Monitoring and Evaluation: A Toolkit for Syringe Services Programs

Data Collection Methods and Pilot Testing

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SHaRP: SUPPORTING HARM REDUCTION PROGRAMS

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Contents

Executive Summary

The purpose of this guidance is to help syringe services programs (SSPs) and other harm reduction programs in establishing and maintaining data collection practices for program monitoring and evaluation. Programs may find this information useful if they have questions about the types of data they might collect, how they might record it, and how they might test out their methods with staff and participants. This guidance is part of a larger Monitoring and Evaluation Toolkit for SSPs that will serve as a resource for programs in all stages of the monitoring and evaluation process.

Data Collection Methods at Harm Reduction Programs
A Review of Unique vs. Duplicate Data Collection and Forms

In this document we cover different data collection methods at harm reduction programs and how to determine which methods are right for your program. None of the below methods or examples would necessarily stand alone. Instead, programs can mix and match based on their goals and needs. Regardless of which method a program chooses, it is important to note that the Centers for Disease Control and Prevention (CDC) and a consensus of harm reduction experts recommend harm reduction programs collect minimal data[1].

Participant-level vs. Encounter-level Data Collection

One of the first decisions you will make when establishing and configuring your data collection system is whether your program will link data collected about an individual ('participant-level' or 'unique' data collection) or collect data anonymously at each encounter ('encounter-level' or 'duplicate' data collection). Both systems have pros and cons, and requirements set forth by your funders or local jurisdiction may factor into your decision.

Participant-level Data Collection

Participant-level (or unique) data collection systems attempt to distinguish unique participants in the system. This is typically done to estimate the number of unique participants and monitor the services used by those participants over time. For most programs, this entails assigning a unique identifier (UID – more information below), and this code is used to monitor participants' service provision in your program. Depending on your state and local jurisdiction (particularly paraphernalia laws), having a unique identifier may provide some legal protections to harm reduction program participants. Unique data collection often allows for more robust data analysis. For example, this system allows a program to calculate the average number of supplies or syringes out per unique participant over an extended period of time. However, unique data collection also presents potential barriers for your participants because it typically means you are asking participants for *more personal information, often when they are first accessing your services.*

Benefits	• Allows for more robust data analysis • Easier to 'follow' participant access and care ○ May be particularly beneficial for programs who provide in-house testing services and notifications • In certain jurisdictions, being a program participant may provide certain legal protections to participants (though, may not protect them from law enforcement interactions more generally)

Challenges	• Participants have to remember their code; and/or staff have to keep track of codes • Can be difficult to create a code that balances participants' privacy and avoiding potential code duplication among participants • Creates higher barrier services, especially if particularly personal/sensitive information is required to create participant code

Encounter-level Data Collection

With encounter-level (or duplicate) data collection, participants are NOT assigned a code, and typically do not complete an enrollment process with your staff. That means that any data collected from participants is not linked to them, and data collected over multiple visits from the same person is treated as separate data entries. Duplicate data collection allows for anonymous data collection. Duplicate data collection systems are generally lower barrier than unique data collection systems. If you do not collect race, gender, and other demographic information during encounters, this can help remove one layer of surveillance participants may experience, and it saves your staff the potentially awkward experience of asking sensitive and/or potentially identifying questions before they have established rapport. (If you still need to collect demographic information for reporting purposes, consider using a Point-in-Time Survey, see guidance here.) Collecting less information saves staff time – both during the actual data collection and during data analysis. Keep your reporting requirements and your internal evaluation priorities in mind when deciding if unique or duplicate data collection is best for your program.

Benefits	• Lower barrier services for participants (particularly if demographic information is not collected at every encounter) • Allows for anonymous data collection • Less data collection time for staff and participants (particularly if demographic information is not collected at every encounter)
Challenges	• Data integrity could be at risk if demographic information still has to be collected at every encounter, due to potential respondent and staff fatigue

Unique Identifiers (UIDs)

If you use unique data collection, you will need to develop a unique identifier (UID). A UID is a code assigned to a single individual that can be used to distinguish that person from others within a group. These codes are generally made up of elements of an individual's identity, such as initials, parents' name(s), etc. Codes are often used to connect an enrollment form to an encounter form, and/or link participant's information and service provision over time. By using

a UID, harm reduction programs can de-duplicate their data to estimate the number of unique individuals that participated in their services. Harm reduction programs typically use UIDs when they need to track participants over time or when their state/local jurisdiction requires it. UIDs may also help with service provision for larger harm reduction programs, where not all participants are immediately recognized by staff/volunteers. For example, if your data system allows for associated notes or reminders with UIDs, your staff can communicate with each other about participant needs. For example, 'Notify Participant 1234 of most recent HCV test results'; 'Ask Participant BB5678 if they like the new cookers'.

