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| Project Title: | Evaluation of UDAAN Programme in Rajasthan 2018-2020 |
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| Location of the project: | Rajasthan, India |
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| Study Coordinator’s name: | K G Santhya |
| Submitted to IRB on: | June 2018 |
| Signature | K G Santhya |

List of acronyms and abbreviations

AFHS Adolescent Friendly Health Clinic

CIFF Children’s Investment Fund Foundation

CEB Census Enumeration Blocks

CAPI Computer-assisted personal interviewing

CMO Chief Medical Officer

DiD Difference-in-Difference

HCD Human Centered Design

IDI In-depth Interview

IIPS International Institute for Population Science

MPV Mission Parivar Vikas

MoHFW Ministry of Health and Family Welfare

NFHS National Family Health Survey

RMNCH+A Reproductive, Maternal, Neonatal and Child and Adolescent Health

RKSK Rashtriya Kishor Swasthya Karyakram

SRH Sexual and Reproductive Health

U-DISE Unified District Information System for Education

WASH Water, Sanitation and Hygiene

# **Summary of proposed research**

The Children’s Investment Fund Foundation has supported the Council to evaluate whether, how, and for whom UDAAN, a multi-component intervention to reduce adolescent fertility in the state of Rajasthan, has an effect. Specifically, we seek to examine the effect of UDAAN programme strategies on girls’ secondary school enrolment and retention, unmarried adolescents’ sexual and reproductive health (SRH) knowledge, attitudes and practices, and modern contraceptive prevalence rate among and method-mix used by young women; and the implementation context, processes, and mechanisms to understand how and why UDAAN may contribute to a reduction in adolescent fertility

We will use a multi-component, mixed methods evaluation strategy to evaluate the effects of UDAAN. We will rely on analyses drawing on publicly accessible, de-identified secondary data to assess the effect of UDAAN on girls’ enrolment and retention in secondary schools and contraceptive uptake and method-mix among young women. We will use a quasi-experimental design with panel surveys in intervention and comparison sites at baseline and endline to examine the effect of the intervention on adolescents’ SRH knowledge, attitudes and practices. The assessments will comprise: (1) a survey, using age appropriate instruments, of unmarried girls and boys in ages 15-19 currently enrolled in Grades 9-12 in 10 government run/aided secondary (up to Grade 10) or senior secondary ( up to Grade 12) schools each in intervention and comparison arms conducted before launching the intervention and its completion; (2) assessment of the quality of counselling services provided to adolescents in Ujala clinic (two clinics each in intervention and comparison arms), using mystery clients twice over the project period (baseline, and endline (about 18 months after the baseline) ; and (3) in-depth interviews with Ujala clinic counsellors twice over the project period, baseline and endline (4 counsellors each in intervention and comparison arms).

We note that some of the questions included in the questionnaire, particularly those related to sexual experiences and sexual and reproductive health problems experienced, might cause some stress and anxiety among adolescents and they may worry about whether their responses will be kept confidential or affect their access to services in the health facility. Young people who will act as mystery clients, in addition, may worry about whether the providers will come to know about their visit as mystery clients. Counsellors, likewise, may be concerned about frankly responding to questions pertaining to their practices in responding to young people who approach them for information or services. To minimize the risk to the participants, we will make all questionnaires anonymous, and names of potential participants will not be recorded in the forms in which their responses are recorded. Moreover, the proposed study will be conducted in a number of clinics and schools, and no reports/papers/other documents that will draw on the data collected will contain identifiers that could link the results with any one respondent or clinic or schools. We will inform potential participants about these steps to minimise risks in the course of taking informed consent. We also acknowledge the need for responding appropriately to respondents’ concerns of personal risk and will train and equip our investigators and research team to deal with such concerns.

While there will be no personal benefit to the potential participants, findings generated in the study will be useful in evidence-based advocacy to improve services specific to adolescents.

# **Study relationships/related project**

This study is part of the UDAAN programme, a multi-component intervention that seeks to reduce adolescent fertility in the state of Rajasthan, implemented by IPE Global in partnership with the Youth Parliament Foundation, Quick Sand, the Manjari Foundation, the Pathfinder International and the Government of Rajasthan, with the support of the Children’s Investment Fund Foundation (CIFF) (see intervention section for more details). CIFF has supported the Council to undertake a multi-component, mixed methods evaluation, including outcome, process and impact evaluation and value for money analysis. The current application is for seeking IRB’s approval for conducting the outcome evaluation of UDAAN.

# **Background**

***Rationale and contribution to the current knowledge base:*** Despite India’s significant progress in reducing child marriage and adolescent pregnancy in the last decade, as many as 27% of 20-24-year-old women were married before age 18 and 8% of 15-19-year-old women were already mothers or pregnant in 2015-16 (International Institute for Population Science [IIPS] and ICF, 2017a). Moreover, India’s progress in addressing the antecedents of child marriage and adolescent pregnancy has been far from satisfactory. For example, while almost all (95%) children in ages 6-10 attend school, this percentage decreases to 88% for children in ages 11-14 and drops further to 63% for children in ages 15-17, with males more likely than females to attend school at ages 15-17. Indeed, just 49% of 15-19-year-old girls had completed secondary education in 2015-16. Adolescents’ agency in day-to-day matters is also limited; just 46% of 15-19-year-old married girls reported that they had some say in such decisions as own health care, major household purchases and visiting their family or relatives. Stereotypical gender role attitudes are upheld by noticeable proportion of adolescent boys – 32% of 15-19-year-old boys believed that contraception is a woman’s business and a man should not have to worry about it. Furthermore, adolescents’ interactions with frontline health workers are limited and they tend to experience a number of constraints in seeking health care when they have a health concern – only 15% of 15-19-year-old girls had met with a health worker in the three months preceding the interview and some 69% reported issues such as difficulty in getting permission to visit a health facility, money for seeking treatment, and finding someone to escort them to the facility, distant location of the health facility, and health system level concerns, including lack of providers, particularly female providers and supplies prevent them from accessing health care. As such, just 10% of currently married girls and 16% of sexually active unmarried girls (i.e., those who had engaged in sex in the month preceding the interview) in ages 15-19 were using a modern contraceptive method in 2015-16.

