

Article

A qualitative assessment among personnel working in community-led development programme settings regarding sexualized substance use

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Abstract: Background: Sexualized substance use (SSU) is the practice of psychotropic substance usage, before or during sexual intercourse in order to increase sexual pleasure and arousal. It has a strong association with sexually transmitted infections (STIs). The present study aimed to assess the knowledge gaps regarding SSUs among the community health mobilizers by interviewing them regarding their knowledge, attitudes, and practices through qualitative approach. Methodology: In-depth interviews (IDIs) were conducted with a total of nineteen community health mobilizers engaged in counselling of sexualized substance users. A semi-structured open-ended questionnaire with socio-demographic information and probes related to SSU was administered. Informed consent was taken from each participant prior to data collection. Results: Gender-wise distribution indicated that 47% of the community mobilizers are men, followed by transgender persons (32%), and women (21%). Responses of participants highlighted that alcohol consumption was the most observed form of SSU. The findings indicated that drug administration through injection was most common, followed by sniffing and swallowing. Sources of drug procurement enlisted by participants included peddlers, peer groups, sexual parties, medical and liquor stores. Only 63% of participants had fair knowledge about STIs such as HIV, viral hepatitis, syphilis, and gonorrhoea. All were familiar with the administration of naloxone injections and the locations of nearby hospitals where patients could be transported in the event of an overdose. Conclusions: The in-depth interviews among the study participants reflected substantial knowledge gaps related to various areas associated with SSU, which highlights the need for periodic workshops and training for upgradation of existing knowledge and practices among community health mobilizers. This will help to broaden their knowledge of different types of SSUs, the latest substances of abuse, the diseases caused by high-risk sexual practices, and additional health and psychological issues associated with SSUs, which would ultimately help in better counseling and management of sexualized substance users. It may also play a crucial role in the strengthening of capacity-building systems and engagements at the community level. This study may be used as formative research by researchers and policy makers to develop study protocols for multi-centric community-based studies among community health mobilizers and sexualized substance users across the country for further validation and exploration.

Keywords: sexually transmitted infection (STI); HIV; viral hepatitis; transgender persons; in-depth interviews (IDIs); formative research

1. Introduction

The use of substances, including alcohol and psychotropic drugs, has a long history and is still a prominent social issue. The use of addictive substances might be legal, socially acceptable, or even religious, but it causes pathological alterations in the brain. Substance users who have developed pathological adaptations are less receptive to in-

terpersonal and social interactions and are more susceptible to compulsive drug seeking and usage [1]. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition recognizes that a variety of substances can contribute to substance-related disorders, including alcohol, caffeine, cannabis, hallucinogens (phencyclidine or similarly acting arylcyclohexylamines, and other hallucinogens, such as LSD), inhalants, opioids, sedatives, hypnotics, or anxiolytics, stimulants (including cocaine and other stimulants), cigarettes, and anxiolytics [2].

Sexualized substance use (SSU) is the use of recreational substances for the purpose of promoting sexual engagement. Chemsex is considered a subset of SSU, which is commonly defined as the use of specific drugs (methamphetamine, mephedrone, γ -hydroxybutyrate (GHB/GBL), ketamine and cocaine) before or during sexual intercourse. It is common among homosexuals, bisexuals, and other men who have sex with men (MSM). According to qualitative research, MSM frequently engaged in SSU/chemsex because they believed that psychoactive chemicals may boost arousal and stamina, enabling prolonged sex sessions. Other reasons given included the following: overcoming lack of confidence, increasing the emotional bond with sex partners, and managing stress. To get a greater rush, methamphetamine or mephedrone can also be injected. This is a high-risk behaviour that can result in HIV and hepatitis C transmission using shared injecting equipments [3]. Additionally, SSU is also known to have a role in survival sex practices which includes selling of sex for subsistence needs like shelter, food, drugs or money. Literature indicated that SSU contributed to favorable sexual and reproductive health outcomes among female sex workers from provinces of China (Ong et al., 2010) [4]. A positive association between stimulant co-administration of SSUs such as cocaine and methamphetamine with increased likelihood of survival sex work involvement was observed in a study among female sex workers [5].

Despite the paucity of research on substance use among transgender (TG) people, it has been demonstrated that this population is more vulnerable to substance use. A transgender person's gender identity differs from the sex they were given at birth [6]. The visibility of transgender community has grown dramatically in recent years, and this greater exposure has brought to light the numerous health inequities that afflict this community, including STIs and HIV/AIDS. Compared to other high-risk groups including MSM and sexual partners of people living with HIV, transgender women have disproportionately high HIV prevalence. High-risk sexual activities like commercial sex work, unprotected receptive anal intercourse is thought to be connected to this. [7].

In order to understand the sexual behaviour of gender-diverse people, research is required among the personnel working in various community-led development programme settings dealing with the welfare of such communities. Therefore, the present study was conducted to assess the existing knowledge gaps regarding SSU among the community health mobilizers by exploring their knowledge, attitudes, and practices qualitatively.

2. Materials and methods

2.1. Study site

This qualitative research was carried out in the month of July 2022 in the national capital territory (NCT) of Delhi in India.

2.2. Study design and gaining access to the study subjects

An orientation and capacity-building workshop on "*Sexualized substance use in transgender people*" was organized for two days, in which working personnel of various community-led development programme settings came from various parts of India. The workshop was a part of the Samarth 3 project. This opportunity was utilized to comprehend the thoughts of the participants and the community health mobilizers who agreed to participate in the research were considered for in-depth interviews (IDIs).

2.3. Participants and eligibility criteria

Community health mobilizers with the following inclusion criteria were enrolled: a) those who agreed to participate and gave consent; b) those with at least 10 years of work experience in the relevant field; and c) those who were not abusing substances for past one year.

2.4. Data collection tool

The IDIs were conducted at the start of the workshop following a brief description of the purpose, objective and possible outcomes of this activity to the participants (Table 1). An experienced research investigator conducted one-on-one IDIs with each participant and recorded their responses. The probes were designed to cover a wide range of issues, including substance use, SSU, methods of substance use, overdose and adverse case management, STIs in substance users, substance use in transgender people and their mental health, and multi-level stigma associated with substance use. IDIs were conducted in Hindi and English as per comprehension ability of the participants. Informed consent from all the participants was taken.

2.5. Data analysis

Handwritten notes were used as raw data. The details of the participants, such as their age, gender, designation, geographical locations of their workplace, years of experience, and responses of the participants to probes were entered in MS-Excel. Normally distributed variables are presented as mean \pm standard deviation, and non-normally distributed variables as median with interquartile range (IQR). The transcribed IDI responses were analyzed through thematic content analysis. The research findings were substantiated qualitatively by the transcribed verbatim. The verbatim were translated into English with pseudonyms and numerical codes to maintain confidentiality. A gap analysis was performed to determine in which areas the community health mobilizers lacked knowledge.

Table 1: Qualitative interview guide

Domains	Enquiries	Probes
Sexualized substance use	What do you know about SSU?	Types of substances, recent substances of abuse such as designer drugs, methods of consumption and procurement, diseases and infections
Prophylaxis	What do you know about prophylaxis for HIV/STI?	“PrEP” and “PEP”
Drug overdose related complications and first-aid procedures	How do you manage in case of drug overdose?	Symptoms of drug overdose, harm reduction, possible ways of getting services
Relapse to addiction	What do you know about relapse after deaddiction?	Rates of relapse, possible triggers
Work challenges	Would you like to share the problems you have faced while working with substance users?	Stigma, discrimination, legal challenges
Work experience	Would you like to share your various experiences working with substance users?	Age group, relationship with family members, role of religion and spirituality, effect on quality of life

3. Results

3.1. Profile of the participants

A total of 19 community health mobilizers participated in the study, of which nine were men (47.4%), four were women (21.1%), five were trans females (26.3%) and one was transmale (5.2%)(Fig. 1a). Their mean age was 36.4 ± 9.2 years and they had 13.3 ± 7.4 years of work experience (median 13 (IQR 10-18)). Most of them (37%) were involved in managerial tasks, followed by counseling (21%), and field mobilization of sexualized substance users (16%) (Fig. 1b). They were associated with one or more community led initiatives and groups majorly spread across five states of India (Fig. 1c).

