

Supervised Injection Facilities

Draft Background and Scope

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Background

Substance use, including the public health crisis in the United States known as the opioid epidemic, is an increasingly common public health concern. In 2018 there were 46,802 opioid overdose fatalities in the US or about 130 Americans dying every day from such overdoses.¹ Drugs may be consumed by various routes, but injection drug use generally has the highest risk of fatal overdose.^{2,3} Overall life expectancy in the US began to decrease in 2015, largely driven by opioid epidemic,⁴ and this trend continued through 2016, the first such decrease since the 1960s.⁵ On October 27, 2017, the Acting Secretary of Health and Human Services declared a nationwide public health emergency regarding the opioid crisis.⁶ The Council of Economic Advisers estimates the overall economic cost of the opioid crisis to society to be \$504 billion, or 2.8% of US gross domestic product.⁷

Injection drug use (IDU) has individual risks beyond overdose. Sharing of the equipment and drugs used for injection can result in transmission of infections such as HIV, hepatitis B, and hepatitis C.⁸ The use of contaminated equipment also increases the likelihood of bacterial infections including local abscesses, suppurative thrombophlebitis, bacterial endocarditis, and bacterial sepsis.^{9,10}

Drug use also has broad community impacts. The distribution and sale of drugs can be associated with violence, theft, and hazardous litter.¹¹ Public intoxication and the visible use of drugs in public spaces can affect all aspects of commercial and non-commercial life in a community.^{12,13}

Harm reduction refers to actions and policies intended to reduce the negative consequences of a behavior.¹⁴ Attempts at harm reduction for people who inject drugs (PWID) in the US has focused mainly on syringe services programs (SSPs) that provide clean needles and syringes either as exchanges for contaminated products or freely to PWID providing a multi-day or multi-week supply.¹⁵ Although some version of these programs exist in most states, they remain controversial.¹⁰

Also controversial is another form of harm reduction that is not yet available in the US, supervised injection facilities (SIFs).¹⁰ SIFs provide a site where clients may go to inject drugs and where medical personnel are present with the ability to provide naloxone, an antidote for opioid overdose,

and other first-responder care.^{16,17} SIFs exist more widely in Europe and have been studied in multiple locations for their effects on reducing overdose death and their effects on communities.^{18,19} In the US, some cities and states are exploring the feasibility and expected outcomes of opening SIFs to address the individual and public impacts of IDU.^{10,19,20}

Stakeholder Input

This draft scoping document was developed with input from diverse stakeholders including researchers, public policy advocates (e.g., harm reduction organizations), social service agencies, public health experts, clinicians, and multinational SIF program managers. This document incorporates feedback gathered during preliminary calls with stakeholders and open input submissions from the public.

We heard from stakeholders about the severe marginalization within society of many PWID, about the frequent overlap of substance use disorders and other mental health disorders, and about the implications of homelessness for many PWID resulting in lack of access to necessary medical and mental health care. Stakeholders described how SIFs can provide a potential way to address some of these needs.

A revised scoping document will be posted following a three-week public comment period. ICER looks forward to continued engagement with stakeholders throughout its review and encourages comments to refine our understanding of the clinical effectiveness and value of preventive treatments.

Report Aim

This project will evaluate the health and economic outcomes of SIF. The ICER value framework includes both quantitative and qualitative comparisons across treatments to ensure that the full range of benefits and harms – including those not typically captured in the clinical evidence such as innovation, public health effects, reduction in disparities, and unmet medical needs – are considered in the judgments about the clinical and economic value of the interventions.

Scope of Clinical Evidence Review

The proposed scope for this assessment is described on the following pages using the PICOTS (Population, Intervention, Comparators, Outcomes, Timing, and Settings) framework. Evidence will be abstracted from randomized controlled trials, high-quality observational studies including high-quality comparative cohort studies, particularly for long-term outcomes and uncommon adverse events, as well as high-quality systematic reviews. Our evidence review will include input from PWID and harm reduction organizations, data from regulatory documents, information submitted

by manufacturers, and other grey literature when the evidence meets ICER standards (for more information, see ICER's [grey literature policy](#)).

All relevant evidence will be synthesized qualitatively or quantitatively. Wherever possible, we will seek out head-to-head studies of the intervention and comparators of interest. Data permitting, we will also consider combined use of evidence in meta-analyses of selected outcomes. Full details regarding the literature search, screening strategy, data extraction, and evidence synthesis will be provided after the revised scope in a research protocol published on the Open Science Framework website (<https://osf.io/7awvd/>).

Populations

The population of focus for the review is all PWID.

We will also seek evidence on subpopulations suggested by the stakeholders, looking for evidence of subgroup effects:

- Housing status, comparing effects in people living with homelessness or unstable housing and those with stable housing
- Injected drug class, comparing effects in people who inject opioids with effects in people who inject stimulants such as cocaine or methamphetamine

Interventions

The intervention of interest will be implementation of SIFs.

Comparators

Data permitting, we intend to compare SIFs to not having a SIF and to SSPs.

Outcomes

The outcomes of interest are described in the list below.

- Individual outcomes
 - Overdose requiring ED or hospital care
 - Overdose mortality
 - Any overdose
 - All-cause mortality
 - Chronic viral infection (hepatitis B, hepatitis C, HIV)
 - Minor bacterial infection (not requiring hospitalization)

- Bacterial infection requiring hospitalization
- Cardiac valve surgery
- Health-related quality of life
- Access to social services (e.g., housing) and primary medical care
- Recovery from IDU with medication assisted treatment (MAT)
- Community and environmental outcomes
 - Syringe/needle “litter” and need for collection and disposal
 - Injecting in public places
 - Crime
 - Police calls/responses
 - Recidivism
 - Community quality of life
- Health system utilization
 - Hospitalizations
 - Emergency department visits
 - EMT/paramedic calls/responses

Timing

Evidence on intervention effectiveness will be derived from studies with at least two-months of follow-up duration.

Settings

The setting of interest will be community SIFs, whether or not they are affiliated with health centers and hospitals, and mobile SIFs. Inpatient SIFs are not part of the scope of this review.

Potential Other Benefits and Contextual Considerations

Our reviews seek to provide information on potential other benefits offered by the intervention to the individuals, caregivers, the delivery system, or the public that would not have been considered as part of the evidence on comparative clinical effectiveness. These general elements (i.e., not specific to a given disease) are listed in the table below.

Table 1.1. Potential Other Benefits or Disadvantages and Contextual Considerations

1 (Suggests Lower Value)	2 (Intermediate)	3 (Suggests Higher Value)
Uncertainty or overly favorable model assumptions creates significant risk that base-case cost-effectiveness estimates are too optimistic.		Uncertainty or overly unfavorable model assumptions creates significant risk that base-case cost-effectiveness estimates are too pessimistic.
Very similar mechanism of action to that of other active treatments.		New mechanism of action compared to that of other active treatments.
Delivery mechanism or relative complexity of regimen likely to lead to much lower real-world adherence and worse outcomes relative to an active comparator than estimated from clinical trials.		Delivery mechanism or relative simplicity of regimen likely to result in much higher real-world adherence and better outcomes relative to an active comparator than estimated from clinical trials.
The intervention offers no special advantages to PWID by virtue of presenting an option with a notably different balance or timing of risks and benefits.		The intervention offers special advantages to PWID by virtue of presenting an option with a notably different balance or timing of risks and benefits.
This intervention will not differentially benefit a historically disadvantaged or underserved community.		This intervention will differentially benefit a historically disadvantaged or underserved community.
Small health loss without this treatment as measured by absolute QALY shortfall.		Substantial health loss without this treatment as measured by absolute QALY shortfall.
Small health loss without this treatment as measured by proportional QALY shortfall.		Substantial health loss without this treatment as measured by proportional QALY shortfall.
Will not significantly reduce the negative impact of the condition on family and caregivers vs. the comparator.		Will significantly reduce the negative impact of the condition on family and caregivers vs. the comparator.
Will not have a significant impact on improving return to work and/or overall productivity vs. the comparator.		Will have a significant impact on improving return to work and/or overall productivity vs. the comparator.
Other		Other

ICER encourages stakeholders to provide input on these elements in their public comment submissions.

Scope of Comparative Value Analyses

As a complement to the evidence review, we will develop an economic model to assess the lifetime cost effectiveness of implementing SIFs relative to relevant comparators. The model structure will be based in part on a literature review of prior published models of harm reduction for PWID. The base-case analysis will take a health care system perspective (i.e., focus on direct medical care costs only). Data permitting, productivity impacts and other indirect costs will be considered in a separate analysis. This modified societal perspective analysis will be considered as a co-base case

when the societal costs of care are large relative to direct health care costs, and the impact of treatment on these costs is substantial. This will most often occur in cases where the incremental cost-effectiveness ratio changes by greater than 20%, greater than \$200,000 per QALY, and/or when the ratio crosses the threshold of \$100,000-\$150,000 per QALY gained. The target population will consist of PWID. Subject to change, the model will likely consist of health states including not on MAT, on MAT, former PWID, overdose, overdose-related mortality, HIV, Hepatitis C, skin infections, and other infections. A cohort of patients will transition between states during predetermined cycles over a lifetime time horizon, modeling patients from treatment initiation until death. In addition, cost-effectiveness will be estimated for shorter time horizons (e.g., five years).

Key model inputs will include clinical probabilities, quality of life values, and health care costs. Probabilities, costs, and other inputs will differ to reflect varying effectiveness between interventions. The effectiveness of SIFs will be estimated from the experience of ex-US SIFs and the literature.

Health outcomes and costs will be dependent on time spent in each health state, clinical events, adverse events (AEs), and direct medical costs. The health outcome of each intervention will be evaluated in terms of overdoses avoided, overdose deaths avoided, and life-years gained. We will explore the possibility of performing a cost-utility analysis, applying quality of life weights to each health state to calculate quality-adjusted life years (QALYs) and equal value life years gained (evLYG). The model will include direct medical costs, including outpatient and inpatient health care utilization, as well as medications. In addition, productivity changes and other indirect costs will be included in a separate analysis as available data allow. Relevant pairwise comparisons will be made between treatments, and results will be expressed in terms of the marginal cost per life-year gained, cost per overdose avoided, and cost per overdose death avoided (as well as cost per QALY gained and cost per evLYG if feasible).

In separate analyses, we will explore the potential health care system budgetary impact of treatment over a five-year time horizon, utilizing published or otherwise publicly-available information on the potential population eligible for treatment and results from the economic model for treatment costs and cost offsets. This budgetary impact analysis will indicate the relation between treatment prices and level of use for a given potential budget impact and will allow assessment of any need for managing the cost of such interventions. More information on ICER's methods for estimating potential budget impact can be found [here](#).

Identification of Low-Value Services

As described in its Value Assessment Framework for 2020-2023, ICER will include in its reports information on wasteful or lower-value services in the same clinical area that could be reduced or eliminated to create additional resources in health care budgets for higher-value innovative services (for more information, see ICER's [Value Assessment Framework](#)). These services are ones that would not be directly affected by a SIF (e.g., reduced hospitalization for overdose), as these services will be captured in the economic model. Rather, we are seeking services used in the current management of PWID beyond the potential offsets that arise from a new intervention. ICER encourages all stakeholders to suggest services (including treatments and mechanisms of care) that could be reduced, eliminated, or made more efficient.

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