GEORGIA COUNTRY REPORT

Implementing a low dead space injecting equipment distribution program for people who inject drugs in low and middle-income countries: a process and outcome evaluation

Community-led LDSS/N Values & Preferences Research
Phase 1 Focus Group Discussions (FGD)

MÉDECINS DU MONDE
INPUD International Network of People who Use Drugs
Burnet
University of BRISTOL
Real World Real People
CUTTS HepC

GEORGIA COUNTRY REPORT

Implementing a low dead space injecting equipment distribution program for people who inject drugs in low and middle-income countries: a process and outcome evaluation

Community-led LDSS/N Values & Preferences Research
Phase 1 Focus Group Discussions (FGD)

Report authors

Madden, A.[1], Schroeder, S.[2], Flynn, M.[2], Voloshin, A.[2], Draper, B.[2], Abesadze, L.[3], Beritashvili, L.[3], Kakulia, T.[3], Kordzadze, T.[4], Lamand, P.[5], Butsashvili, M.[6], Stoove, M.[2].

Affiliations

1. International Network of People Who Use Drugs (INPUD)
2. Burnet Institute
3. Georgian Network of People Who Use Drugs (GeNPUD)
4. Médecins du Monde (MdM) Georgia
5. Médecins du Monde (MdM) France
6. Health Research Union

Translation (Georgian): Lika Gavashelashvili
Layout & Design: Mike Stonelake

Contact details for correspondence

Dr Annie Madden (lead author/investigator)
INPUD
E: anniemadden@inpud.net

Professor Mark Stoove (lead investigator)
Burnet Institute
E: mark.stoove@burnet.edu.au

Publication date: April 2026

Suggested citation

Madden, A., Schroeder, S., Flynn, M., Voloshin, A., Draper, B., Abesadze, L., Beritashvili, L., Kakulia, T., Kordzadze, T., Lamand, P., Butsashvili, M., & Stoove, M. (2025). *Community-led values & preferences: Phase 1 focus group discussions (FGD), Georgia country report – Implementing a low dead space injecting equipment distribution program for people who inject drugs in low- and middle-income countries: A process and outcome evaluation.* INPUD; Burnet Institute, Melbourne, Australia.

Acknowledgements

We wish to acknowledge and thank all the individuals who participated in this study as focus group participants. Your contributions to this study have been critical in building our understanding of low dead space syringes and needles (LDSS/N) and broader hepatitis C (HCV) and harm reduction issues for people who inject drugs in Georgia.

We would also like to acknowledge and thank Lasha Abesadze, Lika Beritashvili and Tamar Kakulia, the community researchers and note takers from the Georgian Network of People Who Use Drugs (GeNPUD) who recruited the participants, organised and conducted the focus group discussions (FGDs) and produced the FGD Summary Reports from the data collected. They have also provided valuable input and feedback on this report. Thanks also to Tamar Kakulia from GeNPUD for overseeing data management and safety.

We would also like to thank the MdM team in Georgia, with special thanks to Tea Kordzadze, Study Co-ordinator and Programs Manager, for providing ongoing support to the development and implementation of the LDSS/N Study in Georgia. Acknowledgment also for Dr Maia Butsashvili, Country Principal Investigator for her oversight and guidance of the study. We would also like to acknowledge the important work undertaken by the staff at the study sites including Hepa Plus (Tbilisi), New Vector (Rustavi), and Step to Future (Gori). Also, thanks to Anna Vakhtangadze for providing transcription services and Lika Gavashelashvili for providing translation services across the project.

We would like to acknowledge and thank the Global Community Advisory Committee (CAB) for the Unitaid HCV Portfolio Projects for their pivotal role in the protocol development, including reviewing the draft protocol and providing ongoing advice and support with the finalisation of the study protocol, feedback on interpretation of preliminary findings and ongoing implementation of the interventions and the research activities. The members of the Global CAB are drawn from the country-based and regional community-led networks of people who use drugs in each of the ten focal countries involved in this research portfolio.

We acknowledge the work of the Médecins du Monde (MdM)-led "CUTTS Hep C Consortium" (which includes research and community technical partners from Burnet Institute, International Network of People Who Use Drugs (INPUD) and University of Bristol) in leading the LDSS/N Study at the portfolio level for the Unitaid HCV Portfolio Grant. We would also like to acknowledge Prof. Mark Stoove as chief investigator, Prof. Margaret Hellard (investigator), Dr Bridget Draper (investigator), Dr Sophia Schroeder (investigator), Dr Nick Scott (investigator), Dr Alisa Pedrana (investigator) & Mia Flynn (investigator) from Burnet Institute and Dr Annie Madden (investigator) from INPUD, Prof. Peter Vickerman (investigator), Assoc. Prof. Jack Stone (investigator) and Dr Josephine Walker (investigator) from Bristol University and Ernst Wisse (investigator) & Pauline Lamand (Consortium Coordinator) from MdM.

We would also like to acknowledge the portfolio investigators who continue to be involved in overseeing the LDSS/N study implementation across the nine countries in which this work takes place: Dr Cobus Olivier (Frontline AIDS), Mat Southwell (Co-Act), Laurie Schowalter (Frontline AIDS), Dr Kimberley Green (PATH), Kiira Gustafson (PATH), Dr Karin Hatzold (PSI), Prof. Lucy Platt (London School of Hygiene and Tropical Medicine (LSHTM), and Prof. James Hargreaves (LSHTM).

We also acknowledge the technical support provided by the the Testing, Prevention and Populations Unit at the Global HIV, Hepatitis and Sexually Transmitted Infections Programmes, World Health Organization (WHO) including Dr Niklas Luhman and Annette Verster.

This project is funded by Unitaid.

Contents

FIGURE PAGE

TABLES PAGE

1. Executive Summary

"A defining feature of this study is its community-led, values and preferences-based approach."

This report presents findings from the community-led values and preferences Phase 1 focus group discussions (FGD) of the Georgia country study for the project *Implementing a Low Dead Space Injecting Equipment Distribution Program for People Who Inject Drugs in Low- and Middle-Income Countries (LMIC): A Process & Outcome Evaluation*. This work is being implemented in nine LMICs by three research consortia and aims to explore how low dead space syringes and needles (LDSS/N) can be introduced and scaled in ways that are effective, acceptable, and contextually appropriate to achieve high uptake and harm reduction coverage.

A defining feature of this study is its community-led, values and preferences-based approach. In all nine countries, including Georgia, people who inject drugs have been engaged not only as participants but as co-researchers and co-designers throughout every stage of the process – from study conception and design, through to implementation and analysis. This approach centres the expertise of people with lived and living experience, ensuring that decisions about LDSS/N introduction and distribution are grounded in the realities, priorities, and needs of beneficiaries.

Taking a community-led values and preferences approach is especially important in the context of harm reduction, where top-down interventions often fail to reflect the nuanced, day-to-day experiences of people who use/inject drugs. It ensures that harm reduction services and the associated distribution models are responsive, rights-based, and focused on reducing harm in ways that are meaningful to the people they are intended to serve and leading to harm reduction services that are more effective.

This report is based on FGD data collection from 75 participants recruited from partnering harm reduction sites. Three community researchers facilitated and documented the

FGDs, where participants provided in-depth insights into current access to needles and syringes (N&S), experiences with existing equipment, and their first impressions of LDSS/N. Participants described ready access to injecting equipment via community-based harm reduction services, with few (if any) limits on current distribution. However, the consistently poor quality of syringes and needles provided through community-based harm reduction services was a major concern with many describing these as fragile, dull, and unreliable. As a result, purchasing higher-quality equipment from pharmacies was common despite the cost incurred, and in some cases, despite negative attitudes from pharmacy staff.

Other factors contributing to purchasing pharmacy equipment included convenience, availability, geographic distance from harm reduction sites, and fear of police encounters at these sites. Participants from outside Tbilisi noted that transportation costs and travel time sometimes made it difficult to consistently access community-based NSPs. It was clear from these accounts that pharmacies are a major access point for sterile injecting equipment for people who inject drugs in Georgia, even though police harassment was often experienced in this context, even when carrying as yet unused equipment alone.

Across all FGDs, participants strongly rejected the idea of reusing or sharing needles and syringes indicating established community norms promoting harm reduction. However, some participants acknowledged that reusing their own equipment still occurred in certain circumstances. For instance, reusing one's own N&S was sometimes seen as the least harmful available option when the pharmacy is closed afterhours, when unable to afford to buy new equipment, and when in withdrawal. Nevertheless, this conflict between strong community norms against reuse and persistence of circumstantial reuse practices, serves to highlight the tension between ideal harm reduction practices on the one hand, and the realities of criminalisation and limited access on the other.

"... participants strongly rejected the idea of reusing or sharing needles and syringes..."

Prisons were identified as one of the few remaining environments where N&S reuse and sharing still occurred routinely. Participants spoke of the complete lack of sterile equipment in prison settings and that injecting continues to occur in these closed environments. The absence of NSPs in prisons stood in stark contrast to the harm reduction progress made in the community. This was highlighted as a potential issue for future advocacy particularly given that some countries in the EECA region do provide NSP access in prisons.

In terms of first impressions of LDSS/N, participants responded positively to the quality and design features of the sample products, particularly the smooth plunger function and the potential for reduced drug residue and BBV transmission. Colour-coded needle gauges and the ability to pair needles and syringes according to individual preference were seen as welcome additions to the harm reduction landscape in Georgia but necessitating accompanying community education. Participants expressed interest in testing the products during the project's subsequent 6-week pilot phase (Phase 2). Participants also emphasised the importance of community-led knowledge mobilisation to support implementation, especially among those less familiar with separate LDSS/N products.

A specific issue that was raised across the FGDs was the use of 'butterflies' (winged infusion sets). Butterflies are typically used by those who inject larger volumes of liquid and/or have veins that are difficult to access and are mostly purchased from pharmacies. In the context of existing butterfly use, several FGD participants questioned whether any of the LDSS/N products could serve as an alternative. This was an important consideration in the context of the study aims, as butterflies retain large volumes of blood and may heighten the risk of BBV transmission if reused. While some participants did not wish to move away from their use of butterflies, other participants were open to exploring LDSS/N alternatives but noted that their suitability could only be determined in practice.

"... participants across all FGDs were enthusiastic about the values and preferences approach..."

Finally, participants across all FGDs were enthusiastic about the values and preferences approach and emphasised how meaningful it was to be asked for their views on injecting equipment before that are procured and distributed. They expressed confidence that LDSS/N products could be a beneficial addition to Georgia's harm reduction response if introduced with adequate education, peer support, and a full range of product options that meet the diverse needs of people who inject drugs including women who inject drugs. The Phase 1 findings offer a strong foundation for moving into Phase 2 pilot and Phase 3 implementation stages and point to several opportunities for addressing persist barriers to access and gaps in quality and choice for people who inject drugs in Georgia.

2. Introduction

2.1 Background on the study, its rationale, and objectives

This community-led values and preferences study is being undertaken to inform the distribution of low dead space syringes and needles (LDSS/N) in low- and middle-income countries (LMIC) and enhance their uptake. Adopting a values and preferences approach seeks to ensure the provision of LDSS/N is aligned with the needs and preferences of local communities of people who inject drugs, to improve the likelihood of LDSS/N uptake and usage.

In the context of suboptimal support for harm reduction in many settings, exploring the 'values and preferences' of people who inject drugs includes understanding needs and preferences relating to drug use and injecting practices such as current access to and quality of N&S, the impact of equipment quality on injecting practices, and reflections on sharing and reuse of injecting equipment in specific contexts. Values and preferences in this study also included LDSS/N specific components such as first impressions and perceived benefits and disadvantages of LDSS/N; preferred LDSS/N types; strategies to support future roll-out, and the role of peer networks in education and knowledge mobilisation. Critically, values and preferences is not only about needs and preferences in relation to drug use and LDSS/N, but also the wider ecological conditions in which people live and the way these conditions can influence and shape what individuals and communities may 'need' and 'prefer'. This includes understanding the structural and social barriers to accessing sterile equipment in specific contexts, such as policing practices, stigma (including gender-based stigma) and the absence of harm reduction services in settings like prisons.

"...injecting drug use remains a key risk factor for blood borne virus transmission, including HIV and HCV."

Better understanding the complex factors that influence the uptake and use of sterile injecting equipment (and LDSS/N specifically) is important, because injecting drug use remains a key risk factor for blood borne virus transmission, including human immunodeficiency virus (HIV) and hepatitis C virus (HCV). This risk is likely reduced through enabling access to LDSS/N due to the reduction in the amount of blood remaining in the LDSS/N after injection (relative to high dead space needles and syringes), which reduces the HIV and HCV transmission risk should this equipment be re-used by someone else. Despite global guidance recommending the distribution of LDSS/N since 2012, high dead space syringes and needles (HDSS/N) continue to be the predominant needles & syringes (N&S) provided in needle-syringe programs (NSPs) in LMIC.

This study on LDSS/N in Georgia is being implemented across nine LMICs, including Georgia, Armenia, Tanzania, Nigeria (two locations), Egypt, South Africa, India, Vietnam, and Ukraine as part of a Unitaid investment portfolio into hepatitis C. Three research consortia are implementing three studies of integrated simplified HCV testing and treatment and harm reduction interventions in ten LMICs (including Kyrgyzstan, not one of the LDSS/N implementation countries) with the aim of reducing HCV transmission risk and improving access to HCV care. The LDSS/N component of this work aims to inform best practice approaches to facilitating the transition from HDSS/N to LDSS/N in harm reduction programs in LMICs.

The specific objectives of the LDSS/N study (across all implementing countries LMIC) are to:

- Explore community values and preferences for LDSS/N;
- Identify barriers and facilitators to access and uptake of LDSS/N among people who inject drugs;
- Design and implement an LDSS/N distribution program informed by community values and preferences;

- Evaluate the effectiveness of this LDSS/N distribution program on increasing LDSS uptake (primary outcome) among people who inject drugs;
- Estimate the effectiveness of this LDSS/N distribution program for reducing blood-borne virus transmission (secondary outcome) among people who inject drugs; and
- Model the potential public health impact (HIV and HCV infections averted) and cost-effectiveness of LDSS/N distribution for people who inject drugs within harm reduction settings.

Evidence from the study will inform national and World Health Organization (WHO) guidance and recommendations on LDSS/N distribution. The research across all countries is underpinned by a WHO Ethics Review Committee (ERC) approved master research protocol and Institutional Review Board (IRB) approved country protocols *(see 3.4 below)*, to ensure research implementation processes and the collected data are aligned across locations.

The LDSS/N Study in Georgia is being conducted by the MdM-led "CUTTS Hep C Consortium" which includes the following research and community technical partners: International Network of People Who Use Drugs (INPUD), Burnet Institute, University of Bristol, and country-level partners the Georgian Network of People Who Use Drugs (GeNPUD) and MdM team in Georgia. The CUTTS Hep C Consortium is also conducting this LDSS/N Study together with country partners in Armenia and Tanzania.

2.2 Overview of the importance of LDSS/N in harm reduction

According to the WHO, around 11 million people inject drugs globally and approximately 1 in 8 (or 1.4 million) of these people are living with HIV (UNODC World Drug Report, 2020). Moreover, according to UNAIDS, injecting drug use accounts for approximately 10% of new HIV infections globally (UNAIDS, 2020).

Despite being curable, HCV affects 58 million people worldwide contributing to 290,000 deaths each year (World Health Organisation, 2021) with people living in LMIC accounting for 80 percent of infections (Razavi, 2020). Additionally, HCV disproportionately affects people who inject drugs (Grebely et al., 2019) which means reducing the risk of HCV transmission via injecting drug use practices is imperative to the global response to HCV. Provision of sterile injecting equipment, primarily N&S, is a harm reduction measure of critical importance to preventing both HIV and HCV infections among people who inject drugs.

"...LDSS/N have the potential to reduce the transmission of BBVs..."

Evidence suggests that in the context of insufficient equipment coverage, LDSS/N have the potential to reduce the transmission of blood-borne viruses (BBVs), in particular HCV and HIV, compared to HDSS/N (Trickey et al., 2022). However, despite global guidance recommending LDSS/N distribution (World Health Organization, 2012), HDSS/N remain the predominant syringe type distributed in low- and middle-income countries (LMICs), and there has been little research into how to introduce LDSS/N and achieve high uptake and sustained use. Research is needed that can generate evidence to inform program practices that support effective harm reduction measures in LMICs, as well as increase their impact. Equally, a sound evidence-base to garner political commitment and sustained investment from the Global Fund (GF) and other donors is also needed.[1]

2.3 The state of BBV and harm reduction policies and access to LDSS/N in Georgia

According to the results of Integrated Bio-Behavioral Surveillance Survey (IBBS) 2022, the prevalence of HIV infection among the general population in Georgia was 0.2% (Georgia

1. This task has become even more urgent in the context of the current U.S. foreign aid funding crisis and the associated large-scale termination of funding for critical frontline harm reduction services.

Department of Public Health, 2024) and only slightly higher among people who inject drugs at 0.9% (Georgia IBBS, 2022). In 2022, HIV prevalence among people who inject drugs in Tbilisi (Georgia's capital city) was 0.5% (Georgia IBBS 2022). Since 2003, all people living HIV in Georgia have access to free antiretroviral treatment (ART) and appropriate quality laboratory diagnostic and treatment adherence monitoring tests within the framework of the Global Fund's HIV/AIDS management programs. ART is provided to patients in Tbilisi and four other regions of the country: Imereti, Samegrelo, Adjara and Abkhazia.

Historically, Georgia had among the highest general prevalences of HCV globally, driven largely by unsafe medical practice and historically higher rates of injecting drug use (Hagan, et al., 2019). In response, Georgia launched the world's first HCV elimination program, the centrepiece of which was to provide universal access to curative, direct-acting antiviral (DAA) treatment (Hagan, et al., 2019). Based on the results of the 2021 nationwide hepatitis C serosurvey (Gamkrelidze, et al 2021), the prevalence of anti-HCV antibodies in Georgia was 6.8% and the prevalence of HCV RNA among adults was 1.8%, representing a 67% reduction since 2015. In 2022, anti-HCV prevalence among people who inject drugs was 58.1% and HCV RNA prevalence was 32.1% (Georgia IBBS 2022). By 2023, 81,000 people were treated achieving a cure rate of 98.9% (Averhoff et al., 2020).

The National Hepatitis C Elimination Program is now in its tenth year, and a large number of people who inject drugs have already been treated. Encouragingly, the 2021 national serosurvey found a significant decrease in HCV infections among people who inject drugs, from 51% in 2015 to 18% in 2021 (Gamkrelidze, et al 2021).

Despite this progress, some barriers to HCV treatment remain, due to concerns among people who inject drugs about side effects (leftover from the early HCV treatment regimens), and fears of stigma and discrimination from healthcare workers. As part of addressing these concerns, Georgia continues to work on simplifying HCV models of care by expanding treatment delivery to community-based harm reduction programs, which also provide peer and psycho–social support during treatment. With large numbers of people who inject drugs treated, re-exposure to HCV has become an issue in Georgia, with stigmatisation of re-exposure presenting an additional barrier to treatment. Structural barriers to re-treatment also exist, with people who use drugs who have been re-exposed to HCV needing to pay for diagnostics and monitoring tests out-of-pocket.

"...re-exposure to HCV has become an issue in Georgia..."

According to the Georgia IBBS 'Population Size Estimation Study of People Who Inject Drugs' in 2022, the estimated number of people who inject drugs in Georgia was 51,000 (45,400 – 57,700) with a national prevalence per general population of 1.39 % (1.23 % - 1.56 %) (Georgia IBBS 2022). The 2022 IBBS also shows the most commonly injected drugs in Georgia currently are opioids including heroin, methadone and buprenorphine. Types of drugs injected during the last 12 months varied between cities. In the month prior to the survey, cities with high levels of opioid use include Rustavi, Tbilisi, Batumi, and Zugdidi but compared to Tbilisi, the rate of stimulant injecting was significantly higher in Rustavi, Telavi, Zugdidi and Kutaisi. Injection of novel psychoactive stimulants (NPS) was also significantly higher in Kutaisi compared to other cities. The rates of stimulant and NPS injection are also more common in older participants (>35 years) compared to younger people (<35 years) (Georgia IBBS 2022).

Currently, harm reduction services/NSPs and pharmacies in Georgia have the following needles & Syringes (N&S) available:

- 1ml, 3ml, 5ml, 10ml, 20 ml syringes
- 23, 25, and 27 gauge needles
- 23, 25, and 27 gauge 'butterflies' or winged infusion sets.

The1ml 27G fixed syringes are low-dead space and typically used for heroin and stimulant injecting in Georgia. HDSS/N injecting equipment – typically 3ml or 5ml syringes and 23G

and 25G needles for heroin and buprenorphine and 10-20 ml syringes (often used with butterflies) for methadone injecting – are also commonly used.

Across Georgia, the above injecting equipment is available free of charge through fixed site NSP, mobile NSP, and outreach. In addition, across the capital city, Tbilisi, there are also ten (10) vending or automatic dispensing machines[2]. There is a limit to provide no more than 35 syringes per individual client at each distribution occasion, and up to 70 syringes for secondary delivery or peer distribution. During COVID, this restriction was removed to facilitate easier access to syringes. According to recent changes, a client should not receive less than 150 syringes per year, and the maximum number is not defined.

"... beneficiaries have not been asked about their preferences..."

Stakeholders report that NSP services are friendly and respectful when they are provided by community-based organisations and peers and many would like to see more NSPs led by community members[3]. N&S are also available at a cost in pharmacies but the scale of uptake at pharmacies is currently unknow. In collaboration with Georgian stakeholders, Phase 3 of this research will seek to explore this issue further.