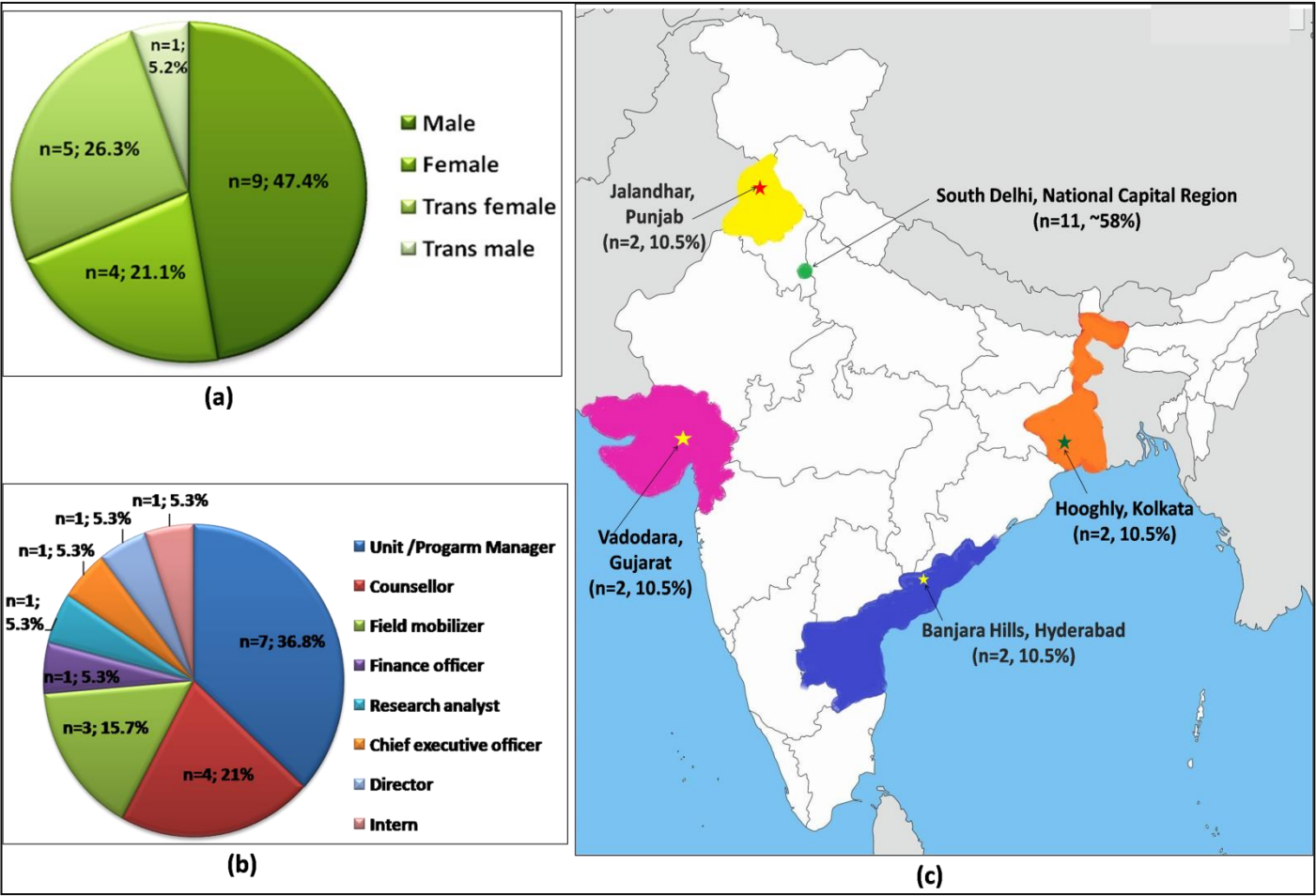


Figure 1: Classification of the participants based on a) gender, b) work profile, and c) the geographical distribution of their organization

3.2. Thematic content analysis

The IDIs were analyzed by thematic content analysis approach and three major themes emerged through their responses under which several sub-themes were identified. The observations and findings in the sections hereon are based on the themes of knowledge, attitudes, and practices of community health mobilizers working for the welfare of sexualized substance users (Fig. 2).

3.2.1. Participants' response to knowledge-assessment probes

3.2.1.1. Sexualized substance use

a) The participants were probed about the various substances that are used for sexual purposes which they had heard or seen, and most of them answered alcohol (n = 11; 58%), M.D. (actual name 3,4-methylenedioxymethamphetamine MDMA; n = 7; 37%), and ATS (amphetamine type stimulants; n = 7; 37%). The participants' responses were classi-

fied as follows: (i) central nervous system (CNS) depressants like alcohol, MDMA, ATS, Avil, (ii) opioids like afeem (opium), heroine, smack, (iii) inhalants like poppers, (iv) cannabis like ganja (marijuana), and (v) CNS stimulants like cocaine.

b) The participants were assessed for their knowledge of designer drugs. "A "designer drug" is defined as a synthetic version of a controlled substance (such as heroin) that has a slightly altered molecular structure in order to evade restrictions against illegal substances [8]. Drug-related deaths have increased as a result of these substances, which have no established medical uses and are frequently missed by standard drug testing. Fentanyl, meperidine, piperazine, and methamphetamine analogues are among the most popular designer medications. Sufentanil, alfentanil, remifentanil, carfentanil, and, more recently, acetylfentanyl are some of the illicitly manufactured fentanyl compounds [9].

The participants lacked knowledge about designer drugs and referred to the following substances as designer drugs: opioids, fentanyl, LSD, meow meow, crystal meth, tramadol, ATS, pregabalin, MD, white sugar, brown sugar, poppers, anabolic steroids, hallucinogens, chitta, cocaine, heroin, and synthetic drugs.

c) The participants were questioned about the most common methods of consumption of substances they had heard from their clients. Most of them responded that injecting (n = 14; 74%), whether intravenously or intramuscularly, was the most common method of substance abuse, followed by sniffing (n = 11; 58%), chasing (n = 12; 63%), and oral (n = 11; 58%). Some of them also mentioned smoking and sublinguals.

d) The participants were assessed for their knowledge of various means for the procurement of sexualized substances, and they mentioned peddlers; pan shops; community friends; slums; liquor shops; border areas; pubs; medical stores; sexual parties; spas; hotels; rickshaw pullers; and sexual partners.

e) According to the participants (n = 12; 63%), sexually transmitted infections (STIs) were the most common diseases they had heard about or seen among substance users. Majority of them believed HIV (n = 11; 58%) and viral hepatitis (hepatitis B, C infections; n = 10; 53%) were the most common STIs. Some of them had also observed reproductive tract infections (RTIs; n = 5; 26%) and other STIs such as syphilis, vaginal/cervical discharge syndrome (VCD), and urethral discharge (UD) among sexualized substance users.

3.2.1.2. Prophylaxis

a) The participants were asked if they were familiar with the terms "PrEP" and "PEP." According to 12 participants (63%), PrEP (pre-exposure prophylaxis) is a medicine used to prevent HIV infection. It is extremely effective at preventing HIV, when taken as prescribed. It reduces the risk of contracting HIV from sex and from injection drug use.

PEP (post-exposure prophylaxis) was defined by 13 participants (68%) as taking HIV medications within 72 hours (3 days) of possible HIV exposure to prevent HIV infection and development of disease. Rest of the participants was not aware about these terms.

3.2.1.3. Drug overdose related complications

a) The participants were questioned regarding the symptoms they had seen in cases of drug overdose. They responded that people typically present with trembling, fear, hallucinations, nausea, vomiting, dehydration, hypertension, redness of the eyes, pin-point pupils, seizures, loss of appetite, breathlessness, anxiety, forgetfulness, disorientation, illusion, mood swings, depression, lack of concentration, excessive drooling, yellowing of the skin, and hyperactivity. The severity of these symptoms varies depending on the level of intoxication.

3.2.1.4. Relapse to addiction

a) The participants were questioned if they had ever witnessed a relapse in substance users after quitting. Only a small number of participants (n = 2; 11%) claimed to have never witnessed a relapse after deaddiction. However, most of them stated that

most of the cases would recur after six months to a year of initial treatment. Two participants stated that 90–100% of cases relapse after first treatment, while one person stated that there are 50–70% of recurrence possibilities within 1, 3, 5, or 12 months of quitting. One participant claimed that, in his experience, relapses occurred in 2 out of every 10 cases (20%), while another claimed that relapses occurred in 6 out of every 25 cases (24%).

b) They were also questioned regarding the potential triggers for relapse in substance users. They mentioned withdrawal syndrome, family problems; interpersonal troubles such as breakups; anxiety and depression as the possible triggers.

"People suffer from withdrawal syndrome after quitting drugs and so start abusing drugs again" - Bharat (CBO3)

"Stress, peer pressure, and sex pleasure are some of the major triggers for relapse" - Vicky (CBO2)

"Relationship, problems in family, office pressure, bullying in college, mind distraction are some of the reasons people start taking drugs again" - Shaurya (CBO4)

3.2.1.5. Work challenges

a) The participants were asked whether they had faced any legal challenges while working for the welfare of substance users. A few individuals experienced criticism and discrimination from their relatives and neighbours, but most of the participants said they did not encounter any legal obstacles.

"Legal barriers not faced till date.... but dealt with structural stigma, people stigma, social stigma, and self-stigma" - Sunil (CBO1)

"Sometimes police says that we are involved in substance sale" - Piku (CBO14)

b) The participants were questioned about the reasons they heard from their clients that contributed to their substance abuse. They responded that their clients started using drugs as a result of peer pressure, to relieve stress, anxiety, and grief, for sexual pleasure, to counteract any feelings of guilt, and to overcome inhibition for sex work.

