ARMENIA 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

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Contents

FIGURE PAGE

TABLES PAGE

1. Executive Summary

"...people who inject drugs have been engaged not only as participants but as co-researchers and co-designers throughout every stage of the process..."

This report presents findings from the community-led values and preferences Phase 1 focus group discussions (FGD) held in Armenia 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 part of a larger cross-consortia study being implemented in nine LMIC, all of which are exploring how low dead space syringes and needles (LDSS/N) can be introduced and scaled in ways that are effective, acceptable, and contextually appropriate.

A defining feature of this study is its community-led, values and preferences-based approach. In all nine countries, including Armenia, 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.

In Armenia, community researchers recruited 41 people who inject drugs to participate in FGDs, with 4–11 participants per group. During Phase 1 FGDs, participants were invited to provide insights into their current access to needles and syringes (N&S) and their experiences with existing equipment. Community researchers then educated participants on low dead space syringes vs high dead space syringes and the potential harm reduction benefits, before distributing a selection of LDSS/N products. Participants were then invited to provide their

initial impressions of the LDSS/N products and asked which of the products they might be interested in trying during a 6-week pilot stage.

While FGD participants considered needle-syringe access to be sufficient, (particularly since the introduction of the Real World Real People (RWRP) Needle and Syringe Program / NSP in Yerevan) they consistently raised concerns about the poor quality of the equipment currently provided. Dull needles, breakages, and leaking syringes were commonly reported, creating serious barriers to safer injecting practices. Many participants described adapting by purchasing equipment from pharmacies or swapping components to assemble a usable N&S. These adaptations, while resourceful, come at a cost for beneficiaries both financially and in terms of increased risk of injecting related harms, and highlight the urgent need to improve the quality of equipment distributed through the NSP.

Re-use or sharing of N&S after another person was generally reported as having declined since the commencement of the RWRP NSP, although some participants acknowledged it still occurs in specific settings and/or circumstances such as prisons, and among women facing greater structural and social access barriers. Re-use of one's own syringe was more commonly described, often linked to the desire to retain high-quality syringes. Barriers to accessing safer equipment were also reported, including policing near pharmacies and stigma from pharmacy staff.

Participants responded positively to the range of LDSS/N products made available for consideration during the FGDs. First impressions focused on the perceived higher quality of these products compared to current equipment, including sharper needles, smoother plunger action, secure fit from the luer-lok mechanism, and potential for reduced leakage. While participants also recognised the benefits of LDSS/N in reducing blood exposure and Blood-Borne Virus (BBV) transmission risk, quality, usability and the range of products to match injecting practices appeared to be the primary drivers of interest and uptake. Participants strongly expressed the need to validate these initial perceptions in real-world settings, during the planned six-week pilot and wider roll out phases.

"... these findings illustrate the value of engaging community members not just as recipients of harm reduction programs, but as experts in their own lives and health ..."

Participants also identified key education and communication needs and feedback on how best to support community understanding of LDSS/N, including clear recommendations towards peer-led messaging on the benefits of reduced blood-borne virus (BBV) transmission and other injecting-related harms, less drug wastage, and improved injecting experience.

Crucially, these findings illustrate the value of engaging community members not just as recipients of harm reduction programs, but as experts in their own lives and health. Involving people who inject drugs in identifying barriers and enablers to access, shaping distribution models, and defining communication strategies is essential for generating more relevant, acceptable and effective NSPs. While early feedback from Armenia suggests that overall needle-syringe coverage is improving, FGD1 findings point to suboptimal quality and range of available equipment. The next phases of this project will introduce a range of high-quality LDSS/N alongside harm reduction education. The degree to which these products meet the realities of people's injecting practices will ultimately determine the success of LDSS/N uptake and usage. These themes will be explored further in Phases 2 and 3 of the study, which will provide deeper insights into individual-level access, experiences, and outcomes.

2. Introduction

"...injecting drug use remains a key risk factor for human immunodeficiency virus (HIV) and hepatitis C virus (HCV) transmission..."

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). The values and preferences approach is being used to ensure the provision of LDSS/N is aligned with the needs and preferences of local communities of people who inject drugs, in order to improve the likelihood of LDSS/N uptake and usage.

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. In relation to the introduction of LDSS/N specifically, values and preferences also includes exploring participants' first impressions and what they perceived as the benefits and/or disadvantages of LDSS/N. Preferences for different LDSS/N types, implementation strategies for future roll-out, and the role of peer networks in education and knowledge mobilisation are also part of exploring values and preferences in relation to LDSS/N.

It is important to note however, that 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), poverty, and the absence of harm reduction services in settings like prisons.

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

This study on how to best introduce LDSS/N into new settings to support high uptake is being implemented across nine LMICs: Armenia, Georgia, Tanzania, Nigeria (two locations), Egypt, South Africa, India, Vietnam, and Ukraine as part of a Unitaid portfolio investment into hepatitis C. Three research consortia are implementing three studies of integrated simplified HCV testing and treatment and harm reduction interventions in 10 LMICs with the aim of reducing HCV transmission risk and improving access to HCV care.

The specific objectives of the LDSS/N study (across all nine 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 this 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) and WHO ERC 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 Armenia 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 Real World Real People NGO and MdM Armenia. The CUTTS Hep C Consortium is also conducting this LDSS/N Study together with country partners in Georgia and Tanzania.

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

"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)."

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.

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.

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

Armenia is a country of ~2.8 million people. It is estimated that approximately 1% of the total male population (~13,700 men) and 0.3% of the total female population (~400 women) inject drugs in Armenia (National Center for Infectious Diseases, 2021). The overall estimated adult HIV prevalence is low at 0.2%, but integrated bio-behavioural surveys conducted in 2021 estimate that 2.6% of people who inject drugs are living with HIV (ibid.). A recent study conducted in Armenia estimated the prevalence of HCV antibodies in the Armenian adult

"There are many contextual and systemic barriers to the provision of, and access to, HCV and harm reduction services in Armenia."

population to be 1.9%, of which approximately one third had untreated chronic infection (Demirchyan et al., 2021). According to the integrated bio-behavioural surveys conducted in 2021, HCV antibody prevalence among people who inject drugs is 39.4% (ibid).

There are many contextual and systemic barriers to the provision of, and access to, HCV and harm reduction services in Armenia. These include the ongoing effects of the punitive Soviet-era legal environment and challenges relating to illicit drug use being treated as a criminal/law and order issue, rather than a health and social issue. Government readiness to enhance harm reduction services and expand access to critical programs for people who inject drugs, such as OAT and naloxone provision, is also a factor. Ongoing concerns exist about the sustainability of service provision depending on funding sources, including whether the government will be in the position to provide domestic funding for required HCV and HIV prevention and treatment services in Armenia. This is of particular relevance given the current Global Fund arrangements are due to end in less than three years - a concern that many LMICs share.

Currently in Armenia, N&S are available free of charge at "Real World, Real People" (RWRP), a non-governmental organisation (NGO) specialised in harm reduction. The Needle & Syringe Program (NSP) at RWRP commenced in August 2019 (prior to this it was provided by another NGO) and is fully funded by the Global Fund. In this context, RWRP is primarily funded to deliver HIV voluntary counselling and testing (VCT), alongside NSP as a prevention program including the provision of certain harm reduction supplies[1]. The RWRP NSP operates in Yerevan (the capital city) and regionally, with distribution occurring at their drop-in centre (DIC) and via RWRP's outreach and peer workers.

In addition to accessing HIV VCT and harm reduction supplies, people attend the RWRP NSP to speak with peers and for consultations with social and legal workers. Typically, outreach workers go to places and areas where people who use drugs gather, where they distribute needles and syringes. Sometimes program beneficiaries will also take needles and syringes to distribute in their own communities (also referred to as 'peer distribution' or 'secondary distribution') to help and support each other. Stakeholders report that RWRP's approach to NSP including engaging outreach and peer workers in service provision, has enhanced community access and engagement with the program primarily due to their person-centred and respectful approach.[2]

Through the Global Fund, 200 N&S are allocated per person, per year (PPPY) in Armenia. As a community-based NGO, RWRP aims to be as flexible as possible in relation to providing the number of N&S program beneficiaries require. RWRP's approach to NSP distribution typically involves providing the full 200 PPPY allocation to beneficiaries in a single service delivery/ outreach encounter. RWRP staff also note, however, that some beneficiaries invariably need less, and therefore take less than the PPPY maximum. Any remaining injecting equipment is used to accommodate greater need from other beneficiaries. Once the PPPY limit is reached in a 12-month period, beneficiaries can request more N&S if they are available. However, resource constraints mean that numbers are limited and would not typically exceed a maximum of 350 per year to any individual program beneficiary.

1. Within existing resources, RWRP is unable to provide the full WHO recommended package of harm reduction interventions. Currently, they provide N&S, condoms, cotton, and alcohol pads but not cookers and other harm reduction supplies and services. Important to note, however, that after a limited procurement in 2024 where Naloxone was distributed to emergency services and the NCID, in 2025 the GF will begin providing Naloxone to an estimated 60% of RWRP NSP beneficiaries for the first time in Armenia.

2. Reported 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 being conducted by INPUD in collaboration with study community partners GeNPUD, TaNPUD & RWRP.

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

According to RWRP, the most commonly injected drugs in Armenia currently are opioids including heroin, chernyashka (acetylated opium), methadone and Subutex, with some stimulant injecting (e.g., methamphetamine/amphetamine) also observed. This information is supported by the Armenian Integrated Bio-Behavioural Surveillance Survey (IBSS) for 2021. The IBSS 2021 also reported desomorphine (benzine) use among people who inject drugs in Armenia (National Centre for Infectious Diseases, 2021). More recently, RWRP staff observed that desomorphine use was once more common, but very few beneficiaries now report using it.