While the ability for program beneficiaries to receive up to 70 N&S per visit suggests high coverage of sterile N&S, anecdotal reports point to concerns about the type and quality of N&S currently distributed by the NSP in Georgia. Equipment availability is largely dependent on the Global Fund to Fight AIDS, Tuberculosis and Malaria is (GFATM). Stakeholders report that beneficiaries have not been asked about their preferences – they are simply offered what has already been procured, which is often the cheapest product available[4]. Even if N&S are procured locally, which can occur if GFATM experiences problems procuring syringes from the global market, the locally procured equipment is typically inconsistent, poor quality, and involves predominantly HDS products.

Another issue is the distribution of so-called "smart" syringes, which auto-destruct. These N&S units automatically lock when the plunger is depressed all the way to the bottom of the syringe (after an injection) and cannot be reactivated without damaging the N&S. Program beneficiaries dislike "smart" syringes and have raised this issue consistently at NSPs. The GFATM Principal Recipient in Georgia, the National Center for Disease Control and Public Health, has committed to not procure these N&S in the future[5]. In Georgia, other than alcohol swabs, the NSP does not currently provide other harm reduction supplies such as spoons, cookers, cotton, or other supplies (i.e., straws or pipes for stimulant use). In the past, the NSP offered vein care cream, cookers, cotton, and medical supplies which were well received by beneficiaries.

Naloxone has been available at no charge through harm reduction programs in Georgia since 2013. Drug checking services are not currently available in Georgia and data on overdose is limited because people are reluctant to report it due to fears of criminal investigation and charges. The 2022 Georgia IBBS data showed that 202 (10%) respondents had overdosed and 511 (25%) of participants had witnessed someone else overdose in the past year, out of which naloxone was used in 322 (63%) of cases. In the cases where naloxone was used, 99 (19%) participants called an ambulance and 36 (16%) of those participants reported that the

2. It should be noted that in Georgia the needles and syringes above 1ml are typically packaged together so '1 syringe' = 1 needle + 1 syringe.
3. Reported to INPUD in the Community Led Monitoring (CLM) Baseline Assessment Report – CLM is a knowledge mobilisation and community capacity building component of the CUTTS Hep C Project that was being conducted by INPUD in collaboration with study community partners GeNPUD, TaNPUD & RWRP.
4. Ibid.
5. Ibid.

ambulance notified the police regarding the overdose. This data also showed that a higher frequency of overdose was observed among younger (≤35 y/o) people who inject drugs (Georgia IBBS 2022). Efforts are being made to increase the focus on overdose prevention. Take-home, injectable naloxone and continuous monthly trainings (on identifying overdose from different drugs and naloxone administration) have become more widely available through harm reduction programs in recent years.

Georgia has provided NSP since 2005, but there are ongoing contextual and systemic barriers to the provision of and access to harm reduction services. Most recently, in May 2025, Georgia enacted legislation commonly referred to as the "foreign agents' law," which requires organisations receiving more than 20% of their funding from international sources to register as agents of foreign influence or else face significant financial penalties. Critics have expressed concern that the law may impede the continuity of services provided by civil society and community organisations and have drawn comparisons to similar legislation in other jurisdictions, including Russia, where such frameworks have been associated with increased restrictions on civic space and dissent. This legislation impacts harm reduction services because many rely on international funding for their operations.

Other barriers to harm reduction services in Georgia include the ongoing challenges relating to illicit drug use being treated as a criminal/law and order issue, rather than a health and social issue. For example, people who use drugs can encounter policing practices that may include targeted surveillance and harassment, including in and around drop-in centres and other harm reduction services. Law enforcement efforts have reportedly involved street-level searches for drug paraphernalia such as N&S. Legal penalties for drug possession, even in minimal quantities, are widely considered to be disproportionate. In addition, stigma and discrimination from healthcare providers also continues to act as a barrier to harm reduction and other health and support services for people who use drugs.[6]

Like other LMICs, there are also ongoing concerns in Georgia about the implications of transitioning from GFATM support to government funding for harm reduction services. Specifically, there are concerns about the potential under-funding of harm reduction services leading to fewer sites and less organisations offering these services. In January 2024, two harm reduction sites transitioned from GFATM support to state support in Georgia. Prior to this transition, the GFATM funding provided case management and medical services; the government funding arrangements will only cover basic services rather than the comprehensive package of harm reduction services. In this context, there are concerns about the readiness of the public health system to deliver harm reduction services in Georgia in the future.

2.4 The role of values and preferences and community engagement in the implementation of LDSS/N:

"Few countries have a formally approved procedure for consultations with NSP program beneficiaries and Georgia is no exception."

LDSS/N distribution programs have been tried in LMIC settings before, but research suggests these programs did not result in high and sustained uptake because they had failed to involve people who inject drugs in the process of LDSS/N product selection (Trickey et al., 2018). For example, LDSS/N supplied in initial rollouts in Eastern Europe and Central Asia were only available in 1ml fixed needle/syringes (small volume syringe with no detachable needle). These types did not match community preferences and therefore uptake of LDSS/N stalled (Zule et al., 2015).

Few countries have a formally approved procedure for consultations with NSP program beneficiaries and Georgia is no exception. Despite program monitoring (during which records are tracked), regular meetings with program beneficiaries and staff, and civil society and activist platforms for involving people in decision-making, people who use drugs report

feeling unheard and like their inputs have not led to meaningful changes[7]. In addition, while the GF Country Coordinating Mechanism (CCM) meetings also provide an opportunity to raise and discuss the needs and preferences of program beneficiaries, this is not a mechanism that is accessible for most community members. Given the lack of a formal consultation mechanism and growing evidence on the value of involving people who inject drugs when trialing LDSS/N distribution programs (Zule et al., 2015), a community-led values and preferences approach was prioritised for researching LDSS/N introduction in Georgia (and in the eight other LMIC involved in the study).

Hence, in both the wider program of research and this specific study in Georgia, community leadership and engagement is embedded across all stages of the work to ensure that the LDSS/N products selected, the distribution strategies employed, and any knowledge mobilisation approaches undertaken have been informed by the values and preferences of the local communities. This includes a Community Advisory Board (CAB) with community members from all ten LMIC overseeing all stages of the research process (from conceptualisation to implementation and interpretation of findings) and the training and formalised support for community researchers and note takers to take a leading role in the collection and analysis of all focus group discussion (FGD) data.

2.5 Overall Study Design – explanation of the study phases:

This is a mixed-methods LDSS/N implementation study involves four research phases:
Phase 1. Assessment of values and preferences for LDSS/N pre-selection
Phase 2. Piloting of LDSS/N products
Phase 3. Implementation and evaluation of LDSS/N distribution program
Phase 4. Mathematical modelling and program evaluation.

Phases will be implemented iteratively. Evidence and the knowledge generated through earlier phases will iteratively inform the design and adaptation of an optimal model for LDSS/N implementation, and the evaluation of the implementation process.

The key population for the study is people who inject drugs accessing NSPs in Georgia. The study is being implemented in study sites across the Tbilisi, Rustavi and Gori regions. Study sites were selected because they already provide NSP services to local community of people who inject drugs and have the capacity to reach a desired number of participants. Sites from multiple locations were selected to identify a range of perspectives from a variety of populations.

2.6 Qualitative, community-led values and preferences research:

"The qualitative, community-led values and preferences research forms the foundation of all program implementation activities for this study."

The qualitative, community-led values and preferences research forms the foundation of all program implementation activities for this study. The data from the community-led values and preferences research is being used to inform the selection of LDSS/N products and identify the barriers and enablers to successful program delivery. This component is also providing an enhanced understanding of how individual, social and structural factors influence study participants' interest in, engagement with, and perceptions of LDSS/N in the context of harm reduction. Results from the values and preference component will assist in tailoring and refining program implementation processes to encourage and sustain LDSS/N uptake and usage and inform future implementation programs.

The values and preferences data is primarily being collected through community-led focus group discussions (FGDs) with people who inject drugs across phases 1 – 3 of the project.

6. Ibid.
7. Ibid.

"Prior to implementation of LDSS/N, FGDs will inform the selection of LDSS/N to be piloted..."

Prior to implementation of LDSS/N, FGDs will inform the selection of LDSS/N (Phase 1) to be piloted over a 4–6-week period by a sample of people who inject drugs (Phase 2). FGDs with pilot participants will help finalise the selection of LDSS/N that will be distributed as part of a 12–18-month LDSS/N implementation and evaluation phase (Phase 3). See further details on the study phases in Figure 1 below:

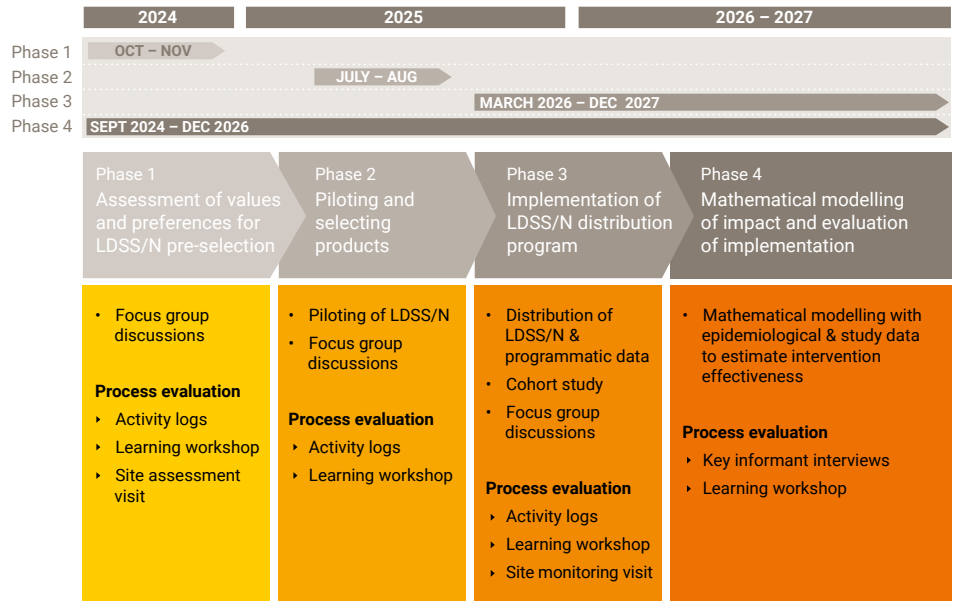


Figure 1: Overview of study phases & values & preferences FGDs

The community-led values and preferences FGD 1-3 will meet the first three objectives of the overall study which are to:

- Explore community values and preferences for LDSS/N;
- Identify barriers and facilitators to access and uptake of LDSS/N among people who inject drugs;
- Design and implement an LDSS/N distribution program informed by community values and preferences.

3. Community-led Values & Preferences: Phase 1 Focus Group Discussions (FGD)

3.1 Methodology

3.1.1 Study Design

"FGD participants were invited [...] to share their values and preferences for the LDSS/N products..."

The Phase 1 FGDs are the formative stage of the research where community values and preferences for a selection of LDSS/N are being assessed to inform procurement and distribution of LDSS/N for the Phase 2 Pilot. Each FGD involved a small sample of community members with recent experience of injecting drug use. FGD participants were invited to discuss their current experience with injecting equipment, practices and harm reduction; to share their values and preferences for the LDSS/N products, and to discuss ideas on pilot distribution approaches and initial input into the design and implementation of community mobilisation and promotion activities to be adapted in later phases of the research.

A cross-consortia process, including the CAB and other consortium partners, was conducted prior to the Phase 1 FGDs to identify and procure a range of LDSS/N sample products (see Appendix 1 – Starter Pack) for consideration by the Phase 1 FGDs. This process was part of a larger cross-consortia process to identify a core or base 'Starter Pack' to be piloted in all countries but that allowed for adjustments in specific country contexts[8].

The base 'Starter Pack' process was led by the INPUD PI (from the MdM Consortium) and the technical adviser from Coact (from the FLA Consortium) – both of whom have extensive experience in the delivery of peer-based NSP and lived experience of injecting drug use. The Portfolio CAB and community partners in each context were also significantly involved in this process and the CAB signed off on the final core 'Starter Pack'[9]. In Georgia, the process of checking and refining the core 'Starter Pack' for the Georgian context included working with GeNPUD to consider a range of context specific factors, including IBBS data and anecdotal information on the type of drugs injected and injecting practices, as well as the types and range of injecting equipment currently being distributed in the cities/regions involved in the study.

In partnership with the CAB and local/consortium partners, INPUD also led a further cross-consortia process to develop participant recruitment mechanisms and other Information, Education and Communication (IEC)/knowledge mobilisation materials for use in the Phase 1 FGDs to explain the benefits of LDSS/N *(Appendix 2 and 3)*. In addition to the above print-based resources, INPUD also led the development and recording of a brief video resource for use as an additional tool in the FGDs to explain each of the sample products in the 'Starter Pack' (the video script was translated into Georgian and a voiceover in Georgian was added). These recruitment and knowledge mobilisation materials are being used in context specific ways across all study countries (using language specific translations, voiceovers and/or sub-titles).

8. A 'Values & Preferences Toolkit' and other publications and resources are planned as future project outputs which will include more detailed information on the processes and rationales that informed both the core 'Starter Pack' and any country-specific adjustments.

9. The final core 'Starter Pack' was also informed and limited by the range of LDSS/N products available at the time (Jan – Aug 2024). This included the lack of a LDSS fixed unit (needle & syringe in one unit) with a larger volume syringe than a 1ml. As a result, the final pack include detachable LDS needles (in various gauges and lengths) to be paired with standard HDS syringes (in various sizes/volumes) to create low dead space options for the majority of participants in the study countries using N&S larger than 1ml. Conversations are ongoing with manufacturers on the possibilities for producing larger volume LDSS fixed unit options in the future depending on the outcomes from Phases 2 & 3 and the specific needs and preferences of participants identified in this study.

3.1.2 Eligibility Criteria:

The study population comprises people who inject drugs attending NSP services at the study sites and their peers. Eligibility criteria include:

- Being aged ≥18 years;
- Reporting recent (previous six months) and regular (at least monthly) injecting drug use;
- Able to communicate in Georgian; and
- Able/willing to provide informed consent.

3.1.3 Participant Recruitment:

"... a specific women-only FGD was organised in Tbilisi ..."

Participants for the Phase 1 FGDs were recruited from across the participating study sites via a purposive sampling approach (participants with a strong connection to the local community of people who inject drugs and with an in-depth understanding and knowledge of local injecting practices). Recruitment was guided by the expertise of the CAB and INPUD and facilitated by GeNPUD and the study site staff. In recruitment, attention was paid to ensuring a diverse representation of local community across age, gender, and diverse injecting expertise and experience. To ensure the perspectives and experiences of women who inject drugs were represented in the FGDs, a specific women-only FGD was organised in Tbilisi *(see further details at Table 1: Phase 1 FGD Study Sites below)*.

Recruitment occurred via community-led recruitment processes whereby the community researchers from GeNPUD and peer outreach workers from the study sites approached NSP beneficiaries and utilised their personal networks of people who inject drugs within the three study cities/regions to identify potential research participants. Recruitment strategies included using a combination of a study poster in local Georgian language *(see Appendix 2 – LDSS/N FGD Recruitment Flyer & Explainer)*, word-of-mouth and community-networking approaches using peer education resource *(see Appendix 3 – LDSS/N Client Resource)*[10]. The opportunity to participate in the Phase 1 FGDs was also advertised at the NSP at the study sites. Interested members of the community were invited to register their interest. Upon contact, the community researchers provided potential participants with an overview of the study's aims and what participation would involve and, if interested, they were screened for eligibility. If the eligibility criteria were met, they were provided with information for attending the FGD.

3.1.4 Informed Consent

All participants were offered a copy of the participant information and consent form *(see Appendix 4 – PICF and Consent Register)*. Prior to the commencement of the FGD, the community researchers read the PICF verbatim to participants in Georgian. Having read (or listened to) the PICF, participants were encouraged to ask any questions. They were then asked for verbal consent to proceed with FGD participation. Consent was documented in the Consent Register *(see Appendix 4)*. No personally identifying information was recorded in the register. The register was signed off by one of the GeNPUD community researchers and provided to the principal investigators (via a secure server) following the FGD.

3.1.5 Participant Demographics

A total of nine (n=9) FGDs were conducted across four (4) study sites participating in the Phase 1 FGDs in the cities of Tbilisi, Rustavi and Gori[11].

10. Both the LDSS/N FGD Recruitment Flyer & Explainer and the LDSS/N Client Resource used in participant recruitment were written, developed, reviewed, edited, and designed by community members with oversight and final sign-off by the Portfolio CAB.

11. Tbilisi is the capital and largest city in Georgia, Rustavi is a city in the southeast of Georgia in the region of Kvemo Kartli about 20 km southeast of Tbilisi, and Gori is a city in eastern Georgia in the region of Shida Kartli about 80 km from Tbilisi.

FGD Number	Site	City/Region
FGD 1	Hepa Plus	Tbilisi
FGD 2	Hepa Plus	Tbilisi
FGD 3*	New Vector	Tbilisi
FGD 4	Hepa Plus	Tbilisi
FGD 5	Step to Future	Gori
FGD 6	Step to Future	Gori
FGD 7	Step to Future	Gori
FGD 8	New Vector	Rustavi
FGD 9	New Vector	Rustavi

* New Vector, Tbilisi will participate in Phase 1 FGDs only (see 3.2 Data Collection below for further detail).

Table 1: Phase 1 FGD Study Sites

Each FGD included between 7 – 10 participants with a total of seventy-five participants across all FGDs. Sixty-four (85%) FGD participants were male and eleven (15%) female. The median age of participants was 48 years. The age range was 27 - 69 years, with 7% (n=5) aged 26-35 years, 31% (n=23) aged 36-45 years, 49% (n=37) aged 46-55 years, 10% (n=8) aged 56-65 years and 3% (n=2) aged over 65 years. All participants had significant experience with drug injection, having used drugs for many years. The participants mainly used opioid-type substances including heroin, methadone and buprenorphine. Specific FGD participant numbers and participant gender and age breakdowns are included in the Table 1 below.

FGD Number	No.of Participants	Gender	Age Range
FGD 1	8	Male (8)	38 – 67
FGD 2*	9	Female (9)	35 – 56
FGD 3	10	Male (10)	41 – 54
FGD 4	8	Male (8)	28 – 52
FGD 5	8	Male (8)	37 – 58
FGD 6	8	Male (8)	44 – 60
FGD 7	9	Male (8)	27 – 54
FGD 8	8	Male (8)	38 – 49
FGD 9	7	Male (5) Female (2)	42 – 69

* Designated FGD for women who inject drugs (see further comment at 6. Limitations & Challenges below).

Table 2: FGD Participant Characteristics

3.2 Data Collection

"FGDs were led by trained and supported peer/community researchers from GeNPUD..."

FGDs were led by trained and supported peer/community researchers from the local community-led network, GeNPUD, (with training and support provided by INPUD, Burnet and MdM). FGDs were audio recorded and a note-taker documented FGD notes. The duration of the FGDs were between 45 – 60 minutes each and were conducted in Georgian. The FGDs were conducted in-person, and all groups followed the Phase 1 FGD Guide *(see Appendix 5 – Focus Group Discussion Guide)*.

A pause was scheduled following the first FGD to allow for a reflections and learning session after an English-translated transcript was available and reviewed by the INPUD PI and Burnet research team. This session, attended by community researchers/note takers, other

members of the country team, the INPUD PI and members of the Burnet research team, provided an opportunity for the community researchers/note takers to share their experience and ask questions, and for the INPUD and Burnet teams to offer feedback to further refine data collection. The remaining Phase 1 FGDs then continued incorporating the discussion and feedback from the reflections and learning session as appropriate.

During the Phase 1 FGDs, the community researchers facilitated discussions about participants' preferences, values and considerations regarding N/S, including current access and barriers to access. LDSS/N sample products in a 'Starter Pack' *(see 'Study Design' above)* were presented to the FGD participants, who were invited to consider the range and brands of potentially available products and discuss their suitability across local drug using practices and their acceptability. This process was supported by a combination of the IEC materials and brief video, as discussed at 3.1.1 above. Participants were then invited to provide their first impressions and identify which (if any) of the LDSS/N products should be made available in a 4-6-week Phase 2 pilot. The facilitator also invited participants to provide initial input into the design and implementation of community mobilisation and promotion activities to support LDSS/N uptake during the pilot phase, as well as preferred pilot distribution models.

"LDSS/N sample products [...] were presented to the FGD participants, who were invited to consider the [...] potentially available products ..."

At the end of the FGD, participants were compensated for their travel expenses, time and expertise with a $10USD Georgian GEL equivalent participant reimbursement fee. Those participants who expressed an interest in participating in trialling selected LDSS/N equipment in the Phase 2 Pilot Study were consented in preparation for the Phase 2 Pilot Study *(see 7.3 below)*.

Note: in Phase 1 an additional FGD was conducted at the New Vector Tbilisi site (in addition to the FGDs at the New Vector Rustavi site), as there were NSP beneficiaries who were interested in participating in the Phase 1 FGDs. The data from the Tbilisi Phase 1 FGD is included in the analysis that follows. However, the New Vector Tbilisi site will not continue as a study site for Phases 2 & 3 *(for further detail and rationale see 7.3 Phase 2 Pilot – Next Steps below)*.

3.3 Data Analysis:

Immediately following each FGD, the audio recording was professionally transcribed verbatim. Once the audio transcripts were available, the community researchers/note-takers de-identified the transcripts and checked them for accuracy. The community researchers/note-takers then developed a FGD Summary Report from detailed notes using a template provided by INPUD, drawing upon selected relevant quotes from the transcript for inclusion in the report. The audio transcript, FGD notes and FGD Summary Reports were professionally translated from Georgian into English and uploaded (along with participant documentation) to a secure cloud-based platform for access by the INPUD PI and Burnet study team based in Australia. The English transcripts were downloaded and further checked and de-identified by the INPUD PI, including checking and confirming any details with the community researchers/note takers in Georgia. All FGD data and participant documentation were saved to the secure server at Burnet Institute in Australia for data analysis purposes and all documents on the cloud-based platform deleted.

Data contained in transcripts, detailed notes and summary reports were then coded by the INPUD PI and two qualitative researchers from the Burnet research team using NVivo software. A qualitative analysis was conducted utilising deductive and inductive coding; focused coding and abstraction, to organise the data and respond to the research questions. The analysis commenced with the application of a predefined set of deductive codes based

"During data analysis, areas of consensus and divergence [...] were identified..."

on the FGD Guide and key research questions developed by the INPUD PI and two qualitative researchers from the Burnet research team. This was complemented by an inductive coding process, which identified additional 'matters of concern' specific to participants' local context. During data analysis, areas of consensus and divergence within and between participants and any significant local contextual issues were identified and are highlighted in the analysis contained in this report *(see section 4: Results & Discussion below)*.

3.4 Ethics approval:

Master protocol for the LDSS/N Study was approved by the WHO ERC (ERC.0004055) on 04 May 2024, the Alfred Hospital ERC in Australia (Project Number: 109182 (Local Reference: Project 350/24/24) on 10July 2024 and Georgia country NCID IRB on 27 June 2024.

4 Results & Discussion

The following section presents findings from FGDs conducted with people who inject drugs in Georgia. Results highlight a range of experiences and perspectives relevant to LDSS/N and harm reduction programming more generally, including current access to needles and syringes, the impact of equipment quality on injecting practices, and experiences of sharing and reuse in specific contexts. Participants' initial impressions of LDSS/N, perceived benefits (including harm reduction and improved injecting experience), preferences for different types, and suggestions for the pilot phase and future roll-out are described. The role of peer networks in education and knowledge sharing is also highlighted, along with structural and social barriers such as policing, stigma, and the lack of harm reduction services in prisons. In addition to informing LDSS/N implementation, these themes provide important broader insights into how harm reduction services in Georgia (and potentially other LMIC) can be improved, adapted, and scaled in ways that are grounded in the lived realities of the communities they aim to serve.

4.1 Current Needle & Syringe Access and Barriers to Harm Reduction

4.1.1 Current Context – Needles & Syringes are Accessible, but Quality is Poor

The majority of FGD participants stated that there are no problems with accessing injecting equipment in Georgia. Currently, N&S are distributed by the community-based organisations/ harm reduction services. Participants were aware of broad limitations on the amount of equipment an individual can take in a single visit or interaction, but did not identify these limits as reducing accessibility.

> *"It is enough, they give you what you need."*
>
> (Participant FGD 1.5)

> *"You can take as much as you need. You don't have a problem, they don't limit you..."*
>
> (Participant FGD 1.4)

However, participants across the FGDs described the N&S received from community-based organisations and harm reduction sites as being of low quality:

> *"The only problem is the quality, nothing more."*

"We have low-quality syringes, the needle breaks soon ..."

> *"We have low-quality syringes, the needle breaks soon, when I couldn't get into the vein the first time, and I used it for the second time, it became dull.."*
>
> (Participant FGD 1.2)

When asked what they pay attention to the most when selecting a N&S - the size of the needle, the length of the needle, the size of the syringe, the good functioning of the piston, etc – the consensus was that they consider *"Everything together"* to gain a holistic picture. One participant explained further:

> *"... some have plastic instead of rubber and [some] have a [good] needle. You look at everything to have a good one."*

Because of the many components of low quality N&S that might fail, one participant put it this way:

"I'd rather pay a little more, buy quality syringe or needle rather than pay attention to anything else."

(Participants FGD 1.4)

Participants also highlighted how issues of quality and choice work together when it comes to decision making in relation to accessing injecting equipment. For example, the poor quality of N&S from community-based organisations was driving many participants to regularly seek out, not just better-quality N&S at pharmacies, but more choice and variety of equipment.

Participants preferred getting their N&S from the community-based organisations because they have to pay to access syringes at the pharmacy and they can experience negative attitudes from pharmacy staff. Yet, a substantial proportion of the FGD participants routinely accessed injecting equipment from the pharmacy because the N&S are considered better quality and there is more variety:

"...what we take from here is completely useless, it's not even called disposable, it's low-quality syringes."

"I get them from a pharmacy, because what we take from here is completely useless, it's not even called disposable, it's low-quality syringes."

(Participant FGD 1.9)

"In the pharmacy, there are higher quality syringes, they have different prices, there is a large selection, and here there is only one type, whatever they get in the tender."

(Participant FGD 1.2)

Some FGD participants felt that purchasing N&S at pharmacies was their only viable option. They stated that for them, it wasn't that they preferred pharmacy over community-based harm reduction services, but rather, they felt they had little choice in the matter (whether they can afford it or not) because the quality of the equipment that is provided free-of-charge is so poor:

"We do not give any preference to a pharmacy as these syringe and needles are expensive there, whether a syringe cost 80 tetri or 1 lari [Georgian currency] when there are 10 or 15 of us, it's already a lot, 10 or 15 laris, and it's a lot for everyone, at least for me."

(Participants FGD 1.6)

Concerns about quality and suitability were also raised by participants in multiple FGDs specifically in relation to the auto-disable syringes (referred to as 'disposable syringes' or 'clever' syringes). The extremely poor quality and lack of functionality of these widely distributed 2ml N&S, even for drug preparation, drove these participants to purchase 2ml N&S from pharmacy despite their cost:

"In a pharmacy, we mainly buy two-milligram syringes. You know those disposable syringes, it breaks so easily, you can't use it properly. It does matter whether you use it for extraction for substance [for preparation] or the other way [for injecting]. I go to the pharmacy mainly because of 2-milligram syringes."[12]

(Participant FGD 1.8)

"Those 2-milligram syringes are not worth a penny, they easily break, it's horrible."

(Participant FGD 1.4)

12. Note: while Georgians use two words to refer to 'shp'ritsi' (syringes) and 'nemsi' (needles), these words are used interchangeably. So, where FGD participants refer to 'syringes' they are referring to both needles and syringes. This is in part because Georgian PWID are not used to the needle coming separately. Typically, the syringe comes packaged with a needle and therefore people refer to '2ml syringe', '5ml syringe', etc., but this includes the needle.

"I will say one thing, I will add, the so-called "clever" syringes and I am so fed up with it and I hate them so much...."

(Participant FGD 1.2)

Participants outside of Tbilisi (Georgia's capital city), added that purchasing injecting equipment from the pharmacy was not just about quality and choice, but also because pharmacies were more conveniently located than the community-based/harm reduction organisations, saving time and travel costs. For example, when asked what factors might influence their decision to purchase N&S at a pharmacy rather than always getting them for free at community-based organisation, one participant from a FGD held in Gori stated:

"The only thing is that there is only one harm reduction service center in the city, we use a car, and we come here from the other area and pick needles and syringes up. But if they do small branches around it would be far better in terms of accessibility. Some people to go directly to a pharmacy rather than paying money for a taxi to get here, one would prefer to go to a pharmacy and buy 5 laris [Georgian currency] worth syringes there."

And another participant added:

"Khidistavi is a village and if I come from there, they will give me 5-10 pieces of syringes, but I can't come because it is far."

(Participants FGD 1.6)

Convenience and shorter distances were considerations across FGDs, alongside issues such as criminalisation and the importance of being able to access N&S close to where they buy and use their drugs – suggesting that deciding where to access N&S is informed by a hierarchy of needs:

"First, distance, its far away, and I'm scared sometimes. It's a situation that's not for it, something that I have in my pocket, I'm eager to do it if I tell the truth. I prefer to buy in the pharmacy than to come out here."

(Participant FGD 1.3)

Another factor in N&S access and uptake was brand preference. Across FGDs, participants expressed a strong preference for the "Brownie" syringe. The "Brownie" is a 2ml Braun brand syringe (braun being brown in German and hence referred to as the "Brownie") which comes packaged with a needle. The "Brownie" was generally considered to be of better quality and made from superior materials than the N&S available through the community-based organisations:

"Brownie brand syringe is far better than the ones distributed here."

(Participant FGD 1.7)

"Brownie is the best. It is the easiest syringe to use, and it is the most reliable one ..."

"Brownie is the best. It is the easiest syringe to use, and it is the most reliable one, I want to say that."

(Participant FGD 1.9)

"...there is not a single syringe cooler than "Brownie."

(Participant FGD 1.2)

"If I have money, I go and buy brownies."

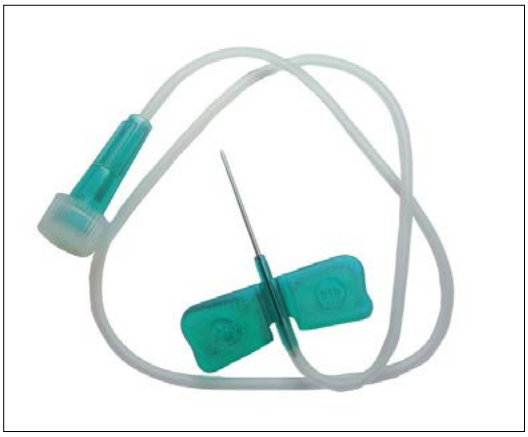
(Participant FGD 1.6)

When prompted by the facilitator, several respondents confirmed that the availability of the "Brownie" is a determining factor in choosing to access their injecting equipment through a pharmacy:

> *"Yes", it has better metal"*
>
> *"Quality"*
>
> *"Others are just garbage", "it is not stuck".*
>
> (Participants FGD 1.2)

While the "Brownie" appears popular among people who inject drugs in Georgia, not all FGD participants were completely satisfied with it. In their view, the quality of the "Brownie" had deteriorated over time. Consequently, some felt that the "Brownie" was better than the very poor-quality N&S available from the community-based harm reduction services, but still "not that great" balanced against the cost of only being able to purchase them at pharmacies:

> *"It's quite expensive, by the way. I cannot buy it [the "Brownie"] for less than a lari [Georgian currency]"*
>
> (Participant FGD 1.5)



Finally, the use of winged infusion sets or 'butterflies' was also discussed. The term 'butterfly' is used due to the plastic wings that sit either side of a needle with a flexible tube attached to the needle hub. The tubing has a connector at the bottom to allow it to be attached securely to standard larger volume HDS syringes (2/3ml, 5ml, 10ml, 20ml and above). Butterflies are typically used for administering larger volumes of liquid and/or injecting into small and difficult to access veins because:

- the design allows the needle to sit flat or close to the skin, which is important for accessing veins close to the surface; and
- the wings also make it easier to grip and control the needle when it is being inserted, which is important for veins that are difficult to access; and
- the large volume syringes can be changed via the connector at the end of the tubing, removing the need for multiple injections, which is important if veins are compromised and there is a need to minimise the number of injections.

"Small veins are easy to find with butterfly."

In Georgia, butterflies are called "Babachka" and while they are provided free-of-charge through community-based organisations, and purchased at pharmacies. In one FGD the facilitator engaged participants in a discussion on the use of butterflies and how they are accessed:

> Facilitator: *"Here, you mention "Babachka", the so-called butterfly. Why do you use butterfly?"*
>
> Respondent 69: *"If you have poor veins, it's easier to find them."*
>
> Respondent 72: *"Small veins are easy to find with butterfly."*
>
> (Participants FGD 1.9)

Facilitator: *"Where do you get it from? Are these needles available to you today?"*

Respondent 69: *"I get them from a pharmacy."*

Respondent 72: *"Yes, a pharmacy. They increase the price every day."*

(Participants FGD 1.9)

Further research into the use and availability of butterflies among people who inject drugs in Georgia is needed. This equipment can retain a large amount of blood following injection (significantly more than standard high dead space (HDS) needles and syringes). This retention can lead to a much greater risk of blood-borne virus (BBV) transmission and systemic and soft tissue infections (SSTIs) if butterflies are shared or reused, particularly in contexts where access to sterile equipment is limited or unaffordable. In this context, any future harm reduction strategies in Georgia should consider alternative lower dead space options that achieve the same utility for people who inject drugs and other pragmatic harm reduction responses that align with community needs and current injecting practices.

4.1.2 Current Context – Strong community norms against sharing N&S

Most focus group participants reported that they do not reuse injecting equipment after someone else. Across the FGDs, the discussion about reusing injecting equipment elicited strongly held viewpoints against sharing N&S and a deep discomfort with the very idea of reusing injecting equipment:

"I must be an enemy of myself to do it"

(Participant FGD 1.8)

"It's unacceptable for me. I can't even imagine doing something like this."

(Participant FGD 1.1)

For most participants, the practice of not reusing N&S that has been used by someone else is a fundamental rule that should never be broken, and their responses conveyed a strong sense of community norms:

"No", "It's out of the question", "It doesn't happen."

(Participant FGD 1.4)

"I've had experience with my own needle; late at night, when I had no other option, I used my personal needle two or three times when it was not yet blunt. But using someone else's needle is unacceptable; it doesn't make sense."

(Participant FGD 1.1)

In addition to established rules within the community against reusing N&S, some participants also highlighted the role of shared knowledge about the risks associated with reusing injecting equipment and personal responsibility to avoid such practices:

"... when I had no other option, I used my personal needle two or three times ..."

"We all know that it must not be done. We know that and we avoid it ourselves."

"A friend may tell me that nothing is wrong with him and well the syringes and needles should not be shared anyway."

(Participants FGD 1.8)

While strict community norms now discourage sharing, participants also reflected on a past when such practices were more common, often compounded by punitive responses to drug use. Participants explained how before NSP was widely available in Georgia, the reuse and sharing of injecting equipment was sometimes unavoidable. This shift in practices was repeatedly attributed to long-standing harm reduction efforts:

"During the Soviet time 20 men used to inject with the same syringe."

(Participant FGD 1.1)

"Everything is available nowadays. Everyone uses it once now."

(Participant FGD 1.5)

Many participants also described strategies they use to prevent others reusing their N&S. These included breaking or damaging the syringe after use so that no one else could inject with it:

"After each consumption, I break its head."

(Participant FGD 1.1)

Others emphasised the importance of personal responsibility in disposing of used injecting equipment properly, not only for harm reduction purposes but as an ethical responsibility towards:

"I'm sorry that I go so far, but after I inject with a syringe, I put it in my pocket and throw it away."

(Participant FGD 1.8)

While focus group discussions (FGDs) can create supportive spaces for collective reflection, they can also sometimes unintentionally generate pressure for participants to align with perceived norms, particularly when discussing stigmatised practices. The participant account below highlights this dynamic when one participant tentatively disclosed reusing their own syringe earlier that day. Perhaps in anticipation of a negative response from others in the group, the participant qualifies their admission by emphasising the exceptional circumstances that led to the decision:

"I had to take my child somewhere and I didn't have enough time. What could I have done?"

(Participant FGD 1.8)

The participant's discomfort, evident in the rhetorical question "What could I have done?", highlights the complex and often conflicting expectations that people who inject drugs manage. This includes navigating (and frequently juggling) criminalisation, caring responsibilities, health risks, and a sincere desire to protect both themselves and others. Rather than emphasising a rule broken, the account reveals the burden of moral labour involved in trying to do the "right thing" under conditions that rarely allow for easy or ideal choices, as one participant reminded their peers in another FGD:

"Maybe we don't live like that now, but we don't know where we will be tomorrow..."

(Participant FGD 1.6)

"I would not share it with another person, but I might use the same syringe twice."

Nevertheless, despite the strong viewpoints and community norms against reusing equipment, reuse of one's own equipment (rather than sharing a N&S that has been used by someone else) was acknowledged (albeit, at times reluctantly) as a contemporary practice that some participants were willing to discuss. These accounts typically referred to practical challenges, such as having no immediate access to sterile supplies or finding oneself in a situation where reusing one's own syringe felt like it was the least harmful practice under the circumstances:

"I would not share it with another person, but I might not have a new syringe at home and use the same syringe twice."

(Participant FGD 1.2)

"There are some risk factors, I know, but when it's yours... Well, it's mine."
(Participant FGD 1.6)

Although widespread access to NSPs has reduced unsafe injecting practices significantly, some participants reported that reuse and sharing of someone else's N&S still occurred in specific situations. In these moments, participants described a range of situational factors such as poverty, closed pharmacies, lack of preparation, or being in withdrawal, as overriding people's usual harm reduction practices:

"If there is a desperate situation, if I am in trouble, I can use my brother's syringe... Usually, pharmacies are closed at night. We can't wait until the morning, as we might be in 'Lomka' [pain]."
(Participant FGD 1.7)

"Poor quality of the needles and syringes and the existing law are the barriers."

"They don't care, at that moment they think that the main thing is to get the drug into their body..."
(Participant FGD 1.9)

One participant summed up the current barriers to access this way:
"Poor quality of the needles and syringes and the existing law are the barriers."
(Participant FGD 1.5)

Taken together, these findings show clear progress in access to sterile injecting equipment and reductions in unsafe practices. However, structural and situational factors – such as poverty, criminalisation, and stigma and discrimination – continue to create barriers to consistent and equitable access. Community-led NSP services remain a vital resource, helping people practice harm reduction even in difficult circumstances.

4.1.3 Current Context – Social and structural barriers to access

4.1.3.1 Police

While the role of law enforcement in shaping access to sterile injecting equipment was discussed, some believed police no longer posed a significant threat when only carrying clean injecting equipment or when accessing N&S through community-based services. But accounts of being stopped or followed by law enforcement, especially after visiting a pharmacy, were recounted and participants expressed widespread concern about carrying drugs, which affected decisions around where and when to access injecting supplies:

"There were times when I left the pharmacy, and I was stopped by [a] police officer."
(Participant FGD 1.5)

"If I've got drug in my pocket, I'll be afraid, sister…not directly related to syringes."
(Participant FGD 1.1)

Across the FGDs, participants provided varied accounts of their experiences with law enforcement, and many were uncertain about how police might respond in any given situation. One participant stated that, in their view, it depends on the individual police officer. The following exchange highlights how uncertainty has led to people who inject drugs in Georgia maintaining an ongoing state of vigilance when carrying N&S on their person:

Facilitator: *"Even if you don't have drugs with you, even if you have not injected drugs?"*

Respondent 2: *"I'm telling you, just in case you have only syringe with you, just recently bought drugs..."*

Respondent 4: *"Do you know what might happen? You know they search for drugs and even the only thing you have is a syringe, they already know where you are planning to go…"*

Respondent 4: *"They search you, take you, check you… They'll definitely take you…"*
(Participant FGD 1.4)

The above accounts underscore how the impacts of poor quality N&S at community-based services stretch beyond issues of cost and inconvenience. The need to purchase equipment from pharmacies also include social harms, such as increased risk of arrest and incarceration.

"I still have a feeling of fear when I go out, why not…. It was noticed years ago, when I left the pharmacy, I was stopped."
(Participant FGD 1.2)

Ultimately, while most participants stated that, for the most part, police were not a significant issue for people who inject drugs in Georgia, instances of contact with police and circumstances that precipitated these contacts had the potential undermine harm reduction efforts and perpetuate cycles of stigma and discrimination for people who use drugs. Taken together, these accounts highlight the importance of providing ready access to high quality injecting equipment through NSP to meet people's needs and diminish societal risk associated with police interactions.

4.1.3.2 Stigma and Discrimination

While some participants stated that they interactions with pharmacy were positive and they felt they were treated like 'any other customer', other participants detailed how experiences of stigma and discrimination from pharmacy staff can act as a deterrent to accessing sterile equipment for people who inject drugs. For example, participants spoke of how their experiences of stigma and discrimination in pharmacies complicated access to equipment. Several participants described being made to wait, receiving derogatory comments within earshot of others, or noticing visible changes in attitude once syringes were requested. These interactions not only impacted access but also reinforced a broader sense of exclusion:

"These guys treat you with respect. You are a human being there, not a junkie."

"When you ask for a syringe, they immediately change their tone. You feel humiliated."
(Participant FGD 1.5)

"There was a case when I bought syringes at the pharmacy, and I heard them say about my mother "his poor mother" and so on…"
(Participant FGD 1.8)

"They look at you with such a look, as if something is wrong with you."
(Participant FGD 1.8)

The above responses reflect how even subtle interactions can reinforce feelings of shame and social exclusion and how everyday access to sterile injecting equipment can be compromised by stigma, forcing people who use drugs away from services they need.

In contrast, community-based NSPs were praised for their dignity-affirming and supportive environments. Participants consistently noted how much easier and safer it was to access injecting equipment through peer-led and harm reduction-focused services. Participants in several FGDs emphasised that staff at these centres were respectful, helpful, and non-judgemental. These environments were seen as safer and more supportive places to obtain injecting equipment and other harm reduction services:

"These guys treat you with respect. You are a human being there, not a junkie."

"Here [community-based organisation] you feel like at home."

"There is a friendly relationship, a very good relationship and no one is dissatisfied."

(Participants FGD 1.4)

Unfortunately, participants also described pervasive experiences of stigma and discrimination that extended beyond harm reduction services into broader health care settings and wider society. These experiences were not only personally distressing but also directly shaped their access to essential services and opportunities for social reintegration. These issues were particularly highlighted by female participants, who reflected on feeling dehumanised or treated with contempt because they are assumed to be a person who use drugs. As one participant put it:

"If you are a drug addict, you are not a human being."

(Participant FGD 1.2)

"If you are a drug addict, you are nothing."

(Participant FGD 1.2)

For these women, the stigma and discrimination was often felt most acutely during interactions with healthcare professionals. Such treatment is known to deter individuals from health-seeking behaviour, even in emergencies. Over time, these experiences can also reinforce feelings of shame and internalised stigma, further marginalising people who are already navigating complex health and social challenges:

"I had to go to the emergency room and had a kidney attack. When they couldn't find the veins and found out I was addicted to drugs, it was terrible... they wanted me to be expelled. And the man who brought me was cursed."

(Participant FGD 1.2)

Another participant recalled being turned away from a mental health facility:

"They didn't even want to touch me. They told me to go away, you are a drug addict."

(Participant FGD 1.2)

With another participant asking rhetorically:

"They told me to go away, you are a drug addict."

"Can you imagine a medical professional treating you like this?"

(Participant FGD 1.2)

Furthermore, these encounters with systemic and interpersonal stigma were compounded by structural barriers such as criminal record checks that restrict employment and social reintegration. Again, these types of concerns were specifically raised by female participants:

"We encounter a problem while having a job and that's the conviction certificate, there, you are a drug addict"

(Participant FGD 1.2)

"Yes, drug addiction, that's what they call us… Some say these things in front of you, some behind your back…"

(Participant FGD 1.2)

Participants in other FGDs also spoke about the powerful effects of social judgment in their communities, where stigma extended beyond individuals who use drugs to anyone perceived to be associated with them. This form of "guilt by association" was described as pervasive and difficult to escape, with assumptions made based purely on proximity or past contact:

> *"Even if you are not a drug user, if you were seen to be with drug users once or twice, everyone would look at you as if you are also a drug user."*
>
> (Participant FGD 1.8)

> *"According to the common saying, from which side you hold the stick, from that side you'll become dirty. Everyone thinks that just because you show around with a drug user you are also a drug user."*
>
> (Participant FGD 1.8)

Despite this, some participants held onto hope that social attitudes might shift over time:

> *"Our country will develop with the passage of time, there won't be any more finger-pointing don't go out with him, he was in prison, he is a drug user."*
>
> (Participant FGD 1.8)

Taken together, these findings highlight persistent barriers in access to sterile injecting equipment in certain settings including pharmacy. While community-based NSP has improved availability and reduced sharing, ongoing structural and social factors including poverty, criminalisation, stigma, discrimination, and gaps in service provision continue to influence unsafe injecting practices and limit access to harm reduction tools.

The data also points to the specific social and structural barriers women who use drugs face, such as stigma, judgment, and gender norms about public visibility and drug use. It also highlights the need to address gendered barriers to both generalist and specialist health services, which can further compound the complexity of women's lives, many of whom are already navigating overlapping responsibilities, caregiving roles, poverty, and the effects of criminalisation.

4.2 First Impressions of the LDSS/N Products

"... several participants mentioned how they appreciated being asked for their opinions on injecting equipment."

Before discussing their initial impression of LDSS/N, several participants mentioned how they appreciated being asked for their opinions on injecting equipment. Some noted how having a say in what is selected for distribution increased the likelihood that equipment will be suitable for their needs and therefore improve the likelihood of uptake and use:

> *"It is done in our favour, it is improved, and we like it of course."*
>
> (Participant FGD 1.3)

Almost all participants had not heard of LDSS/N prior to the FGD. In relation to first impressions, participants were less interested in low dead space and commented more on their quality and were optimistic about their suitability.

> *"Personally, I really liked the quality. It seems to be of good quality, very good quality indeed."*
>
> (Participant FGD 1.4)

> *"It's very high quality, I really like it..."*

> *"I haven't seen anything better than this for I don't know how many years."*
>
> (Participant FGD 1.2)

In response to what they liked about the LDSS/N sample products on first impressions, some participants focused on specific aspects of design, functionality, and quality of materials. The rubber piston was highlighted as a key improvement compared to the current fully plastic plunger, offering a smooth action and greater ease of use and reliability during injection. Participants noted that the plunger did not stick, which reduced anxiety around injecting and made the process feel safer and more controlled. These early positive impressions contributed to a general sense of increased confidence in the equipment:

"These rubber pistons, they are of very good quality..."

(Participant FGD 1.4)

"I like it very much it functions well and is not stuck."

(Participants FGD 1.8)

Another first impression that was identified by some participants was the introduction of different colours to distinguish between the thicknesses or gauges of the LDS needles. This is a new concept for people who inject drugs in Georgia as typically large volume syringes comes packaged with one standard needle. Despite not having previous experience with being able to choose the needle and syringe to best suit their needs and injecting practices, some identified this as the purpose of the different colours:

"These colours give me a sense of difference, right?"

(Participant FGD 1.9)

The facilitator confirmed this and explained that different LDSN colours could be paired with different volume HDS syringes to create a low dead space option for those using higher volume syringes. Participants stated they "liked the colours" and were interested to explore this new option further in the pilot phase. (Participants FGD 1.2)

Despite some participants from the women-specific FGD being so interested in the LDSS/N products, that they were unclear why a pilot stage was even necessary - *"I will tell you everything today... We liked it and we shall try it"* – most participants made it clear that they could not provide strong opinions on LDSS/N until they tested them. While the initial impressions were positive, participants expressed a desire for real-world experience using the LDSS/N products in their own injecting practices and setting before deciding on which products would best suit their needs (if any):

"I like this syringe, but I can't tell you anything about its quality, I haven't tried it yet."

"I like this syringe, but I can't tell you anything about its quality, I haven't tried it yet."

(Participant FGD 1.2)

"Until I use it, I have no questions. Then I will ask more questions."

(Participant FGD 1.3)

"Visually yes, but what will it be like in practice..."

(Participant FGD 1.3)

Across all FGDs, participants showed commitment to the pilot study, with all participants agreeing to participate. There was also a strong consensus that, if made more widely available, the uptake would be strong among people who inject drugs:

"They will like it a lot and everyone will switch to it."

"I think they will be 100% interested."

(Participants FGD 1.2)

"... colour-coding could help people avoid accidental reuse or sharing [...] in settings where multiple people inject together."

As identified above, during the Georgia FGDs, a strong preference emerged for what is referred to as the "Brownie syringe" – a 2ml N&S that participants can only access by purchasing it at pharmacies. Interestingly, when asked about their 'first impressions' of the LDSS/N sample products, one participant responded:

> *"I prefer 'brownies', literally to any of these..."*
>
> (Participant FGD 1.4)

Moreover, some participants asked whether the "Brownie" N&S could be purchased as one of the product choices for the Phase 2 Pilot Stage. The FGD facilitator from GeNPUD pointed out that "Brownies" are not low dead space and therefore, ineligible for inclusion in the study. Although this was understood and accepted by participants, following the opportunity to inspect and examine the quality and range of LDSS/N products in the 'Starter Pack' (see 3.1.1 Study Design above) during the FGDs, several participants were interested in having the opportunity to compare the "Brownies" with the LDSS/N sample products during the pilot phase:

> *"I shall be very happy if these syringes that you have just shown are of such quality that they will replace the Brownie syringes, surpassing the advantages that the Brownie syringes do have."*
>
> (Participant FGD 1.5)

4.3 Perceived Benefits of the LDSS/N Products

Beyond initial impressions, participants identified a range of perceived benefits that LDSS/N products could offer in real-world settings. Many of these related to improving the quality and safety of the injecting process, reducing harm, and addressing common frustrations with existing equipment.

A recurring theme was the frustration participants experienced with currently available needles and syringes, particularly those obtained through community-based organisations. Participants emphasised that the poor-quality equipment availability often broke during use, creating stress, waste, and potential harm. In contrast, LDSS/N products were seen to be of higher quality and more durable:

> *"We don't like the needles that easily break."*
>
> *"Some are easily fragile, as soon as you lift the plunger, it breaks."*
>
> (Participant FGD 1.3)

The different coloured needles were appreciated not only for their aesthetic appeal but also for their practical value. Participants explained that colour-coding could help people avoid accidental reuse or sharing of injecting equipment, especially in settings where multiple people inject together as this exchange in one FGD highlights:

> Facilitator: *"Why do you think they will like them? What do you like about them?"*
>
> Respondent: *"They look much more sophisticated. I really like these colours… You also have mentioned syringe exchange with a friend or reusing your own syringe that sometimes happens. That mistake will not happen again."*
>
> Respondent: *"Then you will say, I hold this colour."*
>
> (Participants FGD 1.6)

And another participant added:

> *"If there are three of us with red, yellow and green syringes, we don't even need to write the name on them. That's it."*
>
> (Participant FGD 1.6)

Participants in several FGDs, including the women-only FGD, also highlighted the benefit of having a range of needle sizes available to meet different injecting needs. They spoke about using different gauges depending on injection site vein depth and/or location, preferences many felt were often unmet with options currently available through the NSP. Therefore, when examining and discussing the LDSS/N product samples, participants immediately commenced assessing the different options available and how they might use them:

> *"If you have a deep vein, this colour is good. If you have it deeper from the surface, a smaller one is better."*
>
> (Participant FGD 1.2)

Many participants demonstrated a strong understanding of how LDSS/N could reduce BBV transmission by minimising the residual blood left in the syringe. This understanding was reinforced through the presentation of FGD Information, Education and Communication (IEC) materials and video (with voiceover in Georgian) and was cited as a compelling reason to try the products. When asked by the facilitator "How important are these factors to you? How concerned or interested are you to test these needles and syringes?" participants responded with:

> *"Yes, yes, it increases our desire to test these samples."*
>
> (Participant FGD 1.8)

> *"Even though we say we shouldn't share, when we face the fact, it might not work. Let's try our best, if some people have to share, it's safer in terms of sharing low dead space syringes."*
>
> (Participant FGD 1.5)

Participants noted the better quality of LDSS/N might make them less likely to break and could reduce the volume of syringes required. They also stressed the associated benefit of minimising drug wastage, which was especially important given the cost and difficulty of accessing drugs:

> *"Let's start with what we were talking about, those syringes that break easily. These ones look so good we'll need less of them as these syringes won't break… It is also of better quality."*
>
> (Participant FGD 1.5)

> *"There are few things. That infections will not spread and the drug that was inside will not remain. That's the main thing… Drug which you will not miss during consumption."*
>
> (Participant FGD 1.1)

"There are few things. That infections will not spread and the drug that was inside will not remain."

While leftover drug residue was a concern for many participants, several participants were also aware that flushing to retrieve leftover drugs could potentially lead to vein damage (which is a 'ever–present' concern for those with compromised veins from many years of injecting drug use). To this end, some participants noted that the reduced dead space in LDSS/N would mean that less drug remained in the syringe, potentially reducing the need for flushing and helping preserve vein health:

"It is not desirable when some part of the drugs stays inside. For example, many do not like to flush it either because of harm to veins."

(Participant FGD 1.5)

When the facilitator probed further about the reduced blood/drug residue in the LDSS/N products and whether this would be a factor that would increase interest in the LDSS/N sample products, the participant was definitive in their response:

"Yes definitely."

(Participant FGD 1.5)

Additionally, some participants raised the legal implications of possessing syringes with visible drug residue. In contexts where possession of even trace amounts can lead to criminal charges, LDSS/N was seen as potentially offering protection:

"Even if you are stopped in the street and the police see you possess a used syringe, there will be less danger, right? Take it for expertise and check what is left inside the syringe, there is less danger."

(Participant, FGD 1.8)

"Regarding this syringe… as you have explained to us that not even a single drop remains inside, if it were available during Misha's[13] time, so many people would not have been imprisoned for the sake of a single drop [of illicit drugs] being left behind."

And added:

"And I was sentenced to nine years because of [the law at that time]."

(Participant FGD 1.1)

While most participants were enthusiastic about the harm reduction potential and practical benefits of LDSS/N, a few were less concerned with residual volume or BBV prevention and focused instead on whether the syringe was simply 'fit for purpose', that is, functional and not painful to use:

"… focused instead on whether the syringe was simply 'fit for purpose' …"

"… we are not the category of people who will make enquiries why more than one drop of liquid is left there or not, [what we care about is] how useful it is for injection, i.e. will it leave some trace [injection mark or scar] or not, how much it will hurt you."

(Participant FGD 1.8)

Despite variable motivations, participants across all FGDs generally expressed a strong willingness to try the LDSS/N products and participate in the pilot phase based on their perceived benefits from a range of different perspectives including safety and ease of use, as well as harm reduction and improved quality:

"The more secure everything is, and the more it is, the better, of course."

(Participant FGD 1.4)

"We are trying to improve our conditions and accordingly we will try our best to share our opinion with you."

(Participant FGD 1.8)

13. This participant is referring to Mikheil Saakashvili "Misha", who served as the third president of Georgia from 2004 to 2013.

4.4 Participant Preferences for Phase 2 Pilot Products

After being provided with the different types of LDSS/N products and asked about which should be provided in the pilot phase (see list of products shown at Appendix 1 – LDSS/N Starter Pack), participants across all five FGDs consistently said "all of the types shown" as captured in the comments below:

> *"I like all the shown syringes and needles..."*
>
> (Participant FGD 1.2)

> *"All is needed, in my opinion."*
>
> (Participant FGD 1.3)

> *"All are acceptable for me."*
>
> Facilitator: *"Do you need all of them to test during injection process?"*
>
> Respondent: *"Yes, I do."*
>
> (Participant FGD 1.9)

When the discussion turned specifically to syringes, most participants indicated a preference for the luer-lok or the 'threaded' syringes rather than the luer slip syringes. This preference primarily related to the extra security that comes with luer-lok syringes. After some discussion, however, it was agreed that both luer-lok and luer slip syringes should be made available to cover different preferences and needs.

In relation to the different sizes or volumes of syringes, most participants identified a preference for the smaller volume syringes - 2ml, 3ml and 5ml - with a lower level of demand for 10ml and 20ml syringes:

> Facilitator: *"Can I ask a question? Do you need 20-milligram syringes as many pieces as five-milligram syringes?"*
>
> Respondent #40: *"No… a little less amount. "*
>
> Respondent #38: *"No, we won't take so many 20-milligram syringes."*
>
> Respondent#40: *"The most "Khadavoi" [meaning commonly used] are five-milligram ones and insulin type syringes."*
>
> (Participant FGD 1.6)

"... preferences were shaped by multiple factors including contextual issues ..."

Other participants, however, outlined how their preferences were shaped by multiple factors including contextual issues such as whether they are injecting alone or in a group where they may need larger volume syringes for preparing and dividing drugs:

> *"When I am alone, I use two-milligram and three-milligram syringes, though I use insulin syringe when I am with a bunch of boys as well as we need three-milligram syringes, five-milligram and ten-milligram ones and in some cases even twenty-milligram syringes."*
>
> (Participant FGD 1.8)

> *"Yes, yes, even 20-milligram syringe is necessary. There is a category of drug users that use 20 milligram syringe for preparing drugs."*
>
> (Participant FGD 1.5)

These comments highlight how preferences and needs are not simply about what drugs people are injecting, where they are injecting on the body, or even the condition of their veins, but also who they are injecting with, and the context in which they are using:

> *"Based on practice, I use all kinds of syringes."*
>
> (Participant FGD 1.8)

"Everyone has different problems. Everyone chooses differently."

> *"Everyone has different problems. Everyone chooses differently."*
> *"Some want thin needles; some want long needles."*
>
> (Participants FGD 1.5)

In relation to the Total Dose low dead space needle (LDSN) specifically, most participants requested the yellow 30G 13mm and orange (or "carrot coloured" as they were called in several FGDs) 25G both 16mm & 25mm needles with some participants also requesting blue 23G 32mm needle. The factors shaping these preferences varied depending on the needle involved including:

- The strong interest in the yellow 30G related to participant preferences for a needle they can pair with a 2ml, 3ml or 5ml syringe when they need a fine gauge needle, similar to the gauge found on a 1ml fixed unit but need a syringe that can hold a greater volume than 1ml.
- The preference for the orange 25G LDSN (in both 16mm and 25mm) largely related to the fact that these needles are closest to the HDS needles that most participants currently use for injecting in surface level veins in the arms and hands, and for some in the groin.
- The thicker gauged and longer blue 23G 32mm LDSN is used by a smaller number of participants for drug preparation and division and/or for injecting larger volumes of liquid into deeper veins in the groin (especially if a 25G 25mm is not long enough for them). In this context, one participant also asked about the possibility of including an even longer LDSN than the blue 23G 32mm for injecting into deeper veins such as in the groin:

> *"I use a large needle."*
>
> [Facilitator shows the blue 23G 32mm LDS needle]
>
> *"And there is no needle bigger than that?"*
>
> (Participant FGD 1.2)

The need for a longer needle than the blue 23G 32mm LDS needle was also raised by participants in other FGDs. When asked by the facilitator whether the Blue 23G 32mm LDS needle was long enough for groin injecting, a participant in another FGD responded:

> Respondent: *"It won't be long enough for me. It is not long enough to inject in groin area."*
>
> Facilitator: *"Do you want it to be bigger?"*
>
> Respondent: *"Yes, yes."*
>
> (Participant FGD 1.9)

For this reason, it was suggested that a longer 38mm Blue 23G LDS needle is included for availability in the pilot phase in Georgia.

The women-specific focus group discussion also highlighted a diversity of injecting practices and preferences, shaped by a range of factors including the type and quantity of drug being used, the site of injection (e.g., vein, muscle, or capillary), and the condition of a person's veins. These variations underscore the importance of offering a full range of low dead space

needles and syringes during the pilot phase, so that women can choose what best suits their individual needs and circumstances.

"Most of all I like these small ones... actually they are all good."

"I like all the shown syringes and needles as don't do it in the capillaries or in the veins, I do it in the muscle... mostly big, two milligram syringe fits me."

"I prefer 3milligram syringe, long needle and insulin type syringe."

(Participants FGD 1.2)

"This 25 can play the role of so called "Babochki" (meaning butterfly)."

The use of butterflies by some people who inject drugs in Georgia and design features that mean they retain a significant amount of blood following injection, underscored the importance of identifying an LDSS/N alternative. One participant suggested that the two orange 25G LDSN (16mm and 25mm) might replace the need for the butterfly because they are a similar gauge to a commonly used butterfly:

"This 25 can play the role of so called "Babochki" (meaning butterfly)."

(Participant FGD 1.5)

In the discussion that followed, the facilitator showed the participants the two options available for the orange 25G LDS needles (a short needle and a longer needle) and one participant responded:

"It will act as a butterfly, as usual."

"Are you a butterfly user? Which is better, smaller or longer?"

"Small... No, both are good."

(Participant FGD 1.2)

Due to their winged design, butterflies, as explained and illustrated on p.25, provide extra flexibility when entering the vein and allow the needle to sit flat against the skin. This is not possible with standard concentric syringes (where the needle tip is secured onto the nib in the centre of the syringe hub). Therefore, depending on where people are injecting on the body (and whether there is a need for the needle to sit flat on the skin), the orange 25G LDSN paired with standard concentric syringe, may or may not replace the butterfly for some participants. Nevertheless, if participants find the orange 25G LDSN suitable but for the concentric design of the syringe, there are non-concentric syringes that can be procured to address this issue. These needle and syringe options, however, being made from hard plastic will not match the level of flexibility provided by the winged and soft tubing design of the butterfly for those for whom this level of flexibility is important.

Therefore, for many participants who currently use butterflies, it is a matter of waiting for the pilot to commence so that they can try the LDSS/N products for themselves and make a considered assessment about whether the LDSS/N alternatives for butterflies are suitable or could be made suitable if the right equipment was made available...

Facilitator: *"Will any of them replace the butterfly for you?"*

Respondent: *"To be examined."*

(Participant FGD 1.8)

It will be important to monitor the above issues following the pilot to see if the LDSS/N equipment made available in the Phase 2 Pilot meets the diverse preferences and needs of participants.

4.5 Transitioning to LDSS/N and Knowledge Mobilisation

4.5.1 Community-Driven Dissemination: IEC Needs and the Role of Peer Networks

As discussions around adopting LDSS/N moved beyond product impressions, participants across the FGDs offered thoughtful and practical recommendations for how to raise awareness and support transition to LDSS/N. There was strong consensus that community-led dissemination strategies grounded in peer networks, face-to-face communication, and trusted harm reduction programs would be essential. Participants in the women-specific FGD also highlighted that education should be ongoing, accessible, and adapted to local contexts, especially for people unfamiliar with LDSS/N or who might be isolated from other harm reduction materials and education:

> *"More engagement, more information and advertising."*
>
> (Participant FGD 1.4)

> *"Place to place it in a special way."*
>
> (Participant FGD 1.4)

> *"It's good to have something new coming in to provide us with information… because many people don't know."*
>
> (Participant FGD 1.4)

"Participants consistently identified peer communication and word-of-mouth as key ..."

Participants consistently identified peer communication and word-of-mouth as key pathways for information sharing. Many offered to play an active role in spreading awareness within their social networks, especially if they were supported with the right tools and messaging. Trust in existing harm reduction organisations emerged as an important foundation for mobilising community knowledge:

> *"Of course, we will share with those around us."*
>
> (Participant FGD 1.5)

> *"We can share all this information with our friends."*
>
> (Participant FGD 1.7)

> *"They will come here, and you can explain to them."*
>
> (Participant FGD 1.6)

Suggestions for raising awareness ranged from structured educational meetings and public information campaigns to informal discussions (like the FGDs) at harm reduction sites and NSP distribution points. Advertising was described as "everything" to make new information and knowledge highly visible and widely known:

> *"There must be an advertisement. Advertising is everything."*
>
> (Participant FGD 1.3)

> *"These types of information meetings are good to provide information."*
>
> (Participant FGD 1.3)

> *"This kind of meeting should be held."*
>
> (Participant FGD 1.5)

Participants also advocated for wider geographic reach for harm reduction services and information in Georgia. There was concern that people living outside of city centres had less access to harm reduction services, information and support, highlighting a need for awareness-raising activities to be extended beyond Tbilisi and into regional areas:

"Harm reduction programs should be in many places. For example, I was in [name of town removed] now and there is no program… they go to [name of town removed], that is 100 kilometres..."

