sobre a disponibilidade, resposta e capacidade de acesso aos serviços de SSR, bem como as necessidades de mulheres na Venezuela em relação à

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Continuação do Parecer: 3.856.056

SSR na fronteira da Venezuela com o Brasil e a Colômbia. Evidências muito limitadas emergiram recentemente da Colômbia. Uma melhor compreensão da situação, em particular para as mulheres, apoiará a formulação de recomendações para melhoria da resposta e prestação de serviços de SSR nessas áreas. Nenhum estudo sobre SHR ou resultados de saúde perinatal de venezuelanos que vivem nas fronteiras, em lados venezuelanos ou brasileiros/colombianos, também foram publicados. Os dados relatados sobre a situação estão surgindo principalmente e esporadicamente na literatura na científica. Isso exige a implementação de uma

avaliação rigorosa para determinar as questões, as necessidades e a extensão em que os sistemas de saúde existentes nas fronteiras com o Brasil e a Colômbia e mais na Venezuela podem apoiar e responder a essa crise, com base em dados bem fundamentados. Consequentemente, o objetivo geral desta proposta é avaliar a situação atual da SSR para jovens mulheres venezuelanas nas fronteiras da Venezuela com o Brasil e a Colômbia. Essa avaliação consistirá basicamente de uma avaliação demétodos mistos e multi fases, usando uma metodologia desenvolvida especificamente para uma avaliação rápida da resposta à SSR em situações humanitárias. Esta metodologia será descrita abaixo. A proposta de pesquisa está focada na fase 1 deste projeto em duas fases, com o objetivo de avaliar a atual situação da SSR para jovens mulheres venezuelanas na fronteira da Venezuela com o Brasil e a Colômbia. A fase 1 visa avaliar a disponibilidade de serviços de SSR, assim como a resposta de SSR prestada a essa população-alvo. A fase 2 consistirá especificamente em uma avaliação das necessidades de SSR entre mulheres venezuelanas nas fronteiras com o Brasil e a Colômbia. Esta pesquisa avaliará o status e as necessidades de saúde sexual e reprodutiva, bem como o uso de serviços de SSR por mulheres venezuelanas na fronteira da Venezuela com o Brasil e a Colômbia.

#### Avaliação dos Riscos e Benefícios:

Riscos

É possível afirmar que não apresenta RISCOS PREVISÍVEIS.

Beneficios:

Não há benefícios para as participantes neste momento. Os benefícios poderão vir após ter o resultado final em termos de melhoria nas suas vidas enquanto migrantes no Brasil.

#### Comentários e Considerações sobre a Pesquisa:

O pesquisador propões emenda para retirar o critério de exclusão de idade inferior a 18 anos, a fim de incluir garotas entre 13 e 17 anos no estudo. Pede a dispensa do TCLE, justificando não ser um estudo intervencionista do ponto de vista físico.

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Continuação do Parecer: 3.856.056

#### Considerações sobre os Termos de apresentação obrigatória:

Foram analisados os seguintes documentos:

- -PB\_INFORMAÇÕES\_BÁSICAS\_1507092\_E1.pdf 07/02/2020
- -Justificativa de Emenda fev2020.pdf 05/02/2020
- -Projeto\_Venezuela\_Fev2020.pdf 05/02/2020

Ver o campo Conclusões ou Pendências e Lista de Inadequações.

#### Recomendações:

Ver o campo Conclusões ou Pendências e Lista de Inadequações.

#### Conclusões ou Pendências e Lista de Inadequações:

Prezado pesquisador, já é entendimento consolidado tanto deste CEP quanto da própria CONEP, manifestado através de cartas e resoluções, que pesquisas envolvendo seres humanos, baseadas em entrevistas, apresentam riscos previsíveis de quebra de sigilo, vazamento de informações e estigmatização dos participantes. Estes riscos devem estar explicitados tanto no projeto quanto no TCLE. O participante deve ser informado e consentir. Nos casos de menores de 18 anos ou outras populações vulneráveis, o consentimento dos pais ou responsáveis, junto com o assentimento do próprio participante, são garantias fundamentais para a condução ética da pesquisa. Por isso, recomendamos que seja apresentado um TCLE para os pais ou responsáveis, juntamente com os Termo de Assentimento em linguagem apropriada para a faixa etária, de acordo com a resolução CNS 466/2012 e demais resoluções e normas que regem a realização de pesquisas clínicas no Brasil.

#### ORIENTAÇÕES PARA A TRAMITAÇÃO DAS RESPOSTAS:

A – Cabe ao pesquisador responsável encaminhar as respostas ao parecer pendente, por meio da Plataforma Brasil, em até 30 dias a contar a partir da data de emissão do referido parecer. As respostas às pendências devem ser apresentadas em documento à parte (CARTA RESPOSTA). Ressalta-se que DEVE HAVER RESPOSTA PARA CADA UMA DAS PENDÊNCIAS apontadas no parecer, OBEDECENDO A ORDENAÇÃO DESTE.

B – A carta resposta deve permitir o uso correto dos recursos "copiar" e "colar" em qualquer palavra ou trecho do texto, isto é, a palavra e/ou trecho ao ser "colado" não deve sofrer alteração.

C – Além da carta resposta, cabe ao pesquisador alterar os documentos solicitados nos campos "Recomendações" e/ou "Conclusões ou Pendências e Lista de Inadequações" e esses documentos devem:

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- I Permitir o uso correto dos recursos "copiar" e "colar" em qualquer palavra ou trecho do texto;
- II Uma versão do(s) documento(s) com as alterações devidamente realçadas, podendo lançar mão de sublinhado, negrito, e/ou outra cor de fonte.

#### Considerações Finais a critério do CEP:

Lembramos ao pesquisador que o estudo só pode ser iniciado após a aprovação pelo CEP, conforme compromisso assumido pelo mesmo com o cumprimento da resolução 466/2012, item XI.2 letra a. Quando for submeter respostas às pendências, verificar se o cronograma de realização da pesquisa, descrito na plataforma Brasil e no projeto anexado, está contemplando o início da coleta de dados APÓS a liberação do projeto pelo CEP.

#### Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_150709 2_E1.pdf	07/02/2020 09:18:25		Aceito
Outros	Justificativa_de_Emenda_fev2020.pdf	05/02/2020 16:08:03	Luis Guillermo Bahamondes	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Venezuela_Fev2020.pdf	05/02/2020 16:07:41	Luis Guillermo Bahamondes	Aceito
Outros	Questionario_Mulheres.pdf	27/09/2019 10:42:00	Luis Guillermo Bahamondes	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_migrantes_portugues_corrigido_2 7set2019.pdf	27/09/2019 10:41:35	Luis Guillermo Bahamondes	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_migrantes_espanhol_corrigido_27 Sep2019.pdf	27/09/2019 10:41:26	Luis Guillermo Bahamondes	Aceito
Outros	Carta_resposta_CEP_27Set2019.pdf	27/09/2019 10:41:14	Luis Guillermo Bahamondes	Aceito
Outros	Declaracao_de_vinculo.pdf	09/09/2019 14:37:34	Luis Guillermo Bahamondes	Aceito
Folha de Rosto	folhaDeRosto.pdf	09/09/2019 14:35:01	Luis Guillermo Bahamondes	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_migrantes_portugues.pdf	09/09/2019 11:22:37	Luis Guillermo Bahamondes	Aceito

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Bairro: Barão Geraldo UF: SP Mu CEP: 13.083-887

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Continuação do Parecer: 3.856.056

TCLE / Termos de	TCLE_migrantes_espanhol.pdf	09/09/2019	Luis Guillermo	Aceito
Assentimento /		11:22:26	Bahamondes	1
Justificativa de				1
Ausência				
TCLE / Termos de	TCLE_Instituicoes_de_Saude.pdf	09/09/2019	Luis Guillermo	Aceito
Assentimento /		11:21:37	Bahamondes	1
Justificativa de				1
Ausência				1
Projeto Detalhado /	Projeto_Venezuela_v1_2_Sep2019_Port	09/09/2019	Luis Guillermo	Aceito
Brochura	ugues.pdf	11:21:22	Bahamondes	1
Investigador	· .			
Orçamento	ORCAMENTO.pdf	09/09/2019	Luis Guillermo	Aceito
	·	11:20:47	Bahamondes	
Cronograma	Cronograma.pdf	09/09/2019	Luis Guillermo	Aceito
_	,	11:20:34	Bahamondes	

Situac	cão	do	Par	ece	r:
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Pendente

Necessita Apreciação da CONEP:

Não

CAMPINAS, 26 de Fevereiro de 2020

Assinado por: Alessandro Rozim Zorzi (Coordenador(a))

Endereço: Rua Tessália Vieira de Camargo, 126

Bairro: Barão Geraldo
UF: SP Município: CAMPINAS CEP: 13.083-887

# Anexo 3 - Autorização do Conselho Tutelar de Boa Vista (Roraima)

#### Autorização para Coleta de Dados

Eu, Jaiza Silva lameira, Conselheira Tutelar de Boa Vista- RR, autorizo a coleta de dados da pesquisa intitulada "Avaliação dos serviços de saúde sexual e reprodutiva para venezuelanas nas fronteiras venezuelanas com o Brasil e a Colômbia", pela pesquisadora Rachel Esteves Soeiro (pertencente à equipe do Dr. Luís Bahamondes (Unicamp)/Organização Mundial da Saúde).

Assinatura e carimbo

Data: 06/01/2021

### Anexo 4: Aprovação estudo 4



### UNICAMP - CAMPUS CAMPINAS



#### PARECER CONSUBSTANCIADO DO CEP

#### DADOS DA EMENDA

Título da Pesquisa: REBRACO - REde BRAsileira em estudos do COVID-19 em Obstetrícia - Comitê de

gestão de crise na Rede de Pesquisa REBRACO e identificação de informações

relevantes ao enfrentamento da pandemia

Pesquisador: Renato Teixeira Souza

Área Temática: Versão: 6

CAAE: 31590120.7.0000.5404

Instituição Proponente: Hospital da Mulher Prof. Dr. José Aristodemo Pinotti - CAISM

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 4.179.679

#### Apresentação do Projeto:

Transcrição editada do conteúdo do registro do protocolo e dos arquivos anexados à Plataforma Brasil Trata-se de solicitação de emenda ao protocolo (E3) originalmente aprovado em 01/06/2020, emendado em 22/06/2020 (E1) e em 29/06/2020 (E2) para inclusão de novo centro coparticipante. A descrição detalhada da solicitação está ao final do parecer.