India has articulated its commitment to promote and protect the rights of adolescents to have information, skills, services and a safe and supportive environment through various policies and programmes. For example, in 2013-2014, the Government of India expanded its Reproductive, Maternal, Neonatal and Child Health programme (RMNCH) to include a focus on adolescents (renamed RMNCH+Adolescents), and in 2014, it launched the Rashtriya Kishor Swasthya Karyakram (RKSK, the national adolescent health programme) that aims to provide a range of information and services to married and unmarried adolescents (Ministry of Health and Family Welfare, 2014). The RMNCH+A programme seeks to meet a number of targets by 2017, many of which pertain to adolescents and youth or are inclusive of them, such as, for example, decreasing the proportion of total fertility contributed by adolescents (15–19 years), and reducing the unmet need for family planning methods among eligible couples.

The implementation of these policies and programmes is, however, marred by several challenges (Santhya and Jejeebhoy, 2014). Several programmes have been implemented poorly and unevenly and have failed to reach the most disadvantaged adolescents; for example, the Council’s research shows that adolescents from socio-economically disadvantaged households were less likely than those from privileged households to have received family life education. The lack of collaboration between and even within departments, varying levels of political support and leadership across sectoral programmes for adolescents and several systemic issues (including inadequately-trained staff, weak monitoring systems and capacities, and delays in the flow of funds and commodities) have impaired successful implementation of adolescent programmes. Further, the limited targeted outreach and information dissemination has resulted in poor community acceptance and minimal mobilization around adolescent issues. Finally, programmes have not typically integrated adolescents’ perspectives on what they want from their lives, how they make choices and what type of services they would utilise.

In recognition of these challenges, IPE Global Limited led consortium of partners is implementing a multi-component intervention, UDAAN, that seeks to reduce adolescent fertility in the state of Rajasthan. The Council has been engaged to examine whether, how, and for whom UDAAN has an effect.

***Design:*** The Council will use a multi-component, mixed methods evaluation strategy, to assess the effect of UDAAN on girls’ enrolment and retention in secondary schools, awareness, attitudes and service utilisation related to sexual and reproductive health matters among unmarried adolescent girls and boys, and contraceptive uptake and method-mix among young women, as detailed below.

The effect of UDAAN on girls’ enrolment and retention in secondary schools will be examined using Unified District Information System for Education (U-DISE) data, a publicly accessible, de-identified database on schools in India (https://student.udise.in/). Using a difference-in-difference design, we will compare changes in girls’ enrolment and retention in Dholpur and Udaipur districts over the intervention period with changes in two comparable, non-intervention districts, namely, Bharatpur and Dungarpur. We matched selected socio-economic characteristics of the intervention districts and the remaining districts in the state and selected two districts with the district averages closest to those of the intervention districts to serve as comparison districts. The indicators on which we matched the districts included the proportion of population belonging to disadvantaged castes and religions, proportion of nuclear families, proportion of population residing in rural areas and transition rates from Grade 8 to Grade 9 and from Grade 10 to Grade 11. We will also conduct a time-trend analysis to assess changes in girls’ enrolment and retention in secondary schools for the state as a whole in 2020 and changes will be compared with the target 2% increase per annum.

UDAAN’s effect on awareness, attitudes and service utilisation related to sexual and reproductive health matters among unmarried adolescent girls and boys will be assessed, using a quasi-experimental design. We will conduct a school-based, panel study before launching the intervention (baseline) and at its completion (endline) among a sample of unmarried adolescent girls and boys in ages 15-19 enrolled in Grades 9th -12th in government run/aided secondary or senior secondary schools in one intervention block (Bari) in Dholpur district and one comparison block in a matched non-intervention district (Karauli). The survey will be conducted in 20 schools, 10 in the intervention and 10 in the comparison arms. We will randomly select 10 schools from among schools that were selected by IPE and its partners for delivering intervention activities. The district for the comparison arm has been selected in three stages. In the first stage, we matched the district average for selected socio-demographic and sexual and reproductive health indicators for 10 districts that have been selected for implementing the RKSK programme by the health department. We selected the one with district averages closest to that of Dholpur. In a similar way, we have selected one comparison block with socio-demographic characteristics similar to that of the intervention block identified for the evaluation. Primary data will be collected from the same students at baseline and endline. The study team will collect the contact details (name, address, telephone no. etc.) from secondary and senior secondary schools from both the intervention and control arms; we note that these details are publicly accessible from the students’ record portal maintained by the education department ‘Shaala Darpan’ database. Even so, the study team will obtain the permission of the District Education Officer and the principal of the schools selected for the evaluation before accessing the contact details and the school principals will be requested to take consent from students in Grades 9-12 in their school for permitting research team to access their contact details. The research team will prepare a list of students who are currently aged 15-19, unmarried and are residing within 5 kilometers from the school and potential respondents for the survey will be randomly selected from this list, using systematic random sampling method.

Finally, UDAAN’s effect on contraceptive use and the method mix among young women will be examined through time-trend analysis, using secondary data at the district and state-level, drawing on publicly accessible, de-identified data, including those from the National Family Health Survey-4 (http://rchiips.org/NFHS/nfhs4.shtml), Performance Monitoring and Accountability 2020 Survey (<https://www.pma2020.org/program-countries/india>) and the Health Management Information System data (<https://nrhm-mis.nic.in/SitePages/Home.aspx>).