(Participant FGD 1.3)

"... it will be critical to build community awareness around the [...] low dead space needles and syringes."

Participants could not identify any communication strategies or approaches to avoid, welcoming all efforts to share information and emphasised that what mattered most was that information made available was accessible and easy to understand. The overall tone was one of readiness and willingness to support the study and one's own community:

"You have started well, please keep it up. Such good communication and good luck."

(Participant FGD 1.1)

"Nothing from what we have talked about, everything was good in this regard."

(Participant FGD 1.5)

"... perhaps providing information to the community members as we were talking today."

(Participant FGD 1.4)

4.5.2 Building Knowledge in relation to Needle & Syringe Choice in Georgia

As Georgia prepares for the Phase 3 implementation of LDSS/N products, it will be critical to build community awareness around the benefits and practical use of separately packaged low dead space needles and syringes. Currently, people accessing needles and syringes in Georgia typically receive pre-packaged units, where a syringe comes with a fixed needle or a single needle type already attached, leaving no room for individual preference or adjustment.

Participants explained that different syringe volumes usually come with the same gauge needle attached (typically 23G), except in the case of very large-volume syringes (10mL or 20mL), where a visibly larger needle (such as 21G) is often included. This limits both choice and harm reduction potential as people currently must accept the pre-packaged N&S provided without the option to request a different gauge needle and/or volume syringe to better suit their individual preferences and circumstances (i.e., what they are injecting, where on the body they are injecting, who they are injecting with, etc.):

"You go to a pharmacy, or you come here, you say I want a three-milligram syringe, they give you a three-milligram syringe and it comes with a needle. These ones do not have fixed needles."

(Participant FGD 1.7)

Another participant added:

"I've often had a three-milligram syringe, a five-milligram syringe and they come with the same gauge needle. A ten-milligram syringe might have a different one, and a 20-milligram one a little bit bigger."

(Participant FGD 1.7)

Participants acknowledged that the ability to mix and match different needle lengths and gauges with different syringe volumes could offer significant benefits both in terms of comfort and vein care. However, they also made clear that this was not currently common practice and would require additional education to become embedded in current drug using practices in Georgia. Understanding the differences between terminology for different N&S,

needle types, including colour coding, gauge, and appropriate application (e.g., for deep veins, muscle, or use in finer veins), will be crucial to support informed choices within the LDSS/N Study and beyond in Georgia:

> *"It hurts a lot when you inject with a big volume syringe, you should use it with the small volume needle, so it hurts less."*
>
> (Participant FGD 1.2)

> *"Big needles are needed for deep veins; you can't inject in vein with small ones."*
>
> (Participant FGD 1.2)

"... participants described surprise or confusion when offered a syringe without a 'fixed needle' ..."

In several discussions, participants described surprise or confusion when offered a syringe without a 'fixed needle' (that is, a needle and syringe packaged together), highlighting the expectation that the two items always come as a set. This is an important cultural and programmatic consideration that should inform knowledge mobilisation strategies moving forward:

> *"The first thing he asked was, 'Doesn't it have its own needle?'"*
>
> (Facilitator reflection, FGD 1.4)

> *"When we open a large-volume syringe, it has its own fixed needle… this needle may be the same for a two-milligram syringe as well as for three and five milligram ones."*
>
> (Facilitator, FGD 1.4)

It is important to acknowledge, however, that Georgian people who inject drugs (including the FGD participants) are highly experienced and knowledgeable about their injecting practices and are therefore likely to adapt quickly to future changes that may occur in relation to transitions to LDSS/N equipment. Given these insights, however, an essential component of Phase 3 will be community education focused specifically on the benefits and practicalities of separate LDS needles. This should include IEC materials, peer-led education, and distribution strategies that allow for meaningful choice between different combinations of needle gauge, length, and syringe volume. Terminology differences and existing norms around fixed syringe and needle sets must also be considered to ensure clarity and relevance in knowledge mobilisation efforts.

5. Phase 1 FGD: Summary of Key Findings

"... participants expressed strong interest in testing and potentially adopting LDSS/N products."

Across all FGDs in Georgia, participants expressed strong interest in testing and potentially adopting LDSS/N products. Initial impressions of the LDSS/N samples were very positive, particularly in relation to product quality, smooth plunger function, and perceived durability compared with currently available equipment. Participants emphasised that reliable equipment that does not break, stick, or waste drugs is a key priority in their injecting practices.

Participants also showed clear preferences regarding equipment choice. There was strong interest in having access to a range of needle gauges, lengths, and syringe volumes, allowing individuals to select combinations suited to their injecting practices, vein condition, and context of use. Smaller volume syringes (2ml, 3ml and 5ml) were most commonly preferred, although larger syringes (10ml and 20ml) were also considered necessary for certain drug preparation and group injecting situations. Participants generally favoured luer-lock syringes for their additional security, while agreeing that both luer-lock and luer-slip options should be available to accommodate different preferences.

For low dead space needles specifically, participants most frequently requested the yellow 30G 13mm, orange 25G (16mm and 25mm), and blue 23G 32mm options, reflecting the diversity of injecting practices including superficial vein access, deeper veins, and drug preparation. Some participants also indicated a need for longer needles for groin injecting. These discussions highlighted the importance of offering a broad product range during the pilot phase to ensure equipment can meet varied needs.

Participants also identified several perceived benefits of LDSS/N products, including reduced blood and drug residue, lower risk of blood-borne virus transmission, less drug wastage, and improved vein care due to reduced need for flushing. The colour-coding of needles was widely welcomed, with participants noting it could help distinguish equipment during group injecting situations and reduce accidental reuse.

Overall, participants demonstrated strong willingness to participate in the pilot phase and expressed confidence that uptake among people who inject drugs would be high if the products prove effective in practice. Participants also emphasised the importance of peer-led education and community dissemination to support the transition to LDSS/N, particularly given that people in Georgia are currently accustomed to pre-packaged needle-syringe units and may need support to understand and utilise separate needle and syringe combinations.

6. Limitations & Challenges

"Gender representation was another challenge ..."

One of the challenges associated with the study was the complexities associated with shifting between Georgian and English. When working with the FGDs transcripts, extra care was taken to ensure they were accurately translated and reflected both subtleties of language, and the meaning of words used by people who use drugs within their local networks. This issue was in part addressed by identifying a qualified, local transcriber who was known to GeNPUD and a local professional translator who was known to MdM Georgia with relevant expertise in public health and harm reduction. In addition, when reviewing transcripts and in data analysis, the INPUD PI also liaised closely with the GeNPUD community researchers to ensure key local terminology was accurately interpreted thus facilitating a culturally contextualised understanding of the data.

Given Georgia's strict drug laws, distrust of research and researchers can be common among people who use/inject drugs. In this context, a community-led approach played a crucial role in participant recruitment and engagement. The GeNPUD community researchers utilised established peer networks to both promote the study (via word-of-mouth) and create safe, trusted and open environments which were key to successful FGD recruitment and facilitation. Notwithstanding the importance of these peer networks, care was also taken not to over-rely on these known networks and connections to achieve participant diversity. This risk was mitigated by utilising the wider (trusted) relationships between GeNPUD, the study sites and other key stakeholders in the study regions of Tbilisi, Rustavi and Gori to promote study and recruit FGD participants.

Gender representation was another challenge, with seven of the nine FGDs comprising only male participants. Therefore, it was considered important to ensure meaningful representation from women, with a women-specific FGD convened with 9 participants. Importantly, this FGD captured several unique insights from female participants that would otherwise have been missed.

Finally, it is important to note that due to the heterogeneity of people who inject drugs and the inherent subjectivity of values and preferences, the findings from this study may not be representative nor generalisable to all people who inject drugs in Georgia. Nevertheless, the findings do offer crucial perspectives to inform the implementation of LDSS/N in LMICs and contribute to new evidence on the effectiveness of community-led research approaches when conducting research with marginalised and criminalised populations.

7. Phase 2 Pilot: Recommendations

7.1 Phase 2 Pilot: LDS product preferences and recommendations

Following the Phase 1 FGDs, the INPUD PI led a preliminary analysis of the Phase 1 FGD data to collate the LDSS/N product recommendations from the nine FGDs and produce a draft LDSS/N Product Procurement List for consideration by the country partners in the Phase 2 pilot. We will next describe some of the key the considerations for procurement before listing the final recommended products and amounts and the approach for distributing the equipment in Phase 2.

7.1.1 Key Considerations and Rationale Behind Recommended Products and Amounts:
Although the FGD participants were enthusiastic to pilot the LDSS/N products, many of these products are new for people who inject drugs in Georgia and therefore it was difficult to predict what the actual uptake would be over the 6-week pilot period. In this context, making a precise estimate of the amounts of each product to procure involved a careful consideration of issues that might affect injecting frequency, including individual injecting practices, the substances being used, and other relevant local/contextual factors.

"The FGD data confirmed injecting practices varied between participants..."

As part of considering these issues, the INPUD PI utilised a combination of existing research evidence, their own extensive knowledge and expertise of injecting drug use and NSP provision, information on local injecting practices gained through the FGDs and consultation with GeNPUD to reach a recommended average number of injections per day per participant for the pilot phase. Many factors were weighed and considered in this process, including that:

- Research evidence shows that people who inject drugs globally typically inject at least once per day but often more frequently and that the number of injections per day vary considerably (Colledge et al, 2020);
- How often people might inject will depend on what drugs they are using, the drug effect they are wanting to achieve, how long they have been using a drug, the condition of their veins and many other factors; and
- The FGD data confirmed injecting practices varied between participants and that any estimate of the number of products to procure would need to account for these variations including that some people will inject more/less than others and that the injecting frequency of individuals will also vary across the 6-week pilot depending on issues such as drug availability, personal finances/circumstances, engagement in treatment, and much more.

Taking all of the above factors into consideration, it was recommended that LDSS/N product procurement for the pilot phase should be based on an average of 3 injections per day per participant for 42 days (7days x 6 weeks = 42 days)

In addition to the above factors, the FGD participants were also mostly experienced, injectors, who discussed vein problems/scarring and difficulties when injecting. While there was not a great deal of discussion in the Phase 1 FGDs on what people were injecting, each participant was asked to provide their specific preferences for the LDSS/N products they wished to pilot, and these have been used to inform the procurement recommendations.

The preferences of FGD participants indicated a greater demand for small – medium sized barrel syringes (2 ml – 5ml) and finer gauge needles (30G & 25G), although, depending on injecting practices, there was also demand for larger barrels (10ml and 20ml) and thicker

"... the expertise of the country study team was critical to the process ..."

gauge and longer needles (23G 32mm & 38mm) among some participants. In summary, the findings pointed to a recommendation to procure more 1, 2, 3 & 5-ml syringes and Yellow 30G & Orange 25G LDS needles (in two lengths) and less 10 & 20ml syringes and Blue 23G LDS needles (in two lengths). This variation in demand is reflected in the upper and lower participant range used as the multiplier in the 'participant column' in in Tables 3, 4 and 5 below.

Further, given expected difficulties importing LDSS/N products into Georgia it was also recommended to over-procure rather than under-procure to avoid the risk of stockouts should demand exceed baseline expectations. Potential concerns about product waste, were alleviated by the fact that any excess product from the Pilot Phase would likely be used in Phase 3 implementation stage.

7.1.2 Recommended Product Procurement List – Phase 2 Pilot

Once the INPUD PI had finalised the recommended product procurement list in (consultation with the Burnet research team), the refined list and suggested amounts were then sense-checked by the country research team (including the GeNPUD community researchers) as part of the Phase 1 Reflections & Learning Workshops/Meetings. Following these meetings and some further consideration of local contextual factors, the INPUD PI worked with the country team to make some minor adjustments to the proposed number of products to be procured in line with current program beneficiary numbers and expected demand and uptake in the Phase 2 Pilot.

The need for adjustments was anticipated as the initial estimated procurement amounts were suggested as a starting point for discussions with the country study team, rather than as a final procurement figure. In this regard, the expertise of the country study team was critical to the process of fine tuning and agreeing on the final procurement amounts. As part of this process, the country team recommended removing the 27G and 30G 1ml LDS syringe, as they felt the 29G 1ml LDS syringe would be sufficient to meet people's needs and were concerned that too many choices of 1ml syringe (that are very similar in gauge) could be confusing for participants. In addition, the country team also requested to add an additional Blue 23G (38mm) LDS needle to the pilot product procurement list in line with FGD participant preferences (see 4.4 Participant Preferences for Phase 2 Pilot Products above). Once agreed, the final list of LDSS/N products and amounts for the Pilot Stage was then provided to MdM as the consortium lead, to proceed with procurement.

Needle Type	Participants	Injections/Day	Study Duration (days)	Total Units
Blue 23G (38mm)	10	3	42	1260
Blue 23G (32mm)	30	3	42	3780
Orange 25G (25mm)	20	3	42	2520
Orange 25G (16mm)	30	3	42	3780
Yellow 30G (13mm)	30	3	42	3780

* Quantities were rounded up to the nearest full box to align with manufacturer packaging.

Table 3: LDS 'Total Dose' Needles – Recommended Products and Amounts

Syringe Type	Participants	Injections/Day	Study Duration (days)	Total Units
29G 1ml fixed unit	75	3	42	9450
2ml 'Nevershare' Luer-Lok & Luer Slip Syringes (in various colours – paired with 'Total Dose' LDS Needle)	30	3	42	3780 (470 luer-lok and 160 luer slip)

* Quantities were rounded up to the nearest full box to align with manufacturer packaging.

Table 4: LDS Syringes – Recommended Products and Amounts

Syringe Type	Participants	Injections/Day	Study Duration (days)	Total Units
3ml	30	3	42	3780
5ml	30	3	42	3780
10ml	20	3	42	2520
20ml	10	3	42	1260

* Quantities were rounded up to the nearest full box to align with manufacturer packaging.

Table 5: HDS Syringes – Recommended Products and Amounts [14]

7.2 Phase 2 pilot distribution approach: key recommendations

Following discussions at the Phase 1 Reflections & Learning Workshop and other meetings, it was agreed that the following approach to LDSS/N distribution would be taken during the Phase 2 Pilot:

"The Phase 2 Pilot should take a flexible approach to the distribution of LDSS/N products ..."

1. The Phase 2 Pilot should take a flexible approach to the distribution of LDSS/N products with participants able to select the specific products based on their specific needs and preferences rather than set packs or requirements to try and/or take all products.
2. At the commencement of the pilot phase, each pilot participant will be invited to attend the NSP at their relevant study site/community-based organisation to discuss the LDSS/N products and their individual needs and preferences.
3. Based on the current distribution approach at their NSP (see section 7.1.1 above) and the advice of the GeNPUD team, the dispensing interval will be every 2 weeks across the pilot phase – the LDSS/N products will be distributed to participants at 3 intervals across the 6-week pilot.
4. LDSS/N products will be dispensed based on stated preferences and participants will be able to choose up to eight (8) LDSS/N products per day for each 2-week interval (e.g. 4 needles + 4 syringes per day). This approach aims to get a good sense of what products participants are choosing to take so that preferences can be accurately assessed (rather than providing all participants with a set package of equipment each fortnight which would not reveal sufficient detail on participant preferences and which products they are not just taking, but also using).
5. Further, participants can return to collect and/or contact outreach worker if more LDSS/N equipment is needed between fortnightly dispensing points.

14. The HDS syringes are included in the Phase 2 Pilot to pair the 'Total Dose' LDS Needles. The Total Dose LDS Needles will pair with any HDS syringe to create an LDS option as the Total Dose LDS Needle significantly reduces the dead space in a standard HDS syringe – thereby creating an LDS option for people who use larger syringes (2ml and over).

"Each study site will work with GeNPUD to [...] document the operation of the pilot ..."

6. To ensure good documentation of the LDSS/N products dispensed during the pilot and to inform the Phase 3 Implementation, Burnet researchers have been working with each study site to revise the current NSP distribution sheet and database to ensure all LDSS/N products are captured. INPUD have also produced an LDSS/N product image sheet to assist study site NSP/outreach workers in recording distribution information accurately in consultation with pilot participants.
7. Each study site will work with GeNPUD to also reflect upon and document the operation of the pilot including the logistics of offering greater choice and any implications from the pilot logistics for the Phase 3 implementation.

7.3 Phase 2 Pilot: Next Steps:

Following the Phase 1 FGDs, all FGD participants (n=75) expressed an interest in participating in the Phase 2 Pilot Study and were therefore offered a copy of the participant information and consent form (PICF) for Phase 2 *(see Appendix 6 – LDSS - PICF Piloting of LDSS).* As the Phase 2 Pilot Study is an implementation phase, Phase 2 participants are required to provide written informed consent[15]. The community researchers and note takers had been trained by Burnet to undertake the signed informed consent process for the Phase 2 Pilot Study. The signed Phase 2 Pilot Study PICFs have been stored in a locked cabinet at GeNPUD office. Due to a delay of approx. six (6) months between the Phase 1 FGDs and the start of the Phase 2 Pilot Study (to allow for the procurement and arrival of the selected LDSS/N products in country) participants will be contacted when GeNPUD are ready to commence the Phase 2 Pilot Study.

Finally, as noted above, in Phase 1 an additional FGD was conducted at the New Vector Tbilisi site (in addition to the FGDs at the New Vector Rustavi site). However, for logistical reasons New Vector Tbilisi will not be included as a study site in Phases 2 & 3. As New Vector Tbilisi and the Hepa + sites are reasonably close geographically (both in Tbilisi), it was also agreed that all 10 FGD participants from the Tbilisi site will be invited to enrol in the Hepa + pilot.

The rationale for this approach was two-fold. First, it would guarantee access to the LDSS/N products for phases 2 & 3 for any participants from the New Vector Tbilisi FGD who wished to continue participation in the study. Second, it would also ensure the maximum number of FGD participants for all study sites (n=75) was maintained into the pilot phase. It was further agreed, that if any participants from the Tbilisi site did not wish to participate in the pilot at the Hepa + site, those additional places would be offered to new participants from the Hepa + site. All new participants will be consented prior to commencing in the pilot. For any new participants from the Hepa + site, preference will be given to recruiting female participants to address issues of under-representation for women who use drugs outlined above.

15. The Phase 1 FGD did not require written informed consent but rather involved verbal consent process with a consent register signed by the community researchers. This process was used as it provided an additional layer of anonymity for FGD participants. This approach will also be used for the Phase 2 & 3 FGDs. The Phase 2 Pilot, however, involves the implementation of a research intervention where participants will be asked to trial new LDSS/N products – rather than simply being asked to provide their views on and preferences for these products. For this reason, written informed consent is required for Phase 2 and will be retained on secure file for 7 years.

8. References

Austin, A., Favril, L., Craft, S., Thliveri, P., & Freeman, T. P. (2023). Factors associated with drug use in prison: A systematic review of quantitative and qualitative evidence. International Journal of Drug Policy, 122, 104248. https://doi.org/10.1016/j.drugpo.2023.104248

Averhoff, F; Shadaker, S; Gamkrelidze, A; Kuchuloria, T; Gvinjilia, L; Getia V., … Nashrullah, M. (2020). Progress and challenges of a pioneering hepatitis C elimination program in the country of Georgia. J Hepatol, 72(4), 680-687. doi: 10.1016/j.jhep.2019.11.019

Clarke, V., Braun, V., & Hayfield, N. (2015). Thematic analysis. *Qualitative psychology: A practical guide to research methods, 3, 222-248.*

Colledge S, Leung J, Larney S, Peacock A, Grebely J, Hickman M, Cunningham E, Trickey A, Stone J, Vickerman P, Degenhardt L. (2020). Frequency of injecting among people who inject drugs: A systematic review and meta-analysis. Int J Drug Policy. Feb;76:102619. doi: 10.1016/j.drugpo.2019.102619. Epub 2019 Dec 18. PMID: 31864107.

Gamkrelidze A, Shadaker S, Tsereteli M, et al. (2021). Nationwide Hepatitis C Serosurvey and Progress Towards Hepatitis C Virus Elimination in the Country of Georgia. J Infect Dis. 2023 Sep 15;228(6):684693

Georgia Department of Public Health, HIV Epidemiology Section. (2024). 2022 HIV Surveillance Summary, Georgia, https://dph.georgia.gov/epidemiology/georgias-hivaids-epidemiology-section/hivaids-casesurveillance .

Georgia Health Research Union. (2022). Integrated Bio-Behavioral Surveillance Survey among People Who Inject Drugs. Risk Behaviours and HIV prevalence trends in target groups with high risk of HIV infection. Study Report 2022, Tbilisi Georgia.

Grebely, J., Larney, S., Peacock, A., Colledge, S., Leung, J., Hickman, M., . . . Degenhardt, L. (2019). Global, regional, and country-level estimates of hepatitis C infection among people who have recently injected drugs. *Addiction, 114*(1), 150-166. doi:10.1111/add.14393 cross-sectional survey. *Harm Reduction Journal, 16*(1), 28. doi:10.1186/s12954-019-0298-2

Hagan LM, Kasradze A, Salyer SJ, Gamkrelidze A, Alkhazashvili M, Chanturia G, Chitadze N, Sukhiashvili R, Shakhnazarova M, Russell S, Blanton C, Kuchukhidze G, Baliashvili D, Hariri S, Ko S, Imnadze P, Drobeniuc J, Morgan J, Averhoff F. (2019). Hepatitis C prevalence and risk factors in Georgia, 2015: setting a baseline for elimination. BMC Public Health. May 10;19 (Suppl 3):480. doi: 10.1186/s12889-019-6784-3. PMID: 32326913; PMCID: PMC6696670.