Introdução: A Doença do Coronavírus-19 (COVID-19) é uma doença respiratória viral grave que, em face à sua rápida disseminação, alcançou alta relevância no panorama global nos últimos meses. Esta doença é causada pelo Coronavírus da Síndrome Respiratória Aguda Grave 2 (SARS-CoV-2), um vírus da família Coronaviridae, sendo o sétimo descrito de sua família a infectar humanos. São vírus envelopados, com morfologia esférica, tendo cerca de 120nm de diâmetro. Seu genoma é constituído por uma fita simples de RNA associada à proteína N, formando o nucleocapsídeo1,2. Desde dezembro de 2019, a COVID-19 demonstrou características epidemiológicas clínicas de rápida disseminação e capacidade de infectar a população geral. Em 13 de março de 2020, a Organização Mundial da Saúde a declarou uma pandemia3. O início da emergência da COVID-19 começou em Wuhan, província de Hubei, China, em dezembro de 2019. De origem zoonótica ainda incerta, com semelhanças à coronavírus residentes de pangolim e

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morcego1,4, causou uma doença respiratória de caráter pneumônico nesta localidade e posteriormente foi descrito o patógeno causador, o SARS-CoV-2. Com o contexto humano atual de deslocamento rápido e interconexão global, o vírus espalhou-se de maneira vertiginosa em janeiro e fevereiro, tornando uma situação de caráter emergencial. Em apenas 3 meses de seu registro como um vírus emergente (dezembro/2019 - março/2020), a doença adquiriu caráter pandêmico3. Em 21 de janeiro de 2020, a situação global da infecção por SARS-CoV-2 estava restrita à Ásia, com majoria dos casos na China. Havia naquele momento apenas 282 casos confirmados no total, sendo que fora do território chinês havia apenas 4 casos: 1 no Japão, 1 na Coréia do Sul e 2 na Tailândia5. No final do mês de janeiro, a doença já acometia outros países do Sudeste Asiático, além de países da Europa, Oceania e América do Norte, com poucos casos registrados. A maioria dos casos (98,92%) ainda estava concentrada na China6. Na metade de fevereiro de 2020, o número de casos atingiu 50 mil, e o número de casos confirmados por laboratório em outros países aumentou principalmente na Europa7. No início de março, o vírus já havia chegado às Américas e à África, tendo crescido em número de casos expressivamente em países como Irã e Itália8. De igual modo, verificou-se um aumento expressivo de número de casos globalmente que culminou com a classificação da infecção pelo SARS-CoV-2 como uma pandemia, existindo até a data, 23 de março de 2020, cerca de 349.211 casos confirmados e 15.308 mortes3. Após a caracterização da transmissão do SARS-CoV-2 humano-humano, ainda no início da epidemia em uma família em Hubei, o patógeno mostrouse altamente contaminante9. A transmissão humana ocorre pelo contato direto, por gotículas de origem respiratórias e/ou superfícies contaminadas10-12. Alguns estudos mostram que o número de reprodutibilidade (R0) deste vírus varia de 3,1 a 6,27, baseados em comportamentos sociais vigentes de contato irrestrito13,14. Ou seja, cada pessoa infectada pelo SARS-CoV-2 pode vir a infectar até seis outras pessoas, em um cenário sem medidas de profilaxia. E foi demonstrado que o vírus é capaz de ser transmitido por portadores assintomáticos, liberando grandes quantidades de vírus na fase inicial da infecção, o que representa um enorme grau de transmissibilidade e de dificuldade no rastreamento da doença na população15,16. As medidas para a prevenção da infecção incluem métodos de higiene (como lavagem de mãos com água e sabão e/ou uso de álcool em gel), e medidas de controle da transmissão, que incluem a mitigação e supressão do contato interpessoal, incluindo o isolamento social até a quarentena obrigatória adotada por alguns governos17-19. Mesmo que os casos sejam majoritariamente de grau leve ou assintomáticos, a COVID-19 pode evoluir para formas graves de maneira abrupta. A doença grave manifesta-se como uma pneumonia induzida por vírus, apresentando aumento da temperatura corporal, diminuição do

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número de linfócitos e células sanguíneas, além de infiltrados pulmonares difusos. O dano alveolar difuso leva à progressão da disfunção respiratória e se associa à disfunção de múltiplos órgãos, determinando o óbito4. A taxa de mortalidade mundial da doença, baseada nos relatórios da OMS, é de aproximadamente 4,2% dos casos confirmados22. A taxa em pacientes críticos foi 49% na China23. Pacientes com comorbidades (doença cardiovascular, diabetes, doenças respiratórias crônicas, hipertensão, câncer) apresentaram maiores taxas de mortalidade (10,5%,7,3%, 6,5%, 6,0%, 5,6%, respectivamente)15. E idosos têm risco de óbito aumentado e com o major número de fatalidade23. A remissão da infecção é variável, de 7 a 21 dias em média em casos leves e moderados, e de 10 dias após hospitalização nos casos de maior gravidade, com isolamento de 14 dias após alta em todos os casos24-26. De acordo com os dados do Ministério da saúde, até o presente (06 de abril de 2020) no Brasil foram registrados de 12056 casos e 553 mortes (taxa de letalidade de 4,6%)27. Diante do quadro da pandemia causada pelo vírus SARS-CoV -2, múltiplas estratégias de enfrentamento da pandemia foram empregadas nos diferentes países e de acordo com as diferentes necessidades das subpopulações que enfrentam essa doença e com o cenário epidemiológico local. Na Itália, por exemplo, as estratégias adotadas pelos gestores de saúde da rede pública da região de Lazio foram utilizadas ferramentas de vigilância epidemiológica, que incluam testagem de casos suspeitos mesmo que leves, serviços de atendimento telefônico para prestar informações gerais sobre COVID-19 e de manejo de casos suspeitos e considerados leves, incluindo necessidade de isolamento e decisão de quando procurar o hospital. Os serviços remotos de atendimento e acompanhamento, seja pelo telefone (tele-atendimento) ou pelo serviço virtual (websites e aplicativo - Lazio Doctor per Covid), foram fundamentais para o combate da pandemia nessa região da Itália28-30. Existe um grande desafio sobre como melhor adequar o provisionamento dos serviços de saúde em momentos como o de pandemia, pois por um lado há um grande enfoque e consumo de recursos para o enfretamento do surto, por outro há o desafio em manter os serviços de saúde aptos em acompanhar as gestantes durante o prénatal sem que haja comprometimento da qualidade do serviço já prestado. A identificação precoce e oportuna de complicações, por exemplo, é essencial para menor morbidade e mortalidade materna e perinatal. Um estudo multicêntrico em 27 maternidades brasileiras mostrou que mulheres que receberem cuidados associado com demoras na identificação e tratamento de complicações tiveram significativamente maior gravidade e maior taxa de mortalidade31. As demoras podem acontecer por decorrência da falta de percepção de sinais ou sintomas por parte da paciente ou outras condições que a impeçam em decidir recorrer ao serviço de saúde (crenças, medos, etc). Um estado de pandemia que demande isolamento social pode, por vezes, afetar no julgamento dos

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pacientes quanto a recorrer ou não ao serviço de saúde e, consequentemente, atuar como barreira de demora no atendimento adequado. Os serviços de Obstetrícia do CAISM (Unicamp, Campinas-SP) e do Hospital Universitário (HU/FMJ, Jundiaí-SP), serviços de referência obstétrica de suas regiões, notaram queda no atendimento do pronto-atendimento nas primeiras semanas da pandemia. O HU/FMJ, por exemplo, que teve em torno de 3.500 atendimentos no pronto-atendimento em Jan/2020, registrou apenas 1.800 em Abr/2020.É estimado que o SARS-CoV-2 cause uma infecção assintomática ou leve em 80,2% dos casos15. Naqueles em que se desenvolvem a COVID-19, os sintomas clínicos descritos comumente são febre, tosse seca, hipo ou anosmia (perda parcial ou total da capacidade de sentir odores), dificuldade em respirar (dispneia), dor de cabeça e pneumonia10. Dados da literatura indicam que os idosos (60 anos de idade), portadores de doença cardiovascular, diabetes, doenças respiratórias crônicas, hipertensão e imunodeprimidos constituem o grupo de risco para o desenvolvimento de casos graves da doença com acometimento respiratório e sistêmico 20,21. Ainda não está claro, porém, quais melhores estratégias de identificação precoce de casos graves na população de gestantes e quais melhores abordagens terapêuticas.O diagnóstico diferencial inclui todos os tipos de infecções virais respiratórias e infecções bacterianas. Dificilmente é possível diferenciar COVID-19 dessas infecções clinicamente ou através de exames laboratoriais de rotina, sendo assim necessário testes laboratoriais específicos32,33. O diagnóstico específico da infecção por SARS-CoV-2 é realizado por testes moleculares em amostras respiratórias, como esfregaço da garganta e nasofaringe, escarro, aspirados endotraqueais e lavado broncoalveolar17. O vírus também pode ser detectado nas fezes e, em casos graves, no sangue. Técnicas já estabelecidas de biologia molecular são utilizadas, destacando-se o método de PCR em tempo real por retrotranscriptase (RT -qPCR), baseado na detecção do RNA viral, na região de transcrição gênica do nucleocapsídeo e/ou spikes virais15. Outros testes, como testes rápidos e sorológicos, também são adotados33. Atualmente, não se sabe se as mulheres grávidas têm major chance de adoecer com o COVID-19 do que a população em geral. nem se são mais propensas a ter doenças graves como resultado da infecção. Sabe-se que as gestantes sofrem modificações inerentes à gestação que podem aumentar o risco a algumas infecções. Quando comparadas a mulheres não grávidas, a mulher gestante quando acometida por infecções por vírus da mesma família que o COVID-19 e outras infecções respiratórias virais, como a gripe, tem um risco maior de desenvolver doenças graves34. O conhecimento de outras infecções por coronavírus e orthomyxovirus durante a gestação associou-se a maiores complicações maternas. Em estudos para infecções SARS e MERS (Middle East Respiratory Syndrome), observou-se a correlação de altas incidências de aborto espontâneo, parto

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prematuro e restrição de crescimento fetal (RCF), dependendo do período gestacional em que ocorreu a infecção 35,36. No panorama global já descrito, sob influência da pandemia do COVID-19, os diversos países estão tomando diversas medidas para conter a expansão da transmissão do patógeno, inclusive o Brasil. Aulas foram suspensas em universidades e escolas, comércios não essenciais foram fechados e há recomendações de isolamento social. No estado de São Paulo, há medidas de fechamento de espaços públicos e privados, como parques e shoppings centers, e quarentena obrigatória37. No âmbito psicológico, o isolamento social está associado a maiores taxas de sintomas depressivos38. Momentos de crise podem gerar aumento do número de suicídios, ansiedade, traumas psíquicos e desenvolvimento de transtornos39-41. Líderes mundiais classificam o contexto atual como uma crise profunda, como a chanceler alemã Angela Merkel ao afirmar que, desde a Segunda Guerra Mundial, não houve desafio à sua nação que exigisse tamanho grau de ação conjunta e união42. O cenário atual é grave e não se sabe quais são as repercussões psicológicas da pandemia na população de gestantes, seus familiares e dos profissionais de saúde envolvidos no cuidado de pacientes afetados por esta pandemia.Os estudos em rede para a obtenção de informações em saúde materna e perinatal mostraram-se potentes ferramentas para a geração de adequadas evidências para o entendimento de condições específicas do ciclo gravídico-puerperal. A Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal já articulou estudos de grande abrangência nacional, como a Rede Nacional de Vigilância de Morbidade Materna Grave43, o Estudo Multicêntrico de Prematuridade (EMIP)44, o estudo COMMAG, o estudo Preterm-SAMBA45 e a MAES-I46. Estes estudos em rede permitiram o desenvolvimento de uma expertise quanto ao desenho metodológico, agrupando pesquisadores de diversas regiões do país com a obtenção de dados em tempo real e consolidação dos resultados por um ou mais centros, com a consequente produção de conhecimento científico relevante. A importância de um estudo em rede que amplie o conhecimento sobre a infecção causada por SARS-CoV-2 durante a gestação é reiterada por todo o panorama antes descrito. A ampliação do conhecimento sobre as repercussões deste vírus na população obstétrica é necessária, tanto para o enfrentamento da atual pandemia de COVID-19 como para futuras repercussões na saúde materna e perinatal. Assim, o atual estudo pretende estabelecer uma rede de colaboração de enfrentamento a pandemia COVID-19, sob o alicerce de um comitê gestor que se valerá de informações relativas às características epidemiológicas e o efeito da infecção por SARS-CoV-2 na gestação em uma coorte de mulheres e seus recém-nascidos atendidos em centros da Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal.

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Delineamento da pesquisa: Trata-se de proposta de estudo quali-quantitativo, observacional, tipo "Quality Improvement", dividido em três etapas/braços: 1- Estabelecimento de rede de colaboração para respostas rápidas no enfrentamento da pandemia COVID-19, com aspectos fortemente administrativos e de controle de qualidade. Nesta fase, aparentemente não haverá envolvimento direto de participantes. 2- Avaliação da vivência da pandemia e a ocorrência de sintomas depressivos e de estresse pós-traumático em gestantes com COVID-19, seus familiares e em profissionais envolvidos na assistência desses casos. Nesta etapa serão envolvidos 90 indivíduos, adultos e menores de idade, divididos em três grupos; Gestantes com suspeita de COVID-19 (n=30), Profissionais de saúde (n=30), Familiares de gestante com suspeita COVID19 (n=30). A todos serão entrevistados por telefone ou pessoalmente a partir de questões/tópicos guias. As entrevistas serão gravadas em áudio. 3. Na terceira etapa/braço do estudo serão avaliados os efeitos da pandemia COVID19 em indicadores de saúde materna e perinatal como o número de nascidos vivos e de óbitos fetais. Não ficou claro se haverá envolvimento de dados individualizados de pessoas ou se haverá a possibilidade de identificar os indivíduos aos quais os dados se referem.

Objetivos: constituir uma rede de colaboração para respostas rápidas no enfrentamento da pandemia COVID-19, avaliar a ocorrência de sintomas depressivos e de estresse pós-traumático em gestantes com COVID-19, seus familiares e em profissionais envolvidos na assistência desses casos e as repercussões da pandemia em indicadores da saúde reprodutiva e perinatal. Materiais e métodos: uma abordagem metodológica mista incluindo um comitê de gestão de monitoramento e avaliação (M&A) para realizar o levantamento de informações relevantes ao atendimento de casos e fará o planejamento de ações corretivas relativas ao enfrentamento da pandemia com a participação de centros da Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal. Realizaremos também estudos qualitativos através de entrevistas semiestruturadas gravadas ao telefone ou presencial, para entender como as gestantes, seus familiares e profissionais de saúde estão lidando com a pandemia SARS-CoV-2 e como isso influencia o cuidado em saúde e o enfrentamento da pandemia. Ainda, realizaremos um estudo ecológico, no qual será realizado a análise mensal do número de nascimentos vivos e óbitos fetais, os efeitos indiretos da pandemia na evolução do número dos partos e óbitos fetais e os fatores associados a esta variação. Será realizada uma análise de tendência entre os períodos prévios, durante e após a pandemia (12 meses antes até 12 meses depois). Síntese e análise de dados: Os dados obtidos para a pesquisa serão de característica associativa e descritiva, visando a caracterização da assistência realizada pelos centros participantes, os aspectos de saúde mental relacionado a vivência da pandemia pelas

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mulheres, familiares e profissionais de saúde e análise de repercussão na saúde reprodutiva (número de nascidos vivos). Será realizada uma análise de tendência entre os três períodos (12 meses prévios, durante a pandemia e 12 meses subsequentes a pandemia) sobre o número de nascidos vivos na cidade de Campinas e óbitos fetais nas cidades em que há centros participantes do estudo. Para os dados qualitativos, as entrevistas gravadas em áudio serão transcritas e o texto obtido será conferido com a gravação. Posteriormente será realizada a análise temática com o auxílio do programa NVivo.

Critérios de inclusão/exclusão: PARA A ETAPA B) Estudo qualitativo por amostra intencional e amostragem por saturação58 de acordo com os seguintes subgrupos: Serão incluídas as gestantes com idade entre 13 e 45 anos, que foram triadas para síndrome gripal no pronto-atendimento (casos suspeitos COVID-19, ver a seguir) e de gestantes que tiveram resultado positivo de PCR para SARS-CoV-2. O pesquisador responsável pelo centro identificará as mulheres elegíveis através de revisão dos atendimentos de casos suspeitos e confirmados através dos registros do Comitê de Controle de Infecção Hospitalar, relatórios de vigilância epidemiológica do hospital e/ou dos registros de atendimentos da unidade de Pronto-Atendimento - uma revisão de prontuário irá auxiliar os pesquisadores a identificar números de telefone para contato com a mulher elegível.

PARA A ETAPA C) Estudo qualitativo por amostra intencional e amostragem por saturação incluindo familiares (acompanhantes) de gestantes que tiveram resultado positivo de PCR para SARS-CoV-2: Como critérios de seleção, convidaremos, que um familiar próximos a gestante (indivíduo que a mulher julgar como "de convívio íntimo", como marido/parceiro, filho, pai, mãe, irmãos, sobrinhos, tios, primos, madrasta, padrasto), indicados pela mesma durante o contato referente a sua participação no estudo, sem distinção de sexo (masculino ou feminino), que tenha idade acima de 18 anos. Um novo contato com esse familiar será realizado e o convite será realizado, sendo incluídos aqueles que aceitem participar da pesquisa. Serão excluídos aqueles que por ventura tenham algum déficit cognitivo e/ou déficit auditivo e/ou de fala, que dificulte o participante compreender a pesquisa e ou responder aos questionamentos, visto que a entrevista será realizada por telefone.

PARA A ETAPA D) Estudo qualitativo por amostra intencional e amostragem por saturação57 de acordo com os seguintes subgrupos de profissionais da saúde (Técnico de enfermagem, Enfermeiro, Docente/Médico contratado, Residente em Ginecologia e Obstetrícia (R1, R2 e R3)): Serão elegíveis para a pesquisa os profissionais da saúde de ambos os sexos (masculino e feminino), com idade acima de 18 anos, que durante a pandemia estavam na ativa, ou seja,

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atendendo em qualquer uma das unidades de atendimento obstétrico (pronto-atendimento, centro-obstétrico, alojamento conjunto, enfermaria patológica, etc). A identificação de pessoas elegíveis será realizada através de consulta ao cadastro institucional de profissionais de saúde da instituição que trabalham nas diferentes unidades e nas diferentes categorias profissionais. Uma listagem única será ordenada com númeração única. Será utilizado um sistema de ordenamento aleatório de números para selecionar os profissionais que serão convidados a participar. Caso não haja concordância em participar, os profissionais com números subsequentes serão convidados até que se atinja o "n" desejado (estima-se 30, mas o método de saturação pode requerer a participação de menos ou mais profissionais).

#### MATERIAIS E MÉTODOS:

Comitê de gestão de crise na Rede de Pesquisa REBRACO e identificação de informações relevantes ao enfrentamento da pandemia: A instituição da REBRACO - REdeBRAsileira em estudos do COVID-19 em Obstetrícia - extrapola a realização de estudo clínico-epidemiológico e tem como objetivo fundamental auxiliar no enfrentamento à primeira onda pandêmica do vírus SARS-CoV-2 no contexto brasileiro. Será implementado um comitê de gestão de monitoramento e avaliação (M&A) que será composto com um gerente de M&A e um assistente de pesquisa. A implementação e atividades do comitê M&A adotados neste projeto foram baseados no Manual de Monitoramento e Avaliação desenvolvido pela Organização Panamericana da Saúde46. Esse projeto terá uma abordagem metodológica mista, podendo ser classificada como um estudo de QualityImprovement.

O Comitê de M&A visa identificar informações relevantes às seguintes matrizes 1) organização dos serviços de saúde participantes da REBRACO; 2) barreiras e facilitadores da implementação de fluxos de atendimento e treinamento de profissionais de saúde; 3) informação e orientações ao grande público, mulheres gestantes e seus familiares e aos profissionais de saúde; 4) frequência de Síndrome Gripal e Síndrome Respiratória Grave relacionada e não relacionada ao SARS-CoV2 em mulheres gestantes atendidas em serviço de urgência/emergência, proporção de morbidade grave e mortalidade materna, frequência de desfechos perinatais adversos; 5) como as gestantes, seus familiares e profissionais de saúde estão lidando com a pandemia SARS-CoV2 e como isso influencia o cuidado em saúde e o enfrentamento da pandemia

Será formulado um plano de gestão de M&A que será baseado fundamentalmente em ações periódicas para acompanhar os dados em tempo real relativos à maioria dos tópicos descritos nas 5 matrizes para realizar tomadas de decisões que possam auxiliar a redirecionar a organização dos serviços de saúde e os planos de cuidado, informar as partes envolvidas sobre o

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enfrentamento da pandemia, identificar a necessidade de ações corretivas e analisar de forma objetiva e sistemática as barreiras e facilitadores do enfrentamento, utilizando-se de instrumentos e indicadores de processo e resultado pré-determinados. Para isso, uma equipe composta por colaboradores do projeto será designada para compor uma equipe de gestão de M&A, que será responsável em desenvolver, implementar e coordenar o plano de atividades. A REBRACO estimulará a participação direta ou indireta de membros de instituições contrapartes, stake-holders (interessados) ou beneficiários diretos e indiretos do projeto, beneficiando o co-gerenciamento das atividades de gestão de M&A do projeto e seu respectivo impacto e alcance de resultados.

Os instrumentos e critérios de avaliação, parâmetros de monitoramento e os demais processos de monitoramento e avaliação serão baseados no Manual de Monitoramento e Avaliação desenvolvido pela Organização Pan-americana da Saúde46. Os instrumentos de gestão de M&A utilizados serão: reuniões técnicas, relatório técnico, relatório de desempenho e relatório de avaliação final.

As reuniões técnicas semanais serão fundamentais para a adequada implementação, desenvolvimento e monitoramento do projeto tendo em vista o melhor enfrentamento. O comitê de implementação, monitoramento e qualidade será responsável pelas discussões técnicas; os membros do comitê de M&A poderão utilizar-se das informações relevantes para formular os relatórios técnicos e também poderão atuar como agentes de correção das atividades previstas pelo comitê de implementação, monitoramento e qualidade.

O relatório técnico de M&A será estruturado com base no plano de trabalho, resultados, indicadores, metas e atividades do projeto e objetiva avaliar a execução e avanços das atividades tendo em vista os resultados identificados nas cinco matrizes em tempo real. As principais seções deste instrumento incluem a descrição dos resultados, dos indicadores, das metas, das ações desenvolvidas, das lições aprendidas/recomendações, da execução financeira e considerações gerais do comitê de M&A, dos colaboradores e da contraparte. O relatório de desempenho auxiliará na avaliação da execução do projeto quanto aos níveis de relevância, eficácia, eficiência, impacto e sustentabilidade do projeto.

Para garantir que os instrumentos a serem empregados na gestão de M&A sejam adequados ao desenvolvimento do projeto, os mesmos serão submetidos a aprovação do comitê gestor do projeto e dos colaboradores da rede. A construção conjunta desses instrumentos aperfeiçoará o processo de M&A e, consequentemente, auxiliará na constituição das atividades da rede e no enfrentamento da pandemia.

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Levantamento de informações relevantes ao enfrentamento da pandemia COVID-19: Os centros participantes da Rede fornecerão informações provenientes dos seus relatórios de vigilância epidemiológica e Comitê de Controle de Infecção Hospitalar (CCIH) relevantes ao comitê de M&A (que se referem principalmente à matriz 4): frequência de Síndrome gripal e Síndrome Respiratória Grave relacionada e não relacionada ao SARS-CoV-2 em mulheres gestantes atendidas em serviço de urgência/emergência, proporção de morbidade grave e mortalidade materna, frequência de desfechos perinatais adversos e relacionada e prevalência de Síndrome Gripal, Síndrome Respiratória Grave e da contaminação pelo COVID -19 em parturientes no período da pandemia.

Uma abordagem integrando métodos mistos, quantitativos e qualitativos, que incluirão gestantes, familiares, colaboradores da REBRACO (gestores) e os profissionais de saúde levantará informações relevantes às seguintes matrizes: 1) organização dos serviços de saúde participantes da REBRACO; 2) barreiras e facilitadores da implementação de fluxos de atendimento e treinamento de profissionais de saúde; 3) informação e orientações ao grande público, mulheres gestantes e seus familiares e aos profissionais de saúde; 5) como gestantes, seus familiares e profissionais de saúde estão lidando com a pandemia SARS-CoV2 e como isso influencia o cuidado em saúde e o enfrentamento da pandemia.

Essa abordagem integrada incluirá: a) Um estudo quantitativo descritivo para identificar as estratégias implementadas no serviço de atendimento obstétrico nas unidades (centros participantes) da REBRACO. Os pesquisadores locais dos centros participantes da REBRACO irão preencher um formulário eletrônico online de coleta de dados (GoogleForm ou MonkeySurvey) que incluirá informações sobre a estrutura da instituição para atendimento obstétrico (número de leitos de enfermaria, alojamento conjunto, centro obstétrico, unidade de terapia intensiva), incluindo número de profissionais envolvidos no atendimento obstétrico (número de médicos, residentes, técnicos e enfermeiros que atuam nos setores de atendimento obstétrico), qualificação dos recursos da unidade para enfrentamento da pandemia (suficiência de material de EPI, por exemplo). O questionário abordará essa caracterização dos serviços de saúde participantes nos tempos antes, durante e após a pandemia por SARS-Cov2. Os dados serão anônimos, não havendo a identificação dos indivíduos, e serão tanto de acesso livre (relatórios institucionais ou da vigilância epidemiológica) ou restritos (de acesso controlado, como relatórios internos, planos de trabalho, etc). Tais informações (relatórios, etc) serão solicitados por cada um dos pesquisadores colaboradores local a cada responsável da instituição. O questionário será enviado mensalmente aos pesquisadores locais, para que preencham (e atualizem) com os dados relativos a suas instituições.

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b) Estudo qualitativo por amostra intencional e amostragem por saturação de acordo com os seguintes subgrupos: - Serão incluídas as gestantes com idade entre 13 e 45 anos, que foram triadas para síndrome gripal no pronto-atendimento (casos suspeitos COVID-19, ver a seguir) e de gestantes que tiveram resultado positivo de PCR para SARS-CoV-2. O pesquisador responsável pelo centro identificará as mulheres elegíveis através de revisão dos atendimentos de casos suspeitos e confirmados através dos registros do Comitê de Controle de Infecção Hospitalar, relatórios de vigilância epidemiológica do hospital e/ou dos registros de atendimentos da unidade de Pronto-Atendimento - uma revisão de prontuário irá auxiliar os pesquisadores a identificar números de telefone para contato com a mulher elegível.O convite para participar da pesquisa será realizado através de contato telefônico alguns dias após o atendimento no setor e no caso das mulheres internadas esse contato será realizado após a alta hospitalar (subgrupos paciente liberada e paciente internada), cerca de 15 dias após a alta. Os casos serão identificados através dos relatórios de vigilância epidemiológica do hospital ou da CCIH.

Casos suspeitos para síndrome gripal serão definidos através do protocolo local da instituição, podendo incluir a presença dos seguintes sinais e sintomas: febre e/ou pelo menos um dos sinais ou sintomas respiratórios (tosse, produção de escarro, congestão nasal ou conjuntival, dificuldade para deglutir, dor de garganta, coriza, saturação de O2 < 95%, sinais de cianose, batimento de asa de nariz, tiragem intercostal e dispneia).

Todas as entrevistas com as gestantes serão realizadas utilizando-se de entrevistas semi-estruturadas seguindo os seguintes tópicos:

- Informações recebidas sobre prevenção e contágio do SARS-Cov2 e a aplicação na sua vida cotidiana;
- Identificar as fontes da informação sobre prevenção e contágio do SARS-Cov2, incluindo informações como fonte jornalística conhecida, fonte jornalística desconhecida, mensagem de celular como aplicativo WhatsApp, mídias sociais como postagens no FaceBook, Instagram e Twitter, mídia falada, escrita ou televisionada, amigos, familiares, profissionais de saúde, membros do governo- agentes sanitários ou membros de cargos executivos como pronunciamento de Governadores, Prefeitos, Presidente da República, etc; Impacto do diagnóstico ou suspeita de infecção COVID-19 nas diferentes áreas da vida da mulher (vida familiar, trabalho, rede de convivência);
- Preocupações e anseios relacionados à pandemia COVID-19;
- Quais medidas poderiam ser adotadas para haver melhor comunicação e informação.
- Uma nova entrevista por telefone com as mulheres do subgrupo RT-qPCR SARS-CoV2 positivo

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será realizada 60 dias após o primeiro contato. Essas entrevistas incluirão os seguintes tópicos:

- Impacto do exame positivo nas diferentes áreas da vida da mulher (vida familiar, trabalho, rede de convivência);
- Preocupações e anseios relacionados ao exame positivo;
- Familiares com sintomas?
- O que poderiam ter feito por mim para me ajudar;
- Aplicação do questionário sobre transtorno de estresse pós-traumático e depressão;
- Informações sobre o recém-nascido.
- c) Estudo qualitativo por amostra intencional e amostragem por saturação incluindo familiares (acompanhantes) de gestantes que tiveram resultado positivo de PCR para SARS-CoV-2.

Como critérios de seleção, convidaremos, que um familiar próximos a gestante (indivíduo que a mulher julgar como "de convívio íntimo", como marido/parceiro, filho, pai, mãe, irmãos, sobrinhos, tios, primos, madrasta, padrasto), indicados pela mesma durante o contato referente a sua participação no estudo, sem distinção de sexo (masculino ou feminino), que tenha idade acima de 18 anos. Um novo contato com esse familiar será realizado e o convite será realizado, sendo incluídos aqueles que aceitem participar da pesquisa. Serão excluídos aqueles que por ventura tenham algum déficit cognitivo e/ou déficit auditivo e/ou de fala, que dificulte o participante compreender a pesquisa e ou responder aos questionamentos, visto que a entrevista será realizada por telefone.

Após a entrevista com as gestantes, será solicitado que elas indiquem um familiar para ser convidado a participar do estudo. O convite para participar da pesquisa será realizado através de contato telefônico, conforme indicação da gestante participante do componente (b).

As entrevistas com os familiares serão realizadas utilizando-se de entrevistas semi-estruturadas seguindo os seguintes tópicos:

- Informações recebidas sobre prevenção e contágio do SARS-CoV-2 e a aplicação na sua vida cotidiana;
- Identificar as fontes da informação sobre prevenção e contágio do SARS-Cov2, incluindo informações como fonte jornalística conhecida, fonte jornalística desconhecida, mensagem de celular como aplicativo WhatsApp, mídias sociais como postagens no FaceBook, Instagram e Twitter, mídia falada, escrita ou televisionada, amigos, familiares, profissionais de saúde, membros do governo- agentes sanitários ou membros de cargos executivos como pronunciamento de Governadores, Prefeitos, Presidente da República, etc; Impacto do diagnóstico (exame positivo) de sua familiar nas diferentes áreas da vida dele (vida familiar, trabalho, rede de

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#### convivência);

- Preocupações e anseios relacionados ao diagnóstico de seu familiar;
- Quais medidas poderiam ser adotadas para melhorar a comunicação e informação.
- d) Estudo qualitativo por amostra intencional e amostragem por saturação de acordo com os seguintes subgrupos de profissionais da saúde:
- Técnico de enfermagem
- Enfermeiro
- Docente/Médico contratado
- Residente em Ginecologia e Obstetrícia (R1, R2 e R3).

Serão elegíveis para a pesquisa os profissionais da saúde de ambos os sexos (masculino e feminino), com idade acima de 18 anos, que durante a pandemia estavam na ativa, ou seja, atendendo em qualquer uma das unidades de atendimento obstétrico (pronto-atendimento, centro-obstétrico, alojamento conjunto, enfermaria patológica, etc). A identificação de pessoas elegíveis será realizada através de consulta ao cadastro institucional de profissionais de saúde da instituição que trabalham nas diferentes unidades e nas diferentes categorias profissionais. Uma listagem única será ordenada com númeração única. Será utilizado um sistema de ordenamento aleatório de números para selecionar os profissionais que serão convidados a participar. Caso não haja concordância em participar, os profissionais com números subsequentes serão convidados até que se atinja o "n" desejado (estima-se 30, mas o método de saturação pode requerer a participação de menos ou mais profissionais).

Dados sobre o setor de atuação no momento da entrevista, idade, tempo de experiência (formação), gênero, tempo de trabalho na unidade e escolaridade serão também coletados. A entrevista com esses profissionais serão realizadas presencialmente nos centros participantes localizados próximos à instituição coordenadora do estudo. Nos demais centros, as entrevistas serão realizadas por telefone.

Todas as entrevistas semiestruturadas serão gravadas em áudio após o consentimento das participantes. Posteriormente, as gravações serão transcritas e o texto obtido será conferido com a gravação. Os textos serão inseridos no programa computacional NVivo para realização da análise. Será realizada análise temática47. As abordagens b), c) e d) serão realizadas em todos os centros participantes pela mesma equipe de pesquisa qualitativa do centro coordenador do estudo.

A amostragem empregada em todos os componentes dos estudos qualitativos será por saturação, porém estima-se em torno de 90 participantes (30 gestantes, 30 familiares e 30 profissionais de saúde).

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Abordagem ecológica: Trata-se de um estudo ecológico, na qual será feita a análise mensal dos dados consolidados de partos e a verificação dos efeitos indiretos da pandemia na evolução do número dos partos (número de nascimentos mensais) e dos óbitos fetais e os fatores associados a esta variação. E será realizada uma análise de tendência entre os três períodos (12 meses prévios, durante a pandemia e 12 meses subsequentes a pandemia).

O tamanho amostral será por conveniência. Serão analisados os registros dos nascidos vivos e óbitos fetais notificados nas bases de dados oficiais (dados consolidados), considerando-se os nascimentos ocorridos nas maternidades da região de Campinas e óbitos fetais nas cidades dos centros participantes, a partir do mês de janeiro de 2019 até 12 meses após o término da pandemia COVID-19: a ser declarada pela OMS e Governo Federal do Brasil.

Serão obtidos dados sócio demográficos, clínicos e perinatais. Os dados serão coletados a partir de uma planilha Excel e armazenados de forma decodificada em banco de dados protegido por senha específica dos pesquisadores.

Comitê de implementação, monitoramento e qualidade: Os pesquisadores da Disciplina de Obstetrícia da Unicamp têm uma vasta experiência em estudos multicêntricos tanto internacionais como nacionais. O estudo será conduzido pela Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal e contará também com o Centro de Estudos em Saúde Reprodutiva de Campinas (Cemicamp), uma organização privada sem fins lucrativos que é o braço de pesquisa do Departamento de Obstetrícia e Ginecologia da Universidade de Campinas, com experiência no planejamento, execução e administração de estudos clínicos e epidemiológicos. Nos últimos 12 anos, a Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal contou com diversos estudos coordenados pela Unicamp em diversa áreas da saúde materna e perinatal, como a Rede Brasileira de Vigilância de Morbidade Materna Grave (participação de 27 centros, financiamento: CNPq/DECIT47), Estudo Brasileiro Multicêntrico de Investigação em Prematuridade (20 centros, financiamento: CNPq/Fapesp49), Ensaio clínico randomizado de pessário e progesterona versus progesterona para prevenção de parto prematuro - P5 trial (17 centros, financiamento: CNPq/DECIT/MS e Bill and Melinda Gates Foundation50), Preterm SAMBA (5 centros, financiamento: CNPq/DECIT/MS e Bill and Melinda Gates Foundation51,52), Estudo exploratório de actigrafia materna - MAES I study (5 centros, Bill and Melinda Gates Foundation53).

Constituir tal iniciativa no Brasil não é uma tarefa fácil. Ela envolve experiência e capacidade em estudos clínicos e epidemiológicos, além do conhecimento e utilização das normas de "GoodClinicalPractice". Esta é a razão pela qual escolhemos incluir centros participantes de

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diferentes partes do Brasil, mas também com experiência prévia na inclusão de mulheres em estudos clínicos e epidemiológicos e com bom desempenho. Em um dos estudos multicêntricos recentes coordenados pela Unicamp, publicamos os processos e as experiências envolvidas no planejamento e condução de um estudo multicêntrico envolvendo coleta de dados clínico-epidemiológicos e de amostras biológicas. Exploramos também nesta publicação as barreiras e métodos adotados para superá-las. Essa experiência documentada e compartilhada exemplificam a atuação da Unicamp frente à coordenação de estudos dessa envergadura. Uma das características importantes descritas nesta publicação é o papel fundamental do comprometimento institucional para o bom desenvolvimento dos estudos. Todos os centros participantes foram previamente contatados sobre suas possibilidades de conduzirem o estudo e esse comprometimento assegurado para, então, garantir-se adequabilidade às condições do projeto em todos eles

Os centros participantes envolvidos no projeto apresentam condições adequadas para conduzirem o estudo. Em cada um dos centros participantes haverá um pesquisador responsável pela coordenação do estudo e um assistente de pesquisa, que irá auxiliar na consolidação dos dados dos relatórios da CCIH e de vigilância epidemiológica do hospital. O sistema eletrônico para armazenamento de dados (RedCap) é a plataforma de escolha para o estudo e permite confidencialidade e segurança no armazenamento dos dados. É nessa plataforma que vamos consolidar e armazenar os dados. A plataforma RedCap tem seu servidor no centro coordenador do estudo (Caism/Unicamp), havendo uma conexão bidirecional vigiada entre os dispositivos de coleta de dados. Realizaremos extrações parciais dos dados consolidados, sem prejuízo ao funcionamento da plataforma de coleta de dados RedCap, para verificar consistência de dados e para informar os comitê de monitoramento e avaliação. Relatórios contendo as informações inconsistentes serão encaminhados aos centros participantes para que verifiquem novamente os dados e para que uma duplachecagem seja feita. O comitê realizará a checagem final do dado revisado.

Desenvolveremos diferentes manuais e protocolos de operação padrão (SOP - Standard Operating Procedure) incluindo os diferentes procedimentos do estudo para coletar e consolidar os dados dos centros participantese realização das entrevistas do componente qualitativo. Todos os assistentes de pesquisa e pesquisadores colaboradores serão devidamente treinados por sessões de videoconferência e webinars a serem desenvolvidos pelo Comitê de implementação, monitoramento e qualidade. Reuniões semanais e grupos de whatsapp entre o comitê, os assistentes de pesquisa e pesquisadores colaboradores ajudarão na comunicação entre as equipes

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e a sanar dúvidas sobre o treinamento e procedimentos do estudo.

O comitê de implementação, monitoramento e qualidade do estudo contará com um monitor geral e um assistente de pesquisa para desenvolver as atividades previstas nos procedimentos desse comitê. As atividades serão desenvolvidas diretamente com o pesquisador responsável pela coordenação do estudo e seus assistentes de pesquisa em cada centro colaborador.

Variáveis: Número total de atendimentos no serviço de pronto-atendimento em obstetrícia na unidade: Número semanal total de atendimentos no serviço de pronto-atendimento em obstetrícia na unidade. Número de atendimentos no serviço de pronto-atendimento em obstetrícia de mulheres com suspeita de COVID-19: Número semanal de casos suspeitos para síndrome gripal, sendo definido através do protocolo local da instituição, podendo incluir a presença dos seguintes sinais e sintomas: febre e/ou pelo menos um dos sinais ou sintomas respiratórios (tosse, produção de escarro, congestão nasal ou conjuntival, dificuldade para deglutir, dor de garganta, coriza, saturação de O2 < 95%, sinais de cianose, batimento de asa de nariz, tiragem intercostal e dispneia).

Motivo de suspeita de COVID-19: quadro sintomático apresentado incluindo, febre - acima de 38°c, tosse, dificuldade de respirar (dispneia), produção de escarro, congestão nasal, congestão conjuntival, alteração ou ausência de percepção de odores, dificuldade para deglutir, dor de garganta, coriza, saturação de o2 < 95%, sinais de cianose, batimento de asa de nariz, tiragem intercostal, fadiga, mialgia, artralgia, dor de cabeça, calafrios, manchas vermelhas pelo corpo, gânglios linfáticos aumentados, diarreia, náusea, vômito, desidratação, inapetência.

Número de internações hospitalares em obstetrícia na unidade: Número semanal de internações hospitalares por qualquer causa em obstetrícia na unidade.

Número de internações hospitalares por COVID-19em obstetrícia na unidade: Número semanal de internações hospitalares por COVID-19 (suspeito ou confirmado) em obstetrícia na unidade.

Número de novos casos de COVID-19 confirmados na unidade: número de óbitos de mulheres durante a gestação ou dentro de um período de 42 dias após o término da gestação, independente da duração ou da localização da gravidez, devido a qualquer causa relacionada com ou agravada pela gravidez ou por medidas em relação a ela, porém não devida a causas acidentais ou incidentais.

Número de óbitos maternos por qualquer causa: número de óbitos de mulheres durante a gestação ou dentro de um período de 42 dias após o término da gestação, independente da

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duração ou da localização da gravidez, devido a qualquer causa relacionada com ou agravada pela gravidez ou por medidas em relação a ela, porém não devida a causas acidentais ou incidentais.

Número de óbitos maternos por COVID-19: número de óbitos de mulheres durante a gestação ou dentro de um período de 42 dias após o término da gestação, independente da duração ou da localização da gravidez, devido a COVID-19. conforme atestado de óbito.

Número de afastamentos de profissionais de saúde devido COVID-19 na unidade: Número semanal de afastamentos de profissionais de saúde devido COVID-19 (contato ou suspeita da doença) na unidade. Número de novos casos de síndrome da angústia respiratória aguda (SARS) em gestantes na unidade:número de novos casos semanal de síndrome da angústia respiratória aguda (SARS), conforme protocolo local da instituição, em gestantes na unidade.

Número de novos casos de síndrome da angústia respiratória aguda (SARS) por COVID-19 em gestantes na unidade: número de novos casos semanal de síndrome da angústia respiratória aguda (SARS) por COVID-19, conforme protocolo local da instituição, em gestantes na unidade.

Número de novos casos de síndrome da angústia respiratória aguda (SARS) em gestantes na unidade: número de óbitos de mulheres durante a gestação ou dentro de um período de 42 dias após o término da gestação, independente da duração ou da localização da gravidez, devido a qualquer causa relacionada com ou agravada pela gravidez ou por medidas em relação a ela, porém não devida a causas acidentais ou incidentais.

Número de leitos designados para alojamento conjunto nas semanas anteriores à pandemia: número de leitos por semana, conforme relatado pelo responsável da instituição.

Número de leitos designados para alojamento conjunto nas semanas de vigência da à pandemia: número de leitos por semana, conforme relatado pelo responsável da instituição.

Número de leitos designados para pré-parto nas semanas anteriores à pandemia: número de leitos por semana, conforme relatado pelo responsável da instituição.

Número de leitos designados para pré-parto nas semanas de vigência da à pandemia: número de leitos por semana, conforme relatado pelo responsável da instituição.

Número de leitos designados para cuidados intensivos nas semanas anteriores à pandemia: número de leitos por semana, conforme relatado pelo responsável da instituição.

Número de leitos designados para cuidados intensivos nas semanas de vigência da à pandemia: número de leitos por semana, conforme relatado pelo responsável da instituição.

Número de nascidos vivos: número mensal de nascidos vivos nos 12 meses anteriores, nos meses de vigência da pandemia e nos 12 meses após o fim da pandemia na cidade de Campinas,

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conforme secretaria municipal de saúde (painel de monitoramento).

Número de óbitos fetais: número mensal de óbitos fetais nos 12 meses anteriores, nos meses de vigência da pandemia e nos 12 meses após o fim da pandemia nas cidades onde há centros participantes do estudo, conforme secretaria municipal de saúde (painel de monitoramento).

Metodología de análise de dados: O relatório técnico de M&A será estruturado com base no plano de trabalho, resultados, indicadores, metas e atividades do projeto e objetiva avaliar a execução e avanços das atividades tendo em vista os resultados identificados nas cinco matrizes em tempo real. As principais seções deste instrumento incluem a descrição dos resultados, dos indicadores, das metas, das ações desenvolvidas, das lições aprendidas/recomendações, da execução financeira e considerações gerais do comitê de M&A, dos colaboradores e da contraparte. O relatório de desempenho auxiliará na avaliação da execução do projeto quanto aos níveis de relevância, eficácia, eficiência, impacto e sustentabilidade do projeto.Os dados obtidos para a pesquisa serão de característica associativa e descritiva, visando a caracterização da assistência realizada pelos centros participantes, os aspectos de saúde mental relacionado a vivência da pandemia pelas mulheres, familiares e profissionais de saúde e análise de repercussão na saúde reprodutiva (número de nascidos vivos). Será realizada uma análise de tendência entre os três períodos (12 meses prévios, durante a pandemia e 12 meses subsequentes à pandemia) sobre o número de nascidos vivos na cidade de Campinas e óbitos fetais nas cidades onde há centros participantes do estudo. Todas as entrevistas semiestruturadas serão gravadas em áudio após o consentimento das participantes. Posteriormente, as gravações serão transcritas e o texto obtido será conferido com a gravação. Os textos serão inseridos no programa computacional NVivo para realização da análise. Será realizada análise temática47. As abordagens b), c) e d) serão realizadas em todos os centros participantes pela mesma equipe de pesquisa qualitativa do centro coordenador do estudo.

Aspectos éticos: O presente projeto de pesquisa estará pautado em todos os princípios enunciados na Declaração de Helsinque e na Resolução 466/12 do Conselho Nacional de Saúde.

A componente gestão do Comitê de gestão de crise na Rede de Pesquisa COVID-19 é um componente de extensão e não de pesquisa, que não haverá coleta de dados dos gestores, e sim a coleta de informações sobre os recursos e detalhes da organização e assistência de cada instituição para o enfrentamento da pandemia.

Na etapa qualitativa, serão convidadas gestantes e parturientes com suspeita de COVID-19 que já

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estejam participando deste estudo na etapa quantitativa. O primeiro contato telefônico para fazer o convite para participar da pesquisa será realizado a partir do número de telefone que consta no cadastro das mulheres neste estudo. As entrevistas semiestruturadas com as gestantes, parturientes e seus familiares serão realizadas por telefone e gravadas após o consentimento. Os termos de consentimento e assentimento informados estão apresentados no anexo 1. As entrevistas com os profissionais de saúde serão presenciais e serão realizadas no local de trabalho, em sala privativa, após a assinatura do TCLE. No entanto, algumas entrevistas serão realizadas por telefone nos centros participantes que estão mais distantes da instituição coordenadora do estudo. Um termo de consentimento a ser obtido por telefone também foi elaborado (anexo 2). Estima-se que a duração das entrevistas será em torno de 30 minutos, podendo ser maior ou menor, conforme o tempo determinado pelo entrevistado. Para cada categoria de participante foi elaborado um roteiro específico para as entrevistas semiestruturadas (anexo 3). O questionário de transtorno pós-traumático será aplicado para as gestantes, parturientes, familiares e profissionais de saúde e também se encontra no anexo 3.

Para os participantes que realizarem a entrevista por telefone, será lido um TCLE preparado especificamente para esse fim. Após o esclarecimento das dúvidas, será perguntado se a pessoa aceita participar da pesquisa e se permite que seja gravada. Se a resposta for afirmativa, será explicado que o gravador será ligado e que essas duas perguntas serão realizadas novamente para ficarem gravadas. Logo após, será iniciada a entrevista. O TCLE será obtido após o profissional de saúde ler esse documento e esclarecer suas dúvidas. O TCLE será assinado e o participante receberá uma via virtual assinada por e-

Todos os participantes serão esclarecidos que poderão recusar-se participar do estudo ou interromper sua participação a qualquer momento sem nenhum tipo de prejuízo.

No caso de haver participantes menores de idade, será solicitada a autorização dos pais/responsáveis legais não apenas para a entrevista, mas também para a inclusão no estudo, bem como a anuência da adolescente.

Será dada garantia aos participantes que sua identidade será mantida em sigilo e nenhuma informação será dada a outras pessoas que não façam parte da equipe de pesquisa. Na divulgação dos resultados do estudo o nome dos participantes não aparecerá. Para garantir o sigilo, as pessoas serão identificadas apenas por números, bem como as gravações e as transcrições das entrevistas.

O componente de implementação da Rede e o estudo ecológico não envolverá dados individuais, mas sim dados agregados sobre os serviços de saúde, seus indicadores, relatórios de assistência.

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Participantes do estudo qualitativo podem se confrontar com sentimentos, estado psíquico ou distúrbios mentais (estresse, pós-traumático, ansiedade, etc) que possam requerer suporte e acompanhamento adequados. Quando houver a suspeita dessa necessidade, os pesquisadores oferecerão encaminhamento para suporte clínico pertinente. caso o participante aceite, será encaminhado ao serviço de psicologia disponível em cada centro participante da pesquisa ou, quando o centro não tiver esse serviço, o participante será encaminhado para a rede referenciada do SUS.

No caso do centro participante ter o serviço de psicologia, o pesquisador será responsável, por agendar a consulta do participante, no ambulatório de psicologia.

Quando não houver o serviço psicologia no centro, ou o participante não quiser passar por consulta no serviço, será fornecido um encaminhamento para o serviço de psicologia da unidade de saúde da cidade. A identificação de possíveis transtornos mentais advindos da experiência em lidar com a pandemia pode ser vista como um benefício indireto, haja vista a possibilidade de, através dessa identificação, iniciar acompanhamento e tratamento adequados.

Local de realização da pesquisa: A pesquisa será realizada no CAISM-UNICAMP e nos diversos centros coparticipantes.

O arquivo do projeto de pesquisa inclui a descrição detalhada do cronograma de execução do estudo em suas três etapas e o detalhamento do orçamento.

Foram apresentados anexos ao projeto de pesquisa (versão de 29/05/2020): Anexo 1 (TALE, TCLE e TCLE para responsáveis por menores de idade para aplicação aos participantes da etapa com análises qualitativas), Anexo 2 (TCLE a ser aplicado a Profissionais de saúde, versão presencial e versão para aplicação por telefone), Anexo 3 (Roteiro para entrevista e questionário de transtorno pós-traumático com gestantes e parturientes, na primeira entrevista e após 60 dias, Roteiro para entrevista semiestruturada com familiares das parturientes e Roteiro para entrevista e questionário de transtorno pós-traumático Profissionais de saúde) e Anexo 4 (organograma da estrutura organizacional e procedimentos do estudo). Os modelos de TCLE/TALE apresentados em anexo ao projeto de pesquisa não foram considerados na elaboração do parecer, considerando-se na análise exclusivamente os modelos apresentados em arquivo específico do TCLE/TALE e obrigatório. Ainda que tenha havido apresentação duplicada de arquivos, a ordenação e a colocação de subtítulos explicativos nos mesmos, em anexo ao projeto de pesquisa, facilitou em muito a compreensão da seqüência de ações e das finalidades dos mesmos.

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#### Objetivo da Pesquisa:

Justificativa: O SARS-CoV-2 tem se mostrado um agente infeccioso emergente de alto impacto. Sua natureza respiratória, sua alta taxa de transmissão e sua letalidade o tornou uma emergência global em saúde. Em tempos de globalização e intercâmbio constante de pessoas em espaços curtos de tempo, além de aspectos multifatoriais sociais, culturais e político-econômicos, a expansão deste patógeno foi agravada. Este panorama culminou para que no dia 11 de março de 2020, a COVID-19 fosse classificada como pandemia pela Organização Mundial da Saúde (OMS). A expansão desse patógeno é factual e suas consequências para a saúde humana estão e serão sentidas de maneira significativa. Devido ainda à baixa ocorrência atual na população gestante (março/2020) e ao seguimento de gestações vigentes, não é claro como a infecção por este patógenocomporta-se em sua completude. Algumas particularidades da infecção por este patógeno só serão constatadas uma vez efetuado um estudo longitudinal minucioso e compreensivo, com um alto número de casos vigiados. Desta forma, o atual estudo tem como proposta entender como o SARS-CoV-2 interfere na assistência em saúde no contexto da saúde materna e perinatal, com resultados potencialmente de alto impacto para o aprimoramento do atendimento nessa área. Além disso; irá possibilitar um constante aprendizado sobre as estratégias de enfrentamento à pandemia, com discussão prospectiva dos casos avaliados e seguimento detalhado; em diferentes cenários, e com avaliação qualitativa dos profissionais e gestantes. O estudo será conduzido pela Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal e contará também com o Centro de Estudos em Saúde Reprodutiva de Campinas (Cemicamp), uma organização privada sem fins lucrativos que é o braço de pesquisa do Departamento de Obstetrícia e Ginecologia da Universidade Estadual de Campinas, com experiência no planejamento, execução e administração de estudos clínicos e epidemiológicos; além de ser oficialmente um HUB-OMS (Centro de Pesquisa da Organização Mundial da Saúde para os países lusofônicos). Nos últimos 12 anos, a Rede Brasileira de Estudos em Saúde Reprodutiva e Perinatal, com a coordenação da Unicamp, desenvolveu diversos estudos em saúde materna e perinatal; incluindo estudos durante a pandemia H1N1 (H1N1pdm09).

Hipótese: 1. As instituições criarão e aplicarão protocolos específicos para o atendimento das mulheres com suspeita ou diagnóstico confirmado de COVID-19. A criação de uma rede de pesquisas é ferramenta útil em momentos de urgência e emergência sanitária, principalmente quando baseada numa estrutura previamente formada. Os serviços de saúde necessitarão de múltiplos ajustes no fluxo de atendimento e de identificação de casos suspeitos, tendo em vista o adequado atendimento de casos suspeitos e o não comprometimento de recursos para

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atendimento dos casos que já fazem parte do atendimento habitual da clínica obstétrica. 2. Gestantes com COVID-19 têm maiores taxas de sintomas depressivos e de estresse pós-traumático, assim como seus familiares. Os profissionais envolvidos no atendimento têm também maiores taxas de sintomas depressivos e de estresse pós-traumáticos. 3. Haverá uma diminuição de nascidos vivos nos meses subsequentes ao término da pandemia. Haverá um aumento do número de óbitos fetais nos meses de vigência da pandemia. Objetivo primário: Este estudo busca estabelecer uma rede de colaboração de enfrentamento a pandemia de COVID-19 em Hospitais e Maternidades de referências que atendem a população obstétrica.

Objetivos secundários: 1. Criar mecanismos de gestão que auxiliem na resposta rápida à crise através da criação de uma rede de colaboração em um momento de emergência sanitária. 2. Avaliar as impressões sobre a vivência da pandemia e a ocorrência de sintomas depressivos e de estresse pós-traumático em gestantes com COVID-19, seus familiares e em profissionais envolvidos na assistência desses casos. 3. Avaliar os efeitos da pandemia COVID19 em indicadores de saúde materna e perinatal como o número de nascidos vivos e de óbitos fetais.

#### Avaliação dos Riscos e Beneficios:

Os pesquisadores informaram quanto aos riscos e desconfortos previstos que "O componente de implementação da Rede e o estudo ecológico não envolverá dados individuais, mas sim dados agregados sobre os serviços de saúde, seus indicadores, relatórios de assistência. Participantes do estudo qualitativo podem se confrontar com sentimentos, estado psíquico ou distúrbios mentais (estresse, pós-traumático, ansiedade, etc) que possam requerer suporte e acompanhamento adequados. Quando houver a suspeita dessa necessidade, os pesquisadores oferecerão encaminhamento para suporte clínico pertinente".

Os pesquisadores informaram quanto aos benefícios previstos que "A identificação de possíveis transtornos mentais advindos da experiência em lidar com a pandemia pode ser vista como um benefício indireto, haja vista a possibilidade de, através dessa identificação, iniciar acompanhamento e tratamento adequados".

#### Comentários e Considerações sobre a Pesquisa:

A EQUIPE DE PESQUISADORES citada na capa do protocolo e na PB inclui RENATO TEIXEIRA SOUZA (Médico, Docente do PPG em Tocoginecologia da FCM/Unicamp, Pesquisador Colaborador do Departamento de Obstetrícia e Ginecologia da FCM/UNICAMP, Pesquisador responsável ), CAROLINA CARVALHO RIBEIRO DO VALLE (Médica, Doutoranda no PPG em Tocoginecologia da FCM/UNICAMP), CHARLES M'POCA CHARLES (Médico, Doutorando no PPG em Tocoginecologia da

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FCM/UNICAMP), GIULIANE JESUS LAJOS (Médica, docente do Departamento de Tocoginecologia da FCM/UNICAMP), GUILHERME DE MORAES NÓBREGA (Graduando no curso de Ciências Biológicas do IB/UNICAMP), JAMIL PEDRO DE SIQUEIRA CALDAS (Médico, Docente do Departamento de Pediatria da FCM/UNICAMP), JOSÉ GUILHERME CECATTI (Médico, Docente do Departamento de Tocoginecologia da FCM/UNICAMP), JOSÉ PAULO DE SIQUEIRA GUIDA (Médico, Doutorando no PPG em Tocoginecologia da FCM/UNICAMP), KARAYNA GIL FERNANDES (Médica, Docente do Departamento de Tocoginecologia da Faculdade de Medicina de Jundiaí/FMJ), MARIA LAURA COSTA DO NASCIMENTO (Médica, Docente do Departamento de Tocoginecologia da FCM/UNICAMP), RODOLFO DE CARVALHO PACAGNELLA (Médico, Docente do Departamento de Tocoginecologia da FCM/UNICAMP), SAMIRA EL MAERRAWI TEBECHERANE HADDAD (Médica, Docente do Programa de Práticas Médicas da Faculdade de Medicina do Guarujá/UNOESTE), SÉRGIO TADEU MARTINS MARBA (Médico, Docente do Departamento de Pediatria da FCM/UNICAMP), SHERLY METELUS (Médica, Doutoranda no PPG em Tocoginecologia da FCM/UNICAMP), SILVANA APARECIDA FERREIRA BENTO (Pesquisadora do Centro de Pesquisas em Saúde Reprodutiva de Campinas/Cemicamp e Centro de Atenção Integral à Saúde da Mulher (CAISM)/ UNICAMP). STEPHANIE PABON LOZANO (Enfermeira, Doutoranda no PPG em Tocoginecologia da FCM/UNICAMP) e THAYNA BATALHOTO GRIGGIO (Graduanda no curso de Medicina da FCM/UNICAMP). O orçamento descrito na PB informa que a pesquisa terá custo de R\$ 39.600,00 para aquisição/pagamento de software (R\$ 1.800,00), serviços de terceiros (R\$ 15.000,00) e equipamentos (R\$ 22.800,00) e será bancado pelos pesquisadores.

A pesquisa foi classificada na Grande Área 4 (Ciências da Saúde) e tem como título público "REBRACO - REde BRAsileira em estudos do COVID-19 em Obstetrícia Comitê de gestão de crise na Rede de Pesquisa REBRACO e identificação de informações relevantes ao enfrentamento da pandemia".

A pesquisa não foi classificada nas áreas temáticas especiais, mas lida com a temática COVID-19, sendo avaliada em conformidade com as recomendações específicas da CONEP para o tema.

A Instituição proponente da pesquisa é o Hospital da Mulher Prof. Dr. José Aristodemo Pinotti – CAISM-UNICAMP. Foram listados as seguintes Instituições Coparticipante e pesquisadores responsáveis: Faculdade de Medicina da Universidade Estadual de São Paulo - FMB/UNESP, Botucatu/SP (Prof. Dr. Leandro Gustavo de Oliveira), Faculdade de Medicina de Jundiaí - HU/FMJ, Jundiaí, SP (Prof. Dr. Ricardo Porto Tedesco), Hospital de Clínicas da Universidade Federal do Rio Grande do Sul - HC/UFRGS, Porto Alegre/RS (Prof. Dr. Sérgio Hofmeister de Almeida Martins-Costa), Hospital Estadual Sumaré Dr. Leandro Francheschini - HES, Sumaré/SP (Dr José Paulo de

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Siqueira Guida), Hospital Moinhos de Vento, Porto Alegre/RS (Profa. Dra. Janete Vettorazzi), Hospital Regional Jorge Rossmann (Instituto Socrates Guanaes - ISG) - Itanhaém, SP (Profa. Dra. Samira M Haddad), Hospital UNIMED (Unimed Belo Horizonte Cooperativa de Trabalho Médico) - UNIMED/BH, Belo Horizonte/MG (Dr. Frederico José Amedee Peret), Instituto Fernandes Figueira - IFF/Fiocruz, Rio de Janeiro/RJ (Prof. Dr. Marcos Augusto Bastos Dias), Maternidade Climério de Oliveira - MCO-UFBA, Salvador/BA (Prof. Carlos Augusto Santos Menezes), Universidade de São Paulo (UE-FMRP-USP) - USP/Ribeirão Preto, Ribeirão Preto/SP (Profa. Dra. Silvana Maria Quintana), Universidade Federal de Minas Gerais - HC/UFMG, Belo Horizonte/MG (Prof. Dr. Mário Dias Corrêa Júnior), Universidade Federal de Pernambuco - HC/UFPE, Recife/PE (Prof. Dr. Elias Ferreira de Melo Júnior), Universidade Federal de São Carlos - UFSCAR/Santa Casa de São Carlos, São Carlos, SP (Profa. Dra. Carla Andreucci Polido), Universidade Federal de São Paulo - UNIFESP/EPM, São Paulo/SP (Profa. Dra. Rosiane Mattar), Universidade Federal do Ceará - MEAC/UFC, Fortaleza/CE (Prof. Dr. Francisco Edson de Lucena Feitosa), Universidade Federal do Paraná - HC/UFPR - Curitiba/PR (Prof. Dr. Dênis José Nascimento), Fundação Santa Casa de Misericórdia do Pará (responsável Dra. Marília Gabriela Queiroz da Luz).

O cronograma proposto para a pesquisa no projeto prevê 36 meses para conclusão. O cronograma descrito na PB indica que a pesquisa será iniciada em 08/06/2020 e será concluída em 30/06/2023, em cerca de 37 meses.

Haverá uso de fontes secundárias de dados (prontuários, dados demográficos, etc), o que foi justificado e explicado da seguinte forma: "As fontes de dados incluem relatórios administrativos (símile a relatórios anuais de atividades), da vigilância epidemiológica e do controle de infecção hospitalar dos centros participantes e as informações do painel de monitoramento da secretaria de saúde do município de campinas (para número de nascidos vivos) e dos municípios dos centros participantes (para número de óbitos fetais)".

O protocolo foi emendado em22/06/2020 (E1), para correção de CNPJ de Centro co-participante (UFPR) e exclusão de centro coparticipante (Instituto de Medicina Integral Professor Fernando Figueira - IMIP/PE) e em 29/06/2020 (E2) (CNPJ) para correção do CNPJ de dois Centros co-participantes.

Em 22/07/2020 os pesquisadores solicitaram emenda ao protocolo (E3) para inclusão de novo centro coparticipante, a Fundação Santa Casa de Misericórdia do Pará (responsável Dra. Marília Gabriela Queiroz da Luz) sob a seguinte justificativa: "Esse projeto é fruto de um desmembramento de uma proposta que originalmente continha outros subprojetos que fazem parte da abordagem clínico-epidemiológica de COVID-19 em obstetrícia proposta pela Rede. A

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atual emenda é relativa a inclusão de um Centro co-participante: Fundação Santa Casa de Misericórdia do Pará (responsável Dra. Marília Gabriela Queiroz da Luz). Tendo em vista que tais modificações não influenciam o protocolo do estudo ou sua execução nos outros centros, realizo procedimento de emenda apenas no centro coordenador (Unicamp)".

#### Considerações sobre os Termos de apresentação obrigatória:

Os documentos e blocos de informação utilizados para elaboração do parecer foram:

Registro do protocolo na Plataforma Brasil: Arquivo "PB\_INFORMAÇÕES\_BÁSICAS\_1599996\_E3.pdf" de 22/07/2020.

Projeto de pesquisa: Arquivo "ProjetoCOVIDPlatBrasil\_22\_07\_20.docx" de 22/07/2020. A leitura do arquivo não evidenciou alterações assinaladas no texto do mesmo e a solicitação de emenda não citou alterações no projeto de pesquisa. Os modelos de TCLE e demais anexos ao arquivo não foram considerados na avaliação, também por não haver qualquer citação de alteração dos mesmos na solicitação de emenda apresentada pelo pesquisador.

Também foram apresentados 14 outros arquivos de versões anteriores do protocolo, que já foram avaliados em outros pareceres, que aparentemente não têm relação com a presente solicitação (E3) e, portanto, não foram considerados para a elaboração deste parecer.

#### Recomendações:

A Comissão Nacional de Ética em Pesquisa (Conep), do Conselho Nacional de Saúde (CNS) orienta a adoção das diretrizes do Ministério da Saúde (MS) decorrentes da pandemia causada pelo Coronavírus SARS-CoV-2 (Covid-19), com o objetivo de minimizar os potenciais riscos à saúde e a integridade dos participantes de pesquisas e pesquisadores.

De acordo com carta circular da CONEP intitulada "ORIENTAÇÕES PARA CONDUÇÃO DE PESQUISAS E ATIVIDADE DOS CEP DURANTE A PANDEMIA PROVOCADA PELO CORONAVÍRUS SARS-COV-2 (COVID-19)" publicada em 09/05/2020, referente ao item II. "Orientações para Pesquisadores":

- Aconselha-se a adoção de medidas para a prevenção e gerenciamento de todas as atividades de pesquisa, garantindo-se as ações primordiais à saúde, minimizando prejuízos e potenciais riscos, além de prover cuidado e preservar a integridade e assistência dos participantes e da equipe de pesquisa.
- Em observância às dificuldades operacionais decorrentes de todas as medidas impostas pela pandemia do SARS-CoV-2 (COVID- 19), é necessário zelar pelo melhor interesse do participante da pesquisa, mantendoo informado sobre as modificações do protocolo de pesquisa que possam afetá-lo, principalmente se houver ajuste na condução do estudo, cronograma ou plano de trabalho.

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- Caso sejam necessários a suspensão, interrupção ou o cancelamento da pesquisa, em decorrência dos riscos imprevisíveis aos participantes da pesquisa, por causas diretas ou indiretas, caberá aos investigadores a submissão de notificação para apreciação do Sistema CEP/Conep.
- Nos casos de ensaios clínicos, é permitida, excepcionalmente, a tramitação de emendas concomitantes à implementação de modificações/alterações no protocolo de pesquisa, visando à segurança do participante da pesquisa, assim como dos demais envolvidos no contexto da pesquisa, evitando-se, ainda, quando aplicável, a interrupção no tratamento dos participantes da pesquisa. Eventualmente, na necessidade de modificar o Termo de Consentimento Livre e Esclarecido (TCLE), o pesquisador deverá proceder com o novo consentimento, o mais breve possível.

#### Conclusões ou Pendências e Lista de Inadequações:

Trata-se de solicitação de emenda ao protocolo (E3) para inclusão de novo centro participante (Fundação Santa Casa de Misericórdia do Pará). Ainda que tenha sido apresentado arquivo do projeto de pesquisa com diversos anexos, a solicitação de emenda nada cita sobre alterações neste arquivo, nem em seus anexos, nem foi possível evidenciar alterações no mesmo. O parecer considera exclusivamente a solicitação explicitada pelos pesquisadores. Caso tenham sido realizadas alterações no projeto de pesquisa ou em seus anexos os pesquisadores devem encaminhar nova solicitação de emenda explicitando as eventuais alterações realizadas e suas justificativas.

Não há pendências por resolver.

#### Considerações Finais a critério do CEP:

- O participante da pesquisa deve receber uma via do Termo de Consentimento Livre e Esclarecido, na íntegra, por ele assinado (quando aplicável).
- O participante da pesquisa tem a liberdade de recusar-se a participar ou de retirar seu consentimento em qualquer fase da pesquisa, sem penalização alguma e sem prejuízo ao seu cuidado (quando aplicável).
- O pesquisador deve desenvolver a pesquisa conforme delineada no protocolo aprovado. Se o pesquisador considerar a descontinuação do estudo, esta deve ser justificada e somente ser

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realizada após análise das razões da descontinuidade pelo CEP que o aprovou. O pesquisador deve aguardar o parecer do CEP quanto à descontinuação, exceto quando perceber risco ou dano não previsto ao participante ou quando constatar a superioridade de uma estratégia diagnóstica ou terapêutica oferecida a um dos grupos da pesquisa, isto é, somente em caso de necessidade de ação imediata com intuito de proteger os participantes.

- O CEP deve ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo. É papel do pesquisador assegurar medidas imediatas adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e enviar notificação ao CEP e à Agência Nacional de Vigilância Sanitária – ANVISA – junto com seu posicionamento.
- Eventuais modificações ou emendas ao protocolo devem ser apresentadas ao CEP de forma clara e sucinta, identificando a parte do protocolo a ser modificada e suas justificativas e aguardando a aprovação do CEP para continuidade da pesquisa. Em caso de projetos do Grupo I ou II apresentados anteriormente à ANVISA, o pesquisador ou patrocinador deve enviá-las também à mesma, junto com o parecer aprovatório do CEP, para serem juntadas ao protocolo inicial.
- Relatórios parciais e final devem ser apresentados ao CEP, inicialmente seis meses após a data deste parecer de aprovação e ao término do estudo.
- -Lembramos que segundo a Resolução 466/2012, item XI.2 letra e, "cabe ao pesquisador apresentar dados solicitados pelo CEP ou pela CONEP a qualquer momento".
- -O pesquisador deve manter os dados da pesquisa em arquivo, físico ou digital, sob sua guarda e responsabilidade, por um período de 5 anos após o término da pesquisa.

#### Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas	PB_INFORMAÇÕES_BASICAS_159999	22/07/2020		Aceito
do Projeto	6 E3.pdf	15:53:44		

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Brochura Pesquisa	ProjetoCOVIDPlatBrasil_22_07_20.docx	22/07/2020	Renato Teixeira	Aceito
2	S DOCESTON OF	15:43:18	Souza	8
Projeto Detalhado / Brochura Investigador	Projeto_COVID_PlatBrasil_19_06_20_e menda1.pdf	19/06/2020 15:49:30	Renato Teixeira Souza	Aceito
Outros	CartaResposta_v2.docx	29/05/2020 15:07:19	Renato Teixeira Souza	Aceito
Outros	Roteiroparaentrevistasemiestruturadaco mfamiliares.pdf	29/05/2020 14:06:39	Renato Teixeira Souza	Aceito
Outros	Roteiroentrevistaequestionarioprofission aisdesaude.pdf	29/05/2020 14:06:14	Renato Teixeira Souza	Aceito
Outros	Roteiroparaentrevistacomgestantesepart urientes.pdf	29/05/2020 14:05:38	Renato Teixeira Souza	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLEprofissionalsdesaudetelefone.pdf	29/05/2020 14:04:39	Renato Teixeira Souza	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLEprofissionalsdesaudepresencial.pdf	29/05/2020 14:04:33	Renato Teixeira Souza	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLEpaisrepresentantelegaltelefone.pdf	29/05/2020 14:04:27	Renato Teixeira Souza	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLEgestantesparturientesefamiliaresm aioresdeidadetelefone.pdf	29/05/2020 14:04:21	Renato Teixeira Souza	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TALEgestanteseparturientemenoresdeid adetelefone.pdf	29/05/2020 14:04:14	Renato Teixeira Souza	Aceito
Parecer Anterior	PB_PARECER_CONSUBSTANCIADO_ CEP_4053444_v2.pdf	29/05/2020 14:01:52	Renato Teixeira Souza	Aceito
Outros	FRostoCovid.pdf	08/05/2020 15:27:57	Renato Teixeira Souza	Aceito
Outros	ParecerConsubstanciadoCaism.pdf	08/05/2020 15:27:28	Renato Teixeira Souza	Aceito
Folha de Rosto	FolhaRostoREBRACO.pdf	08/05/2020 15:25:48	Renato Teixeira Souza	Aceito

### Situação do Parecer:

Aprovado

# Necessita Apreciação da CONEP:

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UF: SP Município: CAMPINAS CEP: 13.083-887





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Não

CAMPINAS, 29 de Julho de 2020

Assinado por: Renata Maria dos Santos Celeghini (Coordenador(a))

Endereço: Rua Tessália Vieira de Camargo, 126 Bairro: Barão Geraldo UF: SP Município: CAMPINAS CEP: 13.083-887

# Anexo 5: Autorização de Copyright para inclusão do artigo 2



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