***Study sites:*** The study will be located in the state of Rajasthan in India. Rajasthan, with a population of 68.5 millions, ranked eighth among the states of India in terms of size of the population in 2011 (Office of the Registrar General of India & Census Commissioner, 2013). Despite the fact that current cohorts of adolescents are better educated and healthier than ever before in the state, many do not make a successful transition to adulthood. For example, relatively small proportions of adolescents, especially girls, complete a secondary school education, relatively few have availed of livelihood skill building opportunities. Wide gender role disparities persist and adolescent girls have limited agency in terms of decision making, mobility and control over resources – just 29% of 15-19-year-old girls have money that they can decide how to use; and 19% were allowed to visit selected locations unescorted (International Institute for Population Science [IIPS] and ICF, 2017b). In the area of health, and notably sexual and reproductive health, premarital sex was experienced by 15% of boys and 9% of girls in 2012 and where experienced it was largely unsafe and for several girls, unwanted (Jejeebhoy and Acharya, 2012). Marriage took place in childhood for about one-third of young women in ages 20-24 and as many as 41% of currently married girls in ages 15-19 have begun childbearing (International Institute for Population Science [IIPS] and ICF, 2017b). One in seven married girls had experienced physical, sexual or emotional violence within marriage. Some 29% of girls and 34% of boys in ages 15-19 justified wife-beating in selected situations. Unmet need for contraception is widespread – some 23% of currently married girls in ages 15-19 reported an unmet need for spacing or limiting contraceptive methods in 2015-16.

**Intervention**

UDAAN is a multi-component intervention that seeks to reduce adolescent fertility.

***Implementation organisations and their relevant experience:***

IPE Global Limited is an international development consulting group providing expert technical assistance and solutions for equitable development and sustainable growth in developing countries. The group’s areas of expertise include social and economic empowerment, health, nutrition and water, sanitation and hygiene (WASH), urban development, education and skills development, among others. Over the last 18 years, IPE Global has successfully implemented over 800 projects in over 100 countries across 5 major continents.

Pathfinder International works in collaboration with governments, NGOs, and community- and faith-based organisations to make contraception available and provide quality care needed to ensure safe childbirth and healthy families. They work in countries with high prevalence of HIV/AIDS, providing a continuum of HIV/AIDS prevention and treatment services and are expanding the integration of these services into reproductive health and family planning programs.

Quicksand is a leading design strategy and innovation consultancy firm from India, recognised globally for its expertise in Human Centered Design (HCD). Their work spans both for-profit and not-for-profit sectors across emerging markets, and has involved envisioning innovative new programs, products and services that are future facing, and still rooted in the everyday reality of people they aim to serve.

The Youth Parliament Foundation is a youth run and led organisation that supports and develops youth leadership to advance rights of young women, girls and other marginalised youth. The organisation works in the areas of advocacy and policy, governance, sexual and reproductive health and rights, mental health, life skills and youth leadership and digital media and learning.

Manjari Foundation, a registered non-profit organisation established in May 2015, helps women from marginalised communities overcome social injustice, poverty and exclusion. The organisation supports rural women initiative at grass-root level to facilitate empowerment so that they can lead a dignified life.

***Nature and objectives of the intervention:*** UDAAN programme strategies include: (1) strengthening scholarship delivery systems, raising awareness about scholarship schemes and mobilizing communities to shift traditional norms about girls’ education to improve girls’ enrolment and retention in secondary schools; (2) implementation of a user-centred design to the Rashtriya Kishor Swasthya Karyakarm (RKSK) to strengthen sexual and reproductive knowledge, attitudes and practices among adolescents; and (3) expansion of the contraceptive method mix for young women by supporting government’s efforts to introduce injectable contraceptives in the public sector family planning programme.

***Strategy 1: Keeping girls in secondary schools***

UDAAN strategy 1 comprises the following activities:

* 1. Strengthening the delivery of five scholarship schemes sponsored by the Government of India and the Government of Rajasthan for students in Classes 9 and 10 who belong primarily to socially disadvantaged caste and religious groups and economically poor households by introducing information technology enabled scholarship management system;
  2. Generating demand for scholarships by raising awareness about these schemes and motivating parents and communities to value girls and their education through multi-pronged communication activities that will be implemented at the block, district and state levels by project staff;
  3. Undertaking a pilot study to assess the amount of financial payment that will motivate parents to ensure that their daughters attend and complete secondary education; and
  4. Developing standard operating procedures and building capacities of government functionaries for effective state wide scale up of strategy 1 activities.

Activities 1.1 and 1.4 will cover all districts in the state, while activity 1.2 will cover all blocks of two districts in the state, namely, Dholpur and Udaipur (a total of 22 blocks) and activity 1.3 will be implemented in Dholpur district only.

***Strategy 2: Designing and demonstrating a new model to effectively engage with adolescents under RKSK by adopting a user centred approach***

Strategy 2 adopts a user-centred approach to design and demonstrate a new model to effectively engage with adolescents under RKSK; the user-centred approach consists of working with the adolescents to understand their real life experiences, needs and generate insights on programming (inspiration and ideation), prototyping a range of cost effective and scalable interventions, and designing and piloting the most promising interventions. Informed by the process of prototyping selected interventions, the IPE and its partners have decided to pilot test the following activities:

* 1. Strengthening the capacity of the Ujala clinic counsellors, and developing a set of counselling tools to provide effective counselling and information about SRH issues in non-judgemental and unbiased manners;
  2. Introducing an incentivised cadre of young people who will deliver a school-based curriculum to students in Grades 9-12 attending government run/aided secondary and senior secondary school in Bari block in Dholpur district to improve adolescents’ access to correct information on SRH topics in a safe and engaging manner, and build a conducive environment for discussion around SRH topics (gender equality, consent and agency); and
  3. Providing telephonic counselling to adolescents by placing dedicated, trained male and female counsellors with the government sponsored helpline services (104/108)

The geographic focus of strategy 2 will be one block in Dholpur district.