In Armenia, like many LMIC, HDSS/N are the most commonly used injecting equipment; with 3-5 ml syringes typically used for chernyashka and 10-20 ml for methadone. The 1ml fixed LDS syringes comprise approximately 15% of the injecting equipment provided in Armenia. In addition to the injecting equipment made available through the NSP, N&S are also available at a cost in pharmacies. There is currently no formal data available on the level of uptake through pharmacies.

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

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 Armenia is no exception. Informal consultations occur when outreach workers are in the field, talking with people who use drugs and sharing information. RWRP holds a monthly monitoring meeting where outreach workers can share the issues raised by community. 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. Although RWRP and some key populations are represented on the CCM in Armenia, there is currently no representative of people who use drugs. Given the lack of a formal consultation mechanisms 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 Armenia (and in the eight other LMIC involved in the study).

Hence, in both the wider program of research and this specific study in Armenia, 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 nine 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 study involving four phases of research:
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.

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

Phases are being implemented iteratively. Existing evidence and the knowledge generated through earlier phases inform the design and adaptation of an optimal model for LDSS/N implementation and evaluation in subsequent phases. Process monitoring and evaluation occurs throughout, informing the parameters for mathematical modelling of public health impact.

The key population for the study are people who inject drugs accessing NSPs in Armenia. The study is being implemented in Yerevan (via RWRP) where it is estimated that nearly half of all people who inject drugs in Armenia are located (National Center for Infectious Diseases, 2021).

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 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 use 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. 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 during the 12–18-month LDSS/N implementation and evaluation phase (Phase 3, see below):

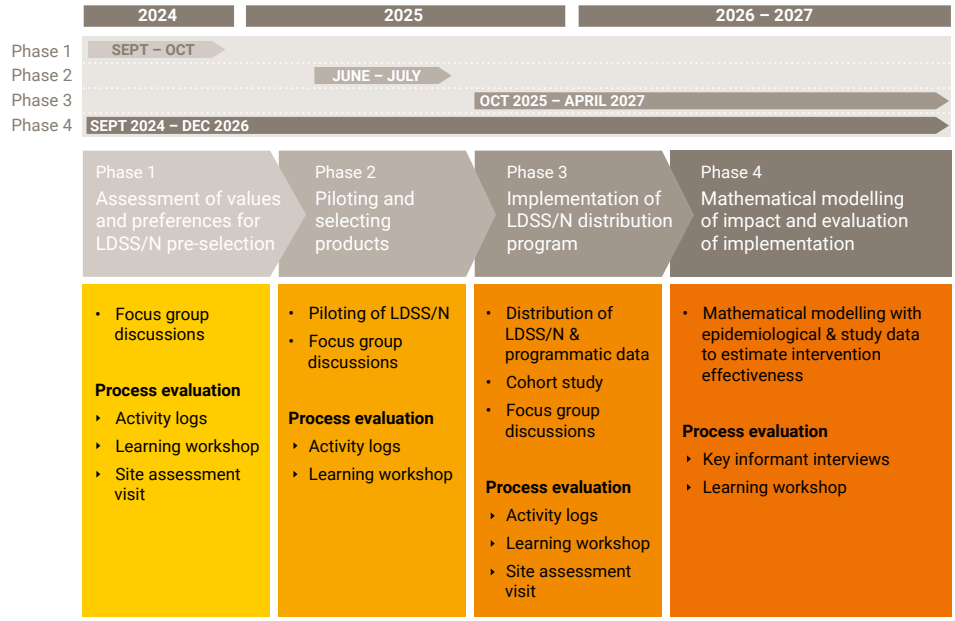

Figure 1: Overview of study phases & values & preferences FGDs

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

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. FGD participants were also invited to provide 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 local/consortium partners, was conducted prior to Phase 1 FGDs to identify and procure a range of LDSS/N sample products (see Appendix 1 – LDSS/N Starter Pack) for consideration by participants in 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 for specific country contexts[3].

"FGD participants were invited to discuss their current experience with injecting equipment, practices and harm reduction..."

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 pack[4]. In Armenia, the process of developing the 'Starter Pack' considered 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 Yerevan and surrounding districts.

In partnership with the CAB and local/consortium partners, INPUD also led a further cross-consortia process to develop participant recruitment mechanisms and other IEC/knowledge mobilisation materials for use in the Phase 1 FGDs (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 a tool in the FGDs to explain each of the sample products in the 'Starter Pack' (the video script was translated into Armenia and a voiceover in Armenian was added). These recruitment and knowledge mobilisation materials were also used in other study countries (using either language specific voiceover or sub-titles).

3. 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.

4. 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 for Phase 1 comprises people who inject drugs attending RWRP services 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 Armenian; and
- Able/willing to provide informed consent.

3.1.3 Participant Recruitment:

Participants for the Phase 1 FGDs were recruited from across the various districts of Yerevan 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 RWRP staff, who have been providing services to the local community in Yerevan since 2019. Specific attention was paid to ensuring a diverse representation of local community across age, gender, and diverse injecting expertise and experience (see further comments in 6. Limitations & Challenges below).

Recruitment occurred via community-led recruitment processes whereby the community researcher and peer outreach workers from RWRP approached NSP beneficiaries and utilised their personal networks of people who inject drugs within Yerevan and surrounding regions to identify potential research participants. Recruitment strategies included using a combination of a study poster in local Armenian language (see Appendix 2 – LDSS/N FGD Recruitment Flyer & Explainer), word-of-mouth and community-networking approaches using the peer education resource (see Appendix 3 – LDSS/N Client Resource)[5]. The opportunity to participate in the Phase 1 FGDs was also advertised at the RWRP premises and NSP DIC. Interested members of the community were invited to register their interest. Upon contact, the community researcher 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 researcher read the PICF verbatim to participants in Armenian. Having read (or heard a description of) the PICF, participants were encouraged to ask any questions, and if they consented to proceeding with FGD participation. Their verbal consent was then documented in the Consent Register (see Appendix 4). No personally identifying information was recorded in the register. The register was signed-off by the community researcher and provided to the Principal Investigators (via a secure server) following the FGD.

"Specific attention was paid to ensuring a diverse representation of local community across age, gender, and diverse injecting expertise and experience."

3.1.5 Participant Demographics

A total of five (n=5) FGDs were conducted at the RWRP premises in Yerevan. Each FGD included between 4 – 11 participants with a total of forty-one (n=41) participants across all FGDs. Thirty-seven (90%) FGD participants were male and four (10%) female. The median age of participants was 52.25 years. The age range was 29 - 67 years, with 8% (n=3) aged 26-35 years, 12% (n=5) aged 36-45 years, 49% (n=20) aged 46-55 years, 29% (n=12) aged 56-65 years and 2% (n=1) 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/chernyashka and methadone. FGD participant numbers and participant gender and age breakdowns are included in the Table 1 below.

5. 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.

FGD Number	No.of Participants	Gender	Age Range
FGD 1	9	Male (9)	38 – 64
FGD 2	7	Male (7)	32 – 56
FGD 3	10	Male (10)	41 – 59
FGD 4*	4	Female (4)	29 – 47
FGD 5	11	Male (11)	39 – 67

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

Table 1: FGD Participant Characteristics

3.2 Data Collection

"FGDs were led by a trained and supported peer/ community researcher from the local community..."

FGDs were led by a trained and supported peer/community researcher from the local community (with training and support provided by INPUD, Burnet, RWRP and MdM). FGD notes were documented by a note-taker and the FGDs were audio recorded with participant consent. FGDs were of 60 to 90 minutes duration and were conducted in Armenian. The FGDs were conducted in-person, and all groups followed a semi-structured FGD Guide *(see Appendix 5 – Phase 1 Focus Group Discussion Guide).*

The community researcher facilitated the discussion among participants about their preferences, values and considerations regarding N/S including current access and barriers to access. The LDSS/N products in the 'Starter Pack' (see 'Study Design' above) were presented to the FGD participants, who were invited to consider the range of potentially available products and discuss their suitability and acceptability. This process was supported by the short 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 the 4-6-week pilot phase. 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.

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

A pause was scheduled following the initial two FGDs to allow for reflections and learning and provide further methodological support to the community researcher. Once the first transcripts were available in English, they were reviewed by the INPUD PI and Burnet researchers. A debrief meeting was then held with the community researcher, note taker, other members of the country team, the INPUD PI and Burnet researchers. This debrief meeting provided an opportunity for the community researcher and note taker 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 debrief meeting as appropriate.

3.3 Data Analysis:

Immediately following each FGD, the audio recording was professionally transcribed (verbatim). The community researcher and note-taker de-identified the transcripts and checked them for discrepancies as they became available. The community researcher and note-taker then developed a FGD Summary Report using a template provided by INPUD including selecting relevant quotes from the transcript for inclusion in the report.

"A qualitative thematic analysis was conducted utilising a dual approach that integrated both a priori deductive coding and inductive coding methods."

The transcript, FGD notes and FGD Summary Reports were professionally translated from Armenian to English and uploaded (along with participant documentation) to a secure cloud-based platform for access by the INPUD PI 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 researcher and note taker in Armenia. 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.

The responses across all data sources were then coded by the INPUD PI and two qualitative researchers from the Burnet research team using NVivo software. A qualitative thematic analysis was conducted utilising a dual approach that integrated both a priori deductive coding and inductive coding methods (Clarke et al., 2015). The analysis commenced with the application of a predefined set of deductive codes based 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 themes and insights associated with the values and preferences of the participants in their specific 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: 108361 (Local Reference: Project 263/24) on 30 May 2024 and Armenia country NCID IRB on 27 June 2024.