It is important that harm reduction programs that assign UIDs have a system in place that allows all individuals to receive services even if they choose not to provide the information for a UID. Otherwise, the UID becomes a deterrent to participation. As such, a blanket code can be used for any individual seeking services who does not wish to enroll at that time. Some harm reduction programs may elect to utilize a catch-all or unknown code, which would be a code that is the same length as a normal code but cannot be assigned, such as one with all the same digits (e.g. 999999 for a 6-digit code). This also allows for all non-unique encounter data to be removed and analyzed separately from unique data. When describing their data, harm reduction programs should be sure to identify the removal of these encounters and explain how this means their unique numbers are an estimate, and are likely an undercount of their actual unique participants.

For more information on UIDs, including pros, cons, and how to develop a code, see this guidance – Using Unique Identifiers Within Syringe Service Programs.

Supply Data

Definition: Supply data can be gathered by tallying the number of services/supplies provided at each encounter. If keeping a tally while providing services is not feasible, you could consider using an inventory method. To do this, you keep track of how many syringes, supplies, etc., you took out for services that day, and how many you returned with after services. For example, you left the office with 50 naloxone kits and came back with 7, so you know you distributed 43 naloxone kits that day.

Benefits	• Data collected from participants are not linked in any way *(This could be eithe a benefit or a challenge, depending on your program's needs. If your funders do not require unique data collection, duplicate data collection can conserve time and energy.)* • Low data entry burden • Minimal data collected = minimal data analysis needed
Challenges	• Allows for minimal evaluation of services and program

Supply data collection is good for…

- Programs with minimal staff or reduced staff capacity
- Programs for whom syringe services are a supplemental part of their programming, not the primary focus (i.e., homeless outreach programs who provide harm reduction supplies in the field)
- Programs with minimal reporting requirements and with fewer technological resources (works great with pa per data collection)
- Capturing data from special events/activities
    - ◊ For example, distributing naloxone or safer sex supplies at a community event

Other Considerations/Caveats

When using the supply method, you can physically tally the information while you are providing services. If you are exchanging in larger quantities, though, tallying may lead to errors/miscounts. If you are concerned about this, you can use a form like the example on the following page.

Example Supply Form*, One encounter per line (Note: The variables you're collecting should be modified to fit what **you** need. Remember to only collect data you will use.)*

Date: 10/01/2022

5

	Syringes Out	# Naloxone Out	Exchanging for how many others?
	50	1	0
	90	0	1
	30	2	0
	150	2	3
Totals:	**320**	**5**	**4**

When you are entering the data into your data management system, you'll aggregate (or sum) all the individual counts. You will NOT enter data line-by-line. Putting data into your data management system may look like the below.

Date	Participants Served	Syringes Out	# Naloxone Out	# Secondary Exchangers
10/01/22	4	320	5	4

Encounter Forms

Definition: Encounter forms record the number of supplies distributed and services completed with each participant each time they visit the SSP.

Benefits	• Can be used with or without UIDs • Can better account for the supplies participants are individually taking, whereas you *CANNOT* do this with the supply form system. ○ For example, with the supply form system, you only know that you had 10 participants today and 500 syringes went out. You do not know how many syringes each participant took with them, which means you cannot calculate median syringes out per encounter. • If initially gathered with paper, it can be straightforward to enter the data into a digital platform (depending on the amount of information gathered) • If kept short, this can be a great way to gather information with less burden on participants and staff
Challenges	• Regardless of length, if it is busy or staff are overwhelmed, collecting even encounter-level data without a UID could be a hindrance to your staff providing quality services

Encounter forms are good for…

- Collecting information about services and/or supplies provided
- Programs that provide services in a variety of spaces/contexts
- Programs that need more detailed data than supply data can provide

Other Considerations and Caveats

If you use encounter forms, we do not recommend capturing demographic information at each encounter. Asking your participants their race, ethnicity, gender, etc. every time they seek services is tiresome for both your participants and your staff. If you do want to capture demographic data, consider doing it through a Point-in-Time Survey (read more about this here).

Encounter forms are easy to use alongside supply form data collection. If your program provides services at both a fixed site and in the field during outreach, you can use encounter forms at your fixed site and a supply form method (tally or inventory) in the field.

Example: Encounter Form, With UIDs (Note: The variables you're collecting should be modified to fit what **you** need. Remember to only collect data you will use.)

Date: _____

Participant Code: __ __ __ __ __ __

Syringes In: _____

Syringes Out: _____

Syringe Size(s) (write in how many out of each size):

_____27 _____28 _____29 _____30

How many naloxone distributed? _____

Education offered (Circle all that apply):

Safer Injection Practices	Overdose Prevention	HIV
HCV	MOUD	Shelter Information

Referrals completed (Circle all that apply):

HIV Testing	HCV Testing	MOUD

Enrollment Forms

Definition: Enrollment forms are often completed at a participant's first visit, or at the initiation of specific services. They often include demographic information, and can include the creation of a unique identifier.