***Strategy 3: Expanding contraceptive choices for young women***

Govt. of India has recently launched an ambitious Mission Parivar Vikas (MPV) initiative which aims to improve access to family planning services by providing assured services, commodity security, building capacity and enabling environment across seven states, including Rajasthan. One of the key objectives of MPV is to introduce injectable contraceptives to expand method choices. Strategy 3 activities will include:

* 1. Developing capacity building programmes, including mobile-phone based training module for services providers, including frontline workers for providing injectable contraceptive services;
  2. Developing a digitised system for tracking injectable contraceptive users;
  3. Engaging community counsellors to reach out to younger women on a pilot basis with injectable contraceptives; and
  4. Undertaking a pilot study to assess the feasibility and user acceptance of self-administration of injectable contraceptive, using subcutaneous administration

# These activities will be implemented in Dholpur district.

# ***Key ethical issues and risks to potential intervention participants:*** The intervention seeks to identify workable solutions for selected critical issues that impinge on adolescent health and development situation in India, including limited school completion among girls, lack of awareness of sexual and reproductive matters, limited agency, stereotypical gender role attitudes and limited access to health services. If proven successful, adolescents in the project settings are likely to benefit from the intervention and the lessons learned from the implementation processes will be useful for modifying adolescent programming in India Even so, we note that intervention can pose some risks to adolescents. For example, the intervention activities may question social norms that undervalue girls’ education and their empowerment and that condemn egalitarian relationships between girls and boys; those who continue to adhere to the stereotypical attitudes can react negatively to adolescents who participate in the intervention. Furthermore, intervention activities can raise adolescent girls’ educational aspirations and failure, if any, of the educational system and their families to meet those aspirations can create stressful situation for adolescents in intervention settings. Another risk could be a breach of confidentiality and/or loss of privacy for adolescents who access services from the Ujala clinics and/or helpline services.

# ***IRB approval for the intervention protocol:*** The intervention protocol has not yet been submitted for ethical review by the implementing partners. It may be noted that although the Council is evaluating the intervention, we do not have jurisdiction per se over the intervention and ethical responsibility for intervention activities rests with IPE Global and its partners. However, the Council staff will sensitize the implementing team, IPE Global and its partners about the risks mentioned above and the importance of putting in place necessary redressal mechanisms as well as measures to maintain the confidentiality of clients seeking services from the UJALA clinics in the intervention sites.

# **Study Goals/Objectives**

The goal of the study is to examine whether, how, and for whom UDAAN has an effect. Specifically, we seek to examine the effect of UDAAN programme strategies on girls’ secondary school enrolment and retention, unmarried adolescents’ sexual and reproductive health (SRH) knowledge, attitudes and practices, and modern contraceptive prevalence rate and method-mix used among young women.

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| **Overview table** | **Data Gathering Activities** | | |
| **Activity number** | Activity 1:  Survey of unmarried girls and boys in ages 15-19, baseline and endline | Activity 2:  Mystery client visits to Ujala clinic | Activity 3:  In-depth interviews with Ujala clinic counsellors |
| **Study population** | Unmarried adolescent girls and boys (15-19 years) enrolled in Grades 9-12 in selected government run/aided secondary and senior secondary schools | Ujala clinic counsellors | Ujala clinic counsellors |
| **Sample size** | 600 unmarried girls and 500 unmarried boys from 20 schools equally divided between intervention and comparison arms | 24 visits to Ujala clinics; 6 per clinic and two clinics each in intervention and comparison arms; therefore, 12 each in intervention and comparison arms at baseline, and endline | 8 counsellors, 4 each in intervention and comparison arms |
| **Location of activity** | Household or other locations convenient to the respondent | Ujala clinic | Ujala clinic or other locations convenient to respondent |
| **Timing** | Project Months 5-6 and 23-24 | Project Months 5-6, 12, 24 | Project Months 5-6, 12, 24 |
| **Method** | Face-to-face interview, using structured questionnaire | Visit to the Ujala clinic to seek service, using the mystery client scenarios pre-assigned and debriefing following the visits | Face-to-face interview, using interview guide |
| **Informed Consent document (Annex #)** | Draft letter seeking permission from the District Education Officer (Dholpur and Karauli districts) for collating student details from the student record portal ‘Shaala Darpan’ (Annex 1)  Draft letter seeking support from the principal of schools selected for the evaluation in obtaining students’ permission for accessing their contact details from ‘Shaala Darpan’ (Annex 2)  Parental consent form (Annex 3), Adolescent Assent form (Annex 4) and Adolescent consent form (Annex 5) | Permission from the health department for conducting mystery client visits and in-depth interviews with Ujala clinic counsellors (Annex 8)  Adolescent consent form for acting as mystery client (Annex 9) | Adult consent form for in-depth interview (Annex 12) |
| **Study Instrument (Annex #)** | Survey questionnaire for unmarried girls (Annex 6) and boys (Annex 7) | Mystery client script (Annex 10)  Debriefing tool (Annex 11) | Interview guide (Annex 13) |

# **Data Gathering Activities**

# ***Activity 1: Survey of unmarried girls and boys ages 15-19 (baseline and endline)***

## Subject Population

As mentioned earlier, the baseline and endline surveys will be conducted among unmarried girls and boys in ages 15-19 from 20 selected schools in intervention and comparison arms. A total of 600 girls and 500 boys (equally divided between intervention and comparison arms) will be interviewed at baseline and endline, respectively.

The study team will collect the contact details of students (name, address, telephone no. etc.) from secondary and senior secondary (classes 9th -12th) schools from both the intervention and control arm from the students’ record portal maintained by the Education Department, ‘Shaala Darpan’ database (see. Annex 1 draft letter for seeking permission from the District Education Officer, Annex 2 draft letter for seeking permission from principal of schools, see the section on compensation and informed consent process for more details). The research team will prepare a list of students who are currently aged 15-19, unmarried and are residing within 5 kilometers from the school and potential respondents for the survey will be randomly selected from this list, using systematic random sampling method.

## Research Protocol

A structured questionnaire has been prepared for the interview of unmarried girls and boys separately (Annex 6 and Annex 7). This questionnaire has drawn upon instruments used in previous Council studies that were approved by the IRB, for example, Towards Youth Responsive Sexual and Reproductive Health Services: Identifying Approaches to enable Health Care Providers to Effectively Impart Sexual and Reproductive Health Services (Protocol # 546), Successful Pathways to Adulthood among Unmarried Adolescents: Drivers and Barriers (Protocol #550), and Transitions to adulthood in Bihar and Uttar Pradesh, India: A study of younger and older adolescents (Protocol #698). The survey will probe various dimensions of adolescent life, including school experiences, the extent to which the respondent has benefitted from scholarship schemes, agency, interaction with parents, knowledge of sexual and reproductive health matters, gender role attitudes, friendship and connectedness, pre-marital romantic and sexual experiences,[[1]](#footnote-1) health and health-seeking behaviour, and awareness and utilisation of adolescent friendly health services. It will also collect information on the religion and caste as well as on ownership of the residential structure and consumer durables and availability of amenities to better understand the socio-economic status of the household to which potential participants belong. The questionnaire has been designed to be age appropriate.