4 Results & Discussion

The following section presents findings from FGDs conducted with people who inject drugs in Armenia, highlighting a range of experiences and perspectives relevant to LDSS/N and harm reduction programming more generally. This section explores current access to and quality of needles and syringes, the impact of equipment quality on injecting practices, and experiences of sharing and reuse in specific contexts. It presents 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. 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. Together, these themes provide important insights into how harm reduction services in Armenia (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 – Access to and quality of needles & syringes

Across all FGDs, participants reported sufficient access to needles and syringes (N&S) through the Needle and Syringe Programs (NSP) or outreach services provided by RWRP. However, a critical concern was the poor quality of the equipment provided, which significantly affected its usability. Participants consistently highlighted the inadequacy of the N&S quality rather than accessibility issues:

"Well actually, we can say that the amount is enough. The outreach worker comes to see us as often as we need. But the quality was not good, the quality of the needles."

> *"Well actually, we can say that the amount is enough. The outreach worker comes to see us as often as we need. But the quality was not good, the quality of the needles."*
>
> (participant FGD 1.1)

> *"Since this program is in place everyone gets what they need, but the problem is they're all faulty, that's the issue."*
>
> (Participant FGD 1.2)

The perception of inadequate quality was reinforced across all five FGDs, with participants detailing specific issues such as dull needles and needle and syringe breakages. These issues caused physical harm and led to problems with drug administration:

> *"Three times it happened to me personally, I usually inject into the groin, and the needle broke, I barely caught it before it went in."*
>
> (Participant FGD 1.2)

> *"And when you inject, your arm gets bruised, brother, you end up with a hole like this, with that needle."*
>
> (Participant FGD 1.3)

Additionally participants raised concerns about the potential for drug to be left behind or trapped within currently available syringes, further discouraging the use of the available N&S:

> *"No, it's not just the needle. Why, brother, half the drug stays inside the syringe. You push, and almost two notches stay there."*
>
> *"In the rubber, true. Under the rubber, it stays on the side."*
>
> (Participants FGD 1.3)

Drug loss caused by leaking syringes was also commonly reported as a key issue:

> *"As for the products provided, some syringes leak from the plunger part, yes it happens."*
>
> (Participant FGD 1.1)

The FGDs show how the quality of equipment is central to participants' choices regarding which N&S to access and/or use. Concerns about current, low-quality equipment not being fit-for-purpose underpinned why many participants reported seeking higher-quality N&S from pharmacies, despite the financial burden this created:

> *"We get the ones from here, but we don't use them. We buy them from the pharmacy because it's not possible to inject with these."*
>
> (Participant FGD 1.3)

> *"If the quality improves, no one will go to the pharmacy to buy them."*
>
> (Participant FGD 1.5)

A unique and creative strategy to mitigate suboptimal equipment was to swap out components from different syringes to create a functional unit:

> *"Yeah, bro, we buy four syringes from the pharmacy, then combine them to make one. We take the needle from one, the plunger from another, and something else from the third..."*
>
> (Participant FGD 1.3)

"We get the ones from here, but we don't use them. We buy them from the pharmacy because it's not possible to inject with these."

In addition to the financial burden of having to purchase additional, better-quality N&S from the pharmacy, these practices also result in wasted harm reduction resources as certain poor quality, unusable components are discarded in favour of components that are 'fit for purpose':

> *"Sometimes they take it, throw away the needle, and use the syringe putting on a new needle they bought themselves."*
>
> (Participant FGD 1.4)

Furthermore, the N&S provided through the NSP were often used as a last resort, rather than as a first-choice option. This highlights how the provision of poor-quality N&S is not only a waste of precious harm reduction resources, but also actively undermines harm reduction efforts:

> *"We only use it when we're in a desperate moment, and you're forced to damage your veins and struggle with yourself."*
>
> (Participant FGD 1.3)

4.1.2 Current Context – Sharing uncommon but reuse being driven by poor quality

Participants suggested that good access to N&S through RWRP harm reduction services meant that they did not need to reuse or share someone else's N&S. Participants clearly understood that such practices were a potential BBV transmission risk, indicating the effectiveness of harm reduction messaging and peer education approaches around the risks of BBV transmission that are an integral part of harm reduction programming:

> *"No! They give us plenty, brother, why would we use just one?"*
>
> (Participant FGD 1.5)

"When you get a good needle, you wash it, and you don't want to throw it away."

Although all FGDs found that participants had sufficient access, meaning the need to reuse someone else's N&S was largely obsolete, some individuals described instances where they reused their own needles and/or syringes. This practice was often motivated by the desire to retain a needle and/or syringe to reuse later (sometimes multiple times) if it was deemed "good" quality:

> *"When you get a good needle, you wash it, and you don't want to throw it away."*
> (Participant FGD 1.3)

> *"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)

This practice of holding onto a 'good' N&S for future re-use highlights how people who inject drugs in Armenia are being forced to adopt suboptimal injecting practices to navigate the poor or inconsistent N&S quality of current equipment. Therefore, better access to quality N&S remains a priority in Armenia.

Interestingly, the women's FGD (FGD 1.4) introduced a different perspective, with some participants acknowledging that reuse of N&S between individuals did occur within networks. Comments from participants suggests that factors such as geographic distance to pharmacies, after-hours unavailability, and even concerns about safety after-hours, act as additional structural barriers for women who inject drugs leading to an increased risk of drug related harm:

> *"There are some [who reuse a syringe after someone else] among acquaintances." "Yes, there are." "It wasn't available; it was late, the pharmacy was closed, or the pharmacy was too far, so they didn't go to get one."*
> (Participant FGD 1.4)

These insights highlight that equipment 'quality' is a critical consideration for harm reduction programming, including regarding the introduction of LDSS/N to NSPs in LMICs. If people who inject drugs cannot trust the equipment provided through harm reduction services, they will continue to seek alternatives and/or be forced to engage in practices that can bring an increased risk of drug-related harm, including skin and soft tissue infections (SSTIs), systemic infections, severe vein damage and amputations, etc. (Saldana et al, 2020). Addressing these concerns is essential for strengthening harm reduction programs and ensuring that available harm reduction resources are being used as effectively as possible.

4.1.3 Current Context – Social and structural barriers to access

4.1.3.1 Prisons

In relation to access barriers participants also raised the lack of access to sterile injecting equipment in prison settings. While participants emphasised that N&S reuse in the general community is now rare, prison environments in Armenia remain a significant exception. Several participants highlighted that sterile N&S remain inaccessible in custodial settings and how structural barriers continue to fuel unsafe injecting practices:

> *"It doesn't happen outside, but inside—there's still that issue in prisons."*
> (Participant FGD 1.2)

> *"In a cell with 4 people, all 4 use the same syringe, they pass it around, and then pass it to another cell. How is that acceptable? "*
> (Participant FGD 1.3)

"The situation in prisons is so bad... They use broken, burned, and repaired syringes. But what else can they do?"

Although individuals in prison attempt to mitigate risks by boiling needles or improvising makeshift syringes, these measures are far from adequate in preventing BBV transmission (Treloar et al. 2015). Participants expressed frustration over the inconsistency in harm reduction efforts, particularly given the continued availability of illicit drugs within prisons:

> *"If drugs are accessible in prisons, syringes should be accessible too."*
>
> (Participant FGD 1.2)

Other participants argued that N&S would never be made available in Armenian prisons because it would require prison authorities to openly admit to injecting drug use in prisons. Some thought that if N&S were to be made available in prisons, such equipment should also be provided with drugs of known quantity and quality to further reduce drug related harms.

Participants also spoke of how the absence of sterile N&S in prisons meant that people are forced to reuse any N&S that are available many, many times and that available units are re-used by multiple people. Participants also said that in addition to reuse and sharing of available N&S, people in prison also fashion injecting equipment by repurposing various items available to them into make-shift injecting devices. This included participants describing examples of prisoners sharpening used needles on matchboxes or using broken and improvised syringes out of necessity:

> *"The situation in prisons is so bad... They use broken, burned, and repaired syringes. But what else can they do?"*
>
> (Participant FGD 1.3)

These accounts highlight the urgent need for policy reforms that include needle and syringe distribution in prisons, recognising that harm reduction measures are essential, and have been shown to be feasible, even within highly restricted environments. The fact that injecting drug use occurs in prisons is acknowledged globally (Austin et al, 2023), and these participant accounts show that the absence of sterile N&S in prisons in Armenia (and most other countries) is forcing people who inject drugs to use dangerous improvised objects which serve to exacerbate health risks and harms. Participants voiced a strong demand for systemic change, arguing that access to sterile injecting equipment in prisons is not only a public health issue but also a matter of basic human rights.

In this context, the needs identified in the Phase 1 FGDs present an opportunity for Armenia to join with other countries in the EECA region who do currently provide NSP in prison (including Kyrgyzstan, Moldova, Tajikistan and Ukraine) with the aim of developing a regional unified approach through inter-government discussions and policy reform.

4.1.3.2 Police

Another theme was the role of law enforcement in shaping access to sterile injecting equipment. Most participants stated that interactions with police were not a significant problem when accessing their N&S through the NSP at RWRP or through outreach workers. But concerns regarding accessing N&S through pharmacies were raised:

> *"It's actually better getting it from you all [RWRP], otherwise, there are certain officers waiting by the pharmacies. You've made things easier."*
>
> (Participant FGD 1.5)

Several participants described experiences of police harassment outside pharmacies, which discouraged them from obtaining needles and syringes through pharmacies even though these are legitimate access points in Armenia. Experiences and anecdotes relating to the presence of law enforcement near pharmacies included being interrogated, and in some cases, demands for bribes:

"Me and him, when we were getting supplies from the pharmacy, it became an issue, there was a hassle for like an hour, two hours."

(Participant FGD 1.3)

"Some young people have issues at home, or they come from families where it's better if not everyone knows about it, yeah... And just to avoid being taken to the police station, they're willing to pay money and avoid the hassle. "

(Participant FGD 1.3)

Such encounters contribute to a climate of fear, pushing people who inject drugs towards riskier methods of obtaining equipment or deterring them from accessing harm reduction supplies altogether. Some participants described how police officers operate on assumptions and targeted profiling, stopping individuals based on their perceived status as people who use drugs:

"... They come and ask about the drug, assume you're a drug user, and that's it: 'Why are you buying that syringe?' But they don't approach just anyone; they need to suspect you, to figure out that you're that type of person, before they approach, bro."

(Participant FGD 1.3)

"...staff attitudes can act as a deterrent for people who inject drugs, particularly for women."

The above accounts underscore how the breadth of harms associated with poor quality N&S available through NSP in Armenia stretch well beyond health-related consequences to include significant social harms including increased risk of arrest and incarceration.

Ultimately, while contact with police had reduced significantly with the establishment of the RWRP NSP, participants still recalled instances of police harassment. The societal consequences of these policing practices can be severe, as they not only undermine harm reduction efforts but also perpetuate cycles of stigma and discrimination for people who use drugs. Taken together, these accounts highlight the importance of providing high quality injecting equipment through NSP that not only meets people's specific needs but is accessible and does not carry the risk of police interactions.

4.1.3.3 Gender-based Stigma and Discrimination

Beyond interactions with law enforcement, participants also detailed experiences of stigma and discrimination particularly from pharmacy staff. While pharmacies represent a legal access point for sterile injecting equipment in Armenia, staff attitudes can act as a deterrent for people who inject drugs, particularly for women. The discussion explored whether women who use drugs are comfortable accessing N&S at the pharmacy including whether they have ever had any issues because of cameras, or feeling embarrassed, or not wanting to go in:

"Well, let me say this: there have been times when they went into the pharmacy specifically for needles, and the salesperson sensed why they needed it, and even was rude to them, but they sort of went in and out reluctantly, got what they needed, and left."

(Participant FGD 1.4)

When asked by the facilitator whether going to the pharmacy is "mainly [a] men's job" several female participants responded:

"Well, sometimes girls go there too, don't they?"

"I've gone too."

"It happens, why not? Sometimes girls go as well."

(Participants FGD 1.4)

This short exchange offers some important insights into the gendered dynamics of accessing needles & syringes through pharmacy in Armenia. While the exchange implies certain gender norms, suggesting that men are generally the ones who are expected to go to the pharmacy, the participant responses point to exceptions to this norm. Nonetheless, statements such as "I've gone too" and "Sometimes girls go as well" indicate that women access pharmacies less frequently and with more hesitation. This difference may indicate social and structural barriers that uniquely shape experiences of women, e.g., stigma, judgment, safety concerns and gender norms about public visibility and drug use.

This subtle but real gender norm at work in these contexts is also evidenced in subsequent responses, where participants described palpable shifts in demeanour towards women when asking for syringes in some pharmacies:

> *"Sometimes they even buy it from a completely different place to avoid suspicion, but still, they're looked at with judgment."*
>
> *"Yeah, as soon as you mention "a needle," they get nervous. And you can tell they already figured out why you're buying it."*
>
> *"They look at you differently, yeah"*
>
> (Participants FGD 1.4)

These data are a starting point for further inquiry into gendered experiences of N&S access, including understanding how stigma, gendered expectations and safety concerns might create unique barriers to women who inject drugs. Further exploration could shed light on a range of neglected issues such as how often women access pharmacies to purchase N&S, the challenges and risks they face in doing so, and the influence of relational dynamics on who collects equipment.

"...gendered experiences of N&S access, including understanding how stigma, gendered expectations and safety concerns might create unique barriers to women who inject drugs."

Access to harm reduction services has improved in Armenia since the commencement of RWRP NSP in August 2019, but participant comments suggest the presence of ongoing social and structural challenges that could be placing female drugs users at particular risk of BBV infection – especially if barriers result in women being reluctant to access harm reduction services. Indeed, the difficulties associated with recruiting female participants for the Phase 1 FGDs (see section 5: Limitations & Challenges below) illustrate the gendered dynamics underpinning drug use in Armenia. In this context, any introduction of LDSS/N in Armenia, must take account of existing access barriers and challenges for women who inject drugs. This should include fostering a wider non-judgmental environment where women who inject drugs can access harm reduction services without fear of discrimination and/or negative consequences for themselves or their families.

4.2 First Impressions of the LDSS/N Products

Luer-lok vs non-luer lok syringes

Participants across all FGDs responded positively to the LDSS/N samples that were showcased during the FGD. Without the chance to try the products, participants, commented on perceived quality, ease of use, and fit-for-purpose design. Many participants noted the sharpness of the needles and the improved safety features, such as the security of the needle on the tip of the syringe due to the 'luer-lok' (screw on) feature as reflected in these comments from participants:

"These are excellent syringes, really high-quality equipment."

(Participant FGD 1.5)

"These syringes are very good as they lock, and the needles do not come off."

(Participant FGD 1.4)

"These are such good needles!"

(Participant FGD 1.4)

Participants across all FGDs also consistently referred to what translated into English as 'control'. In discussing the concept of 'control' participants claimed that the LDSS/N products looked like they would allow the user to see that they are in the vein automatically, without the need to 'aspirate' or pull the plunger back and forth in an effort to check if they are in the vein. Participants suggested that if this was the case it would amount to a significant improvement over existing N&S due to the potential to reduce vein damage:

"I get it, I haven't injected with this yet, but I think with this one, you won't need to give control anymore. Once you're in, it turns red on its own."

(Participant FGD 1.2)

"The advantage is that you don't need manual 'control', it shows when it's in the vein, which is safer. Also, if it's really sharp, that's important."

(Participants FGD 1.5)

"These are excellent syringes, really high-quality equipment."

"... when injecting, for the "control" we aspirate every time pulling the plunger back, and we end up damaging the veins. But this will help us avoid that and protect our veins. You immediately see the blood flow as soon as you insert it. It's really important. I also join the others in expressing my gratitude."

(Participant FGD 1.1)

Participants believed that if their perceptions proved true, the combination of the 'control' and the obvious superior quality of the LDSS/N products would likely result in them being widely accepted and used in their communities should they be distributed beyond the pilot phase. There was a strong consensus that people who inject drugs in Armenia would welcome these products:

"Of course, they will [use them]."

"How could they not be used, brother?"

"It would be great if these needles came to Armenia; they're really good."

(Participant 1.2)

"Yes, if we explain that there's no need to pull back the plunger for control with this, they'll definitely want it".

(Participant FGD 1.4)

"Definitely. You can see the quality of these ones. Even when you just push and pull, you can tell it's a quality product. No doubt about it."

(Participant FGD 1.1)

At the same time, participants emphasised the importance of testing the new equipment themselves before forming a final judgment. While the initial impressions were

overwhelmingly positive, participants expressed a desire for real-world experience, putting the LDSS/N products to use in their own injecting practices and settings, before deciding on which products would best suit their needs (if any):

> *"The first impression is good. We just need to test it out, but it seems promising."*
>
> (Participant FGD 1.5)

> *"Better to try first, then it will become clearer."*
>
> (Participant FGD 1.1)

> *"Let's try it first. No matter how good it looks, but... Otherwise, whatever we say is just visual."*

> *"You have to try it first, like tasting a watermelon."*
>
> (Participants FGD 1.3)

4.3 Perceived Benefits of the LDSS/N Products

Beyond the initial impressions, participants perceived a range of potential benefits of the LDSS/N products that could enhance their injecting experience and reduce harm. A key feature that stood out was the secure fit of the needle to the syringe, which prevents drug leakage – which was a common issue raised by participants in relation to the standard syringes:

> *"I am saying the most important thing is that the needle fits tightly, that's a big deal, because… I've spilled my drugs so many times, I've seen that leakage, it made my heart stop."*
>
> (Participant FGD 1.2)

Participants also appreciated the variety of needle sizes available, which cater to different injection sites and preferences. For example, some participants favoured larger gauge LDS needles for reaching deeper veins (such as the blue 23G or orange 25G LDSN), while others found the finer gauge (yellow 30G LDSN) more suitable for what translated in English to "capillary injections" or for injecting into the very fine veins on hands, feet and other parts of the body:

> *"The orange ones, right? They're perfect for my injections, under my arm. They would fit perfectly, brother. Just for that reason only I liked these needles. And the insulin ones aren't bad either. The thin ones will be used too."*
>
> (Participant FGD 1.2)

"The first impression is good. We just need to test it out, but it seems promising."

Participants also recognised the potential harm reduction and public health benefits of LDSS/N, particularly in reducing HIV and HCV transmission. They demonstrated a clear understanding that lower dead space means less residual blood in the syringe, which decreases the risk of virus transmission – important, as this was the key harm reduction message in the FGD IEC materials and video. Also important is the fact that participants thought the potential for LDSS/N to reduce BBV transmission would be a motivating factor for LDSS/N uptake and usage among people who inject drugs:

> *"That's what I wanted to say. We should provide that information when distributing them, mentioning that there's a lower percentage of virus transmission – if you tell them, they'll be more motivated to take them."*
>
> (Participant FGD 1.4)

"...this one leaves less blood, and there's also less risk of infection, plus there's less drug wasted, and it's easier to inject and fill in the syringe."

"First of all, it reduces the risk of infection for you or someone else, which is a huge benefit. Not accidentally infecting someone or getting infected yourself – that alone makes a big difference."

(Participant FGD 1.5)

Participants also noted that the syringes would minimise vein damage and improve the overall injecting experience by making the process easier and reducing drug wastage. It was clear, that even before trying the LDSS/N products for themselves, participants across the FGDs could see many potential benefits of the LDSS/N products should they be made available in Armenia:

"...this one leaves less blood, and there's also less risk of infection, plus there's less drug wasted, and it's easier to inject and fill in the syringe. For those with bruises, they pull the plunger back for control, so you can feel it."