Benefits	• Can be useful in identifying service needs
Challenges	• Can turn new participants off; they may not be ready to give the requested information • Can be difficult to use as an evaluation tool ○ When you are analyzing data from your enrollment forms, you are not analyzing *current* data for your *current* participants.

Enrollment forms are good for…

- Programs with a formalized enrollment process
  - ◊ This could include a program introduction and/or initial needs assessment with new participants
- Identifying emerging trends among 'new' participants
  - ◊ For example, you could track and state: "40% of our new participants in 2022 were under 30, compared to 30% in 2021."

Other Considerations and Caveats

Data collected via enrollment forms is not necessarily representative of the current state of your participants. You could have a large number of participants who completed an enrollment, but haven't returned for services in the previous year or two. Moreover, behaviors and other characteristics can change over time. For example, once people start getting services at a harm reduction program, their frequency of syringe sharing may decrease. When reporting on your enrollment data, be sure to describe the data set and the denominator (as you would with any other data set). For example, say that the data is enrollment data.

Typically, when a program uses enrollment forms, they will also be using UIDs and encounter forms. The UIDs can link the enrollment and encounter forms, allowing an SSP to track participant's engagement over time.

Example: Enrollment Form, With UID

(Note: The variables you're collecting should be modified to fit what <u>you</u> need. Remember to only collect data you will use.)

Date: _____

Service Location: _____

Zip code of where you typically stay: __ __ __ __ __

What is your current gender identity? _____

What best describes your racial and/or ethnic identity? _____

Participant Code: __ __ __ __ __ __

(first two letters of first name, first two letters of last name, first two letters mother's first name)

Remember, use 000000 if participant does not want to create UID today

Point in Time Surveys (PiTS)

Definition: A Point in Time Survey (PiTS) is a survey or form completed by all individuals who receive services during a defined period of time (e.g., a two-week period every year).

Benefits	• Allows for easy calculations due to clear numerator and denominator • Can be used in conjunction with other tools and allow for less data collection during regular services, which can lessen the data burden on clients and staff
Challenges	• Needs to be executed with strong methodological consistency to produce high-quality data and evaluation results • Increased levels of work for staff during data collection

PiTS are good for collecting…

- Data that can more easily be recalled by clients over long periods of time
    - ◊ 'How many overdoses have you experienced/witnessed in the last three (3) months?'
- One-time data to determine current participant needs
    - ◊ 'If we offered fentanyl test strips, would you use them?'
- Participant satisfaction data

Other Considerations and Caveats

Harm reduction programs may run an annual or bi-annual PiTS, or could use them periodically to get more immediate participant feedback about any number of topics. Learn more about necessary considerations when doing a PiTS in our PITS Toolkit, found here.

Example: Point in Time Survey *(Note: For the sake of space and brevity, we did not include every possible response option. If you are unsure which response options to include on your forms, please reach out to the SHaRP team for further technical assistance. The variables you're collecting should be modified to fit what **you** need. Remember to only collect data you will use.)*

Date: _____

Participant Code: __ __ __ __ __ __

Zip code of where you typically stay: __ __ __ __ __

What is your current housing status? *(Circle one)*

Temporary/unstable Homeless Permanent Declined to Answer

What best describes your racial and/or ethnic identity? *(Circle all that apply)*

American Indian/Alaska Native Asian/South Asian Black/African American

Latinx/Hispanic Native Hawaiian/Pacific Islander White Other

Declined to Answer

Have you experienced an opioid overdose in the last three (3) months? ____Yes ____No

If yes, how many times have you experienced an opioid overdose in the last three (3) months? ____

Have you witnessed an opioid overdose in the last three (3) months? ____Yes ____No

If yes, how many opioid overdoses have you witnessed in the last three (3) months? ____

Have you shared syringes with another person in the last month? ____Yes ____No

Have you shared injection equipment with another person in the last month? ____Yes ____No

Have you reused syringes in the last month? ____Yes ____No

What supplies do you need that we don't currently have? _____

Are you very satisfied, satisfied, dissatisfied, or very dissatisfied with our current hours of operation?

_____

Data Collection Methods at Harm Reduction Programs— Paper, Digital, or Both?

Once you know what data you are going to collect, and when and how often you will collect it, you are ready to determine ***how*** you will collect and store it – with paper, directly into your data management system, or some combination of the two.

Paper Data Collection

Definition: Staff use pen and paper to record service and supply provision. Your staff do not use tablets, phones, or other technology when they work with participants.