Female and male research assistants recruited and trained by Population Council staff members will administer the questionnaire to female and male respondents, respectively. We will interview them face-to-face, for approximately 45 minutes, at their home or at a place convenient to them. In our experience, girls prefer to be interviewed within the home, and interviews are typically conducted in a separate room in the home, in a corner of the courtyard of the home, on the terrace. In case respondents would prefer to be interviewed outside the home, we will make arrangements to hold the interview after-hours in the anganwadi centre (a pre-school facility operated only in morning hours). We opted not to conduct the interviews in the school settings in order to ensure the confidentiality of respondents and privacy for the interview. We propose to use computer-assisted personal interviewing (CAPI) technique wherein the investigator administers the questions to the potential participants and records the responses given by the them using mini laptops for this adolescent survey. The potential participants will not self-administer the questionnaire.

The survey instrument will be administered in Hindi. We will translate the questionnaire into Hindi, back-translate them, and field-test the instruments among a small group of adolescents to see whether any questions might cause distress and should be changed. Three teams, each containing 7 persons will conduct the survey and will complete the fieldwork over a two-month period. Male and female investigators will conduct all interviews with adolescent boys and girls, respectively.

At the conclusion of the baseline survey interview, the field team will explain to all potential participants in the intervention sites that IPE and its partners will be implementing an intervention in their school over the next 18 months, and that they would like to re-interview them at the conclusion of the project. They will inform all the potential participants in the comparison sites that although no intervention activities will be conducted in their school, the study team would like to re-interview them after 18 months to obtain information about changes in their lives since the first round of data collection.

We further note that survey instruments used for the baseline survey will be reviewed and adapted for the endline survey, taking into account contextual and programme changes.

## Risks and benefits to subjects, steps to minimise risk & confidentiality

We note that some of the questions included in the questionnaire, particularly those related to sexual behaviour and experiences of physical and sexual violence, might cause some discomfort and stress among respondents. Moreover, respondents may worry about whether their responses will be kept confidential. To minimize the risk to the participants , the following steps will be taken and we will inform the potential participants about these steps in the course of obtaining their consent for participating in the study. We will take steps to see that data gathered are anonymous and that names are not recorded in the computerised form in which responses will be recorded. Indeed, unique identification numbers will be given to the survey participants; the field team will be instructed to use this identification number when they fill the computerised form. Although we will prepare a database of the baseline survey participants who had agreed to be re-interviewed, using such identifiers as the name of the respondent, their residential address, and the location of their residence in order to correctly identify the original respondents for re-interviewing at the completion of the intervention, no identifying information, will be linked with the data collected. All contact sheets with identifiers will be kept in locked cupboards in the office of the Population Council, New Delhi. Moreover, the proposed study will be conducted in 20 schools, and no reports/papers/other documents that will draw on the data collected will contain identifiers that could link the results with any one respondent, their school or village/census enumeration block. Once the interview is completed, the data will be transferred to cloud-based server in encrypted form, accessible by password and back-up copies of the data will be stored electronically (in secure folders) in our office, accessible by password.

Given that the evaluation will be conducted in intervention and comparison districts, we acknowledge the ethical issues associated with conducting research in a comparison group denied of the intervention, especially if expectations were raised during the baseline survey. However, without credible comparison (i.e. untreated) groups, it is unlikely that evidence will be generated that could make a potentially valuable intervention available broadly or avoid spending resources on an intervention that is unlikely to benefit recipients. Interviewers will be trained to convey, and consent forms will indicate, that no direct benefits will accrue as a result of the study. Findings generated in the study will be used to inform evidence-based policies and programmes to reduce teenage pregnancy.

We also acknowledge the need for responding appropriately to requests from respondents for information or help. We will train and equip our research assistants to refer such requests to IPE and its partners or government facilities, as appropriate. However, while study teams may do their best, we will not be in a position to ensure that a respondent in need obtains appropriate counselling or services.

While there will be no direct benefits to the study respondents, findings generated in the study will be useful in evidence-based advocacy to improve adolescent programming in the country.

Several strategies will be adopted to ensure that interviews will not be overheard by family members or others even when the interviews are conducted at home. The interviewers will be instructed to conduct the interview in a separate room in the home, ask the questions in such a way that these are not heard by others, call on a co-interviewer designated for this purpose to hold parallel discussions with adults or others interested in listening to the interview, or re-schedule the interview so as to enable full confidentiality to the interview.

The data will be stored electronically (in secure folders) by the Population Council. Back-up copies of all data will be stored separately. Moreover, no reports/papers/other documents that will draw on the data collected will contain identifiers that could link the results with any one respondent or area in which they reside. Informed consent documents, kept on paper, will be kept separate from response files and the research team will bring these forms in sealed boxes to the Council’s office in Delhi. Finally, we will sensitize project staff conducting the survey about the importance of maintaining the confidentiality of these data. We will emphasise the respondent’s right to be fully informed and his/her ability to provide informed consent in the course of interviewer training. These forms and data sets will be maintained for one year in case the study team needs to refer back to the forms while analyzing the data and will be destroyed thereafter.

## Compensation and informed consent process

Participation in the baseline and endline surveys will be entirely voluntary. No incentives or compensation will be paid to respondents for taking part in these surveys.

Several steps are proposed for obtaining informed consent and assent for conducting the surveys. These include parental/guardian permission for enrolling minors aged below 18 years in the study, and assent from minors and consent from those aged 18 years to be interviewed. We detail below the steps to be taken.