(Participant FGD 1.3)

"To summarize, I would say that... from the health of our veins to our overall health, each type will have its benefits. The thin ones will be used for injections in the arms, while the thick ones will be used for injections in the groin, but all of them are important."

(Participant FGD 1.1)

4.4 Selection of Products for Phase 2 Pilot

4.4.1 Participant preferences for pilot products

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

"All that we have, they're all necessary for injections from different places."

(Participant FGD 1.1)

"But really, all of these can be used, because it depends on where you're injecting. One day you might inject here, another day there. You can't just stick to one type; all of them are very useful."

"Yes, exactly. Everyone is different."

(Participants FGD 1.4)

Participants also pointed out that depending on what is being injected, how much is being injected, where it is being injected, the condition of a person's veins, and other factors, different needles and syringes will be best, making it essential that all the options are provided during the pilot phase:

"It's interesting; different people use different things. Some need longer needles. For instance, I liked this smallest one, because I injected with "insulin." The thinnest and shortest needle is convenient for me, but other people have different preferences that work better for them."

(Participant FGD 1.1)

"Exactly, that is good for injections in the arms or legs, but you can't use it for injections in the groin area."

(Participant FGD 1.1)

"Also, the dosage varies each time, so you inject in different amounts."

"Yes, it depends on what you're injecting, what the drug is."

(Participants FGD 1.3)

Linked to the above discussion, some participants stressed the importance of including large (20ml) syringes and if possible, an even longer LDS needle than the Blue 23G 32mm shown to facilitate injecting into deeper veins such as in the groin:

"… for the syringe of "twenty," we also need a needle… There are people using the "twenty" as well. Some people are struggling to get to the vein in the groin area, yes, that really happens. You're trying to get it, but the needle is too short…"

(Participant FGD 1.1)

It is also worth noting that a small number of participants also made suggestions on additional harm reduction supplies (other than the LDSS/N products) for inclusion in the pilot which may indicate wider unmet harm reduction needs among the community:

"Shall we get swabs with these, any alcohol swabs?"

(Participant FGD 1.5)

"There's one thing I'd like to clarify. When we start distributing these, are we only going to hand out syringes and needles, or will there also be alcohol swabs and other supplies, like condoms? Just curious."

(Participant FGD 1.4)

"Is there any chance you could provide cardio-aspirin or similar blood-thinning medication that might help us? That's really important for all of us; we all have blood problems."

(Participant FGD 1.1)

4.4.2 Pilot implementation: the importance of choice

"It would be preferable with different sizes. Different people use different sizes."

When asked about their preferences for how the LDSS/N products should be made available in the pilot phase, participants across all FGDs were clear they did not want to be given just one size/limited options but preferred to have access to various products. Perhaps unsurprisingly, the preference of the participants was to be able to access what they need and not be given N&S that do not need or want:

"Different sizes, different sizes. Everyone according to their own needs, like that."

"It would be preferable with different sizes. Different people use different sizes."

"Yeah, different sizes. If I need a 10 [ml], I'll ask for a 10; if I need a 2 [ml], I'll ask for a 2."

(Participants FGD 1.5)

Participants also highlighted that the specific injecting equipment people require can depend on multiple factors that can vary considerably from individual to individual including, but not limited to, what people are injecting, the amount they are injecting, where they are injecting on the body, the condition of their veins, etc. Importantly, participants also raised the fact that the injecting needs and practices of an individual drug user can also change from time to time due to drug availability, changes in drug use patterns, changes in injecting sites due to vein issues, ageing, etc. Therefore, participants believed it was important to make an array of injecting equipment available to individuals at any one time:

"People inject different parts and use different sizes."

"Also, the dosage varies each time, so you inject in different amounts."

"Mixed, brother, at least in the beginning, then we'll figure it out. People inject different parts and use different sizes. They should have a variety of needle sizes".

(Participant FGD 1.2)

"Mixed, with various sizes, bro. The point of mixed packs is that if I want to inject in one spot but can't, I can switch the needle and inject in a different part body. That's the idea. Also, the dosage varies each time, so you inject in different amounts. Yes, it depends on what you're injecting, what the drug is. Mixed would be best"

(Participant FGD 1.3)

One consideration raised by several participants was the potential for 'waste' if the distribution approach taken to the pilot phase was too rigid/inflexible. For example, participants wanted access to the types of LDSS/N products that matched their needs, knowing that their needs might vary during the course of the week or depending on drug availability. Participants recommended avoiding taking an approach that is too prescriptive such as only giving participants access to pre-made packs with set equipment they may not need or use, or which could lead to participants discarding unused equipment:

"The 10cc should be in one pack, the 2cc in another. If I don't need the others, why would I take them and toss them somewhere?"

(Participant FGD 1.5)

"Yes, for example, I need the 10cc and the 20cc. Right, I'll take what I need, and others can take what they need. Yeah, like 10cc, 20cc – someone else might need something else, you know…"

(Participant FGD 1.5)

Although pre-made NSP packs may be easier to distribute, participants strongly preferred a "pick and choose" approach that allows them to select individual items based on their needs. This preference has several practical implications including increasing the variety and quantity of equipment outreach workers must carry and potential difficulties associated with separating supplies in the field. It also raises potential social and logistical challenges, such as increased time for distribution and the risk of drawing unwanted attention to NSP outreach activities. Ultimately, prioritising the needs and preferences of NSP beneficiaries is essential to achieving better public health and harm reduction outcomes, even if it requires more flexible and responsive approaches by harm reduction services.

4.5 Transitioning to LDSS/N and Knowledge Mobilisation

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

FGD participants identified several key information, education, and communication (IEC) needs to support community understanding and uptake of LDSS/N. Participants emphasised the importance of clearly explaining how LDSS/N can reduce the risk of BBV transmission if equipment is reused by someone else, highlighting this as a critical harm reduction benefit. They also noted the need to communicate what they anticipated as the improved "control" offered by LDSS/N – potentially eliminating the need for aspiration and thereby reducing vein damage. Information on the higher quality of the needle – being sharper and less likely to cause vein damage and missed shots – was seen as essential to building trust in the equipment. Additional messaging on the reduced risk of leakage from the syringe and the benefit of less drug being left behind after injection were also seen as important benefits to communicate. Participants felt that clear, peer-led communication on these practical advantages would be key to promoting informed decision-making and supporting safer injecting practices within the wider community of people who inject drugs.

Participants emphasised that the most effective way to spread information about LDSS/N to prepare for Phase 3 implementation is through peer-to-peer networks. They noted that word of mouth is the preferred and most effective method for raising awareness as people who inject drugs often have close-knit networks, where information travels quickly and is perceived as more trustworthy when coming from peers:

> *"Not brochures – by word of mouth."*
>
> *"Yes, by word of mouth! Who needs brochures?"*
>
> (Participant FGD 1.5)
>
> *"We need to spread the word; it should be through us to our friends."*
>
> *"… and now that these have entered the country, for sure everyone injecting will know that a good product has come in…"*
>
> (Participant FGD 1.1)

Written materials were seen as less effective because people may not read them or retain the information in the same way as the might with a direct conversation between peers:

> *"Yes, you might give a brochure, and they might take it but not read it, but if you tell someone directly, it sticks in their mind. If you talk to them, they get a better understanding of what you're saying. Otherwise, they might just take it and toss it aside."*
>
> (Participant FGD 1.5)

Some participants specifically raised the role of peer outreach workers in LDSS/N knowledge mobilisation either in addition to or even as an alternative to printed materials. Participants suggested that outreach workers should be trained to provide simple, clear explanations about LDSS/N:

> *"… train the outreach workers. A brochure alone isn't enough."*
>
> *"...Just explain it to them in two or three sentences, so it's very clear, and that's it. Then, we wouldn't even need a brochure."*
>
> (Participants FGD 1.4)

In summary, there was a strong preference for verbal communication to support LDSS/N knowledge mobilisation efforts in Armenia and drawing on outreach workers to reinforce key information regarding harm reduction benefits for LDSS/N amongst peer networks. Given the strong word-of-mouth communication networks within drug user communities, many participants felt that awareness would spread quickly:

"Yes, you might give a brochure, and they might take it but not read it, but if you tell someone directly, it sticks in their mind."

> *"… within a week, everyone will already know."*
>
> *"In ten days, we'll spread the word."*
>
> (Participant FGD 1.5)

This highlights the self-sustaining nature of information-sharing within drug user networks, reinforcing the importance of peer-led initiatives in harm reduction strategies.

"...not just as peer educators but as part of a community whereby members actively take care of each other and share information..."

4.5.2 People Who Inject Drugs Educating and Supporting Each Other

Many participants raised the fact that communities of people who inject drugs already look after and mentor one another including in relation to harm reduction education and safer injecting practices including peer or secondary distribution. They described how they regularly advise younger drug users on safer injecting practices, reinforcing harm reduction messages during their engagements:

> *"I personally reach out to as many young people as I can, explain everything to them. When I give out syringes, I tell them, 'Brother, don't hesitate, if you need more, I'll give you more, just call me, I'll bring them, just don't reuse them."*
>
> (Participant FGD 1.2)

Despite general consensus around the positive impact of intra-community support, taking on mentorship roles to promote safer injecting practices and share information among their networks was seen to carry some risk. This understanding is illustrated by this conversation among several participants:

> *"If I wanted to give one of the [LDSS/N] syringes you distributed, to a young person and say, 'Use this so you don't spread infection' and they [the police] saw that, they'd give me trouble. But I'm doing something good, giving it to prevent the spread of infection. I could get prosecuted for that."*
>
> *"Yeah, exactly."*
>
> *"So we do things in a way to prevent that kind of situation."*
>
> *"But I'm doing a good thing."*
>
> *"Yeah, it's set up in such a way that this issue has always been there, and the police will always hassle us; we can't change that."*
>
> (Participants FGD 1.3)

It is clear that participants in the FGDs viewed themselves not just as peer educators but as part of a community whereby members actively take care of each other and share information to this effect. These accounts also highlight that peer-led models of NSP distribution are effective because they build on existing levels of trust within the community. Peer-led models are thus central to introducing and promoting LDSS/N in a way that fits with real-world practices. At the same time, the FGDs also show the ways in which ongoing criminalisation of people who use/inject drugs prevents individuals from taking on these valuable peer distribution and mentorship roles within their community. While participants described finding ways to minimise these risks to themselves and other community members, they ultimately felt that their role in harm reduction efforts can never be fully realised while drug use is criminalised.