"People usually start taking drugs out of curiosity, for enhancing sexual pleasure.... some people do drugs for countering their inhibition, to overcome their guilt feeling, some people do it just for fun" - Bharat (CBO3)

"Common reasons which I have heard for doing drugs are to overcome depression after breakupPeople with high ambition take drugs to relieve stress and workload" - Barkha (CBO17)

"First reason, people feel good after taking drugs, next they want to reduce their anxiety, and depression.... but it's vice versa, like people who take drugs become prone to anxiety and depression because they lose their jobs, and their personal lives get jeopardized.... Genetics, and environment also contribute for drug abuse like peer group, hang out places etc" - Sunil (CBO1)

"The reasons which I have heard from my clients are that...they lack confidence for doing sex with same sex...there is lack of confidence for standing on road for sexwork...some people take substance because they have entered to sex orgy parties" - Piku (CBO14)

3.2.1.6. Work experience

a) The participants were asked about the most typical age group they have dealt with during their time in service. Most of them responded that most of the drug users were between the ages of 16 and 40.

"I came across people between 18-45 years for MSM and 18-35 years who are TGs" - Sunil (CBO1)

"Most of the individuals from support groups are between 20-30 years for MSM and 25-40 years for TGs" - Mayur (CBO6)

"20-28 years is the most common age group as per my experience" - Shaurya (CBO4)

"According to me, 16-20 years is the most vulnerable group" - Bobby (CBO15)

3.2.2. Participants' response to attitude-assessment probes

3.2.2.1. Role of religion and spirituality

a) The participants were asked for their opinions on the relevance of religion and spirituality in helping people recover from drug abuse. Most of the participants (n = 14; 74%) held the view that engaging in spiritual and religious pursuits, such as yoga and meditation, can aid in the recovery from substance use. Few participants mentioned that many drug users visit "ojhas" (those who practice black magic), which they had heard during counseling.

"Yes, most of the users go to quacks or ojhas (person who practice black magic)"-Ujjwal (CBO9)

"If we can start meditation through spirituality, this will help to cope up from substance...some people go for meditation...some people start using if they get connected to religious group like religious akhada"-Piku (CBO14)

"Sometimes it is possible but not always.... depends on client mental status"- Mayur (CBO6)

"Many religion and spirituality things play a role in Punjab"- Bobby (CBO15)

3.2.2.2. Effect of substance use on quality of life

a) The participants were questioned regarding how substance abuse affected the standard of living among their clients. According to them, substance abuse caused majority of the users to lose their jobs. Their relationships with their parents, spouses, and friends suffered due to lack of concentration. They struggled financially because they became dependent on drugs and only craved for it. Many drug users started illegal activities, including smuggling, theft, and sex work, for quick cash to buy drugs.

"Substance use has worst impact on livelihood...People start criminal activities like stealing, theft, and they suffer from health problems like hypertension"-Nusrat (CBO8)

"Substance users face financial problems because of job loss, business loss.... their families don't accept them.... such a person becomes alone which makes him very near to violence and he landed up in police station"- Vicky (CBO2)

"Due to substance use, most of the time he/she lose job, they don't feel seriousness about his/her lives...usually they lead their life very messy and most of time they don't use condoms while engaging in sex work"-Sunil (CBO1)

3.2.3. Participants' response to practice-assessment probes

3.2.3.1. Harm reduction

The participants were assessed for their knowledge of harm reduction. The community mobilizers understood harm reduction, which they shared with their clients during counselling. They advised their clients to (i) avoid unprotected sex; (ii) carry condoms and use them during sexual intercourse; (iv) go out with a friend who can monitor their behaviour during drug consumption; (v) hand over their car keys to a responsible person before drinking alcohol and consuming drugs; (vi) stay hydrated and eat while drinking alcohol; (vii) take multivitamins [10]; and (viii) reduce the number of days they drink alcohol or consume drugs per week or month.

3.2.3.2. First-aid for drug overdose

a) The participants were asked if they were familiar with the procedures for administering first aid in the event of a drug overdose. They stated that they were aware of the ABC method (airway, breathing, and cardiopulmonary resuscitation). Individuals who have overdosed on drugs are usually brought to them unconscious and dehydrated. Hence, they administer water, glucose, ORS, and a naloxone injection (an opiate antidote) to such individuals. Individuals who are severely ill are referred and transported to a nearby hospital, which is 10–20 minutes away from their workplace.