For minor boys and girls aged 15-17 years, research assistants conducting the survey will obtain informed assent from potential participants and parental permission before administering the questionnaire to them. We note that conducting research on minors presents ethical challenges. Permission from a parent or guardian will be sought before acquiring assent from all minors. Our field research team will first approach a parent/guardian of potential respondents and seek his/her permission to include his/her child in the study. They will explain to the parent/guardian the purpose and the survey procedure, the risks and benefits of participating in the study, voluntariness of participation and the steps taken to safeguard confidentiality, and inform the parent/guardian that the child still retains the right to decline to participate in the study fully or partially, and that the parent/guardian will not have access to any information provided by the child. They will also inform the parents that a similar survey will be repeated after approximately 18 months. The team member will then seek their written consent to include their child in the study (see Annex 3 for consent form for obtaining parental/guardian permission for interviewing minors).

After parental/guardian permission is acquired, we will seek assent from the child to take part in the study. The field study team will explain to the child the purpose, the study procedure, risks and benefits of participating in the study, voluntariness of participation, right to skip any questions and/or withdraw from the study without penalty, and the steps taken to ensure confidentiality. They will inform the child that we would like him or her to take part in a survey, but that he/she can opt out of it at any time. They will also explain to the child that his/her parent has consented, but that he/she still has the right to decline and will then seek his/her written assent to interview him/her. They will also inform the child that the survey will be repeated after 18 months. The team member will then seek his/her written consent to include him/her in the study (see Annex 4 for adolescent assent form).

If the parent gives permission to participate in the study but the child does not give assent, the child will not be included in the study. Only if both the parent/guardian and the child agree, we will enroll the child in the study.

For respondents aged 18-19, the research team will obtain informed consent from potential participants before administering the survey instrument to them. They will explain to potential respondents the purpose, the procedures, risks and benefits of participating in the study, voluntariness of participation, right to withhold any information and/or withdraw from responding to the questionnaire without penalty, and the steps taken to ensure confidentiality. The team will then seek potential participants’ written consent (see Annex 5 for informed consent form to be used for those aged 18-19 years).

For those who are unable to read the parental permission/assent forms, the contents of these forms will be read out and explained (usual procedure for low-literacy study participants); they will be encouraged to ask questions and the field team will clear any doubts. While the project staff who will obtain the parental permission and informed assent will sign, stating that he/she has explained the content of the parental permission form and informed assent form, we note that there will not be a third-party witness to the informed consent process.

A similar procedure will be followed for taking informed consent at the endline survey as well.

# ***Activity 2: Mystery client visit to Ujala clinics (Adults 18+)***

## Subject Population

We will observe the counselling services provided by Ujala clinic counsellors, using mystery clients, in both intervention and comparison arms. There are two counsellors employed in each Ujala clinic. The intervention will target two clinics in the intervention block and we plan to observe delivery of counselling services in these clinics. We will select two Ujala clinics from the comparison block as well. Therefore, a total of 8 counsellors – 4 each from intervention and comparison arms – will be observed using mystery clients. We will recruit 12 young people (ages 18-22) – six females and six males –to serve as mystery clients.

## Research Protocol:

We propose to use mystery clients because we expect that very few young clients will have the self-confidence to raise questions or pursue an in-depth conversation with the counsellor. We will identify young women and men (18-22 years old whose physical appearance resembles that of 15-19 year-olds) to serve as mystery clients, with the help of local NGOs, from villages that are not located in close proximity to the Ujala clinic selected for the study. A young person will be considered eligible to serve as a mystery client if she/he is aged between 18 and 22 years, she/he is residing in a village that is not located in close proximity to the Ujala clinic, she/he has not been to the Ujala clinic before, she/he demonstrates a talent for role playing and she/ he displays openness about discussing sexual and reproductive matters. Once a young person is thus identified, the study team will enquire about her/his willingness to serve as a mystery client and seek her/his consent to be enrolled in the study.

We will follow the procedure for conducting mystery clients as suggested in the guide published by the Pathfinder International (Boyce and Neale, 2006). We have successfully used this methodology in an earlier assessment of adolescent friendly health clinics in three states of India, including Rajasthan, approved by the Council’s IRB (Protocol #546).

The potential mystery clients identified by the study field team with the help of local NGOs will be trained by the study coordinators. During the training, the study coordinators will familiarise the potential clients with scenario for them to act out, help them phrase their question(s) to the counsellor, give opportunity for them to do a role play of the scenario assigned to them and brief them on potential criteria for evaluating the quality of services. These scenarios may include an unmarried girl seeking treatment for menstrual problems; an unmarried boy seeking information about masturbation and nightfall; an unmarried girl who is under pressure from her boyfriend to engage in sex and hence, seeking oral contraceptives; an unmarried girl seeking information about abortion on behalf of her friend who is also unmarried; an unmarried boy seeking information about sexually transmitted infections; and an unmarried boy requesting condoms (see Annex 10 for a draft script of mystery client scenarios to be enacted). They will be instructed not to undergo any physical examination. The potential clients will also be informed about the clinic that they should visit, and asked to observe everything that the counsellor does or says and not to mention any affiliation with the study at the clinic. To keep the experience of mystery clients as close to real clients as possible, no mystery client will be sent to more than one clinic in a district. Mystery clients will make visits in pairs. Mystery clients will receive a monetary compensation of Rs. 2,000 per interview (approximately $30) to cover their transportation as well as any other incurred expenses. Debriefing of mystery clients will be done by the study team supervisors immediately after the consultation at a place convenient to the client. During the debriefing, mystery clients will be probed about their experience in availing of services at the clinic (registration process, waiting time to see the counsellor etc.), information given by the counsellor (content, comprehensiveness etc.) and the counsellor’s behaviour toward the client (objectivity, level of comfort in discussing issues of sexual and reproductive health matters with the client etc.) (seeAnnex 11 for a draft guide to be used for debriefing the mystery clients). The debriefing may take half-an-hour or one hour.

The mystery client visits will be made twice over the project period – at baseline, and 18 months after the baseline visit (endline). We will follow the procedure described above for the baseline and endline. However, we will recruit a fresh batch of young people to serve as mystery clients for each round.