International Harm Reduction Development Program (IHRDP). (2009). Assessment in Action Series. New York: 2009. Women, Harm Reduction, and HIV: Key Findings from Azerbaijan, Georgia, Kyrgyzstan, Russia, and Ukraine.

Razavi, H. (2020). Global epidemiology of viral hepatitis. *Gastroenterology Clinics of North America, 49*(2), 179-189.

Ritter, A., Barrett, L. (2024). People who use drugs and the right to health. *Harm Reduct J* 21, 215. https://doi.org/10.1186/s12954-024-01132-5

Saldana CS, Vyas DA, Wurcel AG. (2020). Soft Tissue, Bone, and Joint Infections in People Who Inject Drugs. Infect Dis Clin North Am. Sep;34(3):495-509. doi: 10.1016/j.idc.2020.06.007. PMID: 32782098; PMCID: PMC8757538.

Trickey, A., Croxford, S., Emanuel, E., Ijaz, S., Hickman, M., Kesten, J., . . . Vickerman, P. (2022). The Effectiveness of Low Dead Space Syringes for Reducing the Risk of Hepatitis C Virus Acquisition Among People Who Inject Drugs: Findings from a National Survey in England, Wales, and Northern Ireland *Clinical Infectious Diseases, 75*(6), 1073-1077. doi:10.1093/cid/ciac140

Trickey, A., May, M. T., Hope, V., Ward, Z., Desai, M., Heinsbroek, E., . . . Vickerman, P. (2018). Usage of low dead space syringes and association with hepatitis C prevalence amongst people who inject drugs in the UK. *Drug Alcohol Depend, 192,* 118-124. doi: 10.1016/j.drugalcdep.2018.07.041

UNAIDS. (2020). UNAIDS Data 2020. (United Nations publication)

United Nations Office of Drugs & Crime (UNODC). (2020). World Drug Report 2020: Booklet 2. (United Nations publication, Sales No. E.20.XI.6).

World Health Organization (WHO). (2012). *Guidance on prevention of viral hepatitis B and C among people who inject drugs: policy brief.*

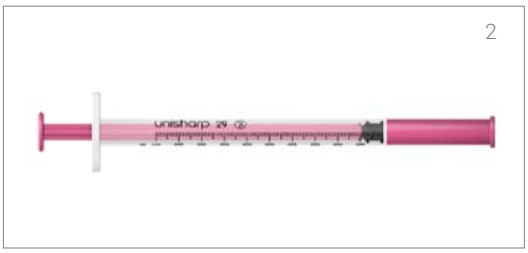
World Health Organization (WHO). (2021). Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021. Accountability for the global health sector strategies 2016–2021: actions for impact. Web annex 1: key data at a glance. Rep., WHO, Geneva. http://apps.who.int/iris/bitstream/handle/10665/342808/ 9789240030985-eng.pdf

Zule, W. A., Latypov, A., Otiashvili, D., Kirtadze, I., Ibragimov, U., & Bobashev, G. V. (2015). Factors that influence the characteristics of needles and syringes used by people who inject drugs in Tajikistan. *Harm Reduction Journal, 12*(1), 37. doi:10.1186/s12954-015-0069-7

9. Appendices

Appendix 1: LDSS/N Starter Pack (Georgia)

LDSS Fixed options

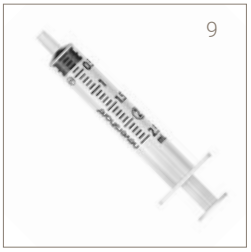


1. Unisharp 1ml fixed combination LDSS 27g - Box of 100
2. Unisharp 1ml fixed combination LDSS 29g - Box of 100
3. Unisharp 1ml fixed combination LDSS 30g - Box of 100

LDSN options

4. Total Dose LDS Needle 23G Blue 1¼inch/32mm - Box of 100
5. Total Dose LDS Needle 25G Orange 1inch/25mm - Box of 100
6. Total Dose LDS Needle 25G Orange 5/8 inch/16mm - Box of 100
7. Total Dose LDS Needle 30G Yellow ½ inch/13mm - Box of 100

HDSS options



8. Nevershare 2ml Luer-Lok (to use with Total Dose Needle) - Box of 100
9. Nevershare 2ml Luer slip (to use with Total Dose Needle) - Box of 100
10. BD 3ml Luer-Lok Syringe (to use with Total Dose Needle) - Box of 200
11. BD 5ml Luer-Lok Syringe (to use with Total Dose Needle) - Box of 125
12. BD 10ml Luer-Lok Syringe (to use with Total Dose Needle) - Box of 100

HDSN options*

13. Braun HDS Needle 25G Orange 5/8 inch/16mm - Box of 100

RDSS option†

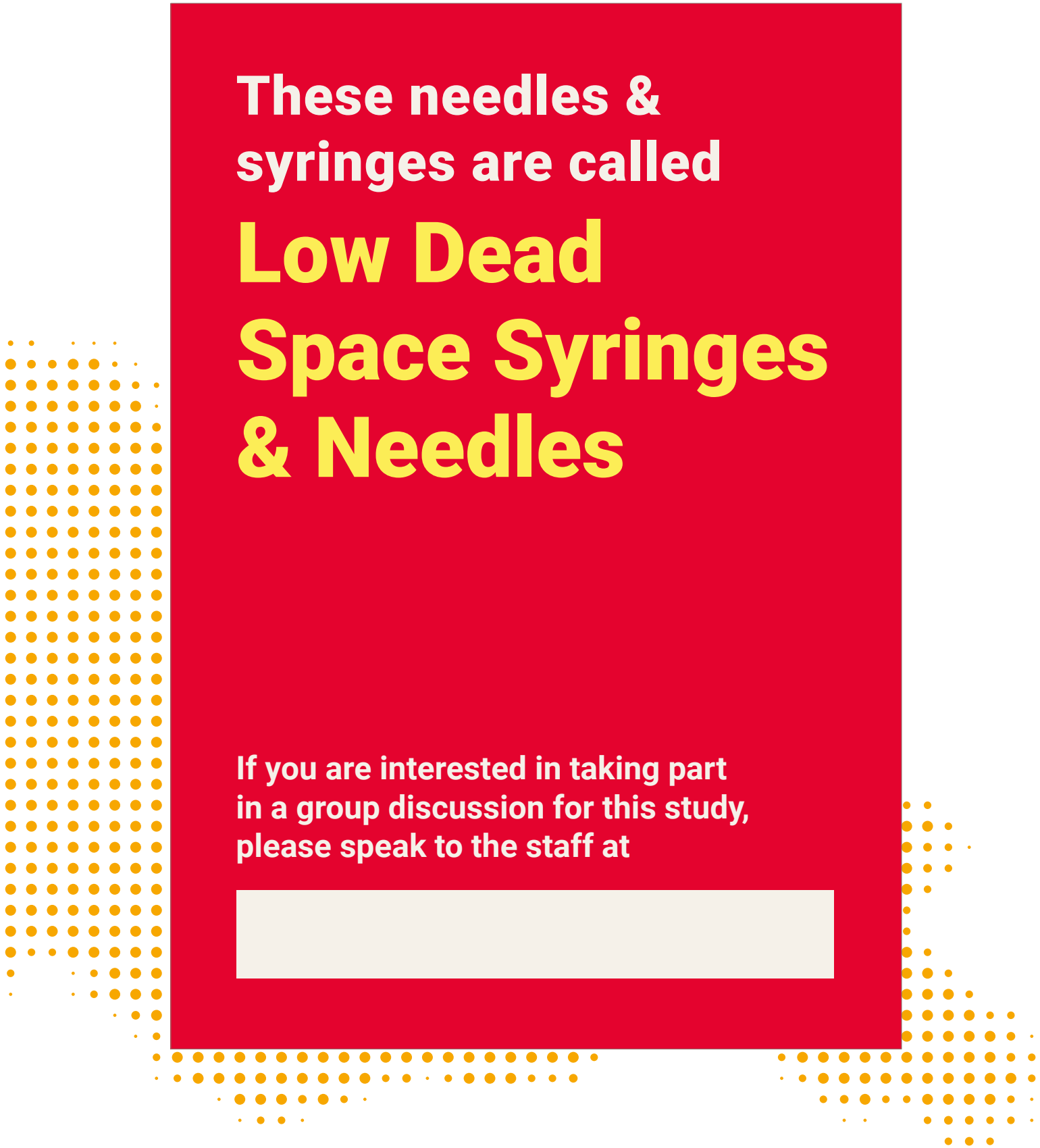
14. Chirana 1ml Luer Slip Syringe - Box of 100
15. Aesthetic Group 1ml Luer-Lok Syringe - Box of 100

---

* Included as a demonstration product only so that participants could see the difference between High Dead Space (HDS) and Low Dead Space (LDS) syringes and needles

† Included as a demonstration product only so that participants could see the difference between High Dead Space (HDS), Reduced Dead Space (RDS) and Low Dead Space (LDS) syringes and needles

Appendix 2: LDSS/N FGD Recruitment Flyer & Explainer



Appendix 2: LDSS/N FGD Recruitment Flyer & Explainer

Why are we doing this study?

Around the world, 58 million people are living with hepatitis C, and there are almost 2 million new infections each year. Hepatitis C is an infection that can lead to serious liver damage. Like HIV, the hepatitis C virus is a blood borne virus which is spread by contact with blood. One of the main ways this can happen is by sharing injecting equipment or using a needle & syringe after someone else has used it. This is because a small amount of blood is left in the needle & syringe after injecting, which can be passed to another person if they re-use the same equipment.

Low dead space syringes & needles have a reduced space between the needle and the plunger (when the plunger is pressed all the way to the end of the syringe), where blood can remain after injecting. Ideally, everyone can use new syringes & needles for every injection. But we know that sometimes people re-use equipment. Low dead space syringes & needles are potentially safer if that happens because they leave less blood in the syringe after injecting and this means less chance of hepatitis C or HIV being passed on if it is present in the blood remaining.

We are doing this study to understand what types of low dead space syringes & needles would suit you best and to then provide them to see if people use them and if there is any impact on preventing new hepatitis C and HIV infections. Before we offer these syringes & needles to everyone using the NSP, we want to hear from you about what you think about these low dead space syringes & needles, see whether you would like to try them for a short pilot period, and then help us to talk about these new syringes & needles to others in your community when we do offer them later on.

Why are you being asked to participate? What are you being asked to do?

We are inviting people who inject drugs and are aged 18 years and over to join a group discussion.

If you agree to participate, you will be asked to attend a 'focus group discussion' with around 10 other people to look at and learn about low dead-space syringes & needles, to discuss your experiences, preferences, and your opinions. This focus group discussion will be facilitated by a community researcher and held in a safe place so that you can speak freely and in confidence. This discussion will take a maximum of one and a half hours and will be audio recorded for note taking purposes. This recording will be kept securely and deleted after the study. No video will be taken.

Appendix 2: LDSS/N FGD Recruitment Flyer & Explainer

Do I have to join the study?

No, it is up to you if you want to join the study. Participation is voluntary.

You do not have to decide today about participating in the study. If you have questions later, you can ask staff at the service on the front of this poster. If you decide not to participate, it will not affect your access to the services you usually use.

What are the potential harms of being part of this study?

We might ask questions or talk about topics that are difficult to talk about. You have the right not to answer any question you don't want to.

We will be collecting information about you that we will keep confidential and only use for the purposes of the study. We plan to keep your information safe by changing your name to an ID number in the study that only the researchers know so you remain anonymous, storing all the data in a safe and password protected place, and destroying the voice recordings after notes have been checked. You will also have the right to leave the study at any point, but once you have participated in a focus group discussion, what you said may still be used in the study (even if you later leave the study) but all comments will be deidentified and remain anonymous.

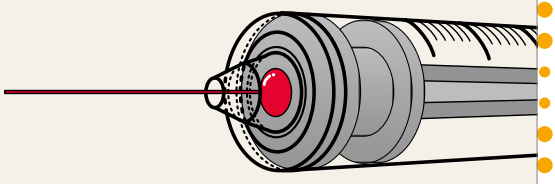
What are the benefits of being part of this study?

Direct benefits:
You will have the chance to share your views about low dead space syringes & needles and if they should be made available. You will also have a chance to try out different types of low dead space syringes & needles and choose which is most suitable for users in your settings.

Indirect Benefits:
Should low dead space needles & syringes prove to be acceptable and effective in your setting, you would have contributed to new research on the benefits of making low dead space needles & syringes available for people who inject drugs.

Will I be paid for my time and transport costs?

You will receive payment for attending each focus group to cover time spent and any out-of-pocket expenses such as transport costs. The amount you will be paid per focus group will be $10 USD.



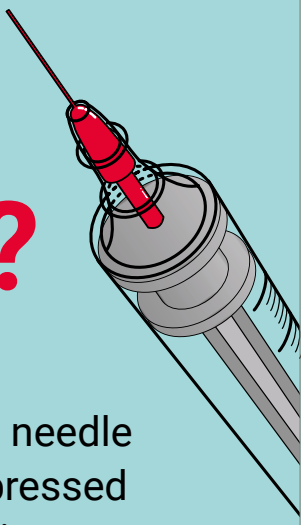
Appendix 2: LDSS/N FGD Recruitment Flyer & Explainer

We are running a research study in your country looking at different types of needles & syringes that can reduce the chance of passing on or getting HIV and hepatitis C if the needle & syringe is re-used or shared accidentally or in an emergency.

Low Dead Space Syringes and Needles

What are they and why use them?

What is Dead Space?



Dead space is the space between the needle and the plunger when the plunger is pressed all the way down to the end of the syringe. This is the space where blood remains after the needle and syringe has been used.

Why is the amount of dead-space important?

HIGH DEAD SPACE

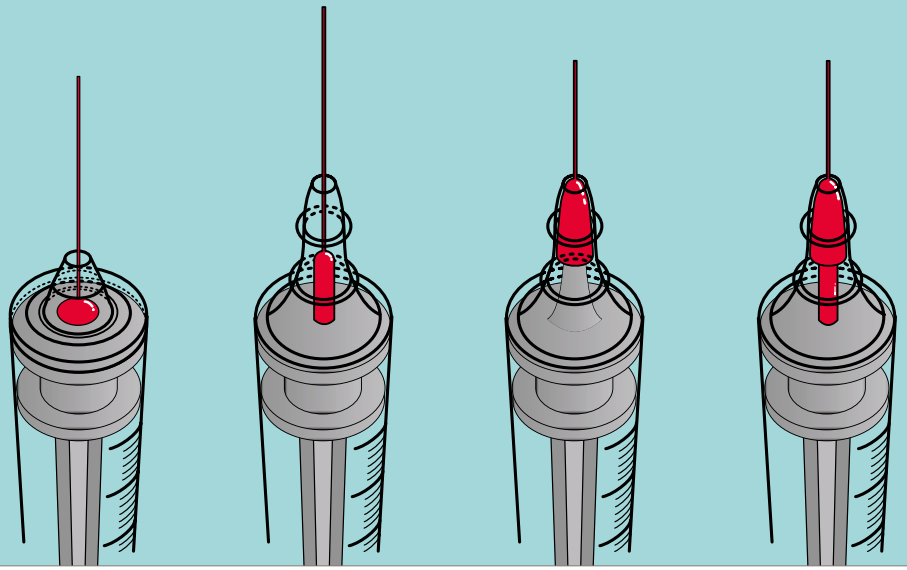
LOW DEAD SPACE

Some needles and syringes have more dead space than others and this can mean that more blood and drug is left behind after injecting. This blood could contain viruses like HIV, hepatitis C or hepatitis B. The lower the dead space, the less blood left behind and the lower the risk of getting or passing on viruses if needles and syringes are reused.

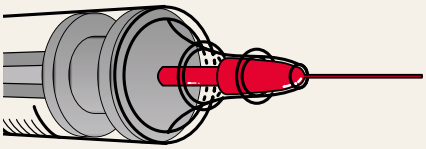
Remember:
Less dead space = less blood = less risk of viruses

Appendix 3 – LDSS/N Client Resource

Different types of Needles and Syringes have different amounts of dead space

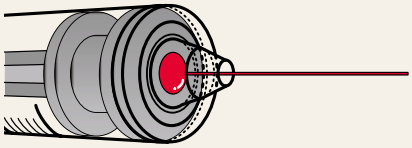


Appendix 3 – LDSS/N Client Resource



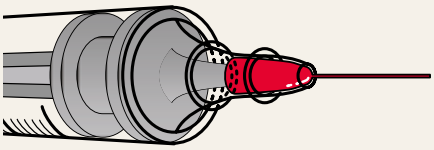
High Dead Space Syringe and Needle (HDSS/N) Combination – larger syringe barrels (greater than 1ml) + standard detachable HDS needles have the

- highest amount of dead space,
- highest amount blood remaining,
- highest amount of virus, and
- highest risk of passing on viruses if re-used.

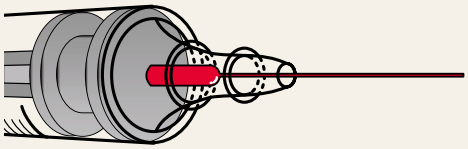


Low Dead Space Syringe (LDSS) Unit – 1ml insulin syringes with the fixed needle (all in one unit) and other LDSS have the

- lowest amount of dead space,
- lowest amount of blood remaining,
- lowest amount of virus, and
- lowest risk of passing on viruses if re-used.

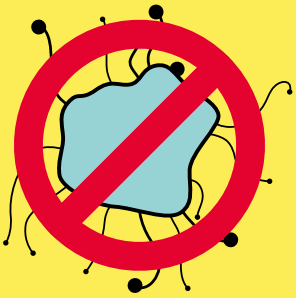


Reduced Dead Space Syringe (RDSS) – Has a rubber spike on the end of the plunger that reduces the dead space by 50% compared to a standard HDSS/N combination. At only 50% reduced dead space, the RDSS does not offer as much benefit to people who inject drugs as LDSN

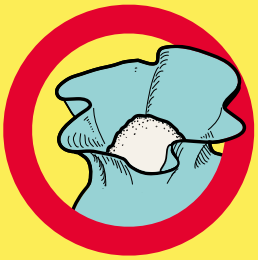


Low Dead Space Needle (LDSN) – These needles have a plastic spike that extends from the base of the needle that fills the dead space between the end of the plunger and the tip of standard high dead space syringes (larger barrels). It reduces the dead space by 85 - 90% compared to a standard HDSS/N combination

What are the main benefits of using low dead space needles & syringes?



Less chance of getting or passing on viruses if works are reused



Less drug is left behind, so less drug is wasted

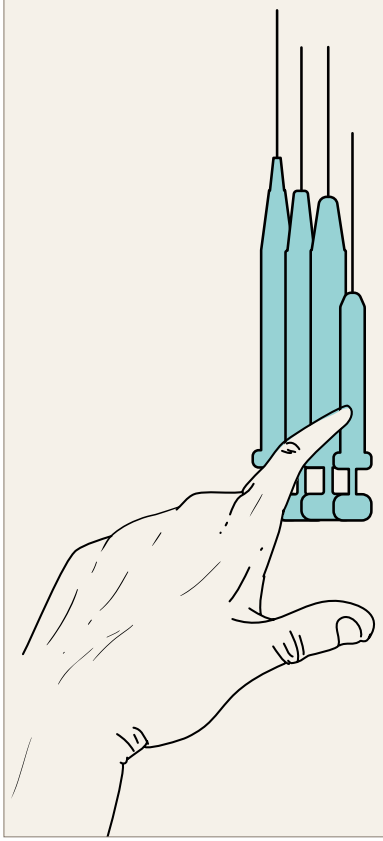
No need to flush as flushing damages veins

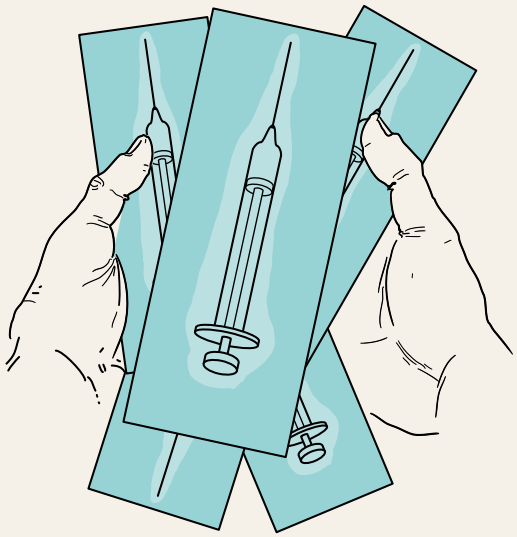
If you have to re-use, low dead space needles and syringes are easier to clean

Take Away Harm Reduction Tips:

Whether you choose to be part of the next stage of the LDSS/N research study, or not, here are some useful, safer using and harm reduction tips to keep in mind:

1. **Choose low** – choose the lowest dead space option for your injecting needs.

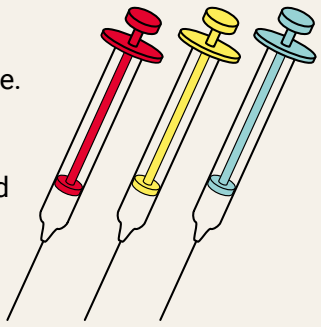




2. **If you can:**
   - always take as many needles & syringes as you need.
   - take enough to have new injecting equipment for every hit.
   - use swabs and clean your hands before injecting.
   - dispose of used needles & syringes safely and return used equipment.

3. If you use with others:

- keep your used needles & syringes separate.
- try marking your needles & syringes so you can tell which are yours.
- or use needles & syringes with the coloured plungers if available.

