Improving utilisation of services for sexual and gender-based violence (SGBV): knowledge, attitudes, practices and perceptions (KAP) in Jahangipuri, Delhi India protocol

Improving utilisation of services for sexual and gender-based violence (SGBV): knowledge, attitudes, practices and perceptions (KAP) in Jahangipuri, Delhi ~~Utilization and acceptance of services for survivors of Sexual and Gender-Based Violence: Knowledge, Attitudes, Practices and Perceptions (KAP) in MSF catchment areas (New Delhi)~~

India protocol

Study proposal

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Study design	Mixed methods: KAP surveys, in-depth interviews & focus group discussions
Study period	November 2017-April 2018
Study site	Jahangipuri, New Delhi, India
Principal investigator	Himanshu M., Dy Medical Coordinator (Epidemiologist), MSF-OCA, India Email:india-epidem@oca.msf.org
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Data collection and analysis:	MSF-OCA India mission, New Delhi
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List of abbreviations

ANC	Ante-natal care
ATFC	Ambulatory therapeutic feeding programme
CI	Confidence interval
CTC	Cholera treatment centre
FGD	Focus group discussion
FSW	Female sex worker
EPI	Expanded Program of Immunisation
GBV	Gender-based violence
HIV	Human immunodeficiency virus
ICRC	International Committee of the Red Cross and Red Crescent
ICRW	International centre for research on women
IDI	In-depth interview
IDP	Internally displaced person
IEC	Information, education and communication
INGO	International non-governmental organisation
IPV	Intimate partner violence
IQR	Inter-quartile range
IRC	International Rescue Committee
ITFC	Intensive therapeutic feeding programme
KAP	Knowledge, attitude and practice
LGBT	Lesbian, gay, bisexual, and transgender
MDR-TB	Multi-drug resistant tuberculosis
MedCo	Medical Coordinator
MoH	Ministry of Health
MoWCD	Ministry of Women and Child Development
MSF	Médecins Sans Frontières
NFI	Non-food items
NGO	Non-governmental organisation
OCA	Operational centre Amsterdam
OCHA	Office for the Coordination of Humanitarian Affairs
PEP	Post-exposure prophylaxis
PEPFAR	(U.S.) President's Emergency Plan for AIDS Relief
PHC	Primary health care
PMTCT	Prevention of Mother to Child Transmission
SD	Standard deviation
SGBV	Sexual and gender-based violence
STI	Sexually transmitted infection
SVS	Sexual and Gender-Based Violence survivors

TB	Tuberculosis
U5	Under 5 (years old)
UN	United Nations
VAW	Violence against women
WASH	Water and Sanitation and Hygiene
WatSan	Water and Sanitation
WHO	World Health Organisation

1 Introduction

1.1 Background

Sexual and gender-based violence (SGBV) is a serious and sometimes life-threatening public health and human rights issue[1]. Available data suggest that in some countries nearly one in four women may experience sexual violence by an intimate partner and up to one-third of adolescent girls report their first sexual experience as being forced[2]. In the context of armed conflict and displacement, sexual violence, including exploitation and abuse, is a well-known and high risk problem. SGBV is often used as a weapon of war, targeting civilian women and children[2, 3].

SGBV has a profound effect on both physical and mental health; in addition to causing injury, violence increases long-term risk of many other health problems, including chronic pain, physical disability, drug and alcohol abuse, and depression[4]. Women with a history of physical or sexual abuse are also at increased risk for unintended pregnancy, sexually-transmitted infections including HIV, and miscarriages[4]. They may also face complications linked to abortions (including unsafe/high-risk abortions), pregnancy (due to trauma or infections) and complications of delivery and neonatal problems such as low birth weight[2]. Social and familial stigma and rejection secondary to SGBV may exacerbate mental health outcomes experienced by survivors[5].

Appropriate and accessible health services providing immediate assistance for survivors can minimise the harmful physical and psychological consequences of sexual violence[2]. Such care involves treatment of injuries; prevention and treatment of STIs (including post-exposure prophylaxis (PEP) to prevent transmission of HIV); vaccination against tetanus; management of unwanted pregnancy or referral to ante-natal care (ANC) for continued pregnancy; psychological support and mental health care; and support for social and legal issues[6].

1.1.1 Definitions of SGBV

Many definitions of sexual violence and SGBV exist. Generally, it is understood to be an umbrella term for any harm that is perpetrated against a person's will, and that results from power inequities that are based on gender roles[24]. Definitions are generally based on the United Nations definition first presented in 1993 when the General Assembly passed the Declaration on the Elimination of Violence against Women[2,4,5]. It was later defined by The Inter-Agency Standing Committee (IASC) in 2005 as '*any sexual act, attempt to obtain a sexual act, unwanted sexual comments or advances, or acts to traffic, or otherwise directed, against a person's sexuality using coercion, by any person regardless of their relationship to the victim, in any setting, including but not limited to home and work.'*[1]

MSF uses the UNHCR definition of SGBV: '*SGBV refers to any harmful act that is perpetrated against one person's will and that is based on socially ascribed (gender) differences between males and females. It includes acts that inflict physical, mental, or sexual harm or suffering, threats of such acts, coercion and other deprivations of liberty, whether occurring in public or in private life.'* [25] This can incorporate a wide range of sexually violent acts taking place in different circumstances and settings. These include, but are not limited to: rape within marriage or dating relationships; rape by strangers; systematic rape during armed conflict; unwanted sexual advances or sexual harassment, including demanding sex in return for favours; sexual abuse of mentally or physically disabled people; sexual abuse of children; forced marriage or cohabitation, including the marriage of children; denial of the right to use contraception or to adopt other measures to protect against sexually transmitted diseases; forced abortion; violent acts against the sexual integrity of women, including female genital mutilation and obligatory inspections for virginity, forced prostitution and trafficking of people for the purpose of sexual exploitation[1].

Whilst we recognize the full range of abuses the term SGBV includes as per the UN Declaration and other international agreements[4] this is considered too broad for the purposes of this study. At the same time, MSF SGBV services focus on the provision of care for physical and psychological consequences of sexual violence as well as physical violence linked to gender. Therefore, this study will focus on physical and sexual violence in an intimate partnership (IPV), non-partner sexual violence (NP-SV) and domestic violence.

Intimate partner violence: Any behavior within an intimate relationship that causes physical, psychological or sexual harm to those in the relationship, including physical and sexual violence, emotional (psychological) abuse and controlling behaviours.
Sexual violence: any sexual act, attempt to obtain a sexual act, unwanted sexual comments or advances, or acts to traffic, or otherwise directed, against a person's sexuality, using coercion, threats of harm or physical force, by any person regardless of relationship to the victim, in any setting, including but not limited to home and work.
Domestic violence: Deliberate, often repetitive physical, verbal, and/or other types of abuse by one or more members against others of a household. The term 'domestic violence' is often used to refer to partner violence but can also encompass child or elder abuse, or abuse by any member of a household.
Whilst we recognise that within this there may be an implicit emphasis on violence against women (VAW), we aim to actively incorporate both genders in this study as there is some evidence to suggest that men are also targets of sexual violence[24], particularly in conflict settings, and also may play a role in the access of survivors to services[1].

1.1.2 Other definitions

Definition of household

A household will be defined as a group of people who slept under the same roof the previous evening and have all been living under the same roof for the past month (this is in order to exclude visitors to the household).

Definition of head of household

The head of household will be defined as an adult household member aged ≥18 years, who states that s/he is responsible for the household members and is present at the time of the survey

1.2 SGBV in India

The marginalisation of specific groups combined with high poverty levels has led to a lack of access to (quality) health care throughout India. Women and children particularly suffer from this lack of access due to the 'traditional' position of women in an essentially patriarchal society. In addition, sexual violence, domestic and social violence and human trafficking have been identified as increasing concerning issues affecting women and children in India[31]. The unprecedented growth of the slum population indirectly impacts on poverty, poor living conditions, limited access to health services and increased vulnerability to health risks. Moreover, the caste system plays a predominant role in determining social norms in India with high levels of inequality leading to far-reaching social exclusion. Gender inequality is pervasive and a direct consequence of this is increased vulnerability.

In a 2012 survey of 370 gender specialists, India was named the worst G20 country in which to be a woman due to sex selection, infanticide and slavery[48]. In Delhi, the overall sex-ratio for young children (aged 0-6 years) is 866 girls per 1,000 boys. Delhi has the highest rates of kidnappings and abductions of young children and women in India. The National Capital Territory of Delhi accounted for 8.9% of all kidnappings and abductions, 45.8% (595 out of 1,299) of child victims (up to 10 years of age) and 34.9% of children aged 10 - 15 years (1,710 out of 4,901 victims)[49].

Although gang rapes have gained huge media attention nationally and internationally, the overwhelming majority of physical and sexual violence takes place within the home. The National Family and Health Survey of India (2005-2006)[50] concluded that 40% of women (aged 15-49) married at least once, experience physical, sexual or emotional violence. According to a 2011 survey[51], sexual violence against a stable partner was the most common form reported by men in India. Next to violence from their partners, many women experience sexual and physical violence by their family and in-laws as well as dowry-related violence and acid attacks.

As reported by the Ministry of Women and Child Development (MoWCD) [52], more than 53% of children in India are subjected to sexual abuse, but most don't report the assaults to anyone. More than 70% of abusers are immediate family members and close acquaintance.[1] Delhi was reported as having the second highest prevalence of all Indian states. Child sexual abuse was reported in 66% of boys and 34% of girls with 54% boys and 23% girls experiencing one or more forms of severe sexual abuse. Children on the street, in institutions and working children are the most vulnerable. It was also reported that 55% of street children are subjected to sexual abuse. A census in 2011 reported 51 000 street children living in Delhi[53].

1.2.1 Legal framework

The ~~new~~ 2013 Criminal Law Amendment Act (CLAA~~); 2013)~~ criminalizes all forms of violence against women. This is defined any act of gender-based violence that results in, or is likely to result in physical, sexual or psychological harm or suffering to women, including threats of such acts, coercion or arbitrary deprivations of liberty, whether occurring in public or private life - (1993 UN Dec. Elimination of Violence against women). It also expands the definition of rape to include all forms of sexual violence-penetrative (oral, anal, vaginal) including by objects/weapons/fingers and non-penetrative (touching, fondling, stalking, etc.) and ~~It~~ states that no hospital, private or public, can deny treatment to a rape victim. Treatment should be provided immediately and free of cost. [2] However, the CLAA has many shortcomings: limited recognition of rape within marriage; no recognition of rape of men (and does not repeal an outdated act that continues to criminalize same sex relations among adults)[3]; it is still based on the concept of 'modesty' as opposed to morality as concerns the mental integrity of victims thus perpetuating stereotypes; and security forces are still legally immune from punishment under the 'Special Powers Act'. [4]

The Protection of Children from Sexual Offences Act came into force on the 14th of November 2012. It defines a child as any person below the age of 18 years and provides protection from the offences of sexual assault, sexual harassment and pornography. These offences have been clearly defined for the first time in law. The Act provides for stringent punishments, which have been graded as per the gravity of the offence. However, the Act also has several shortcomings including a restrictive interpretation of 'penetration'; failure to include forced sexual intercourse by a husband against the wife (above 15 years) as an offence. [5]

In 2014 the Ministry of Health and Family Welfare introduces new guidelines and protocols on 'medico-legal care for survivors/victims of sexual violence.' It outlines the roles and responsibilities of the health sector in ensuring appropriate physical and mental health services are available without discrimination and are accessible, acceptable and of good quality, including treatment for physical injuries, prophylaxis and testing for sexually transmitted infections, emergency contraception, and psychosocial support. It states that health care workers must obtain informed consent of the survivors/victims of sexual violence prior to conducting medical examinations or initiating medico-legal investigations, and that all medico-legal examinations and procedures must respect the privacy and dignity of the survivor. Amongst other things it aims to ensure informed consent and respect autonomy of survivors in making decisions about examination, treatment and police intimation, and notably disallows any mention of past sexual practices 'through comments on

1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3890930/#ref3

2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3890930/#ref3

3 Amnesty Report

4 Amnesty International 2013, https://www.amnesty.org/en/press-releases/2013/03/india-new-sexual-violence-law-has-both-positive-and-regressive-provisions-2/

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size of vaginal introitus, elasticity of vagina or anus' or what has been referred to as the 'two-finger test'. Further, it bars comments of built/height-weight/nutrition or gait that perpetuate stereotypes about 'victims'. Whilst the guidelines have been generally welcomed, questions remain as to whether they have been implemented in practice, and the need to incorporate them into standard medical training and education materials.