## Risks and benefits to subjects, steps to minimise risk & confidentiality

Young people who will act as mystery clients may worry about whether the counsellors will come to know about their visit as mystery clients, but we will take precautions to see that this does not happen. In order to minimize the chance of anyone coming to know that the young person has visited the clinic as a mystery client, we will send the young person to a clinic that is located far from his/her village/ward, and we will not send the same mystery client to more than one clinic in a district and we will recruit a fresh batch of young people to serve as mystery clients for each round. Moreover, no reports/papers/other documents that will draw on the data collected by the mystery clients will contain identifiers that could link the results with the mystery clients, the clinic or the counsellor. Data will be stored electronically (in secure folders) in our office and will be destroyed after the data have been analyzed. During the training, we will emphasize that he/she may end their participation in the exercise at any time without penalty or loss of any benefits to which they are entitled. Moreover, if the exercise makes them uncomfortable and they want to discuss it with a professional, they will be given a phone number at the end of the exercise of persons who will assist them in getting the help they need.

## Compensation and informed consent process

Obtaining consent for conducting mystery client visits at selected Ujala clinic will be a two-stage process. The first step will be to obtain permission from the Chief Medical Officer of the CHC/PHC (see Annex 8 for obtaining permission from the Chief Medical Officer for conducting mystery client visits; permission will be obtained at the PHC/CHC premises). The research assistants will inform the CMO (but not the Medical Officer, auxiliary nurse midwife or counsellor serving the clinic) that one or more youth may visit the clinic to seek sexual and reproductive health services; that they have been trained by the study team to observe key components of service provision during their visits, including the friendliness of staff and the quality of sexual and reproductive health services provided; and that following the clinic visit, the study team will debrief the mystery clients to record their observations. They will also inform her/him that the mystery clients are not being trained to find mistakes or faults at the clinic, but as a key target audience of the clinic, can observe ways in which the clinic might improve to better serve them.

In the second stage, the research assistant will explain to potential mystery clients the purpose of the study, the study procedures, risks and benefits of participating in the study, voluntariness of participation, right to withdraw from the study without penalty, and the steps taken to ensure confidentiality. Additionally, they will inform them that their participation in the study would include training on how to conduct a mystery client visit, a visit to a designated clinic as a mystery client and completion of an interview regarding their experience at the clinic after the visit, and that they will be paid Rs.2,000 (approximately $30) per interview for serving as a mystery client. They will be instructed not to reveal their identity and association with the study to anyone at the clinic and not to undergo any type of physical examination or procedure (see Annex 9for informed consent form for mystery clients; consent will be obtained in the home of the potential mystery clients or at the office of the local NGO that has helped the research team to identify potential mystery clients).

# ***Activity 3: In-depth interviews with Ujala counsellors (Adults 18+)***

## Subject Population

We will conduct in-depth interviews with Ujala counsellors from the same four clinics where mystery clients will visit. We will interview two counsellors in each clinic, and therefore, 8 counsellors will be interviewed from intervention and comparison arms.

## Research Protocol:

We will conduct in-depth interviews with Ujala clinic counsellors to better understand their role in such clinics and the constraints that they face in providing counselling services to adolescents. They will be interviewed at a location in the clinic that offers privacy for the interview or at a place convenient to them that offers privacy; the interview will be conducted by a research assistant trained in conducting qualitative studies. The research assistant will seek permission to use a tape recorder to record the interview. Each IDI will last for about one to one-and-a-half hours.

The interview will focus on the participant’s experience as a counsellor, training received, particularly, in providing services to adolescents, perceptions about the training received, services available and provided to adolescents in the clinic, perceptions about utilisation of these services by adolescents and constraints that adolescents might be facing in accessing these services, perceptions about sexual and reproductive health concerns of adolescents and their service needs, views about the constraints that counsellors face in providing services to adolescents in general and through Ujala clinic in particular, (see Annex 13 for IDI guide for counsellors). We note that all the interviews will be conducted in Hindi, the local language in Rajasthan.

In-depth interviews with counsellors will be conducted twice over the project period, baseline, and end-line (18 months following the baseline).

## Risks and benefits to subjects, steps to minimise risk & confidentiality

Counsellors may be concerned about frankly responding to questions pertaining to their practices in responding to young people who approach them for information or services. To minimise the risk to the participants, the following steps will be taken and we will inform the potential participants about these steps in the course of obtaining their consent for participating in the study. We will take measures to see that the data gathered are anonymous and that names of the IDI participants or their clinic name will not be recorded in the transcripts. As described earlier, although we will retain such identifiers as the name of the respondent, their residential/clinic address, and the location of their residence/clinic in order to get in touch with them for re-interviewing at the completion of the intervention, no identifying information will be linked with the data collected. All contact sheets with identifiers will be kept in locked cupboards in the office of the Population Council, New Delhi. Moreover, the proposed in-depth interview will be conducted in four clinics in two districts, and that no reports/papers/other documents that will draw on the data collected will contain identifiers that could link the results with counsellor or clinic, and that the data will be stored electronically (in secure folders) in our office.

## Compensation and informed consent process

The research assistants will obtain written consent from counsellors prior to conducting in-depth interviews with them. As in the case of adolescents, they will explain the purpose of the study, the study procedures, risks and benefits of participating in the study, voluntariness of participation, right to withdraw from the study without penalty, and the steps taken to ensure confidentiality. They will also inform them that we would like to interview them in-depth for approximately one hour to one-and-a-half hours (see Annex 12for informed consent form for counsellors; consent will be obtained in a location at the clinic offers privacy). We note that as in the case of mystery client visits, we will seek permission from the Chief Medical Officer of the CHC/PHC to conduct in-depth interviews with counsellors serving the AFHC at a time convenient to these providers and without disturbing the provision of services to young people.

**Data Management**

We note that identifiers will be collected both for recruitment purposes (names, addresses) and during consent procedures (signed signatures). No identifying information, however, will be linked with the data collected. All contact sheets with identifiers will be kept in locked cupboards in the office of the Population Council, New Delhi. Consent forms, with written signatures of the parents, adolescents, mystery clients and service providers will be kept in locked drawers in the office of the Population Council, New Delhi.

