

# Piloting New Drug Checking Technologies in British Columbia: Operational Guidance

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**Document purpose:** This document provides operational guidance for drug checking sites wishing to pilot new technologies that have not previously been field tested in British Columbia.

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**Target audience:** Community groups, organizations, health authorities, First Nations, policy makers, and people with lived and living experience that deliver drug checking services across British Columbia.

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## **Acknowledgements**

#### **Land Acknowledgement**

The British Columbia Centre on Substance Use would like to respectfully acknowledge that the land on which we work is the unceded territory of the Coast Salish Peoples, including the territories of the x<sup>w</sup>məθkwəyəm (Musqueam), Skwxwú7mesh (Squamish), and səlíp lwətał (Tsleil-Waututh) Nations. We recognize that the ongoing criminalization, institutionalization, and discrimination experienced by people who use drugs disproportionately harm Indigenous peoples and that continuous efforts are needed to dismantle colonial systems of oppression. We are committed to the process of reconciliation with Indigenous peoples and recognize that it requires significant and ongoing changes to the health care system. We hope that this guidance contributes to developing systems of care that provide safe, respectful, evidence-based support for people at risk of harms from the toxic unregulated drug supply.

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#### **Definitions**

Adulterant: Other substances in drugs besides the expected active ingredient, whether intentional (cuts, buffs, substitutions, etc.), or not (contaminants).

*Cross-reactivity:* The presence of a substance during testing that triggers reactions outside the main reaction expected. This has implications for any kind of test or assay, and can be a cause of false positives.

*Drug checking service(s):* A program that provides drug checking for service users; it can occur across various locations and sites depending on the service delivery model.

*Drug checking technician:* Any person who has received all applicable training required to perform drug checking services.

*Field testing*: Testing a procedure or a product, such as a new technology, in actual situations reflecting the intended use or application.

*Limit of detection:* The lowest concentration of a substance in a sample that can be consistently detected with certainty.

*Pilot project:* Field testing can be conducted through pilot projects, defined as small-scale, time-limited preliminary trials of new initiatives or approaches. Pilot projects are designed to gather and analyze data for testing feasibility and acceptability, assessing associated capital and operational costs, and identifying potential problems before a full-scale implementation.

Sensitivity: The proportion of instances a test correctly detects a substance (i.e., how well a test can identify true positives).

*Specificity:* The proportion of instances a test correctly does not find a substance (i.e., how well a test can identify true negatives).

Validated technology: A technology or innovation that has been evaluated by a third party and has been shown to perform as expected and meet its intended purpose in relevant real-world conditions. The validation process can include: performance evaluation (testing a technology's functionality against predetermined benchmarks, and identifying its technical strengths and limitations); reliability assessment (determining how consistently the technology performs over time and under various conditions); and feasibility analysis (examining whether the technology can be practically implemented and scaled up for widespread use, including an assessment of acceptability and operational costs).









#### Introduction

An ideal drug checking instrument is fast, sensitive, and portable; easy to use with minimal training; requires small samples; and has a low fiscal cost. While no single existing instrument is able to meet each of these requirements, recent research has resulted in the expansion of drug checking technologies available in Canada.

-- New Drug Checking Instruments in Canada: A Summary of Drug Checking Technology Developments (2024)

Unlike medical devices, in Canada, drug checking technologies are not assessed by Health Canada for safety, effectiveness, or quality prior to authorization for sale. Therefore, as drug checking programs consider investing in new technologies, understanding both the strengths and potential limitations of specific drug checking innovations in real-world situations—and the information they are able to provide to service users—is vital. As the unregulated drug supply becomes increasingly unpredictable and complex, it is reasonable to assume that drug checking technologies, including devices, software, and analysis methods will continue to evolve to address changing needs.

Recent advances in drug checking instrumentation and software have included efforts to develop rapid, accurate, easy-to-use, and low-cost drug checking solutions.<sup>1</sup> Other responses have included the development of new lateral flow immunoassay test strips to detect specific substances that have appeared in the unregulated drug supply (e.g., xylazine, nitazenes). There has also been considerable effort put into software development, and researchers are exploring the potential for machine learning and artificial intelligence to enhance service delivery.