1.2.2 Barriers to care

There are clear barriers to accessing care and an unmet medical need for survivors of SGBV. Based on the outcome of individual interviews and 13 focus Group Discussions (FGDs) conducted by the MSF assessment team in Delhi in 2014, communities have limited knowledge about consequences of, and medical care required for SGBV survivors. Perceptions include: no medical care will be received unless the case is first reported to the police; pregnancy was possibly the only medical consequence; legal avenues are often futile; hospitals will be discriminatory, condescending and non-confidential, leading to similar treatment back in the community.

1.3 MSF in India

MSF-OCA and MSF-OCB have been present in India since 1999 when OCA started a Mental Health program in Kashmir (opened in 2001) and OCB a TB project in Mumbai. MSF history indirectly started in 1996 in India when it was awarded the prestigious Indira Gandhi Prize for Peace, Disarmament and Development in 1996 by the President of India.

MSF-OCA currently has projects in Kashmir, Manipur, Chhattisgarh and Delhi. Over the past fifteen years MSF OCA has set a clear priority to be present within conflict affected areas of India. These projects have catalysed change within the MoH's medical responses in MSF catchment areas. For example, the Kashmir Mental Health project has contributed to changing the response to the mental health needs in the valley and MSF starting HIV treatment and MDR-TB treatment triggered a government response in Manipur. More recently concerns for marginalized populations, emerging public health epidemics (DR-TB / Hepatitis C) and widespread SGBV has triggered MSF to focus on specialized medical programs with an advocacy and research role.

Given increasing recognition of widespread SGBV in India, in 2015 MSF started a vertical SGBV program in an urban slum area within Janghir Puri, Delhi. Its primary objective is to increase access to quality medical and psychological care in the community. It also aims to increase awareness and acceptance of the importance of integrating international standards in provision of SGBV care amongst the relevant Ministry of Health (MoH), Ministry of Women & Child Development (MoWCD) authorities and other non-governmental actors.

The Janghir Puri slum area has an estimated population of 250,000. MSF's target population for SGBV services is anyone, male or female, who has experienced sexual or gender based violence; no group is being specifically targeted. This site was selected for the clinic due to the large density of socio-economically vulnerable people (including street children, female sex workers (FSW), child workers and migrants) living and working in this region, likely increasing the proportion 'victims' and 'perpetrators' as well as the risk of health care exclusion.

1.4 Rationale for the study

It is acknowledged that SGBV services are under-utilized across contexts, [1,5] yet factors affecting this are not well understood. In Delhi, MSF's Umeed Ki Kiran clinic has already considered many known barriers to care (documented in published literature as well as during focus group discussions conducted prior to opening the clinic; see section 1.2.2) and adapted services accordingly. Despite this, uptake of services remains far less than expected. As a result a deeper understanding of barriers to care for SGBV is essential. ~~In India focus group discussions were held in 2014 (ref) revealing barriers as mentioned in section 1.2.2. Despite adapted health promotion activities in the MSF catchment area India, the uptake of services has been limited. Moreover, these~~ Whilst FGDs conducted in Delhi in 2014 at the outset of the project provide some useful insights on

barriers to care, ~~covered~~they covered Delhi as a whole and were not focussed on MSF's catchment area in Janghir Puri, and several years has passed since the collection of this data.
Existing guidance on researching SGBV reiterates that 'a necessary, initial question when considering information collection is whether the information sought is actually required'[3]. This is important to avoid SGBV being over-researched and over-assessed, in some cases leading to potentially avoidable harm to participants whilst not yielding any new or additional information or understanding about the problem[3]. Following thorough reflection and consideration of existing literature this study could make a significant contribution to addressing the information gaps regarding knowledge, attitudes and perceptions around SGBV services and their uptake.

Until recently, most research on SGBV consisted of anecdotal accounts or exploratory studies performed on non-representative samples of women[4]. However, the subject has received increased international attention in recent years, and ground-breaking research in the field has greatly expanded international awareness of the dimensions and dynamics of violence[4]. Research and operational literature on SGBV stems from a variety of different disciplines, including, among others, political sciences and international relations, gender studies, anthropology, neuropsychology and law[10]. Prevalence or baseline studies are also increasingly available in a wide range of contexts and focus on social norms around gender and violence and SGBV prevalence[7,9,11–18], as well as various guides for programming, monitoring and evaluation[1,2,4,19–23]. However, little research has tackled the gap between service provision and uptake; data about people who do not seek services is sparse[4]; there is limited information on knowledge and perceptions of SGBV services available[7]; and there is no systematic information about survivors' experiences and perceptions of the services to allow for feedback and adaptions[8]. However, this information is essential to guide the formulation and implementation of effective interventions, policies, and prevention strategies[4]. Furthermore, sensitive and appropriate services, particularly developing innovative strategies for reaching out to survivors, necessitates an in-depth understanding of the local context and sociocultural issues around SGBV[7,9].
~~As a result, we believe that by focusing on knowledge, attitudes, practices and perceptions related to SGBV service provision and uptake we will be addressing a current information gap in the literature. In the Delhi context, this is particularly pertinent as although understanding of survivor access to services is robust for medico-legal services for rape victims, literature is sparse with respect to poor uptake of clinical services by victims of rape, intimate partner violence (IPV) and domestic violence (DV). Moreover, by consulting with affected communities and defining possible strategies/activities people consider would be effective in improving access and uptake we and bridging this gap between barriers and service provision this study will provide valuable new information that will be beneficial to MSF as well as other entities responding to SGBV.~~
~~The findings of this study will support the adaptation and development of strategies to improve utilization of SGBV services, such as SGBV Information, Education and Communication (IEC) strategies, and set~~
A deeper understanding of MSF's target population, particularly knowledge of SGBV and related services and factors obstructing and driving service utilisation is needed. By analysing factors influencing service uptake for SGBV we aim to provide practical recommendations for ~~the improvement of~~ the adaptation and development of strategies to improve utilization of SGBV services, such as SGBV Information, Education and Communication (IEC) strategies, and services in each site to improve uptake and ensure services are accessible and appropriate. In addition, w~~SGBV policy and programming both MSF and national level agencies. W~~e also aim to provide an evidence base to develop, through community consultation, strategies for improving uptake of SGBV services, which may have implications for SGBV policy and programming for both MSF and national level agencies. ~~–~~
~~However, this information is essential to guide the formulation and implementation of effective interventions, policies, and prevention strategies[4]. Furthermore, sensitive and appropriate services, particularly developing innovative strategies for reaching out to survivors, necessitates an in-depth understanding of the local context and sociocultural issues around SGBV[7,9].~~

~~This SGBV survey will provide information on the knowledge and understanding of target communities in regards to the medical and psychosocial consequences of SGBV, the barriers to accessing services for SVS, and the types of services available. This information will assist MSF in understanding how best to deliver effective and accessible care to survivors of SGBV and to advocate for improved care more generally.~~

2 Research question and objectives

2.1 Research question

To identify factors that could improve SGBV service utilisation and acceptance amongst MSF's catchment population in Delhi, India

2.2 Primary objective

To understand how to improve utilization of SGBV services for the population in MSF catchment area Delhi, India

2.3 Specific objectives

1. To understand community knowledge related to SGBV, including its consequences, treatment and clinical services
2. To understand attitudes towards health aspects of SGBV
3. To explore practices related to SGBV care seeking pathways, including barriers and enablers affecting service access and uptake
4. To understand which strategies/activities people consider would be effective in improving access and uptake of clinical services by survivors of SGBV

3 Methodology

3.1 Study design

A sequential mixed methods study is proposed as most appropriate in meeting the study's objectives. We hope this multi-phased sequential mixed methods approach will optimize the validity of our study. It is suggested that a mixed methods approach can offer the most comprehensive and informative data related to SGBV [84] and is '…perhaps the best and most thorough means of understanding violence against women.'[9,]
Error: Reference source not found gives an overview of the study design.

Phase	Approach	Objectives	Methods
1. ~~Formative community-based (exploratory)~~	~~Qualitative~~	• ~~Inform design of KAP survey (questionnaire responses; phrasing of questions etc.)~~ • ~~Enhance understanding of the subject /context~~ • ~~Inform design of training of survey data collection team~~ • ~~Inform development of SOPs including systems for identifying and managing adverse events~~	• ~~IDIs with key stakeholders~~ • ~~FGDs with groups of men and women~~
1. KAP survey	Quantitative	• Provide context specific quantitative data on KAP • Inform design of explanatory qualitative phase	• KAP survey
2. Explanatory research and community-based design of strategies to improve uptake	Qualitative	• Explore/explain tensions and divergences in the findings of each data set and develop a richer understanding of KAP survey data • Identify strategies to overcome barriers identified and improve uptake	• IDIs • FGDs with individuals/ groups identified based on results of phase 1 & 2

TABLE 1: OVERVIEW OF STUDY DESIGN

~~The first phase of formative explorative research will ensure that our approach and tools for the KAP survey are appropriate, comprehensive and adapted to the context.~~ The ~~second~~ first phase of our study, a quantitative KAP survey, will identify trends related to community knowledge, attitudes and practices and establish statistics related to SGBV, care and services. The ~~third~~ s phase will allow us to explain key quantitative findings within the study context [84,85], providing concepts and explanations to complement numerical data or putting 'flesh on the bones of quantitative results, bringing results to life through in-depth case elaboration'[83]. This phase will provide an opportunity to explore potential strategies to improve service utilization in a participatory way. Furthermore, the mutual validation, convergence and triangulation of findings resulting from different methods will enable us to view the subject from different perspectives and look for potential inconsistencies, so enhancing reliability, validity and utility[4].

3.2 Study area and population

The study will be conducted in the catchment areas of the MSF-OCA project in Delhi: Bhalswa Janghir Puri. In 2011 the estimated population of this area was 197,148 (Males = 106,388, Females = 90,760).[88]

3.3 ~~Phase 1: Formative research (exploratory qualitative)~~

3.3.1 Methods

This phase will involve the following methods:

a) In-depth interviews with key stakeholders (MSF team members; other organisations involved with SGBV and service provision; community leaders)
b) Focus group discussion with community members

3.3.2 Sampling and recruitment strategy

Stratified purposeful sampling will be used to select participants who will provide the richest testimonies, and may be supported by snowball sampling should participants recommend further potential candidates to the researcher. MSF teams will facilitate the recruitment of MSF staff and those working with other organisations. FGD participants will be recruited through appropriate local gatekeepers (e.g. local leaders, MSF staff), aiming to ensure representative samples from the community, rather than those with previous knowledge or experience of SGBV and/or MSF services.

FGDs will involve +/- 8 participants sharing the same characteristics, selected with the aim of ensuring maximum homogeneity within groups (in terms of age, education, social background etc.) to create optimum conditions for participants to be at ease discussing sensitive issues[4]. Notably, discussions with men and women will be held separately.

For both FGDs and In-Depth Interviews (IDIs) we aim to reach theoretical saturation through concurrent data generation and analysis, or an iterative process, and so the final number of participants will only be known when this occurs and no new information is being generated[95]. However, generally it is estimated that theoretical saturation can be reached after twelve to fifteen interviews [96] and two to five FGDs[97].

3.3.3 Inclusion and exclusion criteria

In-depth interviews

Inclusion criteria:

- Key stakeholder (staff of organisations involved with SGBV/service provision; community leader etc.); OR
- User of MSF services; AND
- Over 18 years old; AND
- Well enough to participate (based on assessment of MSF team/other gatekeeper); AND
- Consents to participate in the IDI

Exclusion criteria:

- Under 18 years old; OR
- Does not consent to participate in the IDI
- Pregnant or lactating mother
- Elderly population above age of 70 years[6]
- Respondents with acute illness
- On-going treatment in MSF-clinic

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[4] Indian council of medical research. Ethical Guidelines for Biomedical Research on Human Participants; 2006. www.icmr.nic.in/ethical_guidelines.pdf Pg no 28 and 35. The list does not mention elderly population explicitly. However, ERBs are bound to exclude them under the listed category 'vulnerable groups with limited autonomy'. Respondents with acute illness will come under the category 'beneficence v/s non malevolence'.

Focus group discussions
Inclusion criteria:

- Resident of MSF catchment area; AND
- Fitting criteria of group stratification (e.g. male or female); AND
- Over 18 years old; AND
- Well enough to participate (based on assessment of MSF team/other gatekeeper); AND
- Consents to participate in the FGD

Exclusion criteria:

- Under 18 years old; OR
- Does not consent to participate in the FGD
- Pregnant or lactating mother
- Elderly population above age of 70 years
- Respondents with acute illness
- On-going treatment in MSF-clinic

3.3.4 Data collection and analysis

In-depth interviews (IDIs) and focus group discussions (FGDs) will be conducted using flexible participatory techniques.

IDIs will take the format of a discussion and allow participants to focus on the issues they self-prioritise, although a topic guide will be used to ensure all relevant components are covered and so allow thematic comparison (see Appendix 2). Interview questions may be reviewed and refined in response to themes arising during the course of interviews. Interviews will be used to understand the current SGBV and service provision 'landscape' as well to inform design of study processes (training, SOPs, community engagement etc.).

Similarly, FGDs will be conducted based on a framework of themes (see Appendix 3) and guided by a facilitator who will introduce topics for discussion and will facilitate lively and natural discussion amongst participants. FGDs will explore normative perceptions (rather than seeking information in actual behaviours or individual lives) and will focus on perceived options for and barriers to care. Given the sensitive nature of the topic various techniques will be used to facilitate discussion, including 'freelisting' (where participants are asked to list as many types of a given phenomenon as they can; these can then we ranked in order of priority/importance) and 'story completion' (where the beginning of a story is told and participants are asked to reflect on it and complete it as they see fit).

These activities will be recorded and transcribed including careful translation of idioms, metaphors etc. Field notes will be taken throughout the data collection period and analysis will be ongoing. Data will be analysed using the Nvivo qualitative data analysis computer software package[98]. Consent for recording the activities is explicitly mentioned in the consent form (see appendix 2). Analysis will be rooted in grounded theory; text data will be coded and recoded and emerging patterns, themes and relationships will be identified and labelled, allowing repeated patterns of meaning and conceptual categories to emerge from the text rather than from the mind of the researcher[4,85]. Data gathered with different methodologies will be triangulated and negative or deviant cases analysed, and a subset of the data will be analysed by a second researcher in order to enhance reliability.

3.3.5 Interview language

As for all phases of this study, IDIs and FGDs will be conducted in the local language in which the participants are most comfortable.

Topic guides will be back-translated to ensure that meaning and context are captured. Local MSF teams will be involved to ensure appropriate and acceptable terms and expressions are used, and these will be back-translated and checked by another team member familiar with the study.

3.4 Phase ~~2~~1: KAP survey

3.4.1 Survey topics

The household interviews will be based on a KAP questionnaire. This has been developed based on existing tools [1, 4, 20, 21, 24] and contextualised using findings of a 2014 SGBV assessment conducted by MSF in Delhi in 2014 (~~A template is available in a~~Appendix 3~~). ; however, this may be adapted based on information gathered during the formative research phase (e.g. wording of questions and answers, available responses etc.).~~ It ~~will~~ consists of the following sections:

- Socio-demographic information (age, sex, education etc. of the interviewee)
- Knowledge and perceptions about medical and psychosocial consequences of SGBV
- Knowledge and perceptions about availability of medical and psychosocial services for survivors of SGBV
- Barriers and enablers to seeking health care after SGBV

The survey will not ask participants about their individual experiences of SGBV or service use, and will explicitly state at the outset that this is not the aim.

3.4.2 Inclusion and exclusion criteria

We include both adult male and females (aged ≥18 years) to be interviewed. We aim to alternate in each household from adult woman to adult man in the next household, to ensure both female and male participation. We will select a man in the first, third, fifth household etc., and a woman in every second, fourth, sixth household.

A person will be included in the survey if s/he satisfies all of the following criteria:

- Member of the randomly selected household (see section Error: Reference source not found for the definition of a household)

and

- Adult male or female (aged ≥18 years). If there is more than one qualifying adult of the household, one will be selected at random using a random number table (see appendix 7)

A person will be excluded from the survey if s/he satisfies one of the following criteria:

- Refusal to participate in the survey
- ~~Pregnant and lactating mothers~~
- ~~Elderly population above age of 70 years~~
- ~~Respondents with acute illness~~Too unwell to participate
- Under 18 years old

3.4.3 Sample size

The proportion of the population that know that MSF provides SGBV services is unknown so the conservative estimate of 50% was used (this provides the largest sample size). With a precision of 5%, an α-error of 5% and a design effect of 1 (due to the simple random sampling design), n=370 households are required. Assuming a non-response rate of 10%, the total sample size needed is n=407 households per site.

In order to have adequate power in any sub-group analysis, we have increased this sample size 3-fold to allow precise estimates for variables with up to 3 categories (e.g. socio-economic status with categories high, medium and low). This also negates the need for population estimates of different strata that would be required for stratified sampling. The final sample size is thus 1221 households.

Sample size was calculated using OpenEpi[91].

3.4.4 Sampling

A simple random sampling (SRS) survey, with the household as the sample unit, can be carried out as Bhalswa Janghir Puri is a uniformly populated urban setting.

We will use a GPS-based sampling method: Using satellite imagery, an electronic outline of the study site will be replicated in software such as Google earth or Epop. Using this outline, the software can create random points within this perimeter corresponding to the number of households that need to be visited. Teams using either GPS receivers or android phones with GPS localisation functionality, visit the households that coincide exactly with randomly generated GPS points (to prevent selection bias) and interview these households.

~~It is very unlikely that participants randomly selected for the survey also participated in the formative qualitative phase. Should this occur we would approach it in the same way as asking KAP survey participants to be re-interviewed for the third qualitative phase, and ensure a thorough consent process and that the individual has option to decline if this is too burdensome for the individual participant.~~

3.4.5 KAP data collection

Blocks selected according to the sampling frame (see section 3.4.4) will be informed beforehand of the planned study using a letter of information for local leaders (see Appendices). They will be invited to discuss any concerns with the study coordinators. Furthermore, it will be made clear that they are freely allowed to decline the participation of their block without any consequence or penalty. Any refusals will be documented (and reported as a limitation of the study).

If a household cannot be visited due to security concerns, this will be removed from the survey and indicated in the final report as a limitation of the survey. If the random GPS point does not land on a household, we will replace with another GPS point until we achieve the required number of households. We would not select the household closest to the GPS point as this can create a bias as households in sparsely populated areas have a higher probability of selection than those in densely populated areas. Also, the data collector has to choose the 'closest' household which may not always be obvious.

This would exclude commercial and abandoned buildings but not multi-family dwellings. Here we would apply the definition of a household (a group of people who slept under the same roof the previous evening and have been living under the same roof for the past month). If multiple families meet this definition, we would select a household using a random number table.

To be sure that the survey population in the selected block is present on the day of the planned interviews, local leaders will be informed at least one week prior to the interview day (e.g. using motorcyclists delivering letters to the local leaders).

In the households randomly selected according to the above methodology, the purpose of the survey will be explained to the interviewee in the language in which s/he is most familiar and ~~written~~ verbal informed consent obtained to conduct the interview (see section 6.10). S/he will be offered the opportunity to refuse participation in the study at any time during the interview without penalty, and no incentives or inducements will be provided to respondents. If s/he declines to participate this will be accepted, documented and the next household approached; the number of household refusals will be included in the survey report.

All data will remain anonymous throughout the data entry and analysis process. Identifiable data will not be distributed outside the study location, or appear in any report or publication.

The KAP questionnaire is provided in the Appendices.

Following the data collection, the participant will be asked if they are willing to be contacted for a follow up interview. The objective of this will be explained in detail, and should they agree their contact details (telephone number or if not possible, an alternative contact will be agreed) will be

held for this purpose (see section 11 of KAP questionnaire in Annex). It will also be explained that this does not obligate the individual to participate in the interview, and they may freely decline at any point.

The KAP questionnaire is provided in the Appendices.

3.4.6 KAP data analysis

The KAP questionnaires will be administered using smartphones/tablets to ensure high quality data collection, collation and rapid analysis. This will also reduce data entry errors and the need for duplicate data entry as well as saving time in post-field analysis. Data will be uploaded at the end of each day to a secure server and subsequently removed from the tablet so no data is kept on the tablets. In a recent large household survey exploring traumatic events and mental health issues in Kashmir, there was some curiosity around the tablets but once reassured that it was not a recording device and no photos would be taken, participants were very receptive and the team felt there was a perception of importance associated with the tablets which helped rather than inhibited cooperation. However, if participants feel at all uncomfortable about electronic data collection, paper versions of the questionnaires will be administered and entered into the database[93] by the data clerk (supervised by the study coordinator).

All data will be anonymous (names are not collected) and electronic files stored password-protected by MSF. Only survey investigators will have access to these data files. Data cleaning will be done to check for inconsistencies in data entry and responses followed by data analysis using Stata 14[94]. Data will be analysed using the survey specific commands in STATA (svy) which allow for finite population correction factors and adjustment for survey structure (multilevel, staged sampling). Although we aim for a self-weighting sample, we may also need to apply post-estimation survey weights.

After the survey, the questionnaires and ~~written~~ verbal consent forms will be archived for at least 5 years in headquarters.

The descriptive survey results will be presented as number (%) for categorical variables such as sex and mean (SD) for continuous variables such as age. Where continuous variables are highly skewed, they will be presented as median (IQR). Estimates of the objectives of the survey, e.g. the proportion of households that know that MSF provides SGBV services, will be shown as the estimate with 95% confidence interval (95% CI).

Comparisons of differences in the study objectives between selected sub-groups will be reported as an estimate of the difference, the 95% CI of the difference and the relevant p value. For tests of proportions this will be a Chi square test or Fisher's exact test. For differences in continuous study outcomes between two categories a t test will be used unless the data are not approximately normally distributed (in which case a Wilcoxon-Mann-Whitney test will be used). If there are more than two categories for comparison a linear regression analysis will be performed for data approximately normally distributed and a Kruskal-Wallis test for non-normally distributed data. The impact of the clustered design will also be reported as the estimated design effect.

Based on data analysis certain participants may be identified for inclusion in the second qualitative phase of the study. This will be based on trends or patterns emerging in the survey data which warrant further explanation and analysis.

3.5 Phase ~~3~~2: Explanatory qualitative phase

3.5.1 Methods

The methods and participants of this explanatory phase will be refined based on the results of the KAP survey ~~and the findings and experiences of the first qualitative phase and the KAP~~**. However,** ~~potential~~ foreseen **methodologies include:**

a) **In-depth interviews with individuals to explore and explain the results of the KAP survey (specific participant groups will be identified based on survey results)**. KAP survey respondents may be recruited to participate in the second qualitative phase in order to explore interesting findings emerging from the KAP.
b) In-depth interviews with MSF (/other) service users to explore the 'critical path' that enabled them to access services (and how this could be further facilitated for other survivors).
c)
d) In-depth interviews with key stakeholders (NGOs, other entities working with SGBV) to explore results of the KAP survey and develop potential solutions to identified barriers
e) **FGDs with groups of women and men to develop potential solutions to overcoming barriers and facilitate service uptake (again, demographics of groups will be refined based on survey results)**

3.5.2 Sampling and recruitment strategy

As for the first qualitative phase, sStratified purposeful sampling will be used and participant recruitment facilitated by appropriate local gatekeepers (e.g. local leaders, MSF staff). Depending on the final methods and participant groups selected, sampling and recruitment will be as follows:

a) In-depth interviews with KAP respondents: Following analysis of the KAP data, certain respondents may be selected for a follow up IDI (who agreed to be contacted for this reason during the KAP survey). Individuals will be selected based on interesting findings/ specific dynamics emerging from the results warranting further exploration (e.g. individuals with high and low knowledge of SGBV services; individuals reporting very high or very low barriers to services etc.). They will be contacted by a member of the study team using the preferred contact mechanism (telephone number) as stated during the KAP survey. The study team member will explain that the research team would like to conduct an interview, and that participation is voluntary. Should the individual agree, a convenient time and place will be organised (considering issues of privacy and confidentiality). The consent process will be conducted in full, and if the participant gives his/her consent, the interview will take place.
b) In-depth interviews with MSF service users: Should interviews with MSF service users be included in the third phase of data collection, they will be selected from amongst MSF service users in collaboration with MSF team members who will identify potential participants (and evaluate those that are unwell or may be at particular risk of re-traumatisation due to participation) and aiming to ensure inclusion of individuals with a variety of characteristics (e.g. geographical area of origin, age, etc.). They would then be approached initially by a member of the MSF team who would give a brief introduction to the study and explain that a member of the research team would like to talk with them to explain it further and respond to their questions, after which they will have the option to consent to or decline participation (with no adverse consequence to their ongoing treatment with MSF). Should the individual agree, they will arrange a convenient time and ensure a safe and confidential location for the initial meeting (foreseen to be a room in the MSF clinic). The research team (qualitative study coordinator and translator/research assistant will then meet with the service user and explain the study in detail using the information sheet, including risks and benefits and with a particular emphasis on the voluntary nature of participation. Language will be used carefully in order not to presume consent, and after both meetings the individual will be given the option to decline, and/or take time to think about whether they would like to participate. Should the individual wish to participate the researchers will conduct the consent process and begin data collection.

c) In-depth interviews with key stakeholders: Participants will be identified purposively in order to include those that will provide the richest and most pertinent information during exploration of KAP findings. Recruitment may be facilitated by a member of the MSF team, or the study team will contact the individual directly as appropriate. A full explanation of the study will be given, and the consent process will be conducted.

d) FGDs: Participants will be selected at study sites (identified to ensure diverse locations within the MSF catchment area, e.g. different communes, socio-economic status etc.) and will be recruited through appropriate local gatekeepers (e.g. local leaders). After the consent process and discussions with the local leaders, we will explain that we wish to conduct FGDs within the community, and outline the groups we wish to hold (specific groups will be delineated in the field, but could consist of for example: two groups aged 18 to 30 (one of men and one of women); two groups aged 31 to 45 (one of men and one of women); and two groups aged 46+ (one of men and one of women). We will then ask the local leader(s) to facilitate the recruitment of participants. There is a risk that this method of recruitment will imply a bias (see section 4); this will be carefully observed during data collection and mitigated by conducting a robust sample through different community leaders and carefully explaining the study and its objectives to both participants and community leaders. FGDs will involve +/- 8 participants sharing the same characteristics, selected with the aim of ensuring maximum homogeneity within groups (in terms of age, education, social background etc.) to create optimum conditions for participants to be at ease discussing sensitive issues. Notably, discussions with men and women will be held separately.

~~Selection of participants will be informed by quantitative results, and will include the same participants from the survey should this be logistically feasible and deemed to add significant value in explaining quantitative results.~~

The estimated sample size will depend on the participant groups ~~selected based on the findings of the first two phases of the study~~. For both FGDs and IDIs we aim to reach theoretical saturation through concurrent data generation and analysis, or an iterative process, and so the final number of participants will only be known when this occurs and no new information is being generated. However, generally it is estimated that theoretical saturation can be reached after twelve to fifteen interviews and two to five FGDs.

~~(the same principles of saturation will be applied), as will the specific inclusion/exclusion criteria. However, it is important to note that for any group participants will be excluded if:~~

3.5.3 Inclusion and ~~E~~exclusion criteria:

In-depth interviews

Inclusion criteria:

- Individual selected based on results of KAP survey (to explore quantitative results) AND agreeing to be contacted for a follow-up IDI during the KAP; OR
- Key stakeholder (staff of organisations involved with SGBV/service provision; community leader etc.); OR
- User of MSF services; AND
- 18 years old and over; AND
- Well enough to participate (based on assessment of MSF team/other gatekeeper); AND
- Consents to participate in the IDI

Exclusion criteria:

- Under 18 years old; OR
- Does not consent to participate in the IDI

~~The participant is a pregnant or lactating mother~~

Focus group discussions
Inclusion criteria:

- Resident of MSF catchment area; AND
- Fitting criteria of group stratification (e.g. male or female); AND
- Over 18 years old; AND
- Well enough to participate (based on assessment of MSF team/other gatekeeper); AND
- Consents to participate in the FGD

Exclusion criteria:

- Under 18 years old; OR
- Does not consent to participate in the FGD

~~The participant does not consent to participate; OR~~
For participants aged under 18; OR
~~The participant is identified as too unwell to participate by the MSF team or other gatekeeper.~~
~~The participant is a pregnant or lactating mother~~

3.5.4 Data collection and analysis

IDIs and FGDs will be conducted using flexible participatory techniques. IDIs will take the format of a discussion and allow participants to focus on the issues they self-prioritise, although a topic guide will be used to ensure all relevant components are covered and so allow thematic comparison (see template in appendix 3). Interview questions may be reviewed and refined in response to themes arising during the course of interviews.
FGDs will be guided by a facilitator who will introduce topics for discussion and will facilitate lively and natural discussion amongst participants, based on a topic guide (see appendix 3). FGDs will explore normative perceptions (rather than seeking information in actual behaviours or individual lives) and will focus on exploring potential ways to overcome barriers and improve service uptake for SGBV survivors. Various techniques will be used to facilitate discussion, including 'free-listing' (where participants are asked to list as many options as they can) and 'ranking' (where options are ranked in order of priority/importance) and 'story completion' (where the beginning of a story is told and participants are asked to reflect on it and complete it as they see fit).
Topic guides for both IDIs and FGDs will be back-translated to ensure that meaning and context are captured. Local MSF teams will ensure appropriate and acceptable terms and expressions are used, and these will be back-translated and checked by another team member familiar with the study.
Both IDIs and FGDs will be conducted by the qualitative coordinator, with the assistance and translation support of a research assistant/translator (and possibly a note taker should all participants not consent to the audio recording of the FGD).
These activities will be audio-recorded and transcribed and translated when necessary from Hindi (or other local language as appropriate e.g. Bihari or Tamil) to English, including careful translation of idioms, metaphors etc. Translation/transcription will be undertaken by a team of transcribers recruited and trained for this purpose. Permission for recording will be asked at the start of the interview or FGD and if any participants do not consent to recording, notes of the interviews/FGDs will be taken.
Field notes will be taken throughout the data collection period and analysis will be ongoing. Data will be analysed using the Nvivo qualitative data analysis computer software package. Consent for recording the activities is explicitly mentioned in the consent form (see appendix 2). Analysis will be rooted in grounded theory; text data will be coded and recoded and emerging patterns, themes and relationships will be identified and labelled, allowing repeated patterns of meaning and conceptual categories to emerge from the text rather than from the mind of the researcher. Data gathered with different methodologies will be triangulated and negative or deviant cases analysed, and a subset of the data will be analysed by a second researcher to enhance reliability.

~~Data collection will use the same qualitative techniques outlined in the first phase of the study. Topic guides will be developed based on the findings of the first two phases and will be used to explain the findings of the KAP survey (IDIs) and possible ways to overcome barriers and facilitate service uptake (FGDs). Templates of these topic guides are outlined in appendix 3.~~
~~Activities will be recorded, transcribed, and analysed as outlined in the first qualitative phase (see section 3.3.4).~~

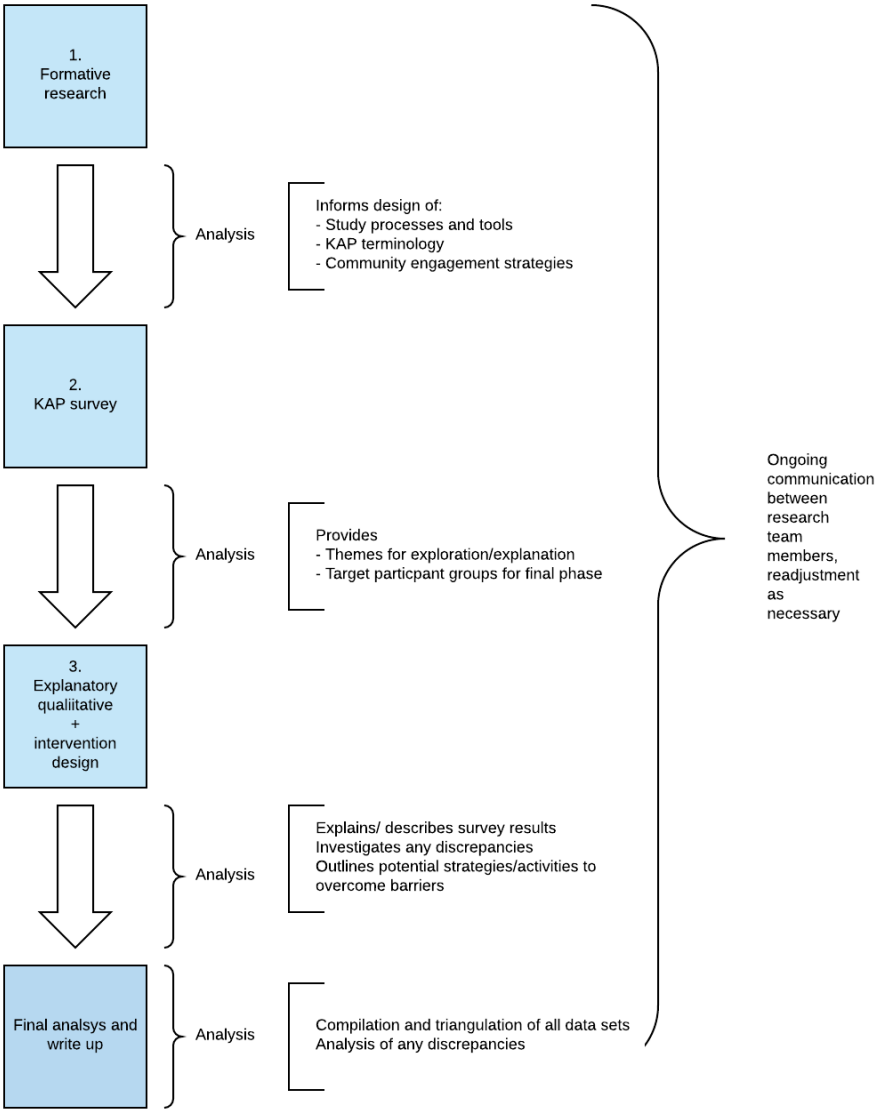
3.6 Data integration

In this study, quantitative and qualitative data will be integrated in various ways. The findings of the KAP survey will be used to inform the design and selection of participants for the second qualitative phase, which will then explore and explain the quantitative results. This will also allow us to triangulate findings obtained from these different methodologies and explore any discrepancies emerging. Lastly, the findings of the KAP survey will also provide the basis for FGDs during the second qualitative phase which will develop strategies for overcoming barriers and issues identified in the first quantitative phase.
Due to the sequential design of this study, we will have the opportunity to explore any divergences between quantitative and qualitative data in the second qualitative phase of the study, should any significant discrepancies arise. Should it remain impossible to reconcile the two data sets, this phase may be extended in order to explain this phenomenon. However, in the likely event that significant divergence remains or the results remain inconclusive, another study will be conducted to test the resulting hypothesis.

- ~~analysed qualitative and quantitative data will be integrated at different points during the research chronology. Formative qualitative research will inform the design of the KAP survey. Questions arising from the analysis of KAP survey data will be used to feed into iteration of themes explored in qualitative activities in the third phase of the study.~~

Practically ~~this~~ effective data integration necessitates ~~means cc~~lose collaboration between the qualitative and quantitative leads throughout the data collection period, with fixed points for interim analysis (~~e.g.~~ post-testing of tools; after each data collection phase).
~~Please see Figure 1 for an overview of our data integration plan.~~

~~Figure~~ 1~~: Data integration plan~~



Due to the sequential design of this study, we will have the opportunity to explore any divergences between quantitative and qualitative data in the final qualitative phase of the study, should any significant discrepancies arise. Should it remain impossible to reconcile the two data sets the final phase may be extended in order to explain this phenomenon. However, in the likely event that significant divergence remains or the results remain inconclusive, another study will be conducted to test the resulting hypothesis.

3.7 Procedures if the research is stopped/ incomplete

It is possible that for reasons beyond our control the research is stopped before data collection is finalized (security, etc.). We recognize this may compromise the validity of analyses and raise questions about dependability of any substantive conclusions generated from the incomplete data. Management of incomplete data will depend on the type of data already collected and the extent to which each data set is incomplete, however, to optimize input from participants we aim to utilize this data as far as possible.

For both quantitative and qualitative data, available data will be analysed and presented alongside a clear explanation of the limitations arising from its incompleteness. Should for example either the qualitative phase not be completed and the quantitative phase proceed, it may still be possible to provide useful reflections on quantitative data collection and results. Similarly, if the quantitative

phase cannot be completed, the available analyses may still produce interesting findings that lead to exploration in the final qualitative phase.

4 Study limitations

Results are not generalizable: This study aims to give an analysis specific to the context of Janghir Puri, Delhi India. The results will not be generalizable to the whole country, nor other regions in India. However, it may be possible to draw out themes or considerations relevant to SGBV programming in different contexts.

No documentation of prevalence: The study will not allow for conclusions to be drawn about the prevalence of SGBV in this area, as the focus is on knowledge, attitude, practice and perceptions related to SGBV and health-seeking behaviour.

Limited/biased disclosure: Due to the sensitive nature of SGBV it is possible that participants will not feel comfortable discussing the issue openly, particularly given low disclosure rates in many contexts, which may affect the data gathered. Whilst we are not asking participants to recount personal experiences of SGBV it is possible that the same factors affecting disclosure (e.g. fear of reprisals; feelings of shame or stigma; different understandings of what constitutes SGBV or the possibility of 'accepted' violence[13]) may limit the information they are willing to share.

Particular attention will be paid to these issues during planning and preparation for the study~~formative data collection~~ and pre-testing of data collection tools; ensuring careful attention is paid to understanding and using appropriate local terminology and definitions around SGBV. Specifically, the wording of introductory sections and questions, and the sequence of questions will be carefully considered in order to establish a rapport and trust, as well as elicit honest and complete responses[99] whilst ensuring robust processes and tools that ensure that participation is voluntary and no obligation is felt by the participant to consent. Efforts will be made to ensure participants feel comfortable to speak as openly as possible (e.g. recruiting FGD participants that share the same characteristics; reiterating issues around confidentiality, anonymity and disclosure etc.). Interviewers and translators will be selected to be as accessible as possible to participants (for example experience has shown that women and girls tend to prefer talking to other women[1]).

Translation/transcription issues: Using translators and transcribers may influence the quality of the research findings. The translation of standard tools may also influence local interpretations, definitions and questions, and so affect the comparability of data. However, this will be minimised by thorough training and ongoing supervision of the study team; careful translation including establishing local glossaries of agreed terminology; and cross-checking transcriptions through back-translation of a subset by another transcriber.

5 Quality control and best practice

Several strategies will be used to optimise the quality of data gathered in line with current best practice:

5.1 Minimising researcher bias

Mechanisms will be put in place to minimise analytical bias from the researcher's perspective (for example, a sub-set of qualitative data will be coded by a second researcher; ensuring an 'audit trail' which shows the development of the methodology and analysis through field notes etc.) Reflection of the role of the researcher as a confounding factor will be documented through field notes and considered throughout the analysis, acknowledging the potential for bias. Triangulation will take place by searching for convergence among the different sources of information gathered to form themes or categories within the analysis, and will include collaboration between quantitative and qualitative researchers[85]. Validation will also be established by including deviant cases and testing emerging theories, instead of only selecting examples which reiterate desirable points[95].

Ongoing collaboration between researchers and supervision will also ensure multiple perspectives are incorporated into data collection and analysis. Practically this will include regular debriefings with the research team and a feedback session with local co-investigators and MSF teams upon conclusion of each data collection phase and prior to analysis. Peer debriefing, including oversight by an impartial researcher who will examine the transcripts, final report and general methodology and provide sparring and feedback will enhance credibility and ensure validity. Furthermore, sharing the study outcomes with participants can also enhance validity of our research by allowing respondents to comment on the accuracy of our data and interpretations[100].

For the qualitative phase, data collection teams will be trained in interview techniques that do not lead or influence participants. The questionnaire instrument is also based on objective question structure (see section 5.2).

5.2 Development and pre-testing of tools

Template tools have been developed based on thorough desk review, including of current international standard data collection instruments, combined with the input of MSF and external stakeholders at various levels, and the findings of an SGBV assessment conducted by MSF in Delhi in 2014. The KAP survey is designed to balance clear, understandable, easily answered questions for respondents in a format that is easily followed by interviewers. ~~These tools will be adapted based on the findings of the formative research.~~ Tools will ~~also~~ be pre-tested in a pilot survey to refine methodology, sequence of questions and response categories, and ensure that interpretation of questions and translation of specific terminology and definitions is consistent and clear. It will also assess the way the activities are perceived by participants in terms of emotional response, burden and sensitivity to the topics discussed[99]. Any context-specific modifications will be justified and documented.

5.3 Selection, training and supervision of study team

The study team will be carefully selected to ensure appropriate characteristics (gender, language etc.) as well as 'soft skills' such as an ability to use non-judgemental language and tone; communication skills and empathy.

Notably, given the linguistic diversity of Jahangipuri we aim to ensure the research team includes members able to communicate in languages of potential participants (e.g. Bihari, Tamil). For the larger KAP survey team this is easier to ensure, however for the smaller qualitative data collection team this may require recruiting and training a small 'pool' of research assistants, allowing us to match the language of participants with the translation capacity of the research assistant.

A thorough training will be conducted. This will include an orientation on SGBV; ethics; research methods; consent process; study protocol and tools; practical exercises and role-plays; stress management; managing difficult situations (e.g. distressed participants or community members), Psychological First Aid (PFA), etc.[4]. The content ~~for the second and third phase teams ww~~ill be developed in collaboration with the MSF field team, and may be refined for the qualitative data

collection team based on experiences during the first KAP phase~~refined based on information gathered during the formative research phase~~. The training will be given by MSF in English or Hindi, ~~the local working language,~~ with translation if needed. An interviewer's manual will also be developed to complement the KAP survey and qualitative methodologies to provide easy guidance notes for data collectors.[99] Please see section 10.2 for details of the proposed training.

Pre-testing the tools will also provide an opportunity for on-the-job training and to share challenges faced and lessons learned amongst the study team, and so ensure early resolution of any concerns or discrepancies in using the research tools. Regular debriefings will be conducted during data collection to ensure a consistent approach and ongoing quality checks, and provide the opportunity for continued training and mentoring.

5.4 Data quality control

For quantitative data, the study coordinator and/or quantitative researcher will review samples of questionnaires each day to check for inconsistencies in the responses recorded and for questions that were not completed. The study teams will also check each other's surveys at the end of each day to ensure consistency and accuracy.

For the qualitative data, a subsection of the transcriptions will be double-checked by another transcriber to ensure that transcription is consistent and of a high quality. If there are inconsistencies found, then transcribers will work together to finalise the transcription. For the analysis, a sub-set of data will be re-coded by a second researcher.

6 Risks, ethical and safety issues

The study protocol will be submitted to the Ethics Review Board of MSF and Ethics committee of Dr.B.R. Ambedkar Medical College, Rohini, New Delhi.