“AIIMS and Safdarjung hospitals are 20 minutes far from intervention area”- Piku (CBO14)

“We take the drug overdosed patients to the nearest government set up which is almost 20 minutes from our organization”-Bharat (CBO3)

“In the event of a drug overdose, we first provide ABC therapy, second we call an ambulance, if we have naloxone injection then we give 2 ml dose to the patient and take him to the nearest hospital”- Bobby (CBO15)



Figure 2. Overview of the study.

3.3. Gap analysis

The study identified knowledge gaps in the following areas among community mobilizers:

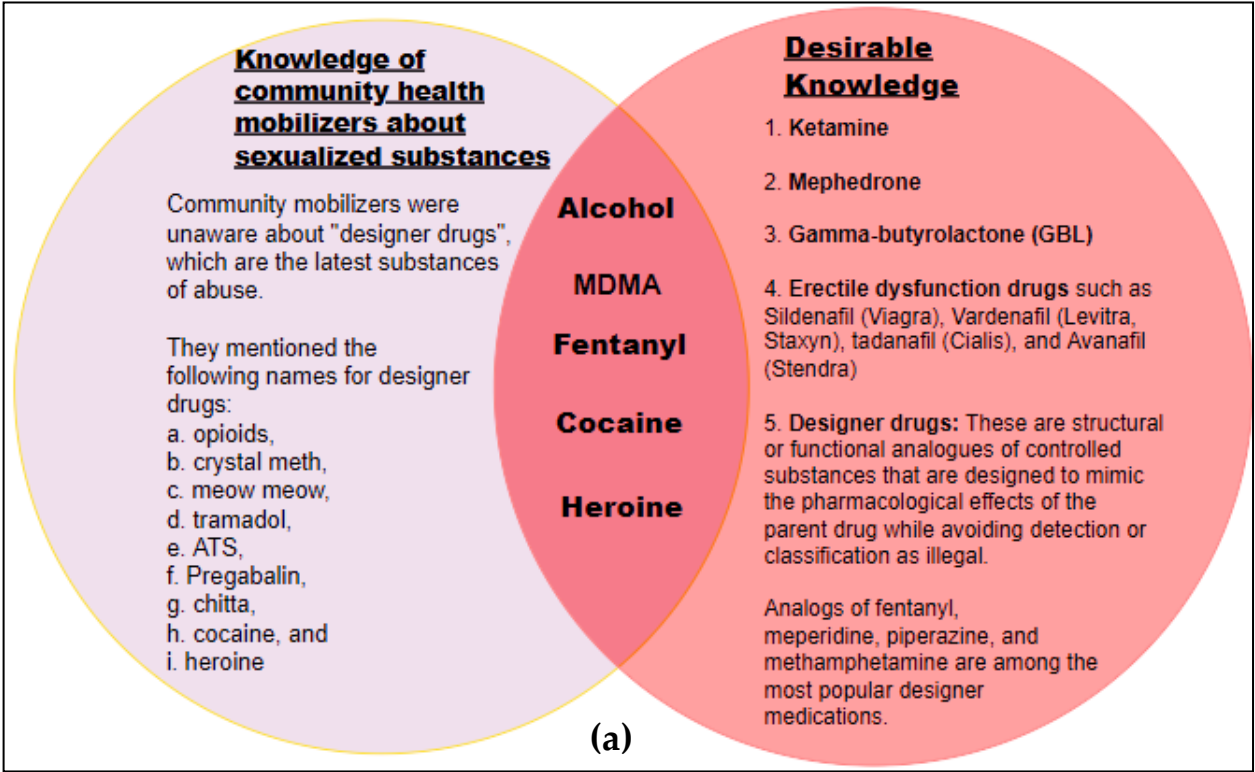
(i) *Sexualized substances*: The participants were unaware about erectile dysfunction drugs, ketamine, and gamma-butyrolactone (GBL) which are very commonly used dur-

ing chemsex. They were also unfamiliar with designer drugs, which are the latest sexualized substances of abuse (Fig. 3a).

(ii) *Drug procurement sources:* The community mobilizers were unaware about the online sources such as mobile dating apps for purchasing drugs.

(iii) *Health problems and psychological issues associated with SSU:* Only 63% of participants had average-to-good knowledge of STIs such as HIV/AIDS, viral hepatitis (hepatitis B and C infections), and mental health issues such as anxiety and depression that are common in sexualized substance users. However, they were unaware of the additional health and psychological issues associated with SSU (Fig. 3b and c).

(iv) *HIV prevention:* Some of the community mobilizers (~30%) are unaware of pre-exposure (PrEP) prophylaxis and post-exposure prophylaxis (PEP), which are preventive medications for HIV/AIDS.