Benefits	• Often faster than using technology in the moment • Never have to worry about power outages/internet connectivity • No stress of technological training for staff/volunteers • May feel more personal and relaxed than when a device is involved
Challenges	• Need to reserve staff time to enter data digitally (Excel or another system) • Duplicative effort (documenting on paper, then putting documentation into your digital data management system) increases likelihood of human error • Potential for consistency issues ○ Examples: Staff leave information off paper forms that would typically get documented through the digital system; or things are captured on paper forms that cannot be entered into the digital system, and therefore cannot be analyzed (Participants are asked to choose a single 'main' drug, but circle both heroin and fentanyl.)

Paper data collection is good for...

- Working in the field
- Collecting minimal information from a high volume of participants
- Backup for a digital collection system
  - ◊ We recommend keeping paper forms available even if you primarily/exclusively collect your data digitally in the event of power outages, internet issues, etc.

Hybrid Data Collection— Paper and Digital

Definition: Staff collect data in the moment with paper and/or a device (tablet, smartphone, laptop, etc.) depending on the setting or circumstances.

Benefits	• Offers flexibility to your staff if they perform services in a variety of spaces ○ Example: Entering data on a device when working in your brick-and-mortar space, and with paper when working in the field
Challenges	• Need to reserve staff time to enter data digitally (Excel, REDCap, etc.) • If your forms are extensive and/or include skip patterns, this may not translate well onto paper forms • Duplicative effort (documenting on paper, then putting documentation into your digital data management system) increases likelihood of human error • Potential for consistency issues ○ Example: Staff leave information off paper forms that would typically get documented through the digital system, or vice versa

Hybrid data collection is good for...

- Programs that work in both an office/clinic setting and in the field
- Programs with staff/volunteers with varying levels of technological literacy/comfort

Digital Data Collection

Definition: Staff enter all data directly into your data management system via a device (tablet, laptop, desktop, or smartphone). They enter data in real-time as they meet with participants.

Benefits	• No need to reserve staff time for data input after services • Ability to run reporting and view up-to-date data anytime

Challenges	• Need to keep all devices charged at all times
	• Need to have backup plan in the event of power or internet outages
	  ○ For instance, the ability to enter data in 'offline mode'
	  ○ We recommend ALWAYS having paper forms available to your staff
	• Time needed to train staff/volunteers on technology and data systems
	• Collecting data on phones, tablets, or computers can be uncomfortable for some clients, and can be a barrier to connecting with a client
	• Slower in the moment to enter data into a digital system than to paper

Digital data collection is good for...

- Programs that use unique identifiers (UIDs)
- Programs with more extensive data collection/longer forms
- Programs that operate mainly in an indoor or office-like setting

Digital Data Management Options

Once you have determined whether you will use paper, hybrid, or digital data collection, the next step is determining where that data will be stored and managed for analysis. Most programs use software tools for their database management. There are a variety of programs available. You are the only one who can determine the best fit for your program based on your program's resources and priorities. Below are questions to answer and thoughts to consider when making your decision.

- *Cost*
  - ◊ What is your budget to build your system?
  - ◊ What is your annual budget to maintain it?
  - ◊ What are your hardware needs?
  - ◊ Think - computers, laptops, tablets, mobile hotspots, etc.

- *Staff*
  - ◊ Who will need access to this system?
  - ◊ Do staff need different levels of access? Does the system allow for that?
  - ◊ Who will be responsible for building and maintaining the system?
  - ◊ Who will be responsible for onboarding and training people who use it?

- *Time*
  - ◊ Do you have staff time dedicated to data entry/analysis/maintenance?
  - ◊ Remember to account for staff training/onboarding time

- *Service volume/Environment*
  - ◊ Do you need offline data collection via tablets/smartphones?
- *Reporting requirements*
  - ◊ Are you primarily reporting basic numbers of participants, supplies, etc.?
  - ◊ Do you have requirements that require more extensive analysis?
    - ♦ If you are doing more extensive analysis, ensure your chosen system can export data into your desired format (SPSS, SAS, etc.)
  - ◊ Do you need a system with the capacity to offer real-time reports and/or analysis (i.e., data dashboards)?

- *Customization*
  - ◊ How much form customization do you need?
  - ◊ Do you need the ability to add individual notes in participants' records?
  - ◊ Do you need the ability to have one participant record open in two spaces at once (i.e., in the exchange space and the on-site clinic)?
  - ◊ Will more than one person need to be in the data management system at any given time?

- *Data security*
  - ◊ Do you need a HIPAA-compliant system?
  - ◊ Who owns the data?
    - ♦ If you don't own your data outright, make sure you have a good data use/data sharing agreement that protects your participants' data. This may be particularly important if you are in a jurisdiction hostile toward SSPs.
  - ◊ Does the data contain potentially identifying information?
  - ◊ Do you have a server?
  - ◊ Do you have a secure place to store paper records?
  - ◊ Do you have a secure place to store tablets?
  - ◊ Do you have multifactor authentication?
    - ♦ Or, are the data password protected?