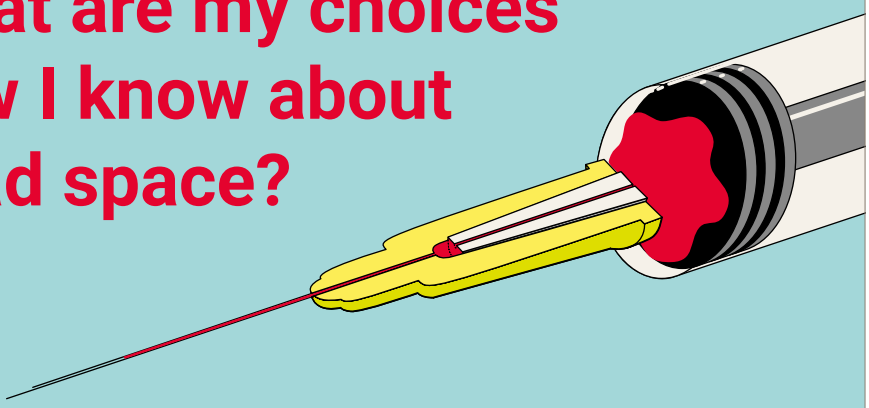


4. If you have to re-use:
try to clean used needles & syringes before reusing.

5. Don't Use Big Needles – use the finest and sharpest needles you can so there is less blood when injecting and to avoid scarring and vein problems.

Most of all, stay safe, and look after yourself and your community.

What are my choices now I know about dead space?



If you already use 1ml insulin syringes (with a fixed needle) and this suits your needs, nothing needs to change – you are already using the best Low Dead Space Syringe option currently available!

But not everyone uses a 1ml fixed insulin syringe. Some people prefer using larger barrels and different length needles (because of what they're injecting, how or where they're injecting, vein issues, and many other reasons). Some people like detachable needles so they can easily change the needle if it gets blunted during injecting. Some people will use different types of needles & syringes for preparing and injecting their drugs. Using a low dead space needle (LDSN) with a standard high dead space syringe (HDSS) provides a low dead space option in these circumstances.

Local information/contact point

Appendix 01: Participant Information and Consent Sheet
LDSS/N Focus Group Discussions (FGD)

Consent Form Identifier / FGD Participant ID code:
Date:
Community Researcher:

This Informed Consent Form has two parts:

- **Participant Information & Consent Sheet** (to share information about the research with you)
- **Participant Consent Register** (for FGD facilitator's signature if you agree to take part)

You will be given a copy of the Participant Information & Consent Sheet

Information Sheet:

Research Purpose
Our study is looking to understand ways of improving access to injecting equipment that reduces risks of HIV and hepatitis C. HIV and hepatitis C are viruses that live in the blood and can be transmitted between people through the sharing of injecting equipment.

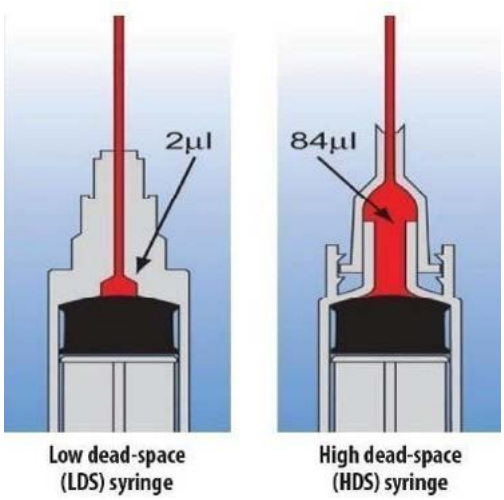
You are being invited to participate in this research study because you are a service user at [service] (or a peer of someone who is) and this service is part of a research project on providing new injecting equipment. People who are over 18 years old, who have injected drugs in the last 6 months and are receiving sterile injecting equipment from this service or via its outreach workers can participate in this study.

This focus group discussion (a small group of people invited to talk about a topic, where the researcher will ask questions and guide the conversation) is a part of a study to understand the community's values and preferences for Low Dead-Space Syringes/Needles (LDSS/N).

A 'low-deadspace' syringe or needle has less space between the needle and the plunger when it is fully pushed in and holds less blood than traditional injecting equipment. If those types of needles and syringes are being reused by someone else, there is less chance that viruses carried in the blood (such as HIV and hepatitis C) are passed on.

Appendix 4 – LDSS PICF and Consent Register

Figure 1 – Mean volume of fluid retained with plunger depressed



Low dead-space syringes (left) have less blood in them after use compared to high dead-space syringes (right).

The World Health Organization recommends the use of LDSS/N but many different types and combinations of LDSS/N exist and not all of them may suit the needs of the community in Georgia.

We want to hear from you about what you see as the potential benefits anddisadvantages, of low dead-space injecting equipment that is being offered currently and/or could be made available at this service, and the things that might influence whether people use them or not.". We also want to hear from you about the potential harms and benefits of different approaches to making low dead-space injecting equipment available here.

The study is being conducted by a group of researchers associated with WHO, Unitaid, MdM, PATH and Frontline AIDS.

The purpose of this form is to (a) share information about the research with you to help you decide if you want to take part in the research, and (b) obtain your oral consent if you agree to take part.

Participation – What this study involves for you
We are asking you to attend a 'focus group discussion' where around ten people will join to talk about the topics of the study. These discussions will take around one hour to one and a half hours and will be audio recorded (no video, just voices).
The focus groups will be held in appropriate places so that you can speak freely and in confidence.

Risks of taking part - Potential disadvantages of taking part in this study
It is possible that you will be at greater risk than you would otherwise be when you participate in this research. Specifically:

1. You may feel that some questions or topics that come up during the focus group (e.g., illicit drug use) make you feel uncomfortable or distressed.

Participant Information Sheet/Consent Form (FGD)
V 1 10 July 2024

Please know that you don't have to respond to anything if you don't feel comfortable, and you can take a break whenever you need to. Facilitators are here to support you.

2. The information you provide on illicit drug use and your additional contact details may be compromised if a breach of privacy / confidentiality occurs.

We will be collecting information about you that we will keep confidential and only use for the purposes of the study. But there is always some chance that this information will be accessed inappropriately, or that other Focus Group Participants talk about what they heard here today (despite agreeing not to). The confidentiality of your data is very important to us and we are taking steps to avoid this happening (more details below).

Confidentiality - How we plan to keep your information safe

If you choose to join and participate in this focus group discussion, you will be asked to talk about your history of injecting drug use and such information could potentially be used against you if it came to the attention of authorities (e.g., through court subpoena).

In some rare cases, we may have to share confidential information if we:

- think you may seriously harm yourself or someone else;
- have been asked to provide this information by a court of law; or
- learn information concerning the protective safety of children.

Over many years of research, we have never been required by law to provide our research information to anyone else. If we were, we would do our best to tell you.

We plan to keep your information safe by:

- Not collecting your name and signature to record that you gave consent (instead we are using a Consent Register signed by the community researcher only).
- using a participant ID number instead of your name. This number will only be known by members of the study team and field workersfor the purpose of contacting you about the study.
- making sure that all contact detail information remains safe and confidential by storing it securely (e.g. on a single site computer with secure password protected and encrypted systems, providing protection from other people accessing it) and separate from any study data.
- Ensuring the permanent deletion of your contact information as soon as data collection is completed..
- Making sure that all data will be made non-identifiable (e.g. no names, dates of births, addresses, places will be included) before it is given to the study team for analysis. Even then, only people in the study team will be able to access it.
- Destroying the voice recordings within four weeks; as soon as the notes are verified and quotes are transcribed, and the principal investigators have checked and accepted the FGD summary reports. This written data will be used for analysis.

Collecting your information and your rights

Appendix 4 – LDSS PICF and Consent Register

We must collect and process your personal information to achieve the purpose of the study, which is to improve access to new low dead-space injecting equipment. Collecting personal information for the purpose of scientific research is legal. Medecins du Monde and its partners will make sure that appropriate measures are followed to protect your rights and freedoms and will only collect information that is necessary for this study.

We will record that you gave verbal consent before any information is recorded or processed using the consent register at the end of this information form. Everyone with access to your personal information will follow the protection measures described in this information form to make sure you remain confidential. Your information will be stored for seven years before it is fully deleted.

You have rights related to your personal data that is collected and processed during this study:

- You have the right to obtain communication (during or at the end of the research) of the information collected concerning your health, held by the site investigator.
- You have the right to access your data, through the site investigator, and request its rectification or completion.

If you have any questions about the collection and processing of your data or you want to exercise any of your rights listed above, you can contact your local site investigator, country investigator, data protection officer, or other study staff listed below.

If for any reason, you are unable to exercise your rights, you can lodge a complaint about the processing of your personal data with the complaint supervisory authority in France for data protection (CNIL) through www.cnil.fr. or the Personal Data Protection Service of Georgia at office@pdps.ge.

Benefits of taking part – potential advantages of taking part in this study

You will have the chance to share your views about Low Dead-Space Syringes/Needles (LDSS/N) and whether they should be made available and your views on how this should be done.

You will receive reimbursement for your participation in each focus group to cover time spent and any out-of-pocket expenses such as transport costs. The amount you will be paid per focus group will be 10USD (27 Georgian Lari).

Your decision to take part in the study

You do not have to decide today whether or not you will participate in the research.
You may also wish to discuss the research with a programme, field or peer worker, trusted community member, friend or family member before making your decision.

Your participation is voluntary (this means that you do not have to take part if you do not want to). If you agree to participate in the focus group, you will be welcome at any point to decline to answer any question. There are no right or wrong answers to our questions. You can also leave the study at any time without this affecting your relationship with the service.

If you decide you no longer wish to participate after the FGD has started, you will still be reimbursed for your travel expenses. Please note that because focus groups are a group discussion, if you decide to leave the study, we will not be able to remove any contributions you have already made in the focus groups because it could change or leave gaps in the group discussion. This means that what you said may still be used in the study (even if you later leave

the study), but all comments will remain anonymous. Your data will not be removed or erased because it would make it impossible to achieve the purposes of the research.

More about the study and who to contact

This study is funded by Unitaid. This study is being led by Medecins du Monde, the Burnet Institute, the International Network for People Who Use Drugs (INPUD), and University of Bristol. Other organisations involved in this study include Hepa plus, New Vector, Step to Future.

This study and how it will be done has been reviewed and approved by the Georgian Health Research Union (HRU) Institutional Review Board (IRB), which is a committee whose task is to make sure that research participants are protected from harm. If you wish to find out more about the ethics committee or ask them about this project or talk to them if you have any concerns, you can contact the HRU IRB secretary via **healthresearchunion@gmail.com.** The ethical aspects of this research project have also been reviewed and approved by the Alfred Hospital Ethics Committee (Melbourne, Australia).

If you have any questions about access and storage of your study data, you can contact the Médecins du Monde Data Protection Officer Jérémie Dron, via dpo.mdm@medecinsdumonde.net. If you request, the Data Protection Officer may access your personal contact details to talk with you.

If you have any **complaints** about any aspect of the project, the way it is being conducted, or any questions about being a research participant in general, then you may also contact: Position: Complaints Officer, Office of Ethics & Research Governance, Alfred Health Email: research@alfred.org.au
Please quote the following project number: 350/24

The study has also been reviewed and approved by the Ethics Review Committee of the World Health Organization (WHO), which is supporting the study (WHO ERC.0004055).

If you have any further queries about our study, please contact the Principal Investigator, Dr Maia Butsashvili via phone: +**995 32 2144447** or email: **maiabutsashvili@gmail.com**. You can also ask me any further questions you have about any part of the research study. Do you have any questions?

Our conversation in the focus group will be audio recorded. Do you give your consent to the recording?

Appendix 4 – LDSS PICF and Consent Register

LDSS/N STUDY
PARTICIPANT CONSENT REGISTER

This register certifies that as the community researcher conducting the FGD that the participant has read, or I have read the Participant Information and Consent Sheet to the participant, and they have given their informed consent to participate in this study and for the FGD to be audio recorded:

Participant ID No.	FGD Number	Date	Time	Venue	Consented (Yes/No)	Signature of Researcher

Participant Information Sheet/Consent Form (FGD)
V 1 10 July 2024

V1
10 July 2024

APPENDIX 2

PHASE 1: FOCUS GROUP DISCUSSION GUIDE

Values and Preferences LDSS/N:

This focus group guide is intended for generating and guiding the focus group discussions with members of the community of people who inject drugs in each of the focal countries.

1. *INTRODUCTION*

Instructions to moderator:

1. As participants arrive, ensure they have given their verbal consent to take part in focus group discussions and have been recorded in the consent log.
2. Register each participant using the 'FGD Participant Sheet' provided, which will assign each participant a number (i.e., participant 1, participant 2, and so on… or list their site-specific unique program identifier). It will also allow you to record key demographic information for each participant such as age and gender identity. Provide each participant with a sticker with their participant number to be displayed during the FGD. Inform participants that providing them with a number will allow them to participate anonymously. Please use this participant numbering system when you refer to participants in the FGD notes.
3. Start the discussion with a setting of "ground rules" for group discussions including a reminder that all discussions are to be kept confidential (i.e. nothing discussed in the group about the personal experiences and opinions will be shared with others outside of this group; participants should let each other finish their sentences/do not interrupt each other; everyone is entitled to have their personal opinion/even if opinions do not align, we treat each other with respect, etc.).
4. Emphasise to the participants that although they will be discussing questions related to illicit drug use and harm reduction, they will not be expected to talk about their own drug use or personal experiences with drug use.
5. Emphasise that participants should not share any information that might incriminate themselves or others.
6. If participants share sensitive info, such as personal experiences around violence, stigma, and discrimination, be prepared to guide and refer such participants to organisations for information support (see the referral list provided in Standard Operating Procedures)
7. You should also inform all participants that audio-recordings are being taken for the purposes of verifying FGD notes and for selecting anonymised quotes only.

Appendix 5 – Focus Group Discussion Guide

V1
10 July 2024

Instructions to the notetaker:

1. When taking notes, please identify the question that goes with your notes. Sometimes participants will discuss things that answer a different question in the guide that hasn't been asked yet, or that can answer more than one question.
2. When capturing some of the key points from the discussion, including useful quotations, please identify the speaker by using their assigned participant number (see point 2 above).
3. Audio-recordings of the interviews will be available to cross-check notes. These will be securely stored, available only to the research team and deleted after the study.

Brief intro script for moderator:

Commence the recording of the FGD now.

Good morning/afternoon, my name is XX. I am working with [add name of organisation and its core purpose]. We are working on a Unitaid funded project to understand the value and potential impact of making low-dead space syringes/needles (LDSS/N) available as a harm reduction item in low- and middle-income countries (LMICs).

To do this we are conducting focus group discussions with people who inject drugs in nine countries (including your country) to gather information on community values and preferences including the potential benefits/harms, advantages/disadvantages, facilitators/barriers associated with low-dead space syringes/needles (LDSS/N) being offered and made available in these countries.

You have been invited to take part in this focus group discussion because we feel that your experiences can contribute valuable information to our understanding and knowledge of the values and preferences of people who inject drugs regarding low-dead space syringes/needles (LDSS/N). This group discussion will last between 60 – 90 minutes.

Your participation in this study is totally voluntary and confidential. You are not asked to provide information that can disclose your personal identity. You can also withdraw from the discussion at any time. The information you provide will be used for the purposes of this study only and will not be disclosed to anyone outside of the research team.

Do you have any questions about the study?

Answer questions, then, begin.

Appendix 5 – Focus Group Discussion Guide

V1
10 July 2024

Thank you for consenting to participate in this study. As discussed during the consent process, this FGD is being audio recorded for our research purposes. These recordings will be securely stored and deleted after the study.

2. FOCUS GROUP DISCUSSION QUESTIONS

Note to the moderator: The order in which the questions are asked may be adapted according to the flow of conversation, but all questions should be covered in the focus group discussions. The first three questions are introductory & scoping questions.

1. **What types of injecting equipment do you currently have access to?** (Probe: what is provided, where and how it's made available (e.g., medical facility/health clinic, community-based facility, peer outreach, etc.)

2. **Do you or people you know have problems accessing injecting equipment/NSP and if yes, tell me about the problems/barriers you have experienced?** (Probe: ask about limits on amounts of injecting equipment, stockouts, lack of ongoing funding for NSP, having to pay, opening hours of NSP, fear of being seen, stigma, attitudes of staff, police attention, not being about to carry N&S on their person, can't take home with them, homelessness, etc.)

3. **Do you or people you know ever need to re-use or share needles/syringes?** Yes/No – explain further.
   (Probe: only needles/syringes they have used themselves or using a needle/syringe previously used by someone else or both? What factors contribute to their decisions to re-use/share needles/syringes?)

4. **Have you heard of/used low dead-space syringes/needles?** (Probe: If yes, what do you know about LDSS/N and how did you get this information?)

   Note: at this point, all participants will be shown different brands/types of LDSS/N to look at and provided with some basic information/explanation of LDSS/N prior to continuing the FGD.

5. **Based on what you now know about LDSS/N, what are your first impressions?** (Probe: do you think that people who inject drugs in your community/other people who you use with would be willing to try or use LDSS/N if they were made available? If yes, why? If no, why not? If unsure, why?)

6. **As explained, because LDSS/N leaves less blood and drug behind after your shot, LDSS/N are thought to reduce the risk of HIV and Hep C transmission if they are reused (that is, after they have been used by someone else).**

   a. **How valuable or important is this for you?** (Probe: does it make you more willing to try LDSS/N? Why/why not?)

b. **What about your community/peers/other people you use with, would this be valued/important to them do you think?** (Probe: would it make them more willing to try LDSS/N? Why/why not?)

7. **Based on what you know now about LDSS/N, are there things that concern you about using LDSS/N or shifting from the needles/syringes you currently use?** (Probe: ask about safety and familiar routines – the value or importance of knowing/trusting how the needles/syringe works, etc.)

8. **What is most important to you when injecting/using injecting equipment?** (Probe: e.g., gauge of needle, length of needle, size of syringe, smooth action of the plunger, that it's all one unit, that the needles & syringe is separate, where the injecting equipment came from, etc).

9. **Based on what you now know and have seen during this FGD, would you be willing to trial LDSS/N for a period of 4-6 weeks?**

   a. **If unsure or no, ask for further information about why unsure/why not.**

   b. **If yes or maybe, ask if they prefer a brand/type of LDSS/N they have been shown and how best to trial the LDSS/N** (i.e., a kit with 3 different brands to trial, random distribution of various brands, etc.).

   c. **If yes or maybe, also ask if people would be willing to come back and tell us what they think about the LDSS/N they trial in 4-6 weeks?** (Probe: discuss how they might record/recall their experiences of the LDSS/N products they trial and whether there is anything that would help with this.)

10. **What would be the best way to get information and education out to people who inject drugs in your community about LDSS/N and the potential benefits of their use?** (Probe: what sort of information would be most important, what format would work best, who should provide the information/education, what would get people's attention, are there things we should avoid/not do, etc.)

3. **CLOSING**
   Ask participants if there is anything else they haven't yet had a chance to say on LDSS/N and would like to add before closing the discussion.

Instructions to moderator:

1. Thank all participants for their time and effort in this group discussion.

Appendix 5 – Focus Group Discussion Guide

2. Remind people again that all discussions must be kept confidential.
3. Instruct participants about the steps following this group discussion (i.e., next phase of the study, how participants will be informed of the outcomes, etc.)
4. Let participants know how they can get in contact with us, in case they have follow up questions or experience any kind of discomfort in the aftermath of the group discussion (this is not expected to happen, but potential contact options should be provided).
5. Let people know where they can access reports from the study once available.
6. Confirm who in the group would like to trial LDSS/N for 4-6 weeks and gather contact information or follow-up contact in accordance with the usual practices used at each study site for contacting beneficiaries.
7. Find an acknowledging way to close the FGD.

Appendix 6 – LDSS - PICF Piloting of LDSS

[INSTITUTION / ORGANISATION LETTERHEAD]

Informed Consent Form
Pilot study and focus group discussion: understanding community values and preferences for low-deadspace syringes

This Informed Consent Form is for people who attend the [service] and/or receive sterile needle/syringes distributed from [service], and who we are invited to participate in this research study. The title of our research project is "Implementing a low dead-space injecting equipment distribution program for people who inject drugs in low and middle-income countries: a process and outcome evaluation" , and this project is led by Médecins du Monde.

Organizations responsible for local data collection: Hepa Plus, New Vector, Step to Future & Médecins du Monde, Georgia
Organization responsible for data collection and processing: Burnet Institute, Australia
Organization responsible for the project (Sponsor): Médecins du Monde, France

Principal Investigator: Prof. Mark Stoové
Country Principal Investigator: Dr. Maia Butsashvili
Protocol version: V1, 10 July 2024

This Informed Consent Form has two parts:

- Information Sheet (to provide you with information about the research)
- Certificate of Consent (to be signed if you agree to take part)

PART I: Information Sheet

1. **Introduction**

Our study is looking to understand ways of improving access to injecting equipment that reduces risks of HIV and hepatitis C. HIV and hepatitis C are viruses that live in the blood and can be transmitted between people through the sharing of injecting equipment. We are doing this research because hepatitis C virus and HIV virus can be easily transmitted when injecting equipment is shared. Transmission happens because these viruses live in the blood and some blood always remains in needles and syringes after they have been used and that means that sharing equipment means that someone else can get exposed to blood that contains the virus. The risk of getting infected or passing the infection on can be reduced with certain types of needles and syringes, depending on how much 'dead-space' the needle/syringe combination has that then holds blood. It is generally accepted that the less 'dead-space' means less blood, which means less chance of passing on any viruses. Low-deadspace needles and syringes are recommended by

the World Health Organization and are available in many countries. We have some evidence already that shows us that they can reduce the risk of transmission of HCV.

You are being invited to participate in this research study because you are a service user at [service]. We invited you because you are over 18 years old, you have told us that you have injected drugs in the last 6 months and that you are receiving sterile injecting equipment from this service or via its outreach workers.

