



Ethical considerations for conducting sexual and reproductive health research with female adolescents engaged in high-risk behaviours in China

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ABSTRACT

Background: Chinese female adolescents engaged in sex trade and substance use are often criminalized and stigmatized. As a result of these cultural, legal and political constraints, ethical concerns can discourage investigators from engaging these adolescents in research. This paper aims to address the ethical tensions between protection and inclusion in conducting sexual and reproductive health (SRH) research with adolescents engaged in high-risk behaviours. Processes of moral reasoning, and examples and practical mechanisms in managing such ethical challenges were presented in the hope of advancing the research ethics policies and practice with adolescents.

Methods: We extracted ethical issues from three previously conducted SRH studies involving 517 Chinese female adolescents. Utilizing the principles of justice, beneficence, and respect for persons as articulated in the *Belmont Report* as a framework, we thematically summarised the key ethical considerations regarding inclusion and protection, then examine the ethical tensions and solutions within the local context.

Results: Findings suggest that the balance between protection and inclusion can be achieved by both considering the evolving decision-making capacity of adolescents as well as the level of risk. A community-based participatory approach shows promise in advancing adolescent engagement and empowerment. Ethically robust approaches contribute to the greater relevance and validity of the findings.

Conclusions: Our studies suggest that it is crucial to achieve adolescents' meaningful involvement in all levels of research and interventions, researchers need to shift their perspectives of the target population from subjects to key stakeholders in design and implementation of research.

Introduction

There are about 1.2 billion adolescents aged 10–19 in the world, and 15% of all female adolescents aged 15–19 live in China [1]. The road accidents, self-harm, gender based violence and other prominent health related issues as well as poor sexual and reproductive health (SRH) have brought global attention to the critical need for SRH and rights for adolescents, particularly socially, legally and economically vulnerable adolescents [2]. In many situations, research is needed to

develop a better understanding of the socio-cultural, behavioural and environmental determinants of their health needs, and to develop age-specific interventions and solutions. Across developing countries, there are coverage and underreporting gaps in data and research related to the adolescents' SRH behaviours, needs, service utilization and health outcomes, particularly in vulnerable situations, that is more specifically in China [3]. SRH research with adolescents engaged in high-risk behaviour often addresses sensitive or illegal issues, such as sexual experience, HIV/STIs status, history of other reproductive tract infections,

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pregnancy and violence, substance use and sex trade. Apart from the cultural, legal and political constraints in China, a variety of ethical concerns inhibit SRH research for both adolescent participants and investigators because of the complexities and uncertainties, for example: consent and assent, risks and benefits assessment, risk management, waiver of parental permission, confidentiality and additional protections against coercion or exploitation and researcher self-protection in research [4,5].

One significant challenge to carry out health research involving adolescents is that current Chinese laws focus on age rather than maturity and moral reasoning of adolescent; public health and medical research guidelines further complicate this issue and often conflict with other laws and regulations. The *Law of the People's Republic of China on the Protection of Minors* (2012) defines a minor as a person under 18 years of age [6], and the legal age of consent for sexual activity is 14 years, regardless of gender or sexual orientation [7]. The primary ethical guidance for protecting human subjects is the *National Administrative Act on Ethical Review for Biomedical Research Involving Human Subjects* (2016) first articulated by the National Health and Family Planning Commission (NHFPC) [8]. It represents a consensus on landmark issues and shows ways to consider ethical issues with minor human subjects. Despite its breakthrough in increasing children's inclusion in biomedical and epidemiology, psychology, social science and behavioural research, the ethical thinking about inclusion of adolescents in research is largely built on ethical thinking regarding children. There is the lack of clear guidelines and legal interpretations to support mature minors' rights and the evolving competency of their decision-making and consent, or to authorize certain groups of mature minors to give their own consent for specific types of health care research that requires approval from an Institutional Review Board (IRB).

The implication of the legal and ethical context is that researchers may avoid conducting research with adolescent population because of anticipated or actual experiences with difficulties in obtaining IRB approval [9]. Consequently, adolescents as a class have often been excluded from participating in SRH research, and the potential benefits of other critical research in China [10]; let alone adolescents involved in high-risk behaviours, despite being the most in need [3,11,12]. The insufficient participation in such research can be a matter of justice to address disparities in health, education and protection; further the absence of data may lead to overestimating the true risks to subjects and unnecessary procedures from IRBs and policy makers. These challenges require not only ethical deliberation by bioethicists, investigators, and IRBs, but also empirical data that can provide an evidentiary basis for research ethics regulations and practices.

The 1978 Belmont Report outlines four basic ethical principles for research: non-maleficence (do no harm), respect for persons, beneficence (maximize benefits), and justice [13]. Consistent with the Convention on the Rights of the Child (CRC), the recognition of the rapidly evolving capacities of adolescents is the key concept guiding ethical considerations of their involvement in research [14]. Over the past two decades, international guidelines have undergone important developments to govern clinical, non-therapeutic biomedical and psychological studies involving children and adolescents [14–21]. These guidelines not only provide frameworks to interpret relevant regulations/rules for the protection of human subjects in light of the various legal, developmental and cultural issues that directly affect the adolescents in research, but also provide practical methodologies for evaluating the circumstances under which adolescents can or should be involved as subjects in research. Whilst SRH behaviour research with adolescents is directly related to public health practice, the ethical principles should be extended to accommodate the broader scope of public health activities that display political and social dimensions, such as community engagement, collective decision-making and governmental administration [4,18,19]. Building on the principles from the Belmont report and current scientific understanding about adolescents' evolving capacities, 2017 UNICEF Innocenti Briefs [5,14] provides an ethically

balanced interpretation of *Inclusion with Protection* of adolescents in health research, including disadvantaged and marginalized adolescents.

This paper aims to review and discuss the ethical tensions between protection and inclusion in conducting SRH research with adolescents engaged in high risk behaviours in China. Utilizing the ethical principles of justice, beneficence and respect for persons as a conceptual framework, we draw empirical evidence from three published SRH studies. Considerations, examples and potential solutions are presented in the hope of advancing the research ethics policies and practice on adolescent SRH and well-being.

Methods

Study setting

Yunnan Province on China's southwestern border is close to the Golden Triangle, which is one of the world's drug trafficking regions. This province has a long and evolving history of drug use and is notorious for being the centre of drug trade. The health consequences documented include a relatively high HIV prevalence and other STIs in China [22]. In 2010, Yunnan Province alone accounted for 22% of new HIV cases in the country despite only making up 3% of the national population, with the HIV prevalence rates concentrated amongst drug users (28%) and female sex workers (FSWs; 2%). Kunming City, which is the largest economic centre and the capital city of Yunnan Province, has an estimated population of 7.2 million, and has been the area of our investigations.

Ethics

Ethics approvals and permissions for the three study protocols, and informed consent forms, information sheets and other requested documents, or any subsequent modification were obtained from the ethical committee of the Kunming Public Health Bureau.

Study design

Between 2010 and 2012, we conducted three interrelated studies among 517 female adolescents aged 15–19 years engaged in sex work and/or illicit drug use, to improve our understanding of their SRH situation and social-cultural context (Table 1). Here, we draw on the study protocols, ethics application documents, records of focus group discussions, and implementation documents of these three studies. Principle-based [23] and case-based approaches [4,18] to moral reasoning were applied to analyse ethical decision-making and research practices. The ethical analysis is a dynamic process, which is implemented in three steps. Firstly, a preliminary review of international ethical concepts and guidelines involving adolescents was conducted before the analysis. The *Inclusion with Protection* when conducting research with adolescents elucidated in the 2017 UNICEF Innocenti Brief served as a tool to conceptualize our analysis of the ethical tensions in the local context of this study. *Inclusion* in research is the right to participate in research that may benefit participants individually and collectively. While *Protections* are safeguards built into research projects to prevent harm to individuals or groups [14]. In the second step, we present the considerations along with ethical principles when conducting research with our participants: justice, beneficence and respect for persons. The third step turns to using the case examples to illustrate practical solutions deliberately created during the implementation of the previous three studies.

Data extraction and management

The project principal investigator and selected co-authors reviewed all research materials of the three studies. The documents included study protocols, questionnaires, in-depth interview guides, ethics

Table 1
The contents and related publications of three previous studies with female adolescent sex workers and drug users reviewed in this study.

Study Title	Study aim	Sampling method	Number of participants	Collaborative partners	Publications
Study 1. Cross-sectional HIV/STIs epidemiologic and behavioural research among female adolescent sex workers (2010)	To describe socio-demographic characteristics, HIV/STIs prevalence, contraceptive practices and healthcare-seeking behaviours of target population	Both “snowball” and convenience sampling methods were employed	201	Local academic institutes, the public health department, Community-based Organisations and Kunming Centres for Disease Control	1. See Ref. [33] 2. See Ref. [34].
Study 2. Qualitative longitudinal study of sexual and reproductive health risks among female adolescents who use amphetamine-type stimulants and sell sex (2011)	To obtain a better understanding of the culture of amphetamine-type stimulants use and related sexual and reproductive health risks in order to inform comprehensive harm reduction and sexual and reproductive health programming	Purposive and targeted venue-based methods	6	Kunming Rehabilitation Center	1. See Ref. [29].
Study 3. Cross-sectional study on sexual and reproductive health knowledge, attitudes and practices in female adolescent sex workers (2012)	To describe the use of contraception and unmet need for contraception; to measure the prevalence and correlates of sexual and gender-based violence	One-stage cluster sampling method	310	The public health department, Community-based Organisations and Four district-level of Centre for Disease Control	1. See Ref. [35] 2. See Ref. [36]

application forms, clinical care information sheets, pre-tests records of questionnaires, interview guides, meeting records of research team and stakeholders, procedure checklist of informed consent, risk assessment protocols, and implementation and monitoring reports. Empirical data of ethical issues and practical mechanisms about how to meet ethical challenges were drawn and verified from above documents; we perused and coded these excerpts, and then further analyzed the coded sections/cases and derived associated themes inductively as displayed in Table 2. Once the coding process was completed, we created summary tables along *Inclusion* and *Protection*. From these matrices, we extracted interpretations of the data for each posed principle: justice, beneficence, respect for persons. The results below describe what we learned from above inductive process.

Results

Ethical considerations and approaches to balance inclusion and protection

Focusing on each of the three ethical principles (justice, beneficence, respect for persons), we discussed ethical considerations and practical mechanisms to address the particular challenges of conducting research with adolescents engaged in high risk behaviours.

Justice: ethical consideration

This principle demands a fair sharing of both risks (burdens) and benefits of research, and is commonly considered at both the individual and the population level [14]. Meanwhile, commitments to health, science, and the community are the core values of public health [24]. Public health values community in two significant ways. Firstly, it recognizes that the success of most health interventions depends on a community’s acceptance, cooperation, or participation. Secondly, it recognizes that to be successful, public health must respect the community’s values and gain the trust of its members [4]. If certain populations of adolescents, such as those engaged in risk behaviours, are excluded from participation in SRH research, they may not share the direct or indirect benefits from targeted public health action. In contrast to some biomedical research, our SRH behavioural studies generally present limited risks to individual adolescents, such as risks of potential embarrassment, disclosure of sensitive information, or other harms to their safety when being identified. These fears or risks could be managed through well-designed study procedures. Adolescents as a group receiving the benefits of behavioural research, and subsequently access to voluntary HIV/STIs and health education have the right to know about their health status and ways to reduce their risk behaviours. Hence, promoting full participation of targeted adolescents is the rationale to achieving social justice in our studies.

Justice: practical mechanisms invoked

In view of the vulnerability of adolescent FSWs or substance users and their unique needs, as well as their complex living environment, we adopted the principle of “nothing about us without us” in the development and implementation of our studies. Two measures undertaken are illustrated below.

Implementing a community-based participatory approach through effective engagement of the target population. In general, scientific experts, policy makers and researchers are responsible for developing “the entire picture” for a research project. This ‘scientific’ mode of generating knowledge and innovations has dominated the SRH sector for decades. Nevertheless, we argue that in the “top-down” design, the health concerns and self-defined information needs of the target population may be ignored in favour of professional preoccupations and concerns [25]. There is a certain level of trust and commitment within the local adolescent FSWs and drug users’ social networks and, through these social units they share knowledge, resources, and information. Experiential knowledge is one of the most powerful forces but

Table 2
The major categories and associated themes of identified ethical issues.

Major categories	Associated themes
Inclusion	<ol style="list-style-type: none"> 1. Measures to ensure the study design suited to the age and sub-culture of target group 2. Measures to maximize potential benefits 3. Collaboration with existing programmes, local healthcare system and CBOs 4. Recruitment approaches to overcome the challenges of crackdown and mobility 5. Efforts and measures in improving participation and engagement of target population 6. Approach to obtain the appropriate proxy consent for minors
Protection	<ol style="list-style-type: none"> 1. Relevant laws and regulations 2. Special training for interviewers 3. Measures to minimize risks and to ensure the privacy, confidentiality and safety of participants 4. Considerations and tools for individual assessment of capacity to make a rational decision 5. Measures to assess the risks/harms, sensitive issues and the level of discomfort 6. Results and feedback from the pre-testing of questionnaire and assessment tools 7. Appropriate resources to provide services, care and support for participants 8. Protocol or procedure for safe referral to local CBOs or healthcare providers

difficult to capture in written documents and websites. Consider a typical day for an adolescent FSW or drug user—the majority of what she does is guided by a lifetime of experiential learning. In the study, we adopted a community-based participatory approach to engage adolescent FSWs because we believe that the approach can increase their power to improve community conditions via iterative cycles of research and action [5]. Learning from the three studies, the community-based participatory approach encouraged researchers to identify, capture, and share the participants' perspectives, needs and experience as well as create practical measures to advance the research. Furthermore, the exchange of the two knowledge domains of researchers and participants creates innovation and solutions to ethical challenges faced by researchers when conducting field work. Multiple inter-group communications, as we explain in the following section, enabled researchers to use the generated knowledge to guide their actions, as well as refine research questions and methods.

Community motivation and empowerment. The collaboration with various local Kunming FSW support organizations and their close involvement in all aspects of the study played a crucial role in achieving the goals of the studies in many ways. Firstly, these community-based organizations (CBOs) had over eight years of experience working with FSWs and carried out weekly outreach services in entertainment settings and street venues frequented by the more hard-to-reach adolescent FSWs. Successful awareness of the study was created and a mapping exercise was done through the CBOs' regular service work. The hotspot mapping yielded 101 locations within four urban areas of Kunming where young FSWs usually provided sexual services. Secondly, these CBOs also assisted in building links with the gatekeepers (managers or owners) of the entertainment venues to facilitate the recruitment procedures. Informal permission was obtained from the gatekeepers for arranging the appropriate space and time of interview, and for introducing potentially eligible participants. Thirdly, peer educators (FSWs from the CBOs) were trained as interviewers on the study procedures, questionnaire administration and research ethics. Last but not least, adequate communication between the study team, the CBOs, the representatives of target population and the gatekeepers increased researchers' understanding of target populations' lifestyles and concerns of risks and harms, which had important implications for refining research questions and methods. The three earlier studies showed that when the researchers provided opportunities and activities for marginalized adolescents to participate in decision making, realize the potential benefits and feel their voices were heard and respected, adolescents developed feelings of self-efficacy and trust, thus they made a positive difference: their meaningful involvement rather than just their participation.

Due to the CBOs' and target populations' greater involvement, in

comparison to the first study with a similar population in Kunming, the number of participants increased in the third study (201 versus 310) and the refusal rate decreased (22% versus 10%). Moreover, the content and information contained in revised questionnaires were more comprehensive, more culturally and ethically appropriate as compared to earlier versions. Lastly, the interpretation of data and findings benefited from CBOs' and participants' advocates and insights.

Beneficence: Ethical consideration

This principle is the ethical obligation to maximize potential benefits to individuals and their communities, and to minimize the risks inherent to research, such as stigmatization or invasions of privacy, by accurately taking participants' views, rights and needs into account [14,18].

In light of public health principles, adolescents may directly (i.e. individually) or indirectly (i.e. as a group if research results are used for advocacy and to inform intervention programmes) benefit from SRH research. A possible beneficial effect of adolescents' involvement in a carefully controlled research environment is to reverse internalized stigma, promote skills in CBOs and a sense of empowerment, leading to an improvement in social capital from expanding the adolescents' experience base [5,14,16].

Beneficence: Practical mechanisms invoked

Evaluating potential risks and benefits. The determination of the risk level in the research is important for IRBs to review, including assessment of how the measures effectively account for, and address, these risks. To balance the protection and inclusion, and also to help inform the IRB review process and advance knowledge about the risks and benefits, our research involved prior focus group discussions during the early study design phase, for which the local FSW and drug users' drop-in centres or CBOs' meeting rooms were used as the "safe and comfortable space". In each group discussion, around 10–12 representatives from peer-support organizations, clinical staff, local IRBs and adolescents from the target group were invited to give insights into the following topics:

- i. What are the possible risks or harms to the target population?
- ii. What are the anticipated benefits underpinning the inclusion of the target population?
- iii. To what extent does the proposed SRH study reflect their interest?
- iv. Feasibility and acceptability of parental or legal guardians' permission to consent for adolescents'/minors' participation in research, and the alternative approach recommended.
- v. Challenges in and solutions for recruitment: settings, timing, partnership resources, training needs, the creative use of incentives.
- vi. Strategies for referral: needs assessment, sources and procedures.

The risks and potential harms regarding our studies were identified

during these formative focus group discussions as following:

- i. Labelling or stigmatizing;
- ii. Pain or discomfort or unanticipated consequences of HIV/STIs screening;
- iii. Encountering identification or arrest due to the exposure of illegal behaviours, such as drug use, drug dealing, stealing, and sex trade.

Based on the results of the discussions, and to appreciate participants' own estimations of risks, harms, needs and inconveniences, the research team refined the questionnaires, study methods and implementation procedures. A modified study protocol was then submitted to local IRBs, with specific protection measures for recruitment, interview, HIV/STI screening, referral, and post-interview care in order to meet the requirements of adolescent minors under the current national laws and regulations.

Building robust referral mechanism. The international best practices indicated that beneficence also requires researchers to ensure the provision of care to adolescent participants, preferably through referrals to collaborating partners for healthcare after the study or research ends. We implemented special referral mechanisms to address the potential harms and risks associated with clinical HIV/STIs screening in the first study.

Firstly, participants who had completed the questionnaire and interview were given an SRH information package that contained seven pamphlets. This series of pamphlets included specific guidance for FSWs to prevent HIV/STIs, the explanation of potential harms and benefits about the screening, the procedures, the meaning of a positive or negative test result, the existing healthcare policy and supporting resources, and referral procedures for free antiretroviral treatment. Participants were given one week to make a decision before the screening visit, so as to ensure voluntary participation.

Secondly, the referral chain was strengthened to address adolescent FSWs' fear of seeking SRH services due to their unfamiliarity with the health facility. According to prior focus group discussions/pre-test results, since most of the interviewees were participants' peers, adolescent minors preferred to seek help from their interviewers and asked them to accompany them in clinical procedures. The experience from the third study suggested that this approach could reduce participants' fear and embarrassment while providing them convenience to undertake the screening in collaborative health facilities. Hence, it improved retention in the clinical screening process.

Thirdly, the financial burden of HIV/STIs screening was taken into account. The majority of adolescent participants were internal migrants. Given their criminalised and highly mobile lifestyle, adolescent FSWs were reluctant or had more difficulties in obtaining medical insurance, thereby potentially having limited access to safe and quality health care. In the first research, by linking with existing local health resources, such as Family Health International' FSW Health Project, Global Fund AIDS Project and government-funded AIDS prevention and treatment scheme, the research team helped adolescent FSWs to overcome some financial burdens and built a link between marginalised young people and mainstream HIV/AIDS services. In our 2010 study, free HIV and other STI tests (syphilis, *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, Condyloma acuminatum, genital herpes simplex virus 2) were provided to participants. For two newly reported HIV-positive participants, subsequently, the post-test counselling for free antiretroviral therapy, subsidised STI treatment in public hospitals and CBOs' supporting resources were provided.

In this epidemiological and behavioral study, the referral mechanism provided participants with more resources to access HIV/STIs healthcare services and made them find the process less burdensome. The referral mechanism was effective in reducing the drop-out rate of participants: a total of 231 adolescent FSWs giving consent to participate in the first research were recruited from 39 different networks,

among whom 87% (201/231) completed the interview and got themselves tested for HIV and STIs. From a public health perspective, the greater participation and voluntary screening also led to other benefits, such as identifying health disparities, preventing or controlling HIV/STIs from this population.

Respect for persons: Ethical consideration

Respect for persons also called respect for autonomy, encompasses both the right of autonomous individuals to make free decisions about research participation consistent with their own values and preferences, and the right of vulnerable persons to be protected from research risk [14]. Research protection for adolescents may rely on their informed consent and/or proxy consent from their parents. All children and adolescents have the right to access rights-based health programmes and research which address their holistic needs [12]. The principle of respect draws our attention to the evolving capacity of adolescents to provide informed consent, which is essential to determine their participation in research. Drawn upon the categories of risk [16], surveys, blood draws, χ -rays and educational interventions are defined as minimal risk. A risk assessment to determine the level of risk for the proposed study is included in the protocol. As low-risk research, where adolescents were capable of making a rational decision, they can, and where appropriate should, be empowered to make their own decisions. In addition, the principle also means that researchers should respect cultural diversity when carrying out studies and communicating with members of affected communities [18].

Respect for persons: Practical mechanisms invoked

Alternative approach for waiver of informed consent for minors. Findings from our three earlier studies showed that the majority of adolescent FSWs (95%) were rural-urban migrants living apart from family and dropping out of school. Nearly 18% (93/517) of the participants were minors in our studies. Given the fact that they were living apart from their parents for years and did not have a regular connection to their families, they became de facto self-supporting adults in daily life. Under this circumstance, adolescents were more knowledgeable about their own situation than their parents, and their priorities and preferences may be at odds with their family and community of origin [14]. Further, the results of prior focus group discussions indicated that it was not feasible nor appropriate to obtain parental/guardian consent because there was a risk of breaking their confidentiality, and posing potential barriers hindering recruitment. Waiving parent permission can be an option in some lower-risk epidemiological and social research involving adolescents [9,18,26,27]. However, it is important to note, even though none of participants were under 14 years old, neither the *Law of the People's Republic of China on the Protection of Minors* (2012) nor the NHFPC regulation (2016) allows for a waiver of parental permission for mature minors in a variety of studies, including surveys of adolescents. There is need for a balance to promote the appropriate inclusion of mature minors while adhering to legal criteria. In such deliberations, particular decisions and actions were justified by ethical theory and evidence in conducting SRH research among adolescents [15,16,28], as well as acknowledging the evolving capacities of children outlined in the Article 5 of the CRC. The research team created a specific three-step approach for each study as following:

- i. All potential participants were clearly informed about the study objectives, the confidential nature of information collected, and their rights of voluntary participation, refusal to answer questions and withdrawal from the study. Also there was a clear statement about the researcher role before the study, so that participants knew the study was separate from any medical treatment or care, and their information collected from the survey would not interfere or be mixed with their clinical medical records.
- ii. A cognitive ability examination was applied to assess an individual's competency in understanding the information on the questionnaire

and the ability to communicate the decisions and give consent.

- iii. A minor could supply a written informed consent from a ‘trusted adult’ as a proxy for a parent. The ‘trusted adult’ who was not in a parenting role could be their relatives, peers, friends, medical staff and health workers from the peer-support organisations.

Adolescents who engaged in high-risk behaviours were often estranged from the parents and living independently. The experiences on the three earlier studies suggested that the balance between the respect for adolescents’ emerging capacity for independent decision-making and the need for special protections for minors could be achieved. Hence, there is a need to mutually consider the evolving capacity and the level of risk entailed by any SRH research.

Sensitization to the subculture of vulnerable adolescents. In each of the three earlier studies, two pilot tests were run among key informants and included leaders of FSWs’ support organizations, frontline doctors, senior peer educators, outreach workers and adolescent FSWs. The information sheets, questionnaires, and interview guidelines were pre-tested and assessed on their readability and the appropriateness for vulnerable adolescents’ subculture.

All research team members were trained to ensure the consistency of the protocol and to uphold ethical principles including non-judgemental attitude. The training provided a very detailed approach to address issues raised in the pre-tests. During these training sessions, some of the key informants of the target population were invited to be the trainers to accurately take into account their views, concerns and attitudes. Two examples of proposed wording of study instruments aimed at minimizing the stigma and potential harms were as follows:

- i. Age issue. During our pre-test of the interview, it became apparent that requesting participants’ date of birth was highly sensitive and they often did not answer for fear of being identified. To reduce the non-response rate, we only collected data on birth year (original question: What year were you born?). When this was refused, the interviewers asked about the participants’ Chinese Zodiac Signs (Chinese Zodiac is a 12-year circle starting from the Rat to the Pig with a symbolic zodiac animal sign in each year. Everyone knows about their signs) to determine the true birth year.
- ii. Sex worker issue. The term ‘prostitute’ is used in Chinese society and in legal documents, but it is a highly discriminatory word. On the other hand, the terminology ‘sex worker’ is under the western linguistic context and had been initially introduced to China by international HIV/STI intervention programmes in early 2000 s. It is still being debated and is not commonly accepted in Chinese society. In particular, the law enforcement departments strongly argue that ‘sex work’ and ‘sex worker’ imply legal recognition of the sex industry. It is worth noting that periodical police crackdowns of sex workers and the industry were ongoing throughout the period of our studies. Thus ‘sex worker’ will cause sensitivity or discomfort if the term is directly used in the questionnaire. Further, our previous studies indicated that adolescent participants were less likely to perceive themselves as sex workers, either because of stigma or because selling sex was perceived to be a temporary measure to earn money or cope with economic hardship, rather than a formal job [29]. With this background in mind, reducing the sensitivity and respecting their personal or social identities were a priority in developing the study instruments. As discussed above, the question was designed and asked in this way: “How long have you being working as a ‘Xiao Jie’ (Miss)?” ‘Xiao Jie’ is a neutral word meaning ‘young lady’ in common situation, and also a euphemism for FSWs in Chinese society. Also the word ‘paying acquaintance’ was used instead of ‘client’ to avoid embarrassment and distress felt by adolescent participants.

In conducting SRH research with marginalized adolescents,

familiarizing one’s self with their sub-culture and using non-stigmatizing instruments proved critical. Consultation and communication with key informants and representatives of a target population should be actively encouraged. In our experience, such activities ensure SRH research adherence to both ethical standards and community cultural norms, and also extend researchers’ perspectives from participants’ angles.

Protect privacy and confidentiality. Confidentiality and privacy were of utmost concern in our studies. All research staff were trained to protect data collected on paper forms and computer documents. Both verbal and written statements were provided to each participant to assure the confidentiality of data collected and that health records were kept under lock and key. All participants remained anonymous in these studies. Participants were free to provide either their real names or made-up names when signing the informed consent.

Each interviewer contacted potential participants to look for their preference of time, venue and contact methods, length and form of sessions (focus group discussion) before conducting face-to-face interview. Besides, collaborative CBOs and clinics provided safe places, such as meeting rooms, consulting rooms and drop-in centres, to facilitate the interviews. Regarding the free gynaecological examination and biological sampling to screen for HIV and STIs, the research partner, Kunming CDC, formed a special team and provided private and quick access to clinical procedures and healthcare. A unique code with a coupon was assigned to match each of their questionnaires with clinical and laboratory results and to avoid using names in any clinical records.

Over the course of the research, no participants complained about the research activities and no one was identified or arrested by any law enforcement departments as a result of the study. The risks and potential emotional and social harms inherent to the research had been minimized by including adolescents’ voice and addressing their needs in the related activities.

Discussion

To our best knowledge, this is first study in China to inform ethically robust ways in which to conduct SRH research with marginalized adolescents.

There is no simple way or uniform answer to ethical concerns when conducting SRH research with vulnerable adolescents because of the diversity of the populations and different contexts of the research. The 2017 UNICEF Innocenti Brief calls on specifically the compatible goals of the inclusion of adolescents in research and the protection from research risks, and emphasizes the nuanced understanding of their capacity, development and the social context of their lives [14]. Our studies suggest that a sensible balance between protection and inclusion could be achieved through sensitively constructed research designs, most importantly, to collaborate with communities and stakeholders who are entrusted with caring for these adolescents.

The approaches of community-based participatory methods in our SRH studies show promise in advancing vulnerable and marginalized adolescents’ engagement and empowerment, that is promote the inclusion. On the other hand, community involvement can be an important protection both in enhancing the quality of research and the quality of research protections. This may be particularly meaningful when exemption for parental permission or proxy consent is adopted.

The lessons learned suggests that it is important to let key stakeholders (leaders of CBOs, representatives of target populations, policy makers, IRBs members, and SRH experts) be involved in the study design and discuss ethical issues at the earliest possible time prior to implementation. Researchers need to shift perspectives about the target population: moving them from the subjects to the key stakeholders in the research [14]. Listening to the expressed needs, examining the *best interests*, understanding the cultural lens and experience through marginalized adolescents’ perspectives should be part of the research

priority setting processes. This strategy helps to generate innovative ideas and results in essential and practical coping strategies for ethical problems. As Coughlin pointed out, “Ethical concerns can be anticipated or identified early and effectively addressed through careful analysis and consultation” [18].

