June 9, 2020

Dear ICER Review Committee,

I wanted to thank you for taking the time and commitment to review the effectiveness of safe consumption spaces (safe injection facilities, or SIF) for the United States. As you write so well in the opening paragraph of the scoping document, the suffering, death and economic consequences of the opioid crisis is devastating.

Overall, I like what you wrote in the scoping document, and your aim to evaluate the health and economic outcomes of SIF. I don't have a whole lot to add, but here are my recommendations:

1. Don't focus solely (or at all) on randomized control trials. I know this is the gold standard for research, but it is logistically impossible, and ethically wrong, to do a RCT for SIF. To my knowledge, there are none that exist, but that should not be held against the study of the effectiveness of SIF. We have lots of observational data and research to demonstrate the effectiveness of SIF, and if we are beholden to the RCT model, we will miss that.

2. We have lots of great cost effectiveness research on SIF in the United States, and I strongly recommend reaching out to Amos Irwin, Alex Kral and Susan Sherman. All have done research in this area. Relatedly, the expert on cost effectiveness modeling for SIF is Ehsan Jozaghi. He's in Canada but was a co-author with the above scholars. Here are two articles they've written together:

   https://journals.sagepub.com/doi/10.1177/0022042616679829

   https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-017-0153-2

3. Lastly, I strongly recommend including people who use drugs (PWUD) on your review committee. This is important as it will give you the point of view of the people most heavily impacted by substance use, but it will also give the review a strong support from the harm reduction community. We love it when PWUD are included in research study, design, evaluation and dissemination, and value and trust people who do the same. I think you would get a lot of quality input from PWUD, and your report will be all the better for the inclusion of the PWUD voice.

Finally, I want to offer my services on this project: I am open to serving on your review panel or working on a contract basis as a consultant to help develop and write the report. I am actively involved in the safe injection facility space in San Francisco, Oakland and nationally, and I work daily with PWUD. I am on the Board of Director of two organizations that want to open SIF in the San Francisco Bay Area, and am active in the San Francisco AIDS Foundation's work in this area, too. Finally, I am the author of a report from Project Inform (PI), and the co-author of a report between AIDS United and PI. They are PDFs, and I know I can't add PDFs to this public comment review, but I will email them (along with my resume) separately to Catherine Koola.

Thanks again for this work and for the opportunity to submit public comment. I look forward to working with you all on this (when applicable), and especially for the final product you publish.

Sincerely,

Andrew Reynolds
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June 9, 2020

Institute for Clinical and Economic Review
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RE: Draft Scoping Document – Comparative Clinical Effectiveness and Value of Supervised Injection Facilities

On behalf of the Drug Policy Alliance, the nation's leading nonprofit fighting for drug policies grounded in science, compassion, health and human rights, I write to thank you for undertaking such an important study and to also provide input about additional considerations for analysis.

We would like to highlight that while this study is welcome, we are concerned about whether the existing body of research will adequately meet review criteria, since no pure Randomized Controlled Trials (RCTs) exist due to ethical considerations and some of the best trials are quasi-experimental or other designs that do not lend themselves to your methodology. RAND Corporation[i] conducted an excellent review of the research thus far and highlighted several key challenges beyond the above-mentioned concern that are also worth noting prior to launching your own undertaking. Ultimately, they did state that they "reduce the risk of a fatal overdose, disease transmission, and harms associated with unhygienic drug use practices; however, there is uncertainty about the size of the population-level effects of SCSs [SIFs]."

If you do indeed continue with your study, we noted some key outcomes that we believe should be included in the study based on prior research in this area:

- The study should include **needle sharing** as a variable of interest. Any analysis on clinical effectiveness and value should account for the fact that every injection event that occurs on-site at a Supervised Injection Facilities (SIFs) is one where needles are *not* shared, thereby being a cost-saving measure through infection/disease averted and indicating the effectiveness of this intervention by reducing this high-risk practice[ii]. In addition, studies on needle sharing practices by SIF participants suggest that their rates of needle sharing were reduced as a result of program participation for injections occurring off-site of the SIF[iii].
- The study should also include **risky injection practices** as a variable of interest. Every injection at a SIF involves increasing safer injection practices, such as providing participants to with individual cookers, alcohol wipes, and sterile tourniquets; and reducing rushed injections as well. These avert numerous potential skin and soft tissue infections (SSTIs), as well as infectious disease transmission. Tracking these saved costs and harms is important for your analysis.
- Another variable of interest should be changes in **injection frequency,** as every injection event poses a risk for overdose, infectious disease transmission, and SSTI. There are some studies that suggest that reduced injection frequency, if not cessation, is an important variable to track for cost saving and efficacy[iv].

The Drug Policy Alliance supports ICER's efforts to document the clinical effectiveness and value of Supervised Injection Facilities. We urge you to include our recommendations for improving the analysis and to consider whether your study will fill the gaps of the RAND review before you begin your undertaking. Should you have any questions or concerns, please do not hesitate to contact me at svakharia@drugpolicy.org or (607) 222-8961.

Thank you,

Sheila P. Vakharia PhD, MSW
Deputy Director, Department of Research and Academic Engagement
Drug Policy Alliance

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[i] Kilmer, Beau, Jirka Taylor, Jonathan P. Caulkins, Pam A. Mueller, Allison J. Ober, Bryce Pardo, Rosanna Smart, Lucy Strang, and Peter H. Reuter. 2018. "Considering Heroin-Assisted Treatment and Supervised Drug Consumption Sites in the United States." Product Page. 2018. https://www.rand.org/pubs/research_reports/RR2693.html.

[ii] Bayoumi, Ahmed M., and Gregory S. Zaric. 2008. "The Cost-Effectiveness of Vancouver's Supervised Injection Facility." Canadian Medical Association. Journal: CMAJ; Ottawa 179 (11): 1143–51.

[iii] Wood, Evan, Mark W. Tyndall, Jo-Anne Stoltz, Will Small, Elisa Lloyd-Smit, Ruth Zhang, Julio S.G. Montaner, and Thomas Kerr. 2005. "Factors Associated with Syringe Sharing Among Users of a Medically Supervised Safer Injecting Facility." American Journal of Infectious Diseases 1 (1): 50–54. https://doi.org/10.3844/ajidsp.2005.50.54; Kerr, Thomas, Mark Tyndall, Kathy Li, Julio Montaner, and Evan Wood. 2005. "Safer Injection Facility Use and Syringe Sharing in Injection Drug Users." The Lancet; London 366 (9482): 316–18. http://dx.doi.org.ezproxy.middlebury.edu/10.1016/S0140-6736(05)66475-6.

[iv] DeBeck, Kora, Thomas Kerr, Lorna Bird, Ruth Zhang, David Marsh, Mark Tyndall, Julio Montaner, and Evan Wood. 2011. "Injection Drug Use Cessation and Use of North America's First Medically Supervised Safer Injecting Facility." Drug and Alcohol Dependence 113 (2–3): 172–76. https://doi.org/10.1016/j.drugalcdep.2010.07.023.

north richmond community health
Wulempuri - Kertheba

North Richmond Community Health's Medically Supervised Injecting Room

ICER Draft Scoping Document for Assessment of Supervised Injecting Facilities

We welcome the Institute for Clinical and Economic Review's (ICER) supervised injecting facility (SIF) draft background and scope paper as part of the evaluation the health and economic outcomes of SIFs. In this submission we provide a brief introduction to the North Richmond Community Health (NRCH) Medically Supervised Injecting Room (MSIR) and our proposed additions to the ICER framework for evaluating SIF effectiveness. We attach the MSIR's model of care as Appendix 1.

Background

The Victorian Government is trialling a MSIR at the NRCH site in North Richmond, Melbourne, Australia. The service was established for an initial two-year trial period, which has been extended for a further three years, based on the evidence gathered in the initial period. Further details about the trial can be found here: https://www2.health.vic.gov.au/alcohol-and-drugs/aod-treatment-services/injecting-room. We have also appended the MSIR's model of care to this document (please see Appendix 1).

Under s.55P(1) of the Drugs, Poisons and Controlled Substances Act 1981 (Victