Tailoring sexual health research practices to meet the needs of adolescent girls in low-and-middle-income countries: findings from Mexico

Argentina E. Servin (arservin@ucsd.edu)  
University of California, San Diego

Ruth Macklin  
Albert Einstein College of Medicine

Sara Wilkerson  
Fordham University

Teresita Rocha-Jimenez  
Universidad Mayor

Gudelia M. Rangel  
Comision de Salud Fronteriza Mexico - Estados Unidos

Celia B. Fisher  
Fordham University

Sabrina Alvarez-Hernandez  
Secretaria de Salud

Sophie O'Bryan  
University of California, San Diego

Research Article

Keywords:

Posted Date: September 28th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-2019635/v1

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Abstract

Background

Sexual and reproductive health (SRH) research is essential for the development of population-tailored evidence-based policies and programs that support sexual health among adolescent girls. However, various ethical challenges create barriers to girls' participation in SRH research in low-and-middle-income countries (LMIC) such as Mexico where sexual health topics are considered a cultural taboo.

Methods

From February to September 2019, adolescent girls ages 16–20 (n = 30) who had participated in the Jovenes Sanos study in Mexico's northern border city of Tijuana, Baja California (ClinicalTrials: NCT03660514) responded to in-depth interviews (IDs) on perceived risks and benefits of participating in studies addressing gender-based violence and HIV.

Results

Emergent themes pointed to the need to ensure consent and incentive procedures are tailored to the developmental level and experience of participants, the importance of the researcher-participant relationship, the potential for research to destigmatize SRH in LMICs and that research can serve as an opportunity to empower girls to express their sexual health medical needs in the future.

Conclusions

Listening to the voices of adolescent girls is a critical step in ensuring consent to SRH research is tailored to the developmental needs of participants and in developing best practices for creating researcher-participant relationships that empower girls' reproductive choices.

Background

Data on adolescent rates of sexually transmitted infections (STIs) and unintended pregnancy indicate that the sexual and reproductive health (SRH) needs of these adolescents are inadequately met. This need remains especially urgent in low-and middle-income countries (LMIC). Approximately 21 million girls aged 15–19 years become pregnant each year in developing countries [1]. Likewise, the highest incidence of gender-based violence (GBV) is generally reported during late adolescence. In a study across 81 countries, 29% of ever-partnered adolescent girls (aged 15–19) reported they had experienced GBV [2]. Specifically, in Mexico, there are 22.8 million adolescents (10–19) (17% of the population) [3], and it has one of the highest adolescent pregnancy rates in the world outside of sub-Saharan Africa, with 58 of every 1000 girls ages 15–19 becoming pregnant each year [4]. Furthermore, half (47%) of adolescent
girls’ report experiencing GBV [5]. These statistics highlight the need for research focused on the SRH of adolescents in order to understand the socio-cultural, behavioral, and environmental determinants of their health needs, and to develop age-specific evidence-based interventions, policies, and programs that support SRH among adolescent girls.

Conducting research focused on SRH with adolescents presents various challenges, especially in LMIC [6, 7, 8]. In Mexico, in addition to the cultural and legal constraints, a variety of ethical challenges hinder SRH research for both adolescent participants and investigators. These challenges are rooted in the complexities and uncertainties surrounding research procedures including consent and assent, risks and benefits assessment, risk management, waiver of parental permission, and confidentiality, among others. Thus, the present study was conducted to collect data from adolescent girls who had participated in a previous SRH intervention study to contribute to enhanced ethical procedures for research centered on the SRH of adolescents and to bridge knowledge gaps in ethical challenges that have not been considered or addressed in past research efforts in Mexico.

**Methods**

This article reports on data from a subset of individuals who participated in a larger project, *Jóvenes Sanos*, a randomized control trial pilot (K23HD084756; PI: Servin) focused on adapting a clinic-based behavioral intervention (Addressing Reproductive Coercion in Clinical Settings) [13, 14], to reduce risk for HIV/STIs, unintended pregnancy and GBV among adolescent girls ages 16–20 years old (n = 100) accessing family planning services at community health centers in Tijuana, Mexico. Specific information regarding the parent study design, eligibility criteria, and outcomes measures are available on clinicaltrials.gov (NCT03660514). For the present study, from February – September 2019, adolescent girls ages 16–20 who participated in the *Jóvenes Sanos* intervention were invited to participate in in-depth interviews (IDIs) (n = 30) when they came to the clinic (either intervention or control site) to complete their 3-month follow-up survey.

**Ethical Considerations**

The study was approved by IRBs at the University of California San Diego and the Universidad Xochicalco, in Tijuana, Mexico. Given that SRH research tends to focus on sensitive topics that adolescents may not want their parents to be privy to, request for guardian permission was waived. Adolescent girls provided written informed consent prior to study participation and compensated $15 USD for their time and travel costs associated with their participation in this sub-study. Spanish speaking female research assistants (RAs) obtained informed consent, and the principal investigator, and/or project coordinator were onsite to answer questions raised by potential participants. A Youth Advisory Board (YAB) established by ISESALUD composed of 50 adolescent girls (ages 15–18) from the school districts neighboring the community health centers striving to vocalize their needs by engaging in advocacy and other activities. For ethical and confidentiality purposes, names of participants have been changed.
Data Collection

Interviews were conducted in Spanish or English in private rooms at the participating health centers. The interviews were audio-taped (identified using only a study-unique identification number) and lasted 60–90 minutes. The interview protocol was informed by the World Health Organization (WHO) guidance on ethical considerations in planning and reviewing research studies on SRH among adolescents [15] as well as our previous qualitative research with vulnerable underserved populations in this setting [16]. Further, the interview followed an open-ended guide that was iteratively revised as data collection and analysis progressed. Questions elicited adolescent girls’ narratives regarding ethical issues that may have impacted their decision to participate and their experience participating in the intervention study.

Data Analysis

IDIs were transcribed verbatim and analyzed in Spanish by a trained bilingual research team. Qualitative analysis was led by the PI in conjunction with two members of the bi-national research team (i.e., one from the US-based team and one from the Mexico-based team). The research team systematically read through transcripts, engaged in open line-by-line coding and constructed a coding scheme based on the content of the transcripts which was iteratively revised until the research team reached consensus. Transcripts were coded in ATLAS.ti version 6.2 to group, label, and describe intersections between emergent themes related to the ethical consideration for SRH research among adolescent research, especially research focused on the intersection of GBV and HIV/STIs in this setting [17, 18]. This analysis adopted deductive and inductive perspectives in which participants’ language and experiences were used to identify and understand their experiences as human subjects in research centered on GBV and HIV/STI prevention [19]. Thematic saturation was reached with the 15th interview; additional interviews were conducted to ensure no new themes emerged and to illuminate the nuances of perspectives through additional quotes. Applying the final coding scheme, inter-coder reliability was assessed and greater than 80% inter-coder consistency was achieved.

Results

Participant Characteristics

Table 1 summarizes sociodemographic characteristics of the 30 participants. The mean age was 17.6 and only 20% (n = 6) were currently enrolled in school. All participants (n = 30) were of Mexican nationality and 23% (n = 7) were from states located in the center and south of the country (i.e., Chiapas, Oaxaca, Guanajuato). Approximately two-thirds of the sample (n = 21) had at least one child under the age of five, and the average age of first pregnancy for these individuals was 16.5 years old. Nearly all (93.3%) participants reported experiencing GBV in their lifetime, and a third (33.3%) reported experiencing GBV recently. Furthermore, 36.6% (n = 11) of the sample reported ever testing positive for an STI and 10% (n = 3) of the participants reported a history of substance use and one of them had been in rehabilitation. Only two participants had previously participated in a research study prior to the Jovenes Sanos study.
Table 1
Characteristics of Adolescent Girls (N = 30) that participated in the Jovenes Sanos study in Tijuana, Mexico.

<table>
<thead>
<tr>
<th>Variable</th>
<th>N = 30 (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Median, IQR)</td>
<td>17.5 (16–20)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Elementary (6 years)</td>
<td>4 (13.3%)</td>
</tr>
<tr>
<td>Middle school (8 years)</td>
<td>18 (60%)</td>
</tr>
<tr>
<td>High School (12 years)</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Currently enrolled in school (high school)</td>
<td>5 (16.7%)</td>
</tr>
<tr>
<td>Birthplace (birth state in Mexico)</td>
<td></td>
</tr>
<tr>
<td>Baja California</td>
<td>21 (70.0)</td>
</tr>
<tr>
<td>Other Mexican state</td>
<td>9 (30.0)</td>
</tr>
<tr>
<td>Ever participated in a research project*</td>
<td>2 (6.6%)</td>
</tr>
<tr>
<td>Ever been pregnant</td>
<td>21 (70%)</td>
</tr>
<tr>
<td>Age of first pregnancy (Median, IQR)</td>
<td>16.5 (13–18)</td>
</tr>
<tr>
<td>Currently using modern contraceptiona</td>
<td>6 (20.0%)</td>
</tr>
<tr>
<td>Ever tested positive for an STI</td>
<td>11 (36.6%)</td>
</tr>
<tr>
<td>Substance use</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Experienced GBV</td>
<td></td>
</tr>
<tr>
<td>Lifetime</td>
<td>28 (93.3)</td>
</tr>
<tr>
<td>Recent</td>
<td>10 (33.3%)</td>
</tr>
</tbody>
</table>

*Prior to the Jovenes Sanos study and/or the current study

a Other than condoms includes intrauterine device (IUD), Depo-Provera, implant, and/or contraceptive pills.

Informed Consent Vulnerabilities

Informed consent requires that an individual’s decision to participate be informed, voluntary, and rational [20]. When asked about their experiences in the Jovenes Sanos study, participants spoke of the importance of waiving guardian permission, the need for clear language, and the importance of individual
volition to guard against the potential for coercion tied to incentives or recruitment in medical settings. Each of these specific issues will be discussed in more detail below.

“Just ask us”: guardian permission as a barrier to informed consent.

The decision to waive guardian permission in adolescent sexual and reproductive health research is one that poses unique ethical challenges for adolescents worldwide [21] and is especially salient for LMIC which may lack of established ethics review procedures for determining when waiver is appropriate [22]. However, reluctance of adolescents to participate in research when guardian permission is required is often based on fear of family stigma and punishment [23, 24]. Given the cultural stigma surrounding adolescent sex in Mexico, examining the extent to which guardian permission is a barrier to SRH among LMIC girls is thus critical to research that can inform developmentally tailored SRH prevention and interventions for this vulnerable population.

When asked about the consent process, participants indicated that they appreciated they were able to consent for themselves. Some suggested that they would have felt uncomfortable or even would have opted not to participate at all were parental consent required.

“If my mom would have needed to provide consent for me, I would have felt very uncomfortable, she would have wanted to know every detail, what the study was about and I would have rather not participated…” – Claudia, 16 years old (control site).

“I think it's best that if they just asked us [girls] if we want to participate... because what if I'm really interested and I want to participate in the study, but my parent or family member say 'no' and don't consent, then I would be left out…” – Erika, 18 years old (intervention site).

“What's this about?”: Participant misunderstanding as an obstacle for rational consent.

Although extensive efforts were made for the study participants to make an informed decision to participate in the study, some participants discussed their confusion at the outset of the consent process and didn’t understand what it meant to be a part of a research project.

“When they first approached me... I thought to myself ‘they are going to investigate me?’... I was curious about what they wanted to know exactly about me. After she explained what she meant by a research study [estudio de investigación], the process and what the study was about, I told them I was interested in participating.” – Angelica, 20 years old (control site).

‘I felt weird at the beginning [of the study], I was a bit concerned because I didn’t know what it meant to be part of a research study or what to expect... after I finished the survey, I felt more comfortable... I was nervous at the beginning because I didn’t know what they were going to do to me [laughs]... I think I’m traumatized from watching all these movies about social experiments and stuff like that [laughs]...” – Valeria, 18 years old (control site).

Thus, to adequately design developmentally appropriate consent procedures for vulnerable youth, requires both assessing youth who do not understand as well as assessing their consent and
comprehension abilities [24].

One such misunderstanding can occur when recruitment is conducted in healthcare settings as some participants reported confusion and thought the research process was part of their standard of care. Importantly, none of the participants reported feeling coerced into participating because they receive health care at that facility.

“She said this [study] was being conducted by the University of San Diego, that they were doing a survey and that they were recruited other girls as well... I found it hard to believe they wouldn’t share my responses with the doctors here, but I thought it sounded interesting, so I decided to participate to learn more about what the study was about...”– Irma, 20 years old (control site).

“The doctor [study] was very clear and told me that they wouldn’t share my responses and that my participation had nothing to do with the care I received, so I told her it was fine and I agreed to participate.” – Luisa, 16 years old (intervention site)

*The incentives shouldn’t be mentioned*

The role of monetary incentives in motivating survey participation has been widely documented and remains an ongoing ethical debate [25]. Although girls had mixed opinions, none of our participants believed the incentives for this research would induce girls to agree to a study they did not wish to participate in. Some girls reported that they did not think incentives should have been provided as they felt that the money would serve to be the primary reason other girls might choose to participate.

“I think that it would be best if they only told them what the study was about .... they shouldn’t say that they are going to offer them money, to see if they are genuinely interested... the incentive shouldn’t be mentioned because a lot of people might just do it [participate] for that reason.” – Natalia, 17 years old (control site).

Other participants felt that they benefited from the study because it was focused on their sexual and reproductive health and because they were also compensated for their time.

“I think it was good for me [to participate] because I learned a lot about my health and also it was good to talk about it [gender-based violence] and share my opinions about it and I also received an incentive for being a part of this...” - Lourdes, 19 years old (intervention site).

**A Relational Approach to Research Empowers Participants**

If vulnerabilities inherent in the research can be appropriately managed, there is significant value to be gained not only by researchers, but by participants as well. Participants highlighted how researchers’ relational approach to consent and interviews helped to create a unique environment where knowledge, affirmation and empowerment could be engendered within the girls and young women who participated in the research. Each of these themes will be discussed in detail below.

“She gave me confidence and seemed trustworthy”: Importance of Relationship with Interviewer
The extent to which adolescents were able to access and benefit from participating in the research project appeared to depend on the nature of their interactions with research team members. Consistent with previous work in other LMIC involving medically underserved women and girls, participants greatly valued their relationships with research staff whom they perceived as trustworthy and caring [26], and impacted their decision to divulge sensitive information or agreeing to participate in research.

“She [study staff] invited me to participate in the study and made me feel comfortable… she gave me confidence and seemed trustworthy… she was very kind and explained to me all the procedures and she told me that if I wanted to stop the interview at any time it was okay, to just let her know…” Erika, 16 years old, (intervention site)

“Topics that are hard to talk about”: De-Stigmatizing Discussion of SRH

Majority of the participants (90%) reported they thought it useful to include sexual and reproductive health (SRH) themes in research and they gained important SRH knowledge by participating in the study.

“I actually learned a lot including how to be more confident and trust myself… it’s important to talk more about these topics that are hard to talk about, for example, HIV. We know it exists because we get tested here, but they don’t talk about how to prevent it and how to take care if you get it…so I think doctors should talk about that during periodic visits that we have here…” – Alicia, 19 years old (control site).

“I think that it’s very useful to continue doing this type of research because there are a lot of adolescents that are not well informed, and they don’t know 100% what STIs are or how to prevent them even though they are sexually active. I think that thanks to this research and the topics they covered, they are educating us, and we are learning a little bit more than we knew before.” – Sofia, 18 years old (intervention site).

Destigmatizing Gender-Based Violence (GBV)

One common ethical issue often raised in trauma-related research is whether the inclusion of sensitive questions heightens psychological distress. Previous research suggests that while reactions to questions of abuse are variable, almost all individuals see benefit of the research for themselves and others, and report that they would be willing to participate in similar research again [27]. Responses from participants in the current study highlight this same idea.

“…She [interviewer] talked about violence against women, and I think that’s good…questions about if I would let someone hurt me… or what would I do if someone hurt me… and it makes me think of some experiences that I had in the past and I feel more aware now… those experience happen to a lot of adolescents here in our community”… – Sandra, 16 years old (control site).

“I liked talking about domestic violence [gender-based violence] because many women do not know that they are experiencing sexual violence from their partners, so then, I imagine that they do it [have sex] to please their husbands but they don’t realize the harm that it can do, right? I think if they don’t feel comfortable, they shouldn’t do it”… – Guadalupe, 18 years old (intervention site).
**Sense of Empowerment**

Majority of the participants reported they felt that their involvement in the study was beneficial or useful for them. Participants discussed how their individual relationship with research personnel allowed for a sense of empowerment, including the initiative to speak to their healthcare provider about family planning.

“Before [participating in] this study, my mom would be with me all the time during my visits, and she would respond to the doctors for me. I did not feel safe or comfortable when responding to them by myself... my mom had to come with me everywhere but when I was invited to participate, I felt safe with the interviewer and after this, I've felt more confident and going to my visits alone now. It’s something that I am proud of.” – Maria, 16 years old (intervention site).

“She taught me about the methods to take care of yourself [birth control], I only knew about the injections and the device, the IUD (intrauterine device), and she told me about other options that I didn’t know about...and I liked learning about it and making a more informed decision... in the end I decided to get the device [IDU] – Priscilla, 16 years old (intervention site).

**Discussion**

In this study, we analyzed the perceived risks and benefits of participation in sexual and reproductive health research among adolescent girls in Mexico. Responses centered around two primary themes: the importance of ensuring consent is tailored to the needs of adolescent participants and the importance of the researcher-participant relationship in facilitating participant empowerment.

Our results suggest that adolescent girls derive satisfaction from their ability to independently understand and make decisions regarding their decision to participate in SRH research without the involvement of their guardians, aligning with previous research suggest parental consent as a barrier in SRH research [28]. Limiting research enrollment to adolescents who can obtain guardian consent may lead to non-representative findings and a continued lack of developmentally appropriate interventions [29]. Providing adolescents the opportunity to independently consent to SHR research is especially important in LMIC, as young women and girls have a right to obtain SRH without guardian permission both for the quality of the research, and as our study shows, from the perspective of the participant.

At the same time, power imbalances and an increased risk for vulnerability [30] between investigator and adolescent participant, require special attention when guardian consent is waived. Therefore, careful attention must be given to ensure the consent process respects the autonomy, rights, and welfare of adolescents [20]. This can be accomplished through developmentally tailored informed consent information, adequate time for questions, and peer consent advocates.

Results from this study also highlight the consent vulnerabilities that emerge when research is conducted in health care settings. In these contexts, an invitation to participate in a research study may lead to
confusion about the investigator’s role and fear that failure to consent will result in denial or discontinuation of services, highlighting the critical need for researchers to ensure full comprehension and the absence of coercion, including a thoughtful approach pertaining to participant compensation. One such approach is to draw on community advisory boards, that include prospective participants, to identify culturally and developmentally appropriate incentives for the nature of the research for which youth will be recruited.

Furthermore, our interviews underscore how perceptions of comfort and safety within the researcher-participant relationship was critical to the success of the parent SRH and our follow-up study. A trusting relationship allowed participants to explore their views on HIV and STIs, topics viewed as taboo for many in their culture, and of which they had previously been uncomfortable discussing in health settings. Adolescent girls who participated in this study reported a sense of empowerment as a result of the information they learned and their relationship with research staff. Further, several participants indicated that discussing gender-based violence in a destigmatizing environment was valuable as many of them had experienced GBV but had not previously disclosed this to others. Contrary to concerns often expressed by ethics review committees, discussions with staff regarding STIs and GBV did not elicit or “trigger” traumatic responses in this sample.

**Limitations**

The findings of this study must be considered alongside their limitations. First, the results of this study were drawn from a small sample of participants aged 16–20 who opted to complete the *Jovenes Sanos* trial 3 months after completion of the initial phase. Thus, findings may not be generalizable to younger adolescents, be representative of those who did not participate in the parent study and may create a risk of recall bias.

**Conclusions**

There are significant unmet sexual and reproductive health (SRH) needs in adolescents in LMIC. Limitations notwithstanding, our results provide important information for conducting ethical research in this domain. Our findings suggest that researchers interested in involving adolescent females in research related to SRH should respect both the importance of the autonomy and dignity of participants as developing persons and the significance of a trusting relationship with study personnel. Attention to such concerns throughout consent and throughout the study itself creates the conditions for future participants’ sense of empowerment in raising SRH issues with healthcare providers and for a higher quality of data only possible through the establishment of relationships of trust.

**Abbreviations**

SRH-Sexual and reproductive health, LMIC-Low-and-middle income countries, STIs-Sexually transmitted infections, IDs-In-depth interviews, GBV-Gender-based violence, RC-Reproductive coercion, WHO-World
Declarations

Ethics approval and consent to participate. The study was approved by the Human Research Protections Program at the University of California San Diego (protocol #181877S) and the Institutional Review Board (IRB) of the School of Medicine, at the Universidad Xochicalco, in Tijuana, Baja California, Mexico. All study procedures were performed in accordance with the relevant guidelines and regulations for conducting research in clinical settings with adolescents and women who have experienced violence. As previously reported, the protocols were informed by the World Health Organization (WHO) guidance on ethical considerations in planning and reviewing research studies on SRH among adolescents as well as our previous qualitative research with vulnerable underserved populations in this region. All adolescent girls provided written informed consent prior to study participation and compensated $15 USD for their time and travel costs associated with their participation in this sub-study.

Consent for Publication. Not applicable.

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

Competing interests. The author(s) have no potential competing interest with respect to the research, authorship, and/or publication of this article.

Funding. This work was supported by the Eunice Kennedy Shriver National Institute on Child Health and Human Development (NICHD) (K23HD084756, PI: Servin) and the Fordham University HIV and Drug Abuse Prevention Research Ethics Training Institute (RETI) and the National Institutes on Drug Abuse (NIDA) (R25 DA 031608; PI: Fisher).

Authors' contributions. AES conducted in-depth interviews, supervised transcription efforts, lead coding and data analysis, contributed to interpreting results and writing the manuscript. RM helped develop interview guides, contributed to interpreting the results and writing the manuscript. SW helped interpreting the results and contributed to writing the manuscript. TRJ and SAH conducted in-depth interviews, participated in coding and data analysis under the guidance of AES and CBF, and contributed to writing the manuscript. SO contributed to interpreting the results and writing the manuscript. GMR supported data collection efforts and contributed to writing the manuscript. CBF helped develop interview guides, contributed to interpreting the results and contributed to writing the manuscript. All authors have read and approved the manuscript.

Acknowledgements. The authors would like to extend a special gratitude to the adolescent girls who participated in this study. The authors also gratefully acknowledge the entire multidisciplinary research team involved in this project, the adolescent girls from the Youth Advisory Board (YAB), the Mexican...
Ministry of Health (ISESALUD), and Dr. Alejandra Padilla Mercado for their assistance with data collection and dissemination of study findings.

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