Data will be stored in password protected computer files that have access limited to the principal investigators. To avoid risks associated with the disclosure of sensitive information during collection, entry and storage, every effort will be made to ensure that participants’ responses are kept confidential. As noted earlier, stored forms will be maintained for one year in case the study team needs to refer back to the forms while analyzing the data and will be destroyed thereafter.

The textual data from the IDIs will be transcribed and translated to English by consultants recruited by the Council. The voice files recording the discussion, if use of recorders was permitted by the study participants, will be destroyed once the transcription is completed. The transcripts will be translated into English and any identifiers that could link the data with any one respondent or clinic will be removed before sharing the transcripts for translation. Textual data and transcripts will be stored electronically (in secure folders) by the Population Council. Back-up copies of all data will be stored separately. Interview transcripts will be maintained for one year in case the study team needs to refer back to the forms while analyzing the data and will be destroyed thereafter.

As per our agreement with our donor, we have to make datasets available and accessible to third parties to undertake novel analysis and generate new knowledge. We will therefore share data collected during interviews with unmarried adolescent girls and boys, including the household survey in a data repository and we will not share data from mystery client visits or in-depth interviews with clinic counsellors. Any third-party researchers wishing to access the data will have to ask for the Council team’s permission and provide a research question suited to the data before data access is granted. We will follow the repository’s data preparation guidelines such as protocols to anonymise data. Therefore, during the informed consent we will explain the process of data sharing and make clear that survey data will be reviewed in detail to remove names, contact information and any other information that we believe would allow someone to identify the study participants.

# **Training and Qualifications of Personnel**

The field-based study team who will be engaged in obtaining informed consent/assent as well as in collecting data will comprise female and male research assistants recruited and trained by Population Council staff. These research assistants are graduates in science or social science streams, are proficient in Hindi and come with 3-4 years of experience in conducting field-based studies under the supervision of the principal investigator of the proposed study. The research assistants will undergo 10 days-long training programme in which they will receive participatory training to conduct face-to-face interviews and an opportunity to acquaint themselves with the study instruments. Additionally, interviewers will receive intensive training in research ethics, with emphasis on ensuring that specific individuals are not identified in data that they collect as well as about safeguards to be taken while gathering data from young adolescents. Training will be conducted by Council staff members and will comprise classroom sessions, as well as mock interviews and role plays to ensure that procedures are fully understood, and field practice sessions with consenting individuals available around the training site.

Moreover, to ensure data quality and adherence to ethical principles, Council staff members will provide on-going supervision and support to interviewers, and their observations will be fed back to the interviewer on a regular basis.

# **Instrument Development**

The study instruments that will be used in the proposed study are adapted from instruments used in earlier studies that were approved by the IRB. We have already shared draft instruments with key stakeholders at the state level to ensure that these instruments collect locally relevant data in a culturally appropriate manner and their suggestions have been incorporated in the revised instruments attached with this protocol. As seen in the questionnaires, we have modified the instruments considerably to elicit age-appropriate information in a culturally appropriate and sensitive manner. Moreover, we have pilot- tested the survey instruments in two villages of Dholpur district among a small group of adolescents to see whether any questions might cause distress and should be changed, and whether the framing of the questions needs to be simplified so as to ensure that the questions are well understood by the study participants. We have revised the instruments based on the insights gather through the pilot-testing.

**Data Analysis**

We propose to use the difference-in-difference (DiD) estimator to estimate the impact of the intervention. We will pool data from intervention and comparison sites and use t-tests to assess whether intended outcomes are significantly different between the two areas. Additionally, we will use regression analysis to assess the impact of the intervention on the outcome indicators after controlling for the effects of potentially confounding socio-demographic covariates. Analysis will compare data from baseline and endline to assess changes in perceptions and experiences over the course of the project as well as shed light on its acceptability and feasibility.

**Dissemination plan**

A report will be prepared that describes the impact of the intervention, drawing on baseline and endline studies. We will disseminate the findings of the study in a number of ways. We will hold data interpretation workshops, in partnership with IPE in district level forums and seek participants’ perspectives on the study findings. Insights from the evaluation will be disseminated, in partnership with IPE and state government departments as appropriate, widely to state and national level government representatives, civil society partners, media and researchers. In all of these activities, we will share aggregated results from study participants. We also plan to prepare articles for submission to peer reviewed journals and for presentation in national and international conferences and seminars.

# Annexes

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| Annex 1 | Draft letter for seeking permission from the District Education Officer (DEO) |
| Annex 2 | Draft letter for seeking permission from school principals |
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| Annex 3 | Parental consent form for adolescents aged 15-17 |
| Annex 4 | Assent form for minors aged 15-17 |
| Annex 5 | Consent form for 18-19+ year-olds |
| Annex 6 | Baseline and endline survey instrument for unmarried girls in ages 15-19 years |
| Annex 7 | Baseline and endline survey instrument for unmarried boys in ages 15-19 years |
| Annex 8 | Form for seeking permission for conducting mystery client visits and interactions |
| Annex 9 | Consent form for mystery clients |
| Annex 10 | Mystery client script |
| Annex 11 | Debriefing guide |
| Annex 12 | Consent form for in-depth interviews wiith Ujala counsellor |
| Annex 13 | In-depth interview guide for Ujala counsellors |

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1. Acknowledging that participants may be reluctant to disclose sexual experiences, questions on sexual experiences will be posed in an anonymous format, in addition to the face-to-face interview method. In the anonymous format, participants will be asked to report whether they have (a) ever had pre-marital sex; and (b) ever experienced forced pre- or extra-marital sex. They will be asked to record their responses on a separate form and place the form in an envelope and seal it and return it to the field research team. Respondents will be informed that the envelope will not be opened in the field, and that only the principal investigators would be able to link the information provided in the envelope with what is provided in the main body of the questionnaire. Envelopes will be opened only at the Council’s office in Delhi. We note that the PI of this study have successfully tested this method in previous studies (IIPS and Population Council, 2010). [↑](#footnote-ref-1)