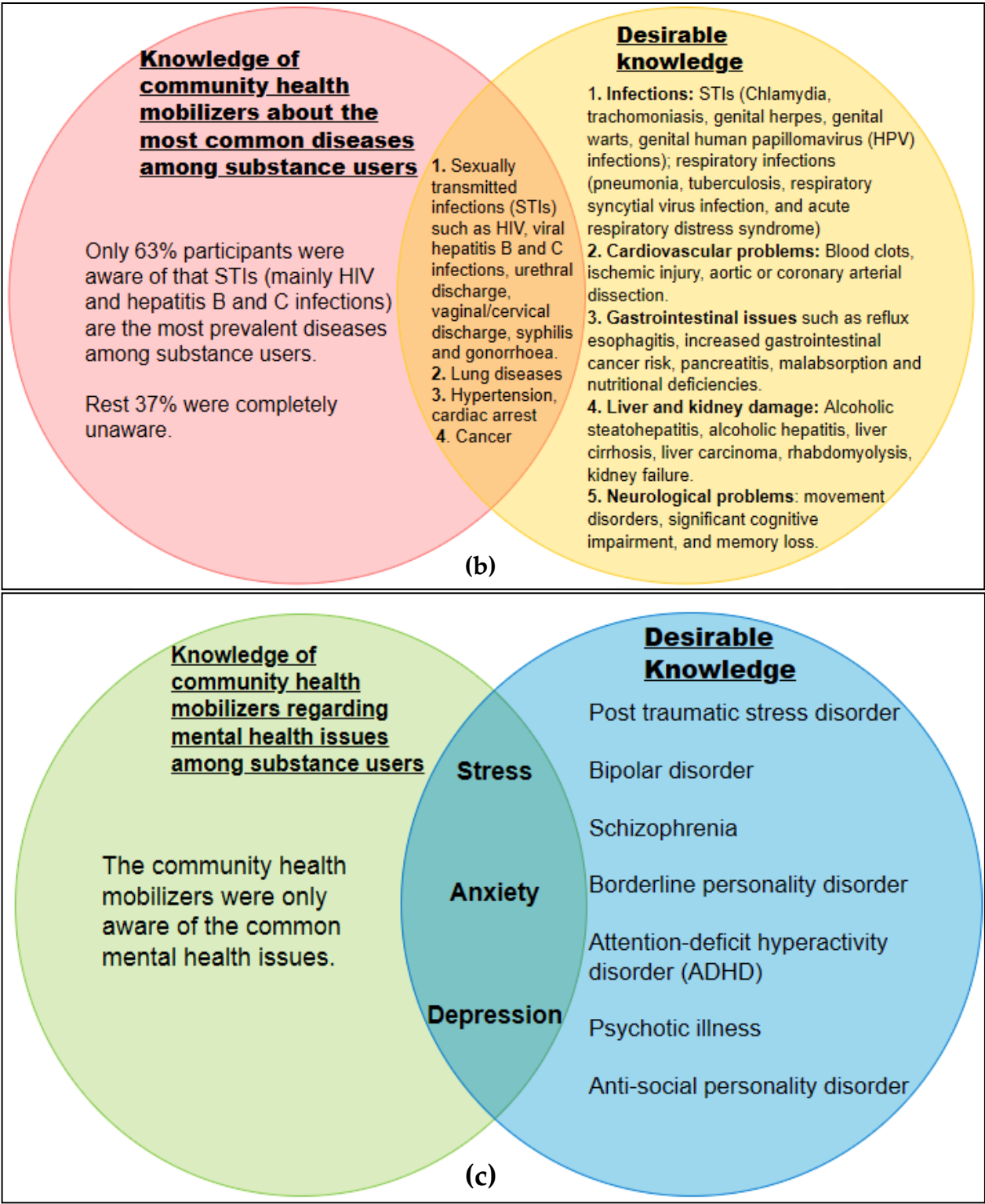


Figure 3. Venn diagrams showing major areas of knowledge gaps in community health mobilizers regarding (a) sexualized substances, (b) health problems and (c) psychological issues associated with sexualized substance use. The overlapping regions of the circles represent the desirable knowledge that the community health mobilizers possessed.

4. Discussion

The present study was formative research in which the data on SSU was obtained through community health mobilizers engaged with counselling and welfare of substance users.

The findings of the present study are consistent with National Institute on Drug Abuse (NIDA) research, which found that substance use increases the risk of infectious

disease transmission, such as HIV and hepatitis C virus (HCV). Intravenous substance use is the leading cause of virus transmission, accounting for approximately 6% of HIV diagnoses in 2015 [11]. Drug abuse can hasten the development of HIV and its consequences, especially on the brain. Clinical studies have revealed that, even in patients who are on antiretroviral therapy (ART), substance use may worsen AIDS-related mortality, accelerate disease progression, and increase viral loads [12]. Furthermore, people with substance use disorders are less likely to take HIV medication on a regular basis, worsening their situation [13, 14, 15].

A study by Gonzalez-Baeza et al. (2018) demonstrated that SSU is associated with high-risk sexual behaviors and STIs in 742 HIV positive MSM. A total of 185 patients (25%) reported having a diagnosis of depression, 175 (24%) an anxiety disorder, 57 (7.7%) a substance abuse disorder, and 9 (1.2%) a previous psychotic episode. The use of mobile apps for sexual encounters among HIV positive MSM was common [16].

A study by Reback and Fletcher (2014) in which they examined substance use patterns among a group of 2136 transgender women suggested that methamphetamine use was significantly higher among HIV positive women compared to HIV negative women (29.2% vs. 20.3%; $p < 0.001$). Alcohol use was seen to be significantly higher in the HIV negative group indicating that methamphetamine use may be uniquely associated with increased sexual risk [17].

A study by D'Amico et al. (2020) found that the most common source of cannabis was recreational cannabis retailers (59.1%), followed by family or friends (51.5%), medical cannabis dispensaries (31.8%), and strangers or dealers (5.5%) [18]. In a study conducted by McCabe et al. (2019), high school students were asked from where they had procured prescription medications (such as opioids, stimulants, and anxiolytics) without a doctor's prescription. The ten sources they have mentioned are as follows: acquired on the internet; taken without permission from a friend or relative; purchased from a friend or relative; obtained from one's own past prescription; purchased from a drug dealer or stranger; and other means [19].

One of the many strengths of the present study lies in inclusion of participants with at least ten years of work experience in the relevant field i.e., counselling of substance users. The study consisted of mixed-group participants (males, females, and transgender persons). They were fluent in their respective local languages and were familiar with the local terminologies that people use to mention substances, e.g., ganja for marijuana, chitta for heroine (in Punjab), afeem for opium, and smack for black heroine. The study identified knowledge gaps in community health mobilizers.

The study has certain limitations too. The participants belonged to only five states of India; therefore, geographic representation was limited. Their facts and assumptions could not be confirmed with sexualized substance users.

5. Conclusions

The present study was conducted to assess the knowledge, attitudes, and practices of community health mobilizers regarding SSU. In-depth interviews with study participants revealed significant knowledge gaps related to various aspects of SSU, implying the need for periodic workshops and trainings to improve existing knowledge and practices among community health mobilizers. This will be beneficial in the expansion of knowledge of different types of SSUs, local terminologies used by people to refer to substances, the diseases caused by high-risk sexual behaviours, and additional health and psychological issues associated with SSU. It may also play an important role in strengthening capacity-building systems and engagement at the community level. Interactions between professionals, community representatives, and counselors/field mobilizers may provide a scope for better challenge mapping at the community level, identification of issues at individual levels, mobilization towards health facilities, and counseling for better management of sexualized substance users. Based on the counselors' assessment of the compliance of the community towards the disseminated information, further counseling for safe sexual practices, substance use, and harm reduction may be

provided. This study may be used as formative research by researchers and policy makers to develop study protocols for multi-centric community-based studies among community health mobilizers and sexualized substance users across the country for further validation and exploration.

Author Contributions: Binata Marik: Investigation, methodology, data curation, analysis, and visualization, writing original draft, writing-review and editing; Nupur Mahajan: Methodology, writing-review and editing; Rohit Sarkar: Resources, project administration, writing-review and editing; Rochana Mitra: Resources, project administration; Rajiv Dua: Resources, project administration; Sumit Aggarwal: Conceptualization, study design, resources, supervision, methodology, data analysis and visualization, writing-review and editing and is the guarantor of the paper.

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Ethics statement and consent to participate: This research work does not have an ethical approval code since this was a subset under the purview of a workshop conducted for SAMARTH 3 as part of knowledge and intervention to support the counsellors and field mobilizers engaged in working among sexualized substance users. Thus, ethical approval was not required for the study. However, informed consent from all the participants willing to take part in the study was sought prior to initiating data collection. The verbatim were translated into English with pseudonyms and numerical codes to maintain confidentiality and anonymity of the participants.

Data availability statement: The datasets generated and/or analyzed during the current study are not publicly available. They are available from the corresponding author on reasonable request.

Conflicts of Interest: None.

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