5. Phase 1 FGD: Summary of Key Findings

"While enthusiasm was high, participants also emphasised the importance of real-world testing to confirm the quality, utility and benefits."

The majority of participants in the Phase 1 FGDs did not consider N&S access to be a problem in Yerevan, especially since the RWRP NGO commenced its NSP in 2019. By contrast, the quality of the equipment provided through this NSP was described as very poor, such that the accessible N&S were unsuitable for injecting in a way that is consistent with safer injecting practices. Examples included dull needles, experiences of needle breakages and leaking syringes and the increased harms that result from having to use poor-quality equipment. Consequently, participants with the means to purchase better quality N&S resorted to accessing injecting equipment from pharmacies against a cost, and/or swapping different parts of various N&S in order to fashion a useable N&S. Beyond the financial burden placed on individuals who have to purchase additional, better-quality N&S from the pharmacy, provision of poor-quality equipment results in wasted resources, as unusable components are being discarded and needing to be replaced with components that are 'fit for purpose'. The fact that participants are consistently engaging in adaptive behaviours simply to ensure they have access to injecting equipment that is 'fit for purpose' suggests an urgent need for improvements in the quality of N&S distributed through harm reduction programs in Armenia.

While participants stated that sharing/re-using of injecting equipment after someone else has declined since the commencement of the NSP and outreach program at RWRP, some participants identified certain settings and circumstances where they believed reusing an N&S after someone else still occurred. However, participant discussions on reusing equipment primarily focused on people reusing their own N&S. Quality played a role in this practice, as participants sought to retain "good quality" syringes for later use. Participants in the women-only FGD said they were aware of people continuing to share and/or reuse someone else's syringe and felt this was due to the additional structural barriers experienced by women who inject drugs when attempting to access harm reduction services. Other access barriers raised by participants included the lack of access to N&S in prisons in Armenia, concerns about police harassment outside of pharmacies, and the negative attitudes of pharmacy staff towards people who inject drugs.

Overall, the findings from the Phase 1 FGDs indicate a strong potential for LDSS/N to be taken up by people who inject drugs in Armenia. Participants reacted positively to the quality and functionality of the LDSS/N products presented and assessed, particularly the quality of both the needles and syringes in relation to sharpness and the smooth action of the plunger, the secure needle fit due to the 'luer-lok' mechanism, greater control and visibility in the injecting process, and reduced dead space. While enthusiasm was high, participants also emphasised the importance of real-world testing to confirm the quality, utility and benefits.

Identified potential benefits of the LDSS/N products included reducing blood exposure, lowering virus transmission risk, preventing drug leakage, and improving injection control. While the perceived quality of the LDSS/N products appears to be the primary motivating factor for uptake among participants (with other factors such as benefits associated with lower dead space and reduced BBV risk seen as more of an ancillary benefit), it remains to be seen whether participant views on the perceived advantages may change following the 6-week pilot and the opportunity to try the products in the context of their daily lives. Moving forward, peer-led education will be critical to ensuring that the full range of LDSS/N benefits are understood and that informed choice drives uptake and consistent use.

6. Limitations & Challenges

"Armenia lacked an established community-led network of people who inject drugs at the study's inception."

Unlike other study locations for the CUTTS Hep C Consortium (Georgia and Tanzania), Armenia lacked an established community-led network of people who inject drugs at the study's inception. This made recruiting community members for the Community Advisory Board (CAB) and for the community researcher/note taker roles more difficult. Despite these challenges, collaboration between INPUD, CUTTS Hep C Consortium and local partners (RWRP and MdM team in Armenia) successfully identified and trained a highly effective CAB member and community researcher. Encouragingly, signs of a developing Armenian Network of People Who Use Drugs have emerged since project commencement, partly due to the capacity building associated with this study.

The complexities associated with shifting between Armenian and English provided another challenge. 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. The qualified local translator identified for this work had relevant expertise in public health and harm reduction and performed this work thoroughly and conscientiously. When reviewing transcripts and during data analysis, the INPUD PI also liaised with the community researcher to ensure key local terminology was accurately interpreted, thus facilitating a culturally contextualised understanding of the data.

A community-led approach also played a crucial role in participant recruitment and engagement. Given Armenia's strict drug laws, distrust of research and researchers can be common among people who use/inject drugs. In this context, the community researcher utilised personal networks to create safer and more open environments which were key to successful FGD recruitment and facilitation. To mitigate risk of over-reliance on a small group of known contacts, and potentially limiting participant diversity, recruitment involved mobilising the wider trusted relationships between RWRP and local networks of people who use drugs, and other key stakeholders in Yerevan and surrounding regions.

Gender representation was another challenge, with four of five FGDs comprising only male participants. Reflections from the local study team suggested that difficulties in recruiting female participants may have been linked to gender-specific barriers, such as male partners restricting women's participation, threats to cut off their supply of drugs, or even threats of violence[6]. Therefore, a women-only FGD was organised and although only four participants attended the FGD, the strategy was crucial to ensure gender inclusiveness within the sample. 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 are neither representative nor generalisable. 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.

6. Comments made in Reflections and Learning Workshop held on 19 November 2024 in Yerevan.

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 five (5) FGDs and produce a draft LDSS/N Product Procurement List for consideration by the country partners. We will next describe some of the key the considerations for procurement before listing the final 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, these are brand new products for people who inject drugs in Armenia and therefore it was difficult to predict what the actual uptake would be over the 6-week pilot period. Careful consideration of issues that might affect injecting frequency (e.g., individual behaviours and practices, the substances being used, relevant local/contextual factors) contributed to the estimation of required amounts of each product.

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 RWRP 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:

- Research evidence shows that people who inject drugs globally inject at least once per day but often more frequently and that the number of injections per day vary considerable between individuals (Colledge et al, 2020);
- How often people might inject will depend on what substance they are using, the effect they are wanting to achieve, how long they have been using a substance for, the condition of their veins and many other factors; and
- FGD data confirmed that injecting practices varied between participants and that any estimate of the number of products to procure would need to account for these variations. Some people will inject more/less than others and 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, etc.

"Given expected difficulties importing the products into Armenia the recommendation was to over-procure rather than under-procure."

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, regular opioid injectors, who discussed vein problems/scarring and difficulties when injecting. These factors were reflected in the preferences of FGD participants who indicated a greater demand for larger barrel syringes and thicker gauge needles and less demand for smaller barrels and finer gauge needles. Participants also highlighted that all products should be made available and would be used, emphasising the need for participant choice.

In summary, the findings pointed to a recommendation to procure more 5, 10 & 20ml syringes and Blue 23G & Orange 25G LDS needles (in various lengths) and less 1ml fixed LDSS units, 2 & 3ml syringes and Yellow 30G LDS needles. This variation in demand is reflected in the higher and lower numbers of participants used as the multiplier in the 'participant column' in in Tables 2, 3 and 4 below.

Given expected difficulties importing the products into Armenia the recommendation was to over-procure rather than under-procure. This strategy would avoid the risk of stockouts

"The country study team offered critical expertise in the process of finalising procurement amounts."

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 community researcher) as part of the Phase 1 Reflections & Learning Workshop. Following the workshop and some further consideration of local contextual factors, the INPUD PI worked with the country team to make some minor downward 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 country study team offered critical expertise in the process of finalising procurement amounts. As part of this process, the country team recommended adding an additional Green 21G (38mm) LDS needle to the pilot product procurement list. The rationale for this additional product was that beneficiaries already have access to a 21G (38mm) HDS needle, and therefore, the team felt an LDS option should be included in the pilot phase for those accessing this needle.

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
Green 21G (38 mm)	5	3	42	630
Blue 23G (38mm)	5	3	42	630
Blue 23G (32mm)	10	3	42	1260
Orange 25G (25mm)	10	3	42	1260
Orange 25G (16mm)	10	3	42	1260
Yellow 30G (13mm)	10	3	42	1260

Table 2: LDS 'Total Dose' Needles – Recommended Products and Amounts

Syringe Type	Participants	Injections/Day	Study Duration (days)	Total Units
27G 1ml fixed unit	15	3	42	1890
2ml 'Nevershare' Luer-Lok & Luer Slip Syringes (in various colours – paired with 'Total Dose' LDS Needle)	5	3	42	630 (470 luer-lok and 160 luer slip)

Table 3: LDS Syringe – Recommended Products and Amounts

Syringe Type	Participants	Injections/Day	Study Duration (days)	Total Units
3ml	5	3	42	630
5ml	20	3	42	2520
10ml	15	3	42	1890
20ml	15	4	42	2520

Table 4: HDS Syringes – Recommended Products and Amounts[7]

7. 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 (over 2ml).

"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..."

7.2 Phase 2 pilot distribution approach: key recommendations

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

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 all products.
2. At the commencement of the pilot phase, each pilot participant will be invited to RWRP office (or another designated setting) to discuss the LDSS/N products and their individual needs and preferences.
3. Based on the current distribution approach at the RWRP NSP (see section 2.3 above) and the advice of the RWRP team, the dispensing interval will be every 2 weeks across the pilot phase – the LDSS/N products will be distributed to participants on a fortnightly basis at 3 intervals across the 6-week pilot.
4. Further, LDSS/N products will be dispensed based on stated preferences and participant can return to collect and/or contact outreach worker if more LDSS/N equipment is needed between fortnightly dispensing points.
5. To ensure good documentation of the LDSS/N products dispensed during the pilot and to inform the Phase 3 Implementation, Burnet have been working with RWRP 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 RWRP NSP DIC/ outreach workers in recording distribution information accurately in consultation with pilot participants.
6. RWRP will 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=41) 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[8]. The signed Phase 2 Pilot Study PICFs have been stored in a locked cabinet at RWRP. Due to a delay of approx. three (3) months between the Phase 1 FGDs and the start of the Phase 2 Pilot Study arising from prolonged procurement times participants will be contacted when RWRP are ready to commence the Phase 2 Pilot Study.

8. The Phase 1 FGD did not require written informed consent but rather involved verbal consent process with a consent register signed by the community researcher. 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.

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9. Appendices

Appendix 1: LDSS/N Starter Pack

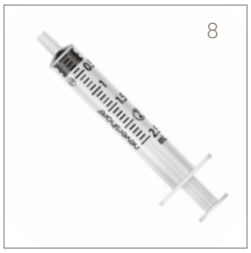
LDSS Fixed options

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

LDSN options

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

HDSS options



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

HDSN options*

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

RDSS option†

13. Chirana 1ml Luer Slip Syringe - Box of 100
14. 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.

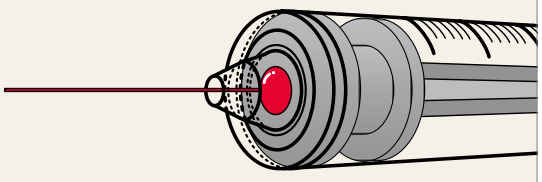
What are the benefits of being part of this study?

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.

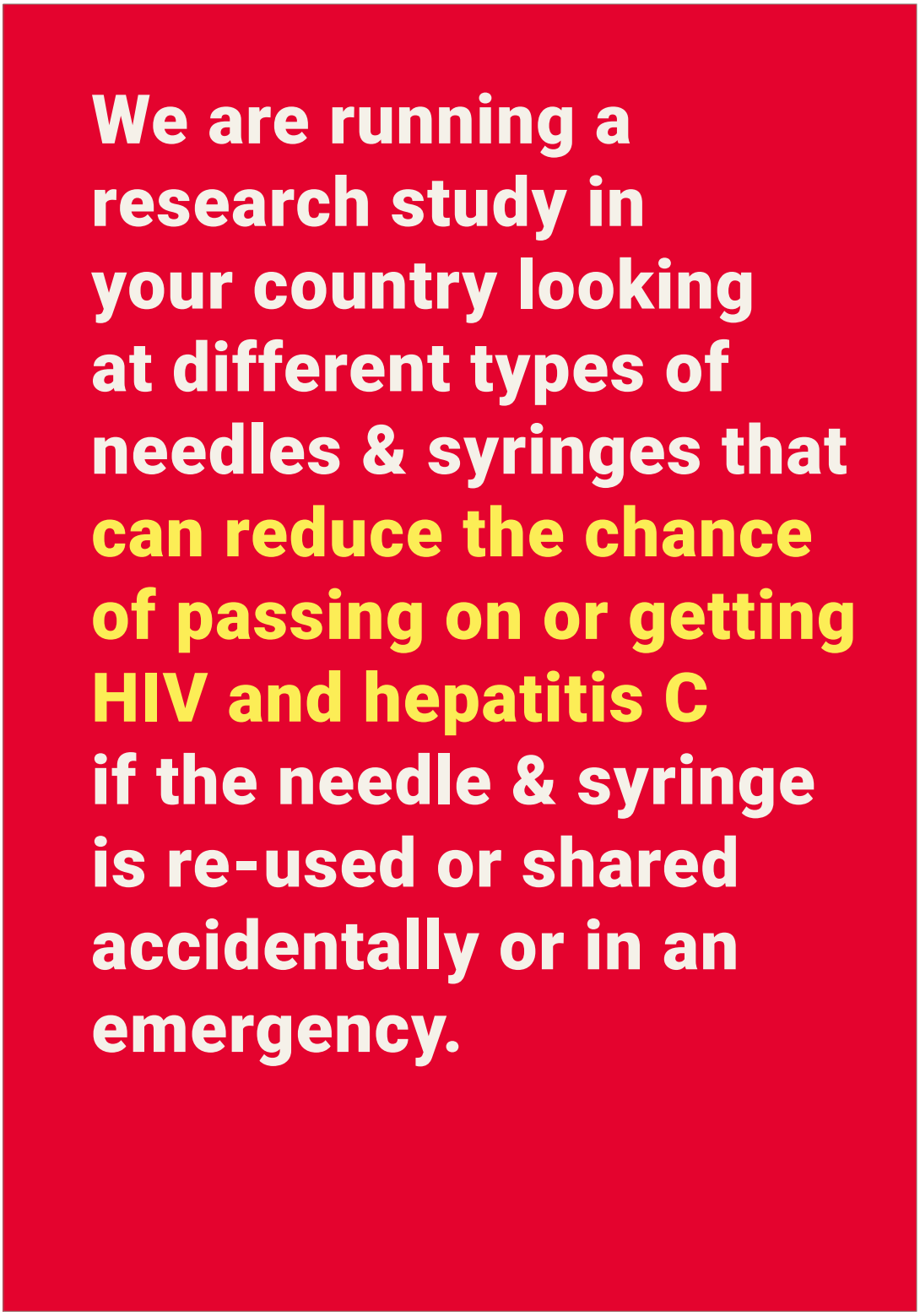
Indirect Benefits:
Should low dead space needles & syringes prove to be acceptable and effective in your setting, you would have contributed to new research on the benefits of making low dead space needles & syringes available for people who inject drugs.

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.



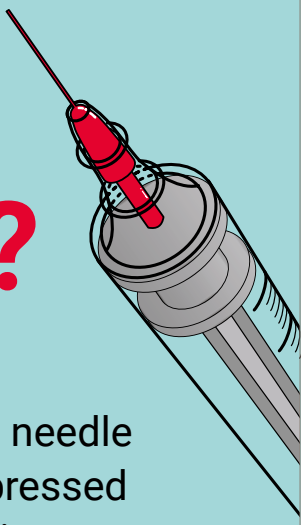
Appendix 2: LDSS/N FGD Recruitment Flyer & Explainer



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

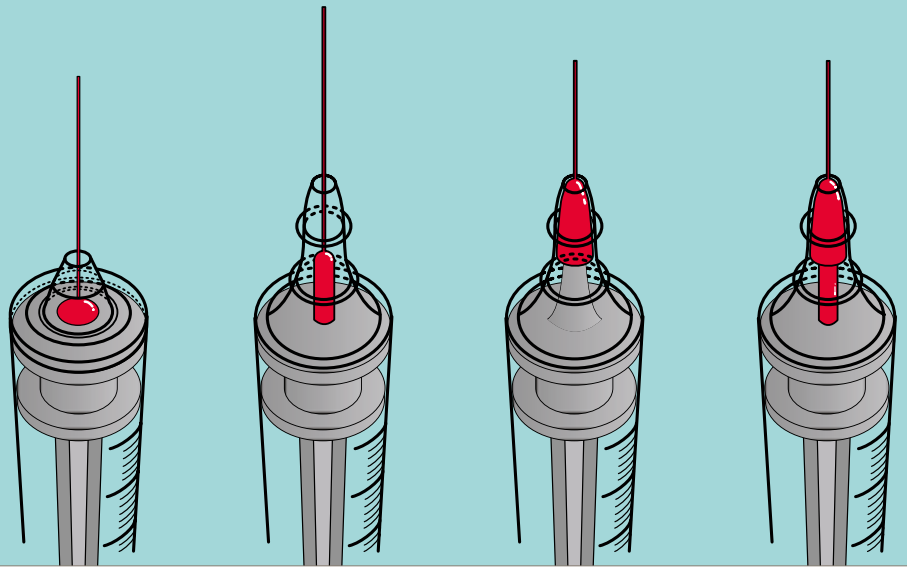
LOW DEAD SPACE

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.

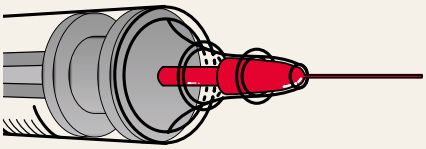
Remember:
Less dead space = less blood = less risk of viruses

Appendix 3 – LDSS/N Client Resource

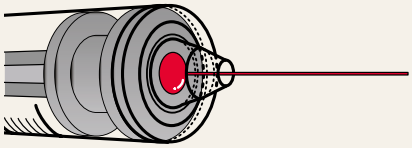
Different types of Needles and Syringes have different amounts of dead space



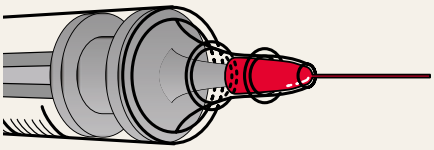
Appendix 3 – LDSS/N Client Resource



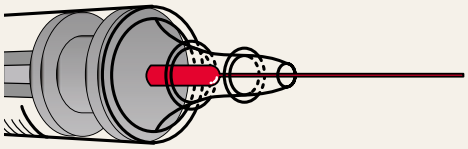
High Dead Space Syringe and Needle (HDSS/N) Combination – larger syringe barrels (greater than 1ml) + standard detachable HDS needles have the
- highest amount of dead space,
- highest amount blood remaining,
- highest amount of virus, and
- highest risk of passing on viruses if re-used.



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.



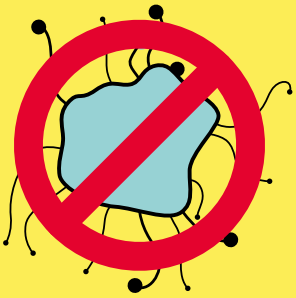
Reduced Dead Space Syringe (RDSS) – Has a rubber spike on the end of the plunger that reduces the dead space by 50% compared to a standard HDSS/N combination. At only 50% reduced dead space, the RDSS does not offer as much benefit to people who inject drugs as LDSN



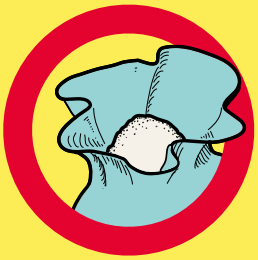
Low Dead Space Needle (LDSN) – These needles have a plastic spike that extends from the base of the needle that fills the dead space between the end of the plunger and the tip of standard high dead space syringes (larger barrels). It reduces the dead space by 85 - 90% compared to a standard HDSS/N combination

Appendix 3 – LDSS/N Client Resource

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

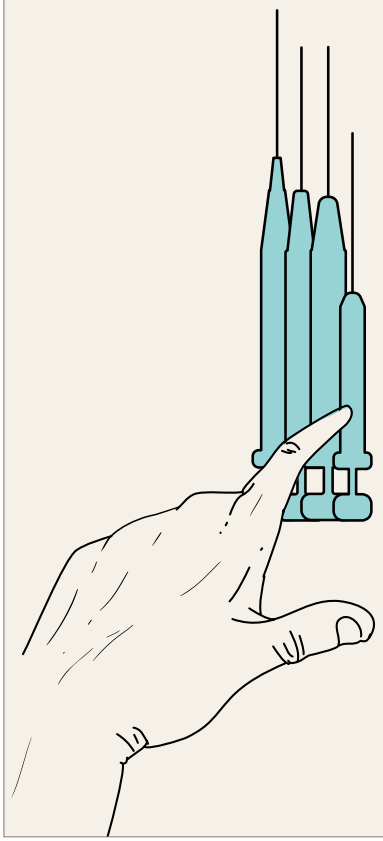
No need to flush as flushing damages veins

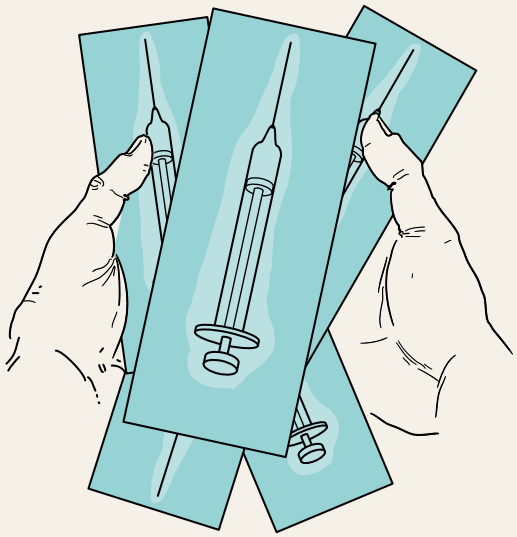
If you have to re-use, low dead space needles and syringes are easier to clean

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.



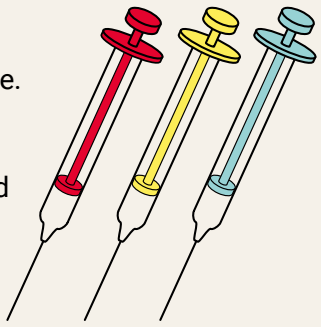


2. **If you can:**
   - always take as many needles & syringes as you need.
   - take enough to have new injecting equipment for every hit.
   - use swabs and clean your hands before injecting.
   - dispose of used needles & syringes safely and return used equipment.

Appendix 3 – LDSS/N Client Resource

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.



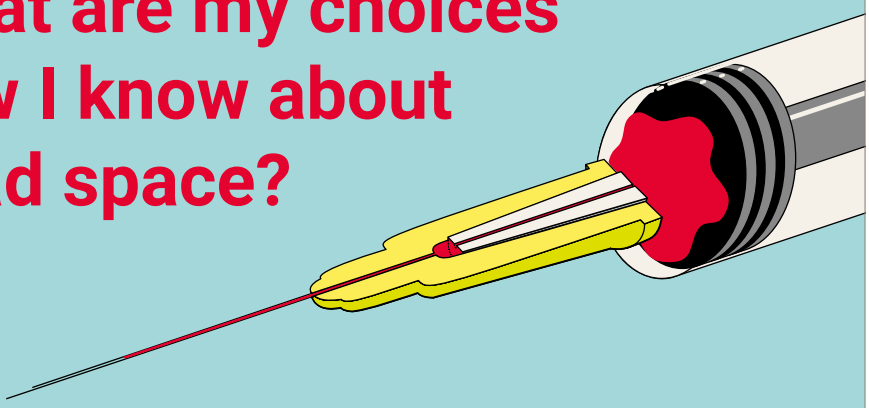
4. If you have to re-use:
try to clean used needles & syringes before reusing.

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.

Appendix 3 – LDSS/N Client Resource

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:

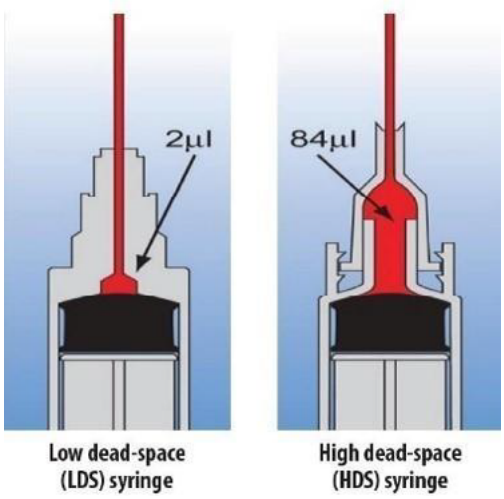
Research Purpose
Our study is looking to understand ways of improving access to injecting equipment that reduces risks of HIV and hepatitis C. HIV and hepatitis C are viruses that live in the blood and can be transmitted between people through the sharing of injecting equipment.

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.

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 Armenia.

We want to hear from you about what you see as the potential benefits, disadvantages, facilitators, and barriers of low dead-space injecting equipment that is being offered currently and/or could be made available at this service. 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.

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

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 Armenian Personal Data Protection Agency at pdpa@justice.am or armenianpdpa@gmail.com.

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 3870 AMD (10USD).

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 Real World Real People.

This study and how it will be done has been reviewed and approved by the Republic of Armenia National Centre for Infectious Diseases (NCID) 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 NCID IRB secretary by contacting Lusine Navoyan via armaidsofficial@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: 263/24

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 Qnarik Sarsygan on +37477120727 or via sargsyanqn30@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

V1
26 June 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
26 June 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.

V1
26 June 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.

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.

Organization responsible for local data collection: Real World Real People (RWRP), Armenia
Organization responsible for data collection and processing: Burnet Institute, Australia
Organization responsible for the project (Sponsor): Médecins du Monde, France

Name of Principal Investigator: Prof. Mark Stoové
Name of Country Principal Investigator: Dr. Qnarik Sargysan
Protocol version: V1, 26 June 2024

The Armenian Ministry of Health has provided permission for this study to be delivered.

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)

You will be offered a copy of the full Participant Information Sheet and the Certificate of Consent.

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?**

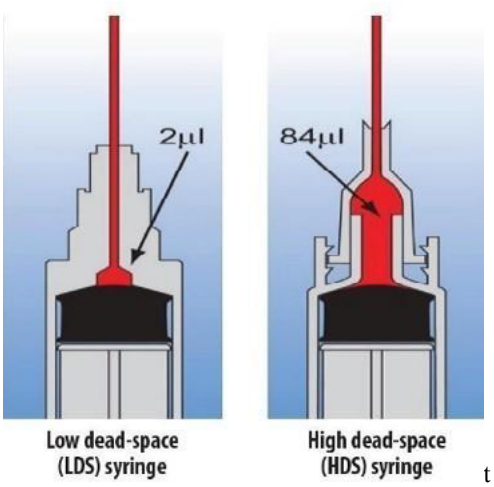
We will start distributing new types of needles and syringes called 'low-deadspace syringes' at [service]. There are many different types of low-deadspace needles/syringes and we have chosen some for you to try based on information we gathered from the first round of focus group discussions where people 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 this 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 3871AMD (10USD) 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 Armenia 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 Armenia, 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.

Appendix 6 – LDSS - PICF Piloting of LDSS

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 theFocus 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 Armenia and will not leave Armenia. Only specific study researchers at your study site will have access to your personal contact information . These will only be used to organise 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 Armenia.

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. Although this is not classified as 'sensitive information', we will follow the same processes as your sensitive information to maintain confidentiality.

Appendix 6 – LDSS - PICF Piloting of LDSS

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 Armenian 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 some quotes of what participants say as examples. This 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 and 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 Armenian Personal Data Protection Agency at pdpa@justice.am or armenianpdpa@gmail.com.

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 Qnarik Sargsysan
Organisation: Médecins du Monde
Telephone number: +37477120727
e-mail address: sargsyanqn30@gmail.com

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

Local site investigator RWRP:
Organisation: Real World Real People
e-mail address:

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 Republic of Armenia National Center for Infectious Diseases IRB, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB or contact them to make a complaint, contact the NCID IRB secretary, contact Lusine Navoyan via armaidsofficial@gmail.com. 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 # 263/24).

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

Appendix 6 – LDSS - PICF Piloting of LDSS

Please quote the following project number: #263/24

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?

Appendix 6 – LDSS - PICF Piloting of LDSS

Please quote the following project number: #263/24

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(Real World Real People) 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