As stated, the lack of clear ethical guidelines and rules in China remains problematic for both researchers and IRB institutions to deal with SRH research involving adolescents, particularly adolescents involved in risky behaviours. There are at least three important limitations when applying current research ethics concepts into adolescent health related research in China. Firstly, current ethics have primarily focused on clinical or biomedical research at the individual level, as opposed to a population health approach. Secondly, the overly broad and incomprehensive definition of children excludes the component of maturity. It remains confusing whether all minors should be treated as children, it raises complex questions (e.g., classification of mature minors and determination of the waiver of parental permission). Thirdly, the lack of analytic strategy of the vulnerabilities (e.g., biological vulnerability or structural vulnerability) also imposes difficulty for researchers and IRBs in dealing with protection and inclusion. Vulnerability is sensitive to context and an individual adolescent may be vulnerable in one situation but not in another. Hence, the uncritical adherence to the overgeneralized rules can pose obstacles to research practice or fail to cater to the adolescents’ interests and disregard their rights [30]. Also seen from this perspective, the 2017 UNICEF guidance emphasizes that national and international laws and regulations influencing research participation by adolescents should promote harmonization, building on the principles of the CRC-including the notions of *best interests* and *evolving capacities* [14].

Parental consent is a major ethical challenge faced by researchers when conducting SRH research with marginalized adolescents. The type of consent and waiver for parental consent can significantly affect participation rates, study costs, selection bias, and sample representativeness [26,31]. The solicitation of parental consent in instances where research participants are deemed minors under domestic law, has been found in other global health research to inadvertently break the confidentiality of the participants in respect to their sexuality and sexual activity, and may trigger social harms in which researchers still face the dilemma of acting in the best interests of adolescents or facing legal implications [14,28]. The evidence from our studies supports that mature minors have the capacity to provide informed consent, and they can constructively inform the research methods and procedures. Taking into account high-risk adolescents’ vulnerability to adverse SRH outcomes, the need for continued special protections, where necessary (e.g., facilitating the process of accessing care and referring to after-care) should be considered in research designs.

Our studies also suggest that researchers should not only be familiar with the ethical concepts, but also need to create measures to put them into practice within the local context. For example, evidence from other research with vulnerable adolescents [9], as well as our study, showed effective communication and engagement of IRB members during ethical analysis can help inform the IRB review process by characterizing the true risks and benefits and validating the methods. As Bruce D. Sales pointed out, “merely following the requirements of law, regulators, ethics committees and IRBs does not absolve the researcher from personal responsibility for resolving possible ethical conflicts that may arise in the conduct of their work” [32].

Conclusion

It is crucial to achieve meaningful involvement of the marginalized adolescents in the design and implementation of the SRH research and intervention programmes. With policy makers and programme funders requiring existing evidence on health needs and intervention effectiveness, appropriately addressing these ethical issues will advance the effective planning and implementation of public health action. With a

careful consideration of evolving capacities and sensitively constructed research design, our study shows that the dual goals of inclusion with protection can be attained. Our study echoes previous studies’ conclusions that the experience with decision-making in real-world situations increases adolescents’ capacity to give informed consent for participation in SRH research. Further, given the complexity of the issues, ethics committees that lack expertise in adolescent health and development are likely to feel uncomfortable and uncertain when dealing with research involving adolescents [14]. Our empirical experience demonstrated that familiarity with relevant regulatory principles, timely and effective engagement of community and IRB members in determination procedures and transparent communication may help navigate the IRB review process successfully. It will also help reduce the ethical challenges and dilemmas faced by the researchers and the ethics committees.

For closing data and evidence gaps, and in light of the emerging complexity of the field and ethical topics, more empirical health studies targeting adolescents, particularly vulnerable adolescents are needed in China. A sound scientific basis should underpin appropriate and efficient programming, policy and advocacy, as well as facilitating the development of a clearer and more effective ethical guideline that reflect real-world scenarios.

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Authors’ contributions

XZ designed and wrote the first draft of the manuscript. SZ provided input to the interpretation of the findings and commented on revisions. SL participated in the study design, editing and consolidating this manuscript. All authors critically reviewed the manuscript and approved the final version.

Conflict of interest

The authors have no financial or personal relationships that might bias this work and no conflicts of interest in the manuscript. The content is solely the responsibility of the authors and does not necessarily represent the official views of financial sponsors.

Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.srhc.2019.02.005>.

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