- *Data structure*
  - ◊ Are you using UIDs (unique identifiers)?
  - ◊ Do you need to link data/track participant data over time?
  - ◊ Do you need to facilitate referrals through your system?
  - ◊ Do you work under a parent organization or with an affiliated program that has an existing software program you are expected to use?

Below are digital data management options commonly used by harm reduction programs. This is not an exhaustive list, and it is unlikely that any one system will fully meet all your needs. Each system has its pros and cons, and even a simple question about cost becomes complicated by pricing models, pricing tiers, access levels, etc. Rather than try to include all relevant information about each system here, we encourage you to further research the systems that interest you. Below, we have included links to each system's website, along with a brief descriptor/special consideration for that system.

- Apricot - Apricot is a case-management software that facilitates advanced care coordination, reporting, and analytics.
- bosWell - bosWell's main clientele are food pantry programs. This is a free software program whose customer testimonials complement its user-friendly interface.
- Google Workspace (Google Sheets, Forms, etc.) - While Google Workspace is free and user-friendly/familiar, there are fewer customer protections in place. Take extra care with data security and privacy measures if you use Google Workspace to manage any participant data.

- Microsoft Office (Microsoft Access, Excel, etc.) - If your organization already has Microsoft Office licenses, this is a low-cost option. Microsoft Office is probably familiar to your staff and volunteers.
- Qualtrics - Qualtrics is a robust survey platform that, while geared toward measuring customer experience, can and frequently does meet the needs of SSPs, healthcare, and research organizations.
- REDCap - REDCap was originally developed to support clinical research projects. It can be a free or low-cost option if your organization is or partners with a REDCap Consortium member. (Many academic institutions are Consortium members; search for partners in your area here.)
- Smartsheet - SmartSheet's main selling point is its project management capabilities. It is highly customizable, with form templates also available.
- SurveyMonkey - SurveyMonkey allows for offline data collection and offers both in-app data analysis and the option to export your data to your preferred analysis platform.
- Paper – Remember, even when using a paper system, there are still the costs of printing and storage. You should also consider the time cost of data entry, and how you'll analyze and use paper-based data.

Don't forget to call on your network. If you know programs that are similar to yours, find out what digital data management system they use, and what they like about it.

Special Consideration: HIPAA Compliance

If your program is a covered entity, you need to consider HIPAA compliance. Even if you are not a covered entity, we recommend protecting your data in the spirit of HIPAA compliance. Remember, you are a steward of your participants' information, and you need to act responsibly, including ensuring a secure WiFi network when utilizing digital data collection and storage software. The below table lays out the HIPAA compliance status of the systems discussed above.

HIPAA Compliant	Not HIPAA Compliant	Can be HIPAA Compliant
Apricot	Smartsheet	Google Workspace*
bosWell	SurveyMonkey	Microsoft Office*
neo360		Paper**
REDCap		Qualtrics*

**HIPAA compliance possible through a Business Associate Agreement (BAA). See Appendix A for more information on BAAs.*

***HIPAA compliance possible through physical security safeguards. See Appendix B for more information on securing physical records.*

Pilot Testing

Pilot testing is a crucial part of developing your monitoring and evaluation (M&E) system. Pilot testing is the process of trying out your system with a small group of people who will be impacted by its use; in this case, your staff and participants. Sufficient pilot testing ensures the data you are collecting will meet your needs and that your data collection system is functional and sustainable for your staff and participants. You should pilot test any new form, including point-in-time surveys.

Goals of Pilot Testing

Though your data collection goals will be unique to your program, pilot testing goals are consistent across programs. Below are common goals of pilot testing. (See Appendix C for more detailed considerations/questions to ask yourself as you develop your pilot testing plan.)

Calculate time involved in data collection and assess if it is acceptable to participants and staff
Validate that questions and response choices make sense and that all staff are interpreting the questions and responses in the same way
Ensure data collection system provides comfort and confidentiality
System functions as expected for staff and participants
Identify areas for staff support and ensure they have access to adequate training and resources
Systems are sustainable for both data collection and data analysis

Rounds of Pilot Testing

Think about pilot testing as two separate but related processes – (1) testing your questions and forms and (2) testing your systems. First, you'll test your questions and forms. Once the forms are complete, you'll test out your whole system to work out any kinks before you officially launch it. Pilot testing is an iterative process, often you'll test, make revisions, and test again until the question, form, or system is working reliably.

Testing Questions and Forms

Some of your SSP's overall M&E priorities will be represented on your forms straightforwardly. For example, you'll know the number of new participants each month from the number of enrollment forms completed by your staff, so finding a way to distinguish between participants is all that is required. Other M&E priorities, though, may require you to consider, draft, and revise questions and response options. For example, if your priority is to understand suboxone access, you'll need to consider the current suboxone options in your area, and barriers to those options. (More on this in the example in Box 1 below.) After drafting, you should first test these questions with 2-5 staff members. Ask them to review in consideration of the goals outlined above - comfort, confidentiality, resources, etc. It is **critical** your front-line staff have buy-in and feel ownership throughout this process, and pilot testing helps facilitate that. Staff involvement can help your team administer your forms accurately and consistently, which strengthens your data integrity.

After making appropriate revisions, you can test with 2-5 participants. This testing doesn't need to be very formal. You

can give participants a paper copy of the form and they can mark it up – crossing out questions or answers they don't like, writing in comments or other answer options, etc. Alternatively, staff can administer the test questions. Make sure the staff and participants understand you're testing these questions for comfort, confidentiality, and understanding. Participants don't necessarily need to answer the questions – they should be considering each of the response options. Staff can take notes throughout this process to keep track of participants' experiences: Do they understand what the question is intended to mean? Is there missing information – either missing context in the question, or missing potential responses? *(*Hint – If you must explain a question or the answer options, you need to reword!).* If the revisions you make are substantial, test again with staff until the question or form is reliably functioning before retesting with participants.

After making necessary revisions, you should retest with your participants. Continue this process until your questions and variables are reliably working. If you continue to have a question or a variable that isn't working (i.e., it isn't understood by participants, staff have to explain what you're trying to collect, etc.), consider removing it from your form. If you press on and include a question or a variable that's not reliable, your findings may not be accurate. See **Box 1** for an example of revising a question based on feedback from staff and participants.

In a nutshell...

1. Draft variables/questions and response options.
2. Staff review.
3. Revise.
4. Participants informally review.
5. Revise.
6. Repeat steps 2 through 5 until all variables/questions and response options are acceptable and reliable.

Box 1. Revising Questions and Answers

Draft 1

Why aren't you receiving suboxone treatment? (check all that apply)

___ Transportation
___ No clinics accepting new patients
___ Other: _____

Notes from testing:

Need other options, people answered cost, no insurance, and scheduling was too difficult

Write-in option is difficult to analyze

Draft 2

Ask only to people not receiving suboxone treatment

What has prevented you from receiving suboxone treatment? (check all that apply)

___ Transportation
___ No clinics accepting new patients
___ Cost
___ No insurance
___ Can't make it work for my schedule

Notes from testing:

Question is leading. It assumes they want to be on suboxone. Some folks don't want to be on suboxone…so it was really awkward to ask them that.

Draft 3

Are you currently receiving suboxone treatment?

___ Yes *(skip next two questions)*
___ No *(move on to next question)*

Are you interested in suboxone treatment?

___ Yes *(move on to next question)*
___ No *(skip next question)*

What has prevented you from receiving suboxone treatment? (check all that apply)

___ Transportation
___ No clinics accepting new patients
___ Cost
___ No insurance
___ Can't make it work for my schedule

Testing Systems

Once your questions have been revised and are acceptable to your staff and participants, you will test your entire system. (Here, *system* means your data collection/analysis from beginning to end – from your staff gathering data from participants to that data being analyzed.) First, you will go through the entire form at least 2-3 times. Test the form in its final format – if it will be completed on paper, complete it on paper, exactly how your participants and staff will see it. If it will be done electronically, pilot test the digital version entering the data into the system. If you have skip patterns, make sure they are working correctly. Answer every question in every possible way, and make sure the correct questions appear when they are supposed to. Check the back end of your system; do you need to reformat your data to be able to analyze it? Practice calculating the metrics you'll regularly use to make sure the data is being collected correctly.

After you have entered and analyzed a fair amount of fake data, it's time for your staff and participants to test the full form administration. (*Note:* You may remember your participants have already seen your forms informally, when they were testing for acceptability and understanding. Now, your participants will see your forms in their final state, and will complete them as they would be completed during actual services.) Your staff can first test with each other to make sure they are familiar with the questions and the general flow of the form(s). Then, they can test with participants. During testing, you'll want to take notes on how it goes and collect feedback, including asking participants the following questions upon completion:

1. Do you have any questions for me about the form we just completed?
2. What did you think about the form? Do you have any initial questions or feedback?
3. Were the questions easy to understand and answer?
4. Did any questions make you uncomfortable? Or are there any questions you think we should remove?

A Note on Pilot Testing with Participants

When pilot testing with participants, you want to make sure you get feedback from regular, familiar participants as well as those who are new or do not use services often. Your regular, familiar participants may feel more comfortable giving you more extensive feedback about why they dislike certain items, or how they would recommend changing them. Newer participants, on the other hand, are unfamiliar with the organization/program norms, and may be able to point out items that familiar participants have become accustomed to but may be problematic to new folks.

Along with making sure both newer and more familiar participants have an opportunity to give feedback, consider how you can get feedback from different segments of your full participant population.