While these innovations hold tremendous promise and have the potential to improve the quality of results that service users receive at drug checking sites, many new technologies and software developments have not yet been evaluated in real-world drug checking service settings. Field testing is necessary to assess feasibility, acceptability, and costs while evaluating if and how these innovations could improve the quality of drug checking analyses and create efficiencies in methods. When a new technology is validated through field testing, the information gathered can help program planners decide if it can be used for service delivery on a larger scale.

<sup>&</sup>lt;sup>1</sup> For example, a 2017 Impact Canada Challenge.supported work on the development of a number of new drug checking technologies. See <a href="https://impact.canada.ca/en/case-studies/drug-checking-technology-challenge">https://impact.canada.ca/en/case-studies/drug-checking-technology-challenge</a>











## **Purpose of This Document**

This guidance outlines an approach for piloting new drug checking technologies to support the ethical use of innovations in community service settings. This document is intended for use by community drug checking organizations partnered with the British Columbia Centre on Substance Use (BCCSU) and their respective health authorities, when there is interest in investing in new technologies, devices, and methods for analysing drug samples in community drug checking services.

The BCCSU requires that partnered organizations agree and adhere to a piloting agreement and associated protocol before field testing a new or unvalidated drug checking technology or software innovation. Much of this approach was informed by resources developed by <a href="Toronto's Drug Checking Service">Toronto's Drug Checking Service</a>, such as their <a href="Onsite Drug Checking Technology Purchase and Partnership Considerations">Onsite Drug Checking Technology Purchase and Partnership Considerations</a>, as well as their work to assess the performance of emerging technologies.

In collaboration with health authorities and the Health Canada Drug Analysis Service, the BCCSU aims to support partnered drug checking organizations using established methods (e.g., Fourier-transform infrared spectroscopy [FTIR]), and fentanyl/benzodiazepine test strips) who are interested in field test piloting a drug checking innovation prior to recommending its routine use in service delivery. This ensures that a standard level of service is maintained across drug checking sites in British Columbia (BC) before, during, and after the pilot, and that the efficacy of the new technology or software is evaluated in real-world settings before determining if it is recommended for future use.

## Potential Benefits of Innovations in Drug Checking Technologies

Exploring innovative drug checking methods offers multiple potential benefits:

#### 1. Increased sensitivity and accuracy

Highly sensitive technologies are necessary to accurately detect novel adulterants that can potentially be harmful when present even at low concentrations. New technologies with higher sensitivity than standard methods used at drug checking services (e.g., FTIR), can help identify adulterants that may be potent in small concentrations that would have otherwise been missed.

#### 2. Improved portability and affordability

New technologies are increasingly designed to improve the accessibility of drug checking by being portable and low-cost. Portable technologies can allow drug checking services











to be more widely deployed in diverse harm reduction settings, including mobile services and in remote areas. Affordable options have the potential of removing barriers for harm reduction organizations with limited financial resources to establish drug checking programs.

### 3. Standardization and increased efficiency

New technologies that include automation aim to be user-friendly and limit the variation between technicians in sample analysis and interpretation of results. Elements of, or full automation, could allow for faster and more efficient processing of samples, supporting drug checking sites with high sample volume, or sites with limited technician staff and resources to commit to ongoing training and skill development.

## **Risks of Using Unvalidated Technologies**

There are important risks to consider when introducing new or unvalidated technologies at drug checking services:

#### 1. Unreliable results

If not formally validated, it is impossible to know for certain whether the results generated by a new technology are accurate. This uncertainty creates the risk of providing unreliable results to service users. Therefore, use of technologies that have not yet been validated must be paired with established technologies used in community settings (i.e., FTIR in combination with fentanyl and benzodiazepine test strips), and validated with advanced laboratory technologies used in confirmatory testing.

#### 2. Conflicting results

When results from a new technology pilot and established methods (FTIR) differ, drug checking technicians must be prepared to carefully explain the conflicting results. Technicians must also make service users aware that the results are preliminary until they are verified through confirmatory testing.

#### 3. Ethical dilemmas

Service users and drug checking organizations may become attached to a new technology during a field testing pilot. However, if the technology does not perform well, its post-pilot use would not be ethical. Removing the technology post-pilot may lead to frustration from service users. To mitigiate this, technicians must make service users aware during the pilot that the new technology is part of a temporary evaluation.











## The Importance of Field Testing

Field testing is essential before considering the implementation of new drug checking technologies to ensure that the technology is effective, benefits service users, and minimizes risk to service users who receive results from these tools.

#### 1. Emphasis on safety

The ultimate priority in piloting new technologies is the health and safety of service users. The new technology should stand to benefit service users for it to be considered for field testing (e.g., potential to identify adulterants that would be missed by FTIR). Potential benefits should be weighed against the potential risks (e.g., inaccurate results). Field test pilots should be structured in a way that minimizes these risks.

#### 2. Evaluating efficacy

Field testing allows for the efficacy of the new technology to be evaluated on real-world samples. For example, we can assess if the technology can accurately identify a target substance in a mixture of compounds encountered in a community drug sample, vs. a laboratory standard of the target substance.

## 3. Assessing limitations

No technology is without limitations. Field testing allows for sufficient time for these limitations to become apparent. For example, by pairing the new technology with confirmatory testing, we can assess if the limit of detection matches what has been advertised, or, in the case of test strips, evaluate if there are potential cross-reacting substances that are common in community drug samples that could interfere with the accuracy of the results.

## **Questions to Ask When Considering a Field Test Pilot**

Below are some key questions for drug checking organizations, health authorities, and the BCCSU to consider before piloting a new technology.

#### Who benefits from the pilot study?

- What organization developed the innovation is it an academic institution, a non-profit, or a for-profit group in the private sector?
- How do drug checking organizations benefit from piloting the technology?
- Do service users stand to benefit from the new technology?
- Can it offer information to service users that standard methods cannot? E.g., identify adulterants below the FTIR detection limit.











## What resources are needed to conduct the pilot?

- What are the additional responsibilities that will be placed on drug checking organizations?
- Can the technology be incorporated into the existing drug checking workflow?
- o Is the pilot feasible based on the additional resources needed?

## Is the developer transparent about the limitations of their technology?

- O What is the limit of detection?
- How often are new substances added to their library?
- Will the developer share information on the limitations of the technology so it is known in advance what it can or cannot detect? E.g., list of library entries; list of known cross-reacting substances.

#### Who owns and receives the data?

- Can the results data generated by the new technology be compiled and accessed by the drug checking organization, associated health authority,
  - and the BCCSU for comparative analysis against standard drug checking methods?
- Can the data be used to benefit broader public health purposes, or monitor drug trends?

For comprehensive lists of considerations see: New Drug Checking Instruments in Canada: A Summary of Drug Checking Technology Developments (BCCSU); Onsite Drug Checking Technology Purchase and Partnership Considerations (Toronto's Drug Checking Service).

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## **Steps for Point-of-Care Services Interested in Initiating a Field Test Pilot**

- 1. Do as much research as possible on the technology/innovation you may pilot. Start with what is already available, especially real-world assessments of efficacy, and potential benefits to service users.
- 2. Develop a document (see **Appendix A**) that describes what the technology is designed to test for; how it will be used by the service (e.g., how it will fit in with current testing methods); limitations and mitigations to manage them; available scientific evidence of validity and reliability; and costs.
- 3. Review this guidance document for a fuller picture of field testing pilot requirements, and determine the organizational capacity to participate in a pilot.
- 4. Submit the background information and Appendix A to the relevant health authority and BCCSU to determine capacity and support for conducting a field test pilot.
- 5. If support and capacity are in place, work with BCCSU and health authority staff to develop a field test pilot agreement and protocol as described in this guidance.
- 6. Once the agreement and protocol are in place, launch the pilot according to the timeline developed.











## **Requirements for Piloting New Technologies and Innovations**

The following key requirements must be met to ensure the consistency and validity of the data collected from the new technology or innovation, and to minimize risks to service users:

#### 1. Agreement

Developing an agreement among field test pilot partners ensures smooth coordination and reduces the risk of errors or miscommunication during the pilot. Before the pilot begins, all stakeholders involved, including health authority representatives, drug checking service organization leadership, providers of the new technology (if applicable), and the BCCSU must sign an agreement, generally in the form of a Memorandum of Understanding, that:

- o Defines pilot timelines (e.g., six months for data collection, plus time for analysis).
- Ensures timelines permit collection of sufficient data to support analysis (e.g., when piloting a new test strip and the adulterant is novel or rare).
- Outlines signatory roles and responsibilities during the pilot, including a commitment by the drug checking organization to adhere to the pilot protocol, associated scripts and messaging, and data capture processes. This is also where BCCSU commits to developing messaging scripts, and publishing findings in a report if applicable.
- Outlines data sharing processes. For example, when piloting test strips, a list of known cross-reacting substances should be shared by the manufacturer before beginning the pilot. When piloting a drug checking instrument, the agreement must support the sharing of results between the technology provider, the community drug checking organization, and the BCCSU, with particular consideration of where results are stored and how they can be retrieved (e.g., from a local dashboard or cloud). If applicable, a library entry list should be shared before the start of the pilot to prepare for inconsistencies between the new technology and existing methods.
- Defines a successful field testing pilot outcome, such as determining whether continued use of the new technology is supported once the pilot is complete.
- Outlines circumstances in which a pilot would be terminated while still in progress.
  For example, if preliminary analysis of results from a test strip pilot demonstates an unacceptable rate of false positives or false negatives.

#### 2. Pilot study protocol

A clear pilot study protocol must be established, and appended to the agreement. This will help ensure that:











- Communication with sevice users about the pilot, including known limitations associated with new technologies that have not yet been validated, is clear and transparent.<sup>2</sup>
- Methods for using a new technology are clearly outlined and consistent among different drug checking technicians and across different drug samples to ensure reliable results are obtained. Workflow should be considered to minimize as much extra or unnecessary labour as possible by drug checking technicians.
- Data collection processes are clearly defined (e.g., captured in the BCCSU drug checking database (see Figure 1).



 All results provided to service users include

Figure 1. Example of data collection feature added in the BCCSU database

- analysis from established technologies (FTIR and specific test strips) in addition to the new technology (see 3, below).
- Procedures are in place to support technicians to communicate with service users when there is a discrepancy between the results obtained from established and new technologies.
- Preliminary results are shared among partners during the pilot, and final results and findings are shared widely once the pilot is complete.

#### 3. Pairing with established technologies:

As has been outlined, new technologies must be paired with established methods and instruments (FTIR, specific test strips) to allow for comparison of results.

- This comparison illuminates the limitations and/or benefits of the new technology, as the limitations of a new technology may not be immediately apparent.
- Pairing use of the piloted technology with established methods and instruments ensures the quality and consistency of results being shared with sevice users at point-of-care.

<sup>&</sup>lt;sup>2</sup> Information provided to service users should include: What the technology is, and what it may tell us that the FTIR/test strips cannot regarding their sample; that the pilot is temporary, and that the purpose of the pilot it to evaluate the efficacy of the new technology; that service users can choose whether or not to have their sample tested with the new technology; that the results generated by the new technology are preliminary until verified by confirmatory testing; that samples can be sent for confirmatory testing anonymously with service user permission; and that sevice users can return with their sample ID code to retrieve their confirmatory results at a later date











#### 4. Confirmatory testing:

Samples tested with new technologies must also be sent for confirmatory testing through Health Canada's Drug Analysis Service to ensure that the results obtained are verified.

- Confirmatory testing through Health Canada offers the gold-standard level of results via quantitative nuclear magnetic resonance, liquid chromatography–mass spectrometry, and/or gas chromatography-mass spectrometry.
- Sites must stay within the allotted number of samples they can submit within a defined time frame for confirmatory testing, as agreed upon by Health Canada's Drug Analysis Service and the BCCSU.
- Service users should be given the opportunity to receive confirmatory testing results of their sample tested with the pilot technology at a later time.

#### **Post-Pilot Activities**

Once a field test pilot is complete and findings are developed, the BCCSU will prepare a final pilot report in collaboration with pilot partners.

Where pilot results are found to have met the desired outcomes identified in the pilot agreement developed prior to launch—and recognizing that for data to have optimal value at the provincial level it must be incorporated into the provincial system—recommendations or considerations for further use of the innovation or technology may be incorporated into the final report.

#### Conclusion

Drug checking continues to be a critical harm reduction tool as the unregulated drug supply in BC evolves. While the introduction of new technologies and other innovations holds promise for improving service delivery, it is essential that they are field-tested, validated, and accompanied by established methods to ensure a rigorous level of drug checking quality is maintained. Only through careful piloting, transparency, and evaluation can service providers and their funders determine if, where, and how new technologies and other innovations can be incorporated into BC's drug checking ecosystem to best support drug checking as a public health intervention.











#### **Resources**

BCCSU. New Drug Checking Instruments in Canada: A Summary of Drug Checking Technology Developments (January 2024). Available at https://drugcheckingbc.ca/wp-content/uploads/sites/4/2024/04/BCCSU New drug checking technologies2 2024.pdf

Toronto's Drug Checking Sevice. Drug Checking Technologies Overview (September 2023). Available at <a href="https://drugchecking.community/resource/drug-checking-technologies-overview/">https://drugchecking.community/resource/drug-checking-technologies-overview/</a>

Toronto's Drug Checking Service. Onsite Drug Checking Technology Purchase and Partnership Considerations (April 2023). Available at <a href="https://drugchecking.community/resource/onsite-drug-checking-technology-purchase-and-partnership-considerations/">https://drugchecking.community/resource/onsite-drug-checking-technology-purchase-and-partnership-considerations/</a>

Thompson H, McDonald K. (2023) Considerations for Purchasing Drug Checking Technologies: Perspectives from Toronto's Drug Checking Service. *Int J Environ Res Public Health*. Available at https://pmc.ncbi.nlm.nih.gov/articles/PMC10418928/pdf/ijerph-20-06486.pdf











## Appendix A: Information About the Technology or Innovation of Interest

Details about you and your organization		
Organization name:		
Your name:		
Contact E-mail:		
Today's Date:		
Method of interest		
Name of technology or innovation:		
Brief summary describing the nature of the technology or innovation (e.g. test strip, drug analysis technology such as FTIR or PSMS, software innovation):		
Additional backgr	ound information	
What substances was the method designed to test for?		
How will the service provider use the method?		











In what scenarios will the method be used?	
How will the method fit in with current testing methods and practices?	
Potential benefits	
What potential benefits associated with the method of interest led to your organization's wish to explore its use?	
Known lii	mitations
Are there any health and safety considerations?	
How much time is required to obtain a result?	











Are there any other known limitations?	
Are there mitigations at the program level that could help manage limitations identified?	

Existing scientific evidence	
Is there existing evidence with respect to the method's validity? Please outline.	
Is there existing evidence with respect to the method's reliability? Please outline.	





Providence





relevant to considering its use in BC?	

Со	sts
Is purchase cost information about the method available? If so, please outline.	
Is there operational cost information about the method available? If so, please outline.	

#### **Next Steps**

If, after compiling this and other relevant information for review, your group is interested in field testing this technology or innovation, please reach out to the BCCSU drug checking team at <a href="mailto:drugchecking@bccsu.ubc.ca">drugchecking@bccsu.ubc.ca</a> to arrange a time to discuss. Be sure to append a completed copy of this form, and copy your health authority liaison.