Please read this information sheet carefully and in full before deciding whether to participate in this research. Don't hesitate to ask us any questions about this information. You may want to talk about it with a friend, a relative or one of the research staff.

Participation in this research is voluntary (if you don't wish to take part, you don't have to). Not taking part will not compromise or alter access to any other services.

After going through this information, if you decide you want to take part in the project, you will be asked to sign the consent form. By consenting you are telling us that you:

- Understand what you have read;
- Consent to being part of a focus group discussion; and
- Consent to the use of your focus group discussion data as described;

To participate in the study, you must give your free and informed consent in advance. "Informed" means that you will have received clear information about the research so that you understand how the research will be done, any potential issues, and your rights as a participant. You will also be informed by the investigator of any new information about the study that may change your decision to participate.

You have rights related to your personal data that is collected and processed during this study. We will explain what personal data is collected and your rights in the section on "Your Information".

2. **What is the purpose of this research?**

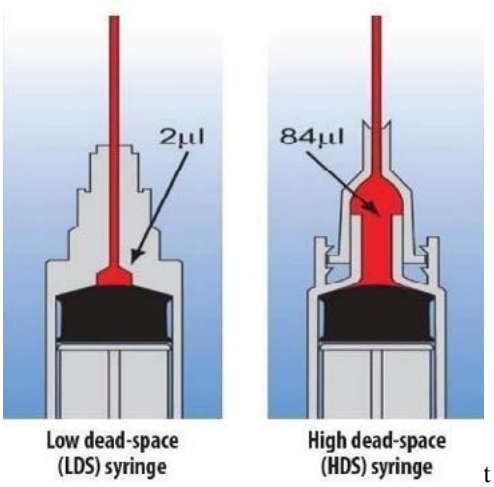
We will start distributing new types of needles and syringes called 'low-deadspace syringes' at [service]. There are many different types of low-deadspace needles/syringes and we have chosen some for you to try based on information we gathered from the first round of focus group discussions where people talked about what they would like.

The first step is having a small group of people trying out these needles and syringes and measuring if people take them and use them, and then getting some feedback on how they found using them. Then, if these needles and syringes are acceptable to people, we will offer them to anyone coming to [service] for a year. During these next 4-6 weeks, we want to understand how you go using these new types and if you continue taking and using them. We also want to hear from people who choose to try and choose not to try the new types of needles and syringes about their experiences of using them.

The new needles and syringes

Injecting equipment called 'low-deadspace' needles and syringes keep less blood in them after being used. If those types of needles and syringes are being reused by someone else, there is less chance that viruses carried in the blood (such as HIV and hepatitis C) are passed on. This is because a 'low-deadspace' syringe or needle has less space between the needle and the plunger when it is fully pushed in and holds less fluid than traditional injecting equipment.

Figure 1 – Mean volume of fluid retained with plunger depressed



t

Low dead-space syringes (left) have less blood in them after use compared to high dead-space syringes (right).

In this part of the study, we will be focussing on finding out more about which types of low dead-space needles and syringes you would prefer so that we can get the right ones for distribution during the next phase of this study.

Study procedures:

This research will involve distributing a few different types of low- dead-space syringes to you for 6 weeks and then asking you to participate in a focus group discussion (a small group where a facilitator leads a discussion about specific topics) at the end of the 6-week period.

1. **Receiving low dead-space injecting equipment to try**

For the next 6 weeks, you will be able to receive a range of low dead-space needles and syringes from this needle-syringe program (e.g. via [service] at the drop-in-center and through outreach workers). The equipment that you normally receive will be available to you as well. You can pick up any or all types as often as you would like, in accordance with needle / syringe program at [service] usual policies (but you will be able to access the new types of needles and syringes AND the usual number of your other types).

We will provide you with information and education materials to help you reduce your risk of experiencing difficulties or negative effects associated with using this new equipment for your injections. We will also provide you with information on who to contact so that you can report any negative effects you may have experienced from using the new equipment.

At the end of the 6 weeks, you will be invited to participate in a Focus Group Discussion (a kind of workshop where a facilitator leads a conversation about a list of topics) with up to 10 people who also were given these new needles and syringes to try.

2. Focus Group Discussions

The focus group discussion is a part of a big study to understand how people who inject drugs use injecting equipment and what types of equipment they prefer. Focus group discussions are a type of workshop facilitated by a researcher in which participants get to share their opinions on a topic of interest. We are conducting focus group discussions with up to 10 participants which will last approximately 60-90 minutes and will be audio recorded. The focus groups will be conducted in appropriate places so that you can speak freely and in confidence.

We are conducting these focus group discussions to understand what you think is / is not good about the low dead-space injecting equipment you tried. This will help us choose the right equipment to make available in your country.

We are interested in your feedback on the types of needles/syringes that you used and which ones you think would be good to keep distributing to people who inject drugs at [service]. We would also like to hear your opinion on what information people would need to have if they want to use this new equipment.

3. Contacting you to arrange Focus Group Discussions

We will ask that you tell us how to best reach you when it is time to arrange a time and place for the Focus Group Discussions to be held. You can give us your preferred contact details (name, mobile number, place where we can find you, secondary contacts – e.g., the contact details for people who know how to get in touch with you if we cannot find you, such as family, friends or a worker) or other ways for our peer/outreach workers to get in touch with you. This information will be stored safely and only people who are conducting this research will have access to this information.

Please remember that it is okay to change your mind at any time. If you agree to take part in this study today, but at the end of the 6 weeks you decide that you do not want to participate in the Focus Group Discussions, this will not affect your relationships with the research team, the staff at [service], or your ability to access harm reduction services such as needle / syringe program, condoms, or counselling.

When you attend the Focus Group Discussions, we will go through the participant information again and ask that you consent verbally to participation in the focus group and for the discussion being audio-recorded. No signature will be required at that point.

4. Data we collect from the service

You collect injecting equipment from [service] and the staff giving you the equipment will record the date and the number and types of needles/syringes that you collect each time you come. We will access this data from all participants and count it, to learn which needles/syringes were collected the most and if this has changed over time.

Duration

The new 'low-deadspace' needles/syringes will be distributed to you for the next 6 weeks. The Focus Group Discussions will take 60-90 minutes and be done at the end of the 6 weeks.

Risks

We have identified three key risks and ways to reduce them (below). It is possible that other risks may come up that we have not anticipated.

1. Breach of privacy / confidentiality of information provided on illicit drug use, the additional contact information

We will follow strict procedures to keep your information safe to reduce the risk of a breach of privacy / confidentiality (i.e. that the information is accessed by someone who should not have access to it). The contact details provided to the study staff will be kept separately from your survey answers and test results.

In some rare cases, we may have to share confidential information if we:

- think you may seriously harm yourself or someone else;
- have been asked to provide this information by a court of law; or
- learn information concerning the protective safety of children.

Over many years of research, we have never been required by law to provide our research information to anyone else. If we were, we would do our best to tell you.

2. Discomfort when answering questions on illicit drug use

If you feel uncomfortable about any questions being asked during the Focus Group Discussions, you do not have to respond to them.

3. Difficulties performing your injections with the new equipment

If you have not used the low dead-space injecting equipment options before, there is a small risk that you may experience injection related difficulties and/or injuries that you wouldn't otherwise experience if you were injecting with the equipment you usually use. If the products don't suit you, you don't have to use them, and the usual needles/syringes will continue to be available to you.

Benefits

There may not be any direct benefit for you. The feedback we receive from you about the different types of needles and syringes you used as part of this research will help us select which 'low dead-space' needles/syringes we will make available at [service] for the next 12-18 months. The feedback you give us might change the needles/syringes that are available for the next part of the study.

Also, your participation in the pilot study will help us understand if the way we want to collect data for the study will work for the next part of the study and if we should make sure people know anything else about the needles/syringes offered before they might try them.

Reimbursements

You will not receive any compensation for trying the new LDSS/N. When you attend the focus group discussions at the end of the 6 weeks, you will receive 10USD (27 Georgian Lari) to reimburse you for the time and effort to participate.

Confidentiality

You will be asked to talk about your history of and current injecting drug use and such information could potentially be used against you if it came to the attention of authorities (e.g., through court subpoena).

There is a small chance that this information would be accessed by people outside of the research team, including if requested by authorities.

We are minimising these risks by: 1) using a participant ID number known only to members of the Georgia study team and outreach workers (for the purpose of contacting you about the study) instead of your name, 2) ensuring all contact information remains confidential by storing it safely in Georgia, and; 3) making sure that all data collected will be de-identified (e.g., a new study ID will be assigned instead of your usual participant ID, and there will be no names, no phone numbers, and no address included) before sharing it with others on the research team.

Over many years of research, we have never been required by law to provide our research information to anyone else. If we were, we would do our best to tell you.

Your information

We must collect and process your personal information to achieve the purpose of the study, which is to improve access to low dead-space injecting equipment. Collecting personal information for the purpose of scientific research is legal, and Medecins du Monde and its partners will make sure that appropriate measures are followed to protect your rights and freedoms and will only collect information that is necessary for this study.

We will collect your consent before any information is recorded or processed, using the Certificate of Consent at the end of this information form and the Consent Register for the Focus Group

Discussion specifically. Everyone with access to your personal information will follow the protection measures described in this information form to make sure you remain confidential.

Information about you that we collect during the research will be stored in a secure place (e.g., a secure, password-protected server or file on a password protected computer at the study site; locked cabinets in a locked office).

Personal contact information
Your personal contact information (your name and phone number) will be collected so we can get in touch with you when it is time for your next study visit. Only the staff involved in data collection will have access to this, and your contact information will be kept separate from all the other information we collect for this research.

The personal contact information we will collect includes:

- Your full name
- Your phone number

This personal contact information will be kept by the study site / investigators in Georgia and will not leave Georgia. Only specific study researchers at your study site will have access to your personal contact information. These will only be used to organize the focus group discussions, or to remove your study data if requested. If you have any questions about access and storage of your study data, you can contact the Data Protection Officer from Médecins du Monde listed below who may also, for the purpose of answering your request, have access to your personal data.

Sensitive information
For the pilot of LDSS, the sensitive information we will collect includes:

- Information about the types and number of needles and syringes you take at this service

The information we receive from [service] about the number and types of needles and syringes you collect will not include your name or your contact details when the research team sees it. This information about number and types of needles and syringes will only have a study ID code (this is different to your usual program ID that [service] asks for when you collect injecting equipment) when it is provided to the research team. The study ID code will be assigned to you by study staff or data manager in Georgia.

For the Focus Group Discussions, the sensitive information we will collect includes:

- Information about the types of needles and syringes you take and use, and your experience using them

We will also collect information about your personal life should you decide to share this with the group. Although this information is not classified as 'sensitive', we will follow the same processes as your sensitive information to maintain confidentiality.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers, Data Protection Officer, in case you have any question or wish to exercise your rights regarding your personal data, or staff at this service involved in delivering the research will be able

to see it. Any information about you will have a number on it instead of your name. This number is called your unique study ID code (allowing your study information to be linked only to this study ID code - also known as encoded information), and only the researchers at your study site will know which unique study ID is related to you. We will keep that information safe by storing it in cabinets with locks or on a password protected computer file.

Your encoded information (which is the information connected to your unique study ID code and not your name) will only be available to the following:

- The organisations and researchers directly involved in the study – Medecins du Monde, Burnet Institute, International Network of People who Use Drugs, University of Bristol, respectively based in France, Australia and United Kingdom
- The funder of the study – Unitaid, based in Switzerland (for data statistics)
- If requested, the independent experts in charge of re-analysing the information to verify the result of the study, before any publication of results. They will only access your encoded information if there is an issue with the quality of the study or if requested specifically by the journal.
- The collaborating organisations and researchers involved in the study in other countries – PATH/PSI, Frontline AIDS, and London School of Hygiene and Tropical Medicine in the USA and UK respectively

Your information will only be seen and used by the individuals listed above and will follow all Georgian and international protection regulations. Medecins du Monde's insurance company may also access your sensitive information if there is a dispute. If this happens, we will make sure to keep your personal information confidential.

Your information will be stored for seven years before it is fully deleted. You have the right to restrict the processing and analysis of your data. Your data may not be removed or erased after analysis has begun because it could make it impossible to achieve the purposes of the research.

The research team will analyse these data using statistical methods to understand how rolling out the new injecting equipment has influenced people's use of injecting equipment distributed at the study sites and to choose the types that will be distributed for the next 12-18 months at [service].

The information you share during the focus group discussions will be collected by a note-taker. We will also audio-record the discussion to be able to later write out quotes of what participants say as examples. Audio recordings will be deleted as soon as they have been transcribed (typed out) and all identifying information has been removed, within 4 weeks of the discussion. The written information will be stored securely and will not be linked to anyone's name. Only members of the research team, the note-takers, and a translator will have access to this data. We will summarise and interpret the findings from the notes transcribed audio files.

You have the right to request access to the information about you that is collected and stored by the research team at any time during the study, and you may choose to withdraw from this study.

Your encoded information may be used for future scientific research relating to harm reduction and drug use. You can refuse for your information to be used in future studies.

Results

Firstly, the results from this part of the study (the pilot study) will help us pick the best needles/syringes to make available at [service] and other participating local needle-and syringe programs in the next part of this study. Also, we will describe how we did the pilot study and how we got feedback from pilot participants to help other needle/syringe programs in other places do a similar piece of work to choose the best available needles/syringes for their clients.

The results of this research project (including this part and the other parts) will be published and presented in many formats, including in academic journals, scientific meetings or meetings with government and other key stakeholders. Results may also form part of university student theses. Results from this research project will be used to advocate for further funding to support sustainable provision of needle and syringe programs.

We will share the summary results with all study sites, where you can receive a written copy or ask the staff to explain what the research found.

The information included in the results will be shared in such a way that you cannot be identified in any publication or presentation.

We will ensure that all findings are communicated in ways which respect the authentic views and interests of the local communities participating in the study. The research team will ensure that none of the work reinforces negative stereotypes or attitudes towards people who inject drugs. Our Community Advisory Board will be engaged at various stages of analysis and reporting for input into the findings and their interpretation.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose by telling the study staff. You will still be able to access injecting equipment available at this site. It is your choice, and all your rights will be respected. If you withdraw from participating in the LDSS pilot before the data has been analysed and request to have your data removed, we will remove your data from the study database where this is possible.

You have rights related to your personal data that is collected and processed during this study.
You have the right to obtain communication (during or at the end of the research) of the information collected concerning your health, held by the site investigator.

You have the right to access your data, through the site investigator, and request its rectification or completion. You have the right to restrict the processing or analysis of your data. Your data may not be removed or erased after analysis has begun because it could make it impossible to achieve the purposes of the research.

Removal of your data related to trialling the LDSS pilot options is possible until we start analysing the data.

Removal of your data from the Focus Group Discussions is not possible. We are unable to remove your data after analysis has begun because when processing your data for analysis, we will remove

any information that could potentially identify you. This means that we will not be able to trace the data back to you to remove it.
If you have any questions about the collection and processing of your data or or you want to exercise any of your rights listed above, you can contact your local site investigator, country investigator, data protection officer, or other study staff listed below.

If for any reason, you are unable to exercise your rights, you can lodge a complaint about the processing of your personal data with the complaint supervisory authority in France for data protection (CNIL) through **www.cnil.fr** or the Personal Data Protection Service of Georgia at **office@pdps.ge.**

Who to Contact
If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Name of local investigator: Dr. Maia Butsashvili
Organisation: Health Research Union, Georgia
Telephone number: 995 32 2144447
e-mail address: maiabutsashvili@gmail.com

Name of Consortium principal investigator: Prof. Mark Stoove
Organisation: Burnet Institute
e-mail address: mark.stoove@burnet.edu.au

Local site investigator [service]: [name]
Organisation: [service]
e-mail address: [email]

Data protection officer: Jérémie Dron
Organisation: Médecins du Monde
e-mail address: dpo.mdm@medecinsdumonde.net

This proposal has been reviewed and approved by the Georgian Health Research Union (HRU) Institutional Review Board (IRB), which is a committee whose task is to make sure that research participants are protected from harm. If you wish to find out more about the ethics committee or ask them about this project or talk to them if you have any concerns, you can contact the HRU IRB secretary via **healthresearchunion@gmail.com**. The ethical aspects of this research project have also been reviewed and approved by the Alfred Hospital Ethics Committee (Melbourne, Australia). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is supporting the study (WHO ERC.0004055). The ethical aspects of this research project have been approved by the Alfred Hospital Ethics Committee (Melbourne, Australia; Project #350/24).

If you have any complaints about any aspect of the project, the way it is being conducted, or any questions about being a research participant in general, then you may also contact:
Position: Complaints Officer, Office of Ethics & Research Governance, Alfred Health
Email: research@alfred.org.au
Please quote the following project number: 350/24

You can ask me any questions about any part of the research study or anything I have just told you. Do you have any questions?

PART II: Certificate of Consent

I have been invited to participate in a study to try new low dead-space needles and syringes and participate in a focus group discussion at the study end. The study seeks to find out more about the types of low dead-space needles and syringes that should be made available at this service that I access. The focus group discussions will ask questions about drug use and injecting practices, but I do not have to answer these questions if I do not feel comfortable.

		Participant Initials
1	I have read the above information on this study, or it has been read to me. I understand that I will be offered a copy of this document to keep.	
2	I have had the opportunity to ask questions about it and any questions that I have asked have then been answered to my satisfaction.	
3	I understand the purposes, procedures, and risk of the pilot of LDSS research project and what I am required to do as a participant.	
4	I understand that I am free to withdraw at any time during the project without affecting my future care	
5	I understand and consent that personal and sensitive information/data, such as health service data (harm reduction equipment) may be processed during this study	
6	I understand and consent that data about me may be shared via a public data repository or by sharing directly with other researchers outside my country, and that I will not be identifiable from this information	
7	I understand that there will be a second, verbal consent process to complete when I participate in the focus group discussions.	
8	I consent voluntarily to participate as a participant in this research where I will be given the chance to try new injecting equipment.	
9	I consent for my encoded information to be used in future studies.	

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Signature of witness**

_____

Date _____
Day/month/year

Print name of participant:

Signature or Thumb print of participant:

Date:

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. they will be able to access novel injecting equipment at participating study sites
2. they will be contacted after 6 weeks to arrange a Focus Group Discussion
3. they will be invited to participate in a Focus Group Discussion with up to 10 needle-syringe program clients, lasting for 60-90 minutes
4. they will undergo a separate consent process for the Focus Group Discussion

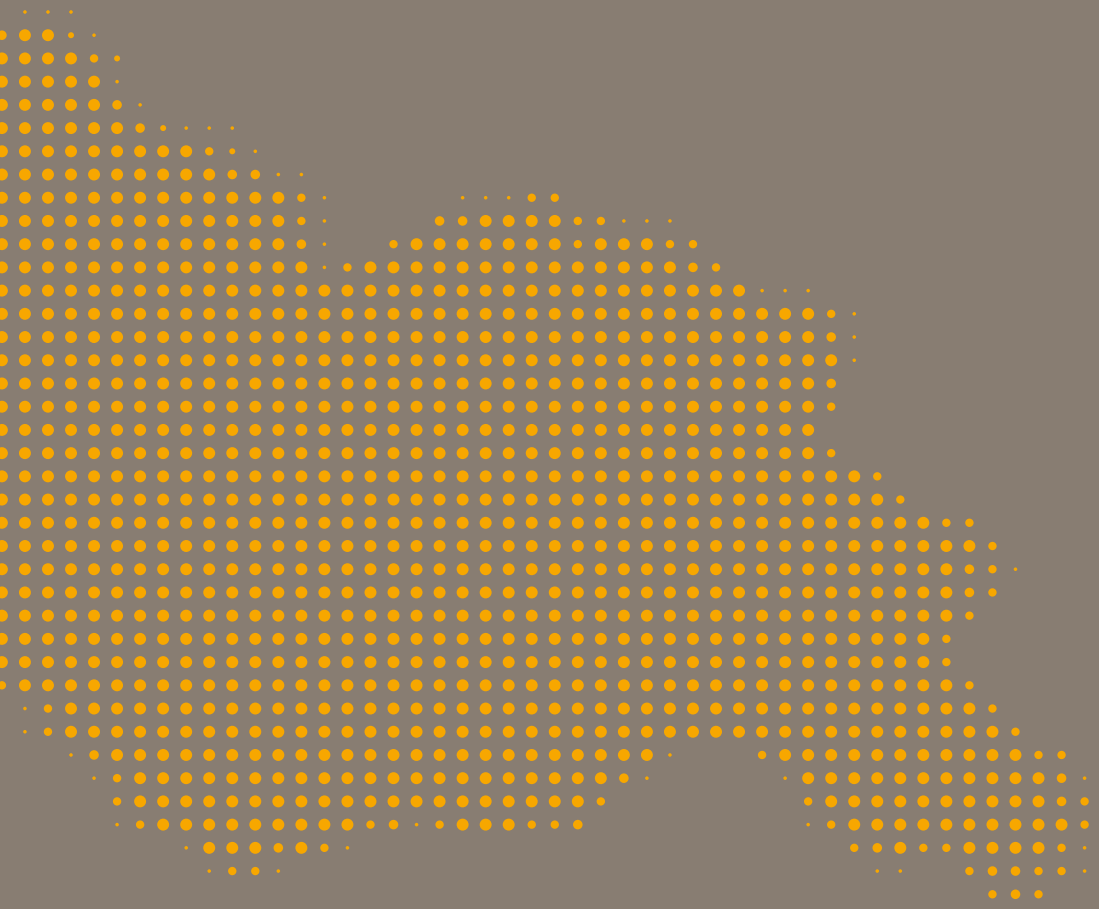
I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year



CUTTS
HepC