Depending on who you serve, you may need to consider the below questions. *This is not an exhaustive list, it's meant to get you thinking!*

- Do you serve folks of vastly different ages?
- If you serve people who are multilingual and/or people whose primary language is not English, have you created culturally-appropriate forms in their preferred languages?
  - Each form in a different language needs its own testing process
- Do you serve people from very urban and rural areas?
- If you have participants who prefer injecting and participants who prefer smoking, have you gotten feedback from both groups?

Staff should note how long it took to administer the form and should answer the below questions to provide feedback on their own experience administering the form.

1. Overall, how did administration go?
2. Did the participant struggle with any of the questions?
3. Did you need to explain any of the questions?
4. Were the answers and notes sufficient?
5. Were there any answers you didn't know how to categorize?
6. How was the flow of the form? Did the skip patterns work? Was the order of any questions confusing?
7. Did the form bring up questions for the participant, or resources you'd want to have handy to share with them?

*(**Note:** See Appendix D for an example pilot testing form.)*

Once your staff has tested the form(s) with a few participants, you can make revisions as needed. Along with making any edits to the questions, answers, and general flow of the form(s), you should also test data analysis. With your test data, run practice analyses to determine if you get the data you need. You may discover you need to change a question type or a set of answer options. You can also determine if you need to add data validation for any responses.

In a nutshell...

1. Enter LOTS of fake data.
2. Test all response options.
3. Make sure skip patterns works correctly.
4. Run test analyses on your fake data.
5. Analyze the data how you will analyze your real data (e.g., make tables and graphs).
6. Make sure your forms are set up to get you the data you need to fulfill your reporting requirements and/or determine if you're meeting your goals.
7. Participants complete forms, independently or through staff administration.
8. Participants should complete forms however they will complete them when they are finalized.
9. If staff will administer the forms when finalized, staff should administer them during testing.
10. If participants will complete forms independently when finalized, participants should complete them independently during testing.
11. Staff and participants provide feedback on their experience.
12. Run more test analyses on the participant's test data.
13. Make revisions, repeat steps 3 – 4 until forms and system are acceptable and reliable.

Appendix A. Business Associate Agreement (BAA)

A Business Associate Agreement is an agreement between a HIPAA Covered Entity (CE) and another entity that provides services to the CE. This entity is the Business Associate (BA). The BAA specifies certain standards and safeguards that will ensure HIPAA compliance. The agreement outlines what practices are expected of the BA in order to protect the CE's data, and what procedures to follow should any violation or data breach occur. Examples of common business associates are software companies that store CE data, or external IT support. Covered Entities can also be business associates of other covered entities – for example, if you work with another organization to provide HIV testing onsite, then you may be business associates. And SSPs that are not covered entities may be business associates of covered entities – for example, if they provide hepatitis C medical case management for a clinic – if they may come into contact with PHI that belongs to the CE.

Because a covered entity may not authorize its business associate to make any use or disclosure of protected health information that would violate the HIPAA Privacy Rule, business associates are obligated to adhere to similar procedures as they would if they were a covered entity themselves. Additional information and a sample agreement can be found here: https://www.hhs.gov/sites/default/files/model-business-associate-agreement.pdf.

When writing or reviewing BAAs, pay special attention to if there is an indemnification clause, which lays out if there is any fiscal responsibility for handling the resolution if a privacy breach occurs. Example language can be found below.

"Business Associate agrees to indemnify, defend and hold harmless Covered Entity and its employees, trustees, members, medical staff, representatives, and agents (collectively, the "Indemnitees") from and against any and all claims (whether in law or in equity), obligations, actions, causes of action, suits, debts, judgments, losses, fines, penalties, damages, expenses (including reasonable attorney's fees), liabilities, lawsuits and/or costs incurred by the Indemnitees, arising or resulting from a breach of the terms and conditions of this Agreement [referring to the BAA] or a violation of the Health Insurance Portability and Accountability Act (HIPAA), the Health Information Technology for Economic and Clinical Health Act (HITECH) or HIPAA Regulations by Business Associate or its employees or agents."

Appendix B. Physical Security Safeguards

Generally, HIPAA mandates any physical records containing protected health information (PHI) be "secured against theft, fire and water damage, and erroneous destruction," and "stored and used so as to minimize incidental disclosure of PHI."[4] If your program is a covered entity and must be HIPAA compliant, apply your existing HIPAA guidelines to any SSP physical documentation.

If your program is *not* a covered entity, we recommend acting in the spirit of HIPAA. This would include securing physical records with lock and key, and limiting staff/volunteer access to those documents. If your team does fieldwork, put clear processes in place for securing documents while in the field, and storing documents promptly and properly when back in the office. You should also create a document retention policy. Consider:

- How long will you keep physical records?
- How often will information from physical records be uploaded into your digital data management system?

Additional Resources

Properly Storing HIPAA Documents
What are the Requirements for Storing Physical HIPAA Documents?
Yale's HIPAA Policy & Guidelines for Physical Security

[4]MOS, "What Are Requirements For Storing Physical HIPAA Documents?"

Appendix C. Questions and Considerations When Developing Your Pilot Testing Plan

- *Calculate time involved in data collection and assess if it is acceptable to participants and staff.*
    - How long does it take staff to administer the forms?
    - How long does data entry take?
    - How much does filling out the forms slow your services?
        - Does it create a long[5] wait for participants?
        - Does it create a crowded waiting room that infringes on confidentiality?
- *Validate that questions and response choices make sense.*
    - Do staff and participants understand the questions and answers on the forms/surveys as intended?
        - Are you using plain language?
        - Are you using an appropriate reading level?
        - If participants have trouble reading, are staff/volunteers ready and able to help them complete forms that participants would typically complete on their own?
    - If using multiple choice are the correct/adequate response options available?
        - Are participants having trouble choosing an answer?
            - Answer options should be discreet (they don't overlap) so participants can easily choose just one that fits their situation.
            - Answer options should be easily understood.
        - Answer options should be complete (the list is comprehensive, participants aren't regularly selecting 'other')
    - If using "select all that apply" questions, are the correct/adequate response options available?
        - Do you need to add additional response options? (hint: if you're filling in the 'other' option regularly, your response options aren't adequate.)
    - Do participants have follow-up in response to certain questions? What additional information might staff need when administering the question(s)?
    - Does the flow of questions make sense?
- *Ensure data collection system provides comfort and confidentiality,*
    - Are staff comfortable asking the questions?
    - Can staff explain why you are collecting this data?
    - Are participants comfortable answering the questions?
        - Is there a way for participants to decline to answer a question?
        - Is there a way for staff to mark a participant declined to answer?
    - If you ask for potentially sensitive information, do you explain confidentiality protections and provide a private space?

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[5] 'Long' will depend on how long your participants are used to waiting. They may already be used to waiting 15-20 minutes, and a new form you are piloting only adds an additional 5 minutes, which is acceptable to your participants and staff. If your participants are used to waiting 5 minutes, an additional 5 minutes may be unacceptable to them.

- *System functions as expected for staff and participants.*
    - Do the skip patterns/branching logic work correctly?
    - Is the survey programmed/formatted correctly?
    - If doing enrollment or a point-in-time survey, how will staff know if the participant has already completed that form?
      Does the system function for the staff as expected, with minimal in-the-moment issues?
      Do front-line staff and participants have access to the analyzed data?
- *Identify areas for staff support and ensure they have access to adequate training and resources.*
    - Do staff have the resources/referrals/knowledge to answer participant questions that may arise?
        - For example, if you are asking about their most recent HCV test, and participants mention they would like to get tested, are you able to do that in-house or readily provide a referral? Do staff have that information?
- *Systems are sustainable for both data collection and data analysis.*
    - Is this level of data collection sustainable?
        - If your forms are long, will your staff ask every participant every item, every visit? If so, how will this change your participants' experience? How will you generate buy-in for this?
        - If you are creating/testing your data collection during a slower season, consider your peak service times, and if your staff will be able to collect data during those times as well.
    - Is this level of data analysis sustainable?
        - For example, if you have a short-term volunteer or intern primarily completing data analysis, what happens when they leave the organization?
    - How long does it take to analyze and use the data?

Appendix D. Example Pilot Testing

Question	Notes for Interviewer	Notes from Pilot Testing
Have you completed an enrollment with *SSP NAME* before? Would you like to complete one today? **Did the person agree to participate?** Yes No, they already completed an enrollment with *SSP NAME* (STOP, do not continue) No, they have not completed an enrollment and they do not want to complete one (STOP, do not continue)	If participant has already competed an enrollment with *SSP NAME*, record answer, stop and do not continue. If participant doesn't want to participate, record answer, stop and do not continue	
How old are you?	Enter a number.	
What race/ethnicity are you? *Check all that apply*. American Indian/Alaska Native Asian/South Asian Black/African American Latinx/Hispanic Native Hawaiian/Pacific Islander White Other Declined to Answer	Read options. Multiple answers are OK. If client says *Other* no need to specify which.	
Would you describe your housing as: *Check one.* Temporary/unstable Homeless Permanent Declined to answer	Read options. Congregate housing/couch surfing would be considered temporary/unstable. Renting is considered permanent.	
Have you had an HIV test before? *Check one.* Yes No Unsure Declined to Answer	Read options.	

The Supporting Harm Reduction Programs (SHaRP) team at the University of Washington offers expert technical assistance about harm reduction data monitoring and evaluation. To reach out to the SHaRP team, please e-mail sharpta@uw.edu . Follow SHaRP on Instagram at @UW_SHaRP .

To request technical assistance from the National Harm Reduction Technical Assistance Center, go to https://harmreductionhelp.cdc.gov/.

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