The study will be conducted in accordance with the World Health Assembly of 1975 concerning ethical aspects in human tests. The Helsinki declaration[101] principles will be followed, including:

- Researchers will protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of participants.
- The study is based on thorough knowledge of the literature and other information.
- A research protocol has been established and submitted for consideration, comment, guidance and approval to the research ethics committee of MSF, and will be reviewed by the ethics committee of the designated country of study.
- The research team has appropriate qualifications to fulfil their role; they will be trained where applicable and supervised by the co-investigators.
- The population stands to benefit from the results of the research; through improved access to SGBV services.
- The predictable risks and benefits for study participants have been assessed and described in this protocol. The importance of access to health care for survivors of SGBV outweighs the risk which can come with this study (emotional reactions, reliving experiences of SGBV, confidentiality breach – e.g. in FGD) and the risks can be mitigated: Confidentiality rules, no questions asking for disclosure, emotional support available.
- Participation is voluntary, and precaution will be taken to protect the privacy and confidentiality of personal information of participants.
- All participants will be informed on the aims, methods, potential risks and benefits of the study, as well as their right to refuse to participate and to stop at any time. Only hereafter, informed consent will be requested.
- The results of the study will be shared with participating communities through a report/poster.

Specific attention has been given to ethical issues linked to researching SGBV given its sensitive nature and the specific challenges data gathering poses, and to ensure the physical, psychological and social well-being of participants, communities, and those involved in gathering the information itself, in line with existing guidance and best practice[4,23.]

Procedures to manage any ethical or safety issues will be refined with MSF teams during thorough planning and preparation prior to commencing data collection~~the first formative phase of data collection~~, in line with existing MSF protocols and procedures (security, medical etc.) and MSF management lines (see draft SOP in appendix 4).

Based on thorough literature review and discussion with MSF team the following ethical issues and risks common to all data collection methods have been identified.

6.1 Risk of distress to participants

Whilst participants will not be asked to explain their own experiences of SGBV during this study, questions may be intrusive and upsetting for those who may have personal experience of the issue and may result in participants disclosing incidences of SGBV. There is also a risk that participation may be associated with instances of SGBV, such that participants may be stigmatised, either during the data collection or following the dissemination of results. The following mitigation strategies are foreseen:

Comprehensive explanation and informed consent process: we will ensure clear and thorough explanations are given to both communities and participants, including the rights of participants, the implications of partaking and explain that there is no consequence for people who decline

participation. In addition, we will ensure it is clear at the outset that the aim is not to discuss personal experiences of SGBV, but to collect general information to improve our understanding of barriers and collect potential solutions. We will ensure that our consent process is carefully phrased and does not assume consent.

Community engagement and consent: By ensuring community-level understanding of the study (including participant recruitment) we hope to minimise the risk that any individual would be stigmatised as a result of participation. Equally, dissemination of findings will be carefully managed to ensure participants cannot be identified from their stories, see section 6.9.

Appropriate and pre-tested tools and questions: we have developed questions for both qualitative and KAP data collection focus on capturing social norms and care seeking and do not tacitly imply disclosure of experiences. Tools will ~~be strengthened by data collected during formative research and again~~ refined through pre-testing, including checking with data collection teams and participants how they feel during data collection and any pressure to disclose personal experiences.

Preparation of research team: we will ensure that interviewers and translators are carefully selected, are appropriate to the context, receive proper training and support and have appropriate interviewing skills (including an ability to use non-judgemental language and tone; communication skills and empathy). Interviewers will be trained to be aware of the effects the questions may have on participants and how to respond, including role-plays and managing situations of distress. Training will also include exercises to help field staff examine their own attitudes and beliefs around SGBV to be aware of any potentially harmful attitudes or perceptions which may distress participants or affect findings.

Sensitive data collection: A good rapport and environment of trust will be established and carefully worded explanations and introductions to the study and particularly sensitive questions will be used, including reminding the respondent that s/he has the right to refuse to answer any question and can choose not to continue the interview or to stop at any time. If a participant becomes upset during the interview, the interviewer will offer the opportunity to take a break or discontinue. Given that research shows that trauma survivors see their participation as important in helping others[85] we will explain thoroughly the potential this study has in this regard and aim to end the interview on a positive note[20]

Foreseen psychosocial support: we will also ensure that both immediate and longer terms support is available for any participants that become distressed. This will include that the data collection teams are trained in psychological first aid. As the study will take place in MSF's catchment population, participants can also be referred MSF services for medical and psychosocial support as needed. We will also ensure that both communities and participants have access to information about MSF's SGBV services and support irrespective of participation, should the presence of the MSF team or awareness of the study subject cause distress to non-participants.

6.2 Risk of distress to study team

There is a risk that the study team might also suffer from stress or distress through hearing potentially upsetting stories[2] or managing difficult situations.
To mitigate this, training will include a stress management component and emotional support will be provided through regular debriefing sessions. Counselling/psychosocial follow-up will be available through routine MSF activities should it be requested/needed by any team members. Particular consideration will be given to the possibility that members of the study team may have experienced some form of SGBV themselves so may need specific support[4].

6.3 Risk to safety/of harm to participants and study team

It is noted that in researching violence 'the safety and even lives of women respondents and interviewers may be at risk'. Given the sensitive nature of SGBV it is possible that research activities may trigger issues affecting the safety of participants, for example they may fear of reprisal and recriminations, as well as stigma and shame in discussing such issues. Equally, in the instance that there is a situation of past/ongoing SGBV within the household/community, there is a potential risk of harm to the participant should the perpetrator react badly to the discussion (e.g. with aggression or violence, during or after our visit). There is also the risk that discussing this sensitive topic could create a 'backlash' amongst the community or a strong reaction amongst more conservative groups who consider the study inappropriate or threatening, which may pose a risk to participants and/or the data collection team and/or other MSF staff.

The safety and security of all those involved in the study is of paramount concern, and will be continuously monitored. Whilst standard MSF security protocols will be strictly observed additional safeguards linked to the study have been considered:

Community engagement and ~~consent~~authorisation: this will be carefully negotiated in close collaboration with MSF project teams and the community during thorough planning and preparation prior to commencing data collection. ~~and informed through the first formative research phase for the second and third phases of data collection.~~ Meetings will take place with community leaders to discuss the study (and to intro~~o~~du~~e~~ce MSF tho those who are not already familiar with the organisation~~those who do not yet know MSF, we will introduce).~~ In doing so we recognize that this context is complex and heterogeneous, and ensuring consultation with local leadership will require sensitive negotiation and the inclusion of a diverse range of official and unofficial figures. The MSF outreach/IEC team has established links with a diverse range of leaders which will be drawn upon during this process. This will ensure the inclusion of both 'official' leaders such as ward leaders; elected local body representatives; and block representatives, as well as 'unofficial' leaders such as religious leaders (imams, priests); unelected political leaders; women's health workers (e.g. mitanin, ASHA); and other members of 'grassroots' NGOs/CBOs). The team will meet also with other community key stakeholders such as Traditional Birth Attendants, community health workers, etc., and to be informed what role they would like to play in the study, as well as beyond the study.

The authorization process will involve consulting with identified leaders on other potentially influential figures in their area that should also be involved in the process.

The team will meet also with other community key stakeholders such as Traditional Birth Attendants, community health workers, etc., and to be informed what role they would like to play in the study, as well as beyond the study.

We foresee that prior to commencing data collection the study will be explained to community leaders who will have the opportunity to ask questions and express thoughts and concerns ~~about the study subject and processes, and community consent for participation will be negotiated.~~ For each data collection site we aim for community leaders to agree to support the study; should any leaders oppose the study or wish their community does not participate, further consultation would take place aiming to reach a consensus of participation. However, should resistance continue, a decision will be taken on whether or not to include the community in the study, after consultation with the mission team and careful consideration of the risks and benefits. It is possible that the community in question may be withdrawn from the study, and this will be acknowledged in the limitations. Concerns raised by community leaders with respect to cultural sensitivity will be addressed by suitably modifying interview guides.

Careful framing of study subject: Much guidance on researching SGBV suggests framing studies using a 'safe' name, for example WHO suggests presenting SGBV studies as research on health, well-being and life experiences.[23] However, this must be appropriate to the context and any use of deception comprehensively justified after careful consideration of questions such as: 'Is there any need for incomplete disclosure? Would some form of deception be used? Would this harm the research participants, the researchers, and/or society in general in any way?'. However, in the Delhi context 'sexual violence' has been the subject of ongoing communication campaigns and media coverage. The term has been used openly when communicating with the community and stakeholders and this is seen to pose minimal risk to participants, research teams or MSF. However, during planning, preparation and data collection careful attention will be paid to any potential risks or

harms, including the risk of stigma/discrimination, or risk to safety/wellbeing of any individual or groups of individuals, linked with conducting the subsequent data collection will be carefully evaluated (and weighed against the risk of limited disclosure should framing the study under a 'safe' name be re-considered).

~~Any potential risks or harms linked to limited disclosure will be evaluated against the risk of stigma/discrimination, or risk to safety/wellbeing of any individual or groups of individuals, ensuring that any 'deviations from the truth will not impose any short or long term hazard for the participating subject'. This concern is clearly inherent to this study, where the reverse could be true: namely that public knowledge of the SGBV focus of the study could potentially lead to harm or stigmatization for the participants. Voluntary and informed participation will filter participants fearing stigmatization.~~

Training of study team: Training of the study team will include understanding of and sensitivity to political, sociocultural, security and economic factors that may affect the safety and security of those involved. Interviewers will also be trained to terminate or change the subject of discussion should an interview be interrupted at a sensitive moment[102].

Confidentiality, privacy and anonymity: This will be protected as far as possible; see section 6.9.

Ongoing monitoring and follow up: The safety and security aspects of data collection will be monitored and evaluated on an ongoing basis. All concerns or incidents will be reported through standard MSF incident reporting mechanisms, and if it is deemed that the safety of the participants or the study team is compromised in any way the activity will be stopped or restructured to address any concerns. Strategies for responding to potential security threats will be formulated in advance, in line with MSF security protocols[1]. We will also explain that participants may approach the MSF team at a later date should any negative unintended consequences occur as a result of their particpation[9].

Careful sharing of results/dissemination: Sharing findings may imply risks to individuals, communities or MSF staff or programmes, so reporting results and/or disseminating data will also be subject to the same process of continuous review and evaluation to ensure that it is both safe and appropriate to do so[1].

6.4 Risk of disclosure of personal experience of SGBV

It is possible that participants may disclose their own experiences of SGBV, despite clear explanation that this is not the aim of the study. To mitigate/manage this, the following measures are foreseen:

Careful explanation of the study: Interviewers will explain the objective of the study, including the risks and benefits. It will be made clear that the aim is not to document personal experiences of SGBV; however, they may share them only if they would like to and feel comfortable to. It will also be explained that assistance is not linked with participation; information about MSF services will be shared verbally and with a short information sheet; and people may request assistance without disclosing details of their experiences to the research team or participating in the interview/FGD. They may also approach a member of the research team following the interview/FGD and confidentially request assistance, again without disclosing any details of their experience.

Support and referral: The data collection team and MSF counsellor will be prepared for the immediate support of any participant disclosing an instance of SGBV. Following that, this will be available through referral to routine MSF activities, in line with the MSF SGBV guidelines and comprise of medical care and emotional support[103]. Referrals for follow-up services will be confidential and only made with the consent of the individual[1]. Interviewers will be trained in how to handle a disclosure of this nature in a sensitive and ethical way. This will include consideration of any legal issues or obligations around reporting abuse, MSF protocols and respecting the principles of autonomy and confidentiality[4].

In line with best practice we also plan to use a short information sheet for participants with details of MSF services and other resources~~. This will be developed with the MSF team during the formative~~

~~research phase of the study.~~ (appendix xx). The study team will also be briefed on appropriate referral pathways should they encounter individuals requiring medical attention unrelated to SGBV during the study.

Note: Based on previous SG~~V~~BV research it is suggested that there is little uptake of available referral services, although there only anecdotal information available about the reasons why . Thus, should a participant be referred to MSF services we will also ask if they consent to follow-up and to their data being kept for this purpose. We will then follow up with the MSF team at a given point post data collection to establish how many of those referred actually sought services.

Legal management of disclosure: In India laws on the mandatory reporting of the discovery in research of the criminal sexual assault state that it is mandatory to report SGBV against victims below age of 18 years only. We will not share any information gathered during the studies with authorities or other external agencies.

If a participant asks assistance to report a case of SGBV to the police or other authorities, MSF will provide information and support, in line with MSF SGBV guidelines. Likewise, if the research team is informed of SGBV against survivor less than 18 years of age, MSF will offer and provide the clinical care and write the Medico-Legal Certificate (MLC) following MoH and MSF SGBV guidelines **and offer clinical care.**

6.5 Risk of disclosure of knowledge of SGBV

It is also possible that participants may disclose knowledge of instances of past/ongoing SGBV between third parties. Management of this situation will be carefully considered in line with MSF protocols. In such an instance, expert advice would be sought aiming to respect the principles of confidentiality and do no harm, whilst also avoiding collusion and putting others in situations of ongoing risk[102]. Legally, the research team is not obliged to act on the information. However, the informant (participant) will be provided with information of MSF clinical services and advised to motivate the survivor in seeking medical help.

6.6 Risk of disclosure of perpetration of SGBV

It is possible that during our activities a participant discloses they have committed or perpetrated an act of SGBV. As above, management of this situation will be carefully considered on a case-by-case basis, in line with MSF protocols such as writing and reporting of sexual violence including the Medical Legal Certificate, in consultation with the MSF Project and Medical Coordinator and seeking expert advice if necessary.

6.7 Risk of stoppage of study due to community opposition

Given the sensitive nature of the research, one possible reason for stoppage of the study is community reaction to the questions asked to participants result into the stoppage of research. This issue will be considered in more detail in collaboration with the mission team during planning and preparation for ~~the formative research~~data collection ~~phase~~, and its management will depend on the exact circumstances or manifestation of the opposition.

6.8 Risk of low participation rates

It is possible that participation rates for the survey and/or interviews fall below expectation. Should significant problems be faced in recruiting participants we will pause the study and go through a process of consultation with communities and/or relevant stakeholders to ascertain the reasons for these difficulties. If this can be overcome through a change in our approach/recruitment processes, then this will be made and we will recommence the study (with a careful analysis of any ethical issues and the voluntariness of participation).

If this cannot be overcome we will a) ascertain if/how data collected this far can be analysed (see above section on incomplete data), and b) assess if the study as a whole can proceed without this component, albeit with modified objectives/results (for example, if recruitment for the KAP survey is problematic, it may still be possible to utilize qualitative data to meet some of the study objectives and inform MSF activities; if recruiting for the IDIs and/or FGDs is problematic, the KAP data will still provide useful insight; etc.).

6.9 Confidentiality, privacy and anonymity

Protecting confidentiality and ensuring privacy and anonymity is essential to ensure both participants' safety and data quality. The following provisions are foreseen:

Private interview locations: All individual interviews and group discussions will be held in carefully selected locations, including in the MSF community room and spaces provided by other NGO's, which are appropriate to the study site to optimise safety and privacy and minimise unnecessary attention or suspicion. Surveys, IDIs and FGDs will be conducted in complete privacy (except for children under the age of two). In cases where privacy cannot be ensured, interviewers will be encouraged to reschedule the interview for a different time or place. Achieving this level of privacy may be difficult and may require more careful consideration and/or resources than might be needed for research on less sensitive topics[4]; this will be given careful consideration during ~~the formative research phase~~planning and preparation for the study. Previous strategies such as holding interviews outside or in other appropriate spaces will be considered, in collaboration with the mission team.

Confidentiality limitations for FGDs: Prior to commencing the FGDs participants will be asked not to repeat anything discussed outside the group, and not to divulge the identities of other FGD participants. However, all participants will be made aware that confidentiality cannot be guaranteed and this is specified in the consent forms and information sheets.

Re-contacting phase 1 participants for inclusion in phase 2: Participants in phase 1 KAP data collection ~~–~~will be asked if they are willing to be contacted for an IDI as part of phase 2. KAP respondents who agree to this will no longer be anonymous, which poses potential risks. Specifically breaches in data storage and security could lead to the identification of participating individuals and put them at significant risk. However, the linkage between datasets potentially adds value to the study. As a result, anonymising codes or record numbers will be used as far as possible. Individual identifying data will be separated from KAP data immediately following data collection and stored electronically in a 'key' document linking a number to personal identifiers. The original identifying data will be destroyed and specific measures taken to ensure the security of the 'key': it will be stored in a password protected file, on a password protected and encrypted computer which will be located in the MSF office in a locked room when unattended).

Training of research team: All members of the research team (including transcribers) will be thoroughly briefed on issues of confidentiality during the training and required to sign a confidentiality agreement. Interviewers will be trained to guide the discussion away from stories of personal experiences or any conversation that may identify individuals in the community.

MSF identification: ~~The issue of MSF identification and visibility will be considered during the formative research phase, in collaboration with the MSF team. This will involve a careful analysis of the risks and benefits of wearing MSF ID. However a~~As MSF outreach team uses MSF ID in there IEC and outreach work we foresee no major issue with this, however ongoing monitoring will allow us to amend his approach if necessary.

Anonymization and confidentiality of data: All data will be anonymised to ensure it cannot be linked to a specific individual or group of individuals, including documents and audio recordings, and will be stored with an individual code. All data will be stored in password protected files. Upon completion of the study, the identifiers and the household lists will be destroyed. Recordings, notes and consent forms will be stored securely by MSF UK for 5 years after which point they will be destroyed.

Mitigating risk of residual disclosure: Particular care will be taken during the presentation of the research findings to ensure that the information is sufficiently aggregated so that no single community or individual can be identified. Informed consent will be obtained from all participants on whether or not they agree to be quoted. Specific quotes and examples will be considered and if they could lead to identification of respondents via deductive disclosure the details in the data will be modified.[100]

Breaking confidentiality: In certain very exceptional circumstances confidentiality may be broken, in line with MSF protocols and best practice, should disclosure present a serious and potentially life-

threatening risk to the participant or another individual or group. For example, if a participant threatens his/her own life; a participant threatens to seriously harm another person; or when child abuse or neglect is suspected and it is in best interest of the child .

6.10 Informed consent

Informed consent is the voluntary agreement of an individual who has the legal capacity to give consent. To provide informed consent, the individual must have the capacity and maturity to know about and understand the study and the implications of participation and be legally able to give their consent. In India, informed consent can be provided by any participating individual above the age of 18 years.

~~Written~~ Verbal consent will be sought from all individuals participating in the study. Comprehensive information sheets and consent forms have been prepared and adapted to each activity and participant group (see appendix 1 and 2).

Environment: The environment where the process of consent is conducted will be a private, confidential, and 'safe' setting.

Explaining the study: The study will be explained in detail to all participants in the language they are most comfortable (Hindi, English or other language as appropriate), including the objectives, risks, benefits and voluntary nature of participation, and they will be given the opportunity to ask questions. Participants will also be informed that data collected will be held in strict confidence. To ensure that the participant is aware that the study includes questions on potentially sensitive topics, the interviewer will forewarn the participant that some of the topics are difficult to talk about. The respondent will be free to terminate the interview at any point and to skip any question that he/she does not want to answer.

Emphasizing voluntariness: Researchers will take necessary steps to minimize the possibility that participants (especially from vulnerable communities) will feel obliged to participate either due to pressure from community/MSF gatekeepers or from the researchers themselves. It will also be explained that assistance will be available regardless of participation (or refusal) and that no adverse consequences will occur as a result of refusal to participate. Questions regarding consent in the ICF are phrased in a way that does not predicate consent, and ensures potential participants have the space to ask questions and/or decline to participate.

Ensuring participant's comprehension: researchers will aim to ensure that the prospective participant has sufficient knowledge and comprehension of all the elements of informed consent to enable him/her to make an informed decision whether to participate in the research. The fact that an individual is prepared to verbally consent ~~sign the ICF~~ and has no unanswered questions does not necessarily represent sufficient evidence of an adequate level of comprehension. Rather than simply confirming the participant's consent, the prospective participant will be asked to explain in his/her own words their understanding of the research and implications of participation. Should comprehension be lacking or inaccurate the team will provide further explanation until they feel it is adequate.

Documentation of informed consent: The individual who assumes responsibility for documentation of informed consent ~~and the consenting participant~~ should sign and date the ICF, in the presence of the participant. ~~each other's presence. Should the participant be unable to sign his/her name a thumbprint will be used.~~

Consent for audio-recording: Both IDI and FGD participants will be asked specifically to consent to the audio-recording of interview/discussion. Should one or several participants decline, notes will be taken of the activity.

Consent process for illiterate participants: In the case of participant illiteracy, the study procedure will be explained to the participant in language so chosen by the participant. This process will be witnessed by an impartial individual whose presence is not objectionable to the participant. ~~The participant can consent via a fingerprint. Signature of impartial witness to the consent form will be obtained.~~

7 Benefits

Overall we feel that the benefits of this study - with the potential to safe life, alleviate suffering and restore dignity- outweigh the potential risks. Benefits can be seen at multiple levels:

Individual level: Participation may benefit individuals as it provides opportunity to share information about SGBV and MSF's services, and so may lead to improved access to/uptake of support and services. ~~Furthermore, e~~Evidence from literature also suggests that participation in research can in itself be felt to be beneficial to women surviving violence (for example cathartic, empowering, contributing to longer term change) . Furthermore, whilst it is possible that there is no direct benefit to the research participant, they may benefit indirectly as their participation may help to identify factors that could improve SGBV service utilisation and acceptance of such service in the near future.

Community level: Communities will benefit from participating in the study through raised awareness of SGBV and the treatment, services and support available. It is also possible that the study will catalyse change in the medium/longer term; for example, raising awareness of the issue of SGBV may open dialogue/lessen taboo/stigma and so facilitate access to services for survivors, and potentially prompt communities/other local organisations to contribute to improving the situation.

MSF programming: The study will provide essential data for the MSF team in India. It will establish an evidence base on which to create strategies for improving the uptake and effectiveness of the SGBV services provided. Furthermore, by extrapolating themes and considerations, it is possible that findings may also contribute to new ways of understanding and responding to SGBV in different countries and contexts.

Policy and provision of services: This study will also provide important data to support policy development and advocacy to work with the MoH towards provision of services and increased uptake.

8 Collaboration and community engagement

8.1 Institutional collaboration

This study will be carried out as collaboration between MSF-OCA, and Baba Saheb Ambedkar Medical College, New Delhi. The collaborators – having extensive experience in the subject and context, will be part of the investigation team. The collaborators will provide scientific and strategic support to MSF-OCA. The collaborators will participate in community meetings, data collection, interviews and process of data analysis. The collaborators will be co-authors of all publications and reports thereof.

MSF-OCA is the study sponsor and is responsible for the funding. It oversees data collection, analysis and report writing. Permission for publication must be obtained from MSF OCA.

A Data Sharing Agreement per MSF protocol will be signed between MSF and the collaboration partners.

Study results will belong to MSF-OCA.

8.2 Community engagement

Community-engaged research approaches involve members of the community in various aspects of a research endeavour to improve the health of populations, and in India have shown to have had many benefits, learning new insights about the community and facilitating development of community-engaged interventions. In addition, engagement of the community has led to community empowerment and generated a deeper interest in the health problem under study among the participants. This empowerment enabled community members to act upon other problems of interest to the community.
We aim to engage with, and gain community support for the study. Authorities and communities (such as local leaders, religious leaders, opinion makers) in the study area will be informed (information sheet shared, see information sheet in appendix 1) about the purpose of the study and their endorsement will be sought e.g. through a community meeting. This will explain the study in its broader sense. Everyone will be invited to discuss any concerns with the study coordinators. Furthermore, it will be clearly stated that they are freely allowed to decline the participation of their cluster without any consequences or penalty.

9 Dissemination and implementation of findings

Beyond the benefits of the study, the obligation to ensure results are properly interpreted and benefits are optimised and used to feed into advocacy, policy and programmes is recognised. Through the development of a dissemination plan and the involvement of consultative stakeholders in its design we will outline how findings will disseminated and implemented.

Project level: Findings will be used to inform MSF service provision, specifically IEC strategies. They may also influence MSF policy and practice in other contexts.

Policy level: Through collaboration with the MoH and sharing of findings with national level stakeholders, findings will be used to inform policy and advocate for improvements/changes in linked with study results. This will be done by holding meetings with relevant stakeholders to explain the findings and sharing a 'policy brief' containing a summary of relevant findings. We will ensure that the findings reach relevant users, and that they are communicated and understood clearly[66] through clearly produced documents/outputs, meetings and presentations, and that all data is anonymised.

Community level: Once information has been shared with the local ethical committee and the MoH, then the information will be shared with the community. Meetings will be held with community leaders and a summary of the results will be shared alongside recommendations/ plans/efforts to improve services by MSF. In addition, small group meetings will be organised in the community to share the study findings. These will be integrated into ongoing MSF activities in the community combined with information about services available to survivors. From the outset, we will also explain clearly that as MSF we cannot respond to all needs but are working with the MoH and other partner organizations to support the establishment of health services. By sharing findings with participants and communities we hope to increase awareness and uptake of services. Findings will also be critical in informing appropriate MSF community engagement and health promotion/education strategies, aiming to equip women with information that will facilitate decision making. An important part of the study explores how the community themselves see the best strategies to improve utilisation and acceptance of services. We will use these findings to ensure the community are part of the solution and continue to monitor their perspectives with regards to how we plan, offer and implement services.

The content of the summary will be carefully reviewed by MSF teams and collaborators, and any highly sensitive or problematic results may be excluded should they pose a potential risk to individual participants or communities. We will also 'pilot' the dissemination of findings and ask feedback to ensure the material and presentation is acceptable; should any concerns be raised the content or presentation will be altered and the summary re-piloted.

Participants: Individual participants will be given the option to receive a summary of findings, and to leave their contact details for this purpose, as part of the consent process. This will be reconfirmed at the end of the interview. The exact strategy for this will be adapted based on the content of the findings and the participant group.

10 Implementation of the study in the field

10.1 Study team

The human resources foreseen for the study is as follows:

1 x principal investigator
Qualitative team
1 x qualitative coordinator
2 x research assistants/translators
4 x transcribers/translators
Quantitative team
1 x quantitative coordinator
12 x KAP data collectors

The study will be overseen by the **principal investigator.** They are overall responsible for the final version of the protocol, overall quality of the study and data analysis, and the final report. They will oversee the whole study including:

- Preparation of all necessary documents (protocol, questionnaires, informed consent forms)
- Preparation of the field component of the survey (training of the data collection teams, logistics, materials) together with the MSF team in the field
- Follow-up of the field component of the survey
- Data entry
- Data analysis
- Report writing

Study coordinator-quantitative (x1): Leads the quantitative component of the study, including protocol development; recruitment and training of study team; supervision of data collection and survey team; data analysis and contribution to write up. They directly lead one data collection team and supervise the other quantitative team leader and ensure quality control and consistency between the two data sets.

Study coordinator-qualitative (x1): Leads the qualitative component of the study, including protocol development; recruitment and training of study team; supervision of data collection and survey team; data analysis and contribution to write up. They directly lead one data collection team and supervise the other qualitative team leader and ensure quality control and consistency between the two data sets.

KAP survey team: Each data collection team will be composed of two data collectors. Given the timeframe of the study it is estimated that 6 data collection teams of two people will be needed, so a total of 12 data collectors. They will be responsible for conducting the surveys, accurately recording data and contributing to planning and debriefings.

Qualitative data team:
Two research assistants/translators will be recruited to translate interviews and assist the qualitative researcher with data collection as needed. This will include one male and one female, who will assist/translate interviews/FGDs as appropriate to the participant/group (e.g. all activities with female participant's will be conducted with a female translator; activities with men with a male). They will be responsible for supporting recruitment of participants, translating interviews and FGDs, and contributing to debriefings and ongoing analysis.

A team of four transcribers will be recruited to transcribe the interviews and FGDs and translate them into English. Terms of reference for the qualitative research team are in appendix 6.

10.2 Training of data collection team

Quantitative component

Four days training will be given to all data collectors to familiarise them with the background of the survey, the questionnaires, the tablet and software, the information sheet and the informed consent form. The training will be given in English with translation if needed by the principal investigator. It consists of an intensive review of the questionnaires and the information sheet including role-plays. As the interviews will be held in the regional language, the principal investigator should ensure that all data collectors are using the same and correct wording for providing information to the households and for the interviews.

The 2-day training will be followed by 2 days for a pilot survey. The pilot will be conducted in a village/ section not included in the study and selected after study cluster allocation has been performed. The pilot survey allows for the testing and possible final adaptation of the questionnaires and informed consent to field conditions. We intend to conduct a minimum of one test interview for the maternal and child health components per data collection team (with 8 teams), so a minimum of sixteen pilot interviews. Training and implementation will be conducted in collaboration with the local MoH.

Qualitative component

For the ~~first~~ qualitative component, a 4-day training will be conducted followed by a one day pilot of the topic guides and a further 1 day of debriefing and revision of tools if necessary (6 days in total).

Pilot interviews /FGDs will be held to pre-test the tools with each participant group. Following the pilot a debriefing/review of the pilot will be conducted to ensure appropriateness of tools, consistency between data collection teams and address any challenges faced. Throughout the data collection tools may be refined through daily discussions of interviews and issues emerging.

TABLE 2: OVERVIEW OF TRAINING/PILOT PLAN FOR QUALITATIVE DATA COLLECTION

Day 1	• Introduction to MSF and MSF in India
	• Introduction to study and methods
	• Introduction to qualitative research
	• Introduction to SGBV
	  · Preconceptions/risk of bias
	  · Dynamics in India

Day 2	• Risks and obligations of research team (brain storming)
	• Ethical considerations, including:
	  · Confidentiality
	  · Informed consent
	  · Disclosure and referral
	  · Risks and benefits

Day 3	• Interviewing and translating skills • Managing difficult situations (role play) • Stress management • Psychological First Aid • Practical planning of data collection (daily plan, community engagement etc.)
Day 4	• Run through and discussion of topic guide • Role play consent process • Practical exercises with topic guide, audio recording • Feedback, questions and lessons learned
Day 5	• Pilot of topic guides
Day 6	• Review of pilot: challenges and lessons learned

	• Discussion of topic guide and amendments necessary (language, discussion flow etc.) • Definition of ongoing supervision and support

Transcribers will also receive a one day training including background information on MSF, the study, and practically focussing on transcription techniques and research ethics, with a focus on privacy and confidentiality, and data management and storage.

Training materials developed specifically for this context will be used, and training methods will be participatory with a focus on practical exercises (e.g. role play, problem solving, discussion etc.) and provide opportunities for the team to reflect upon and share their existing knowledge and experience. This will be supported with ongoing supervision and support, largely through daily debriefings, to address any issues arising.

~~For the third qualitative phase of the study, training will be adapted if the same team are involved in data collection. A recap of the training will be provided, followed by roles plays with topic guides (1 day), piloting tools (1 day) and debrief (1 day), as per the training plan outlined above.~~

10.3 Suggested MSF support in the field

- Support in contextualising the study and tools as appropriate for the study site, including establishing referral pathways, security analysis, context briefings etc.
- Administrative support for study preparation at the field level and during the field component, such as presentation of the survey protocol to the ethics committee of the MoH and payment of data collection teams.
- Human resource support, such as recruiting the data collection team as needed.
- Logistical support for study preparation at the field level and during the field component, such as organizing sufficient cars and drivers, providing communication tools and MSF ID (e.g. aprons, vests or arm bands ~~should these be deemed necessary after local consultation during formative data collection))~~ to the data collection teams, providing stationary and printing the questionnaires and consent forms.

10.4 Study planning

See **Table** 3 for a preliminary timeframe of the field component per study site. Please note, this will vary according to factors specific to each study site (e.g. transport, in-country travel, limitations on accessing target groups etc.).

TABLE 3: PRELIMINARY PLAN OF THE FIELD COMPONENT

Date ***[2017]***	Phase	No. of working days	To do
	Phase 12: KAP	1	Travel days for arrival
		~~5~~4	Final preparation of the study
		4	Training including the piloting tools
		30	Data collection
		3	Buffer days / debriefing
		1	Travel days to return
		20	Data analysis and writing up
	Phase 32: Explanatory qualitative	1	Travel days for arrival
		~~4~~2	Final preparation of the study
		2	Training including the piloting tools
		10	Data collection and writing up
		3	Buffer days / debriefing
		1	Travel days to return
		10	Data analysis
		30	Final analysis and write up
		30	Manuscript preparation and feedback to partners and study participants
		Total: ~~178~~155 days	

11. Logistics

10.5 Supplies needed

Supplies to conduct the study will be purchased via the country management.

See table 4 for a list of required supplies.

Photocopies of all necessary documents will be coordinated by the Country Management Team.

TABLE 4: SUPPLIES NEEDED FOR THE STUDY

Item	**No. needed per team**	**Total needed [6 x survey teams 1x qualitative team 4 x transcribers]**

Back pack/shoulder bag	1	7
Clipboard	2	14
Pencil	3	21
Rubber	2	14
Sharpener	2	14
Ink pad	1	7
MSF ID (aprons/vests if required)	2	14
Plastic folder	3	21
Random number table (see appendix 7)	1	6
Electronic tablets for KAP data collection	1	6
Computers (for transcription of qualitative activities)	4	4

10.6 Transport needed

Phases 1 & 3 (qualitative data collection): 1 x car and driver
Phase 1, ~~2 (~~KAP survey~~)~~: 2/3 x cars
Phases 2, ~~1 & 3 (q~~Qualitative data collection~~)~~: 1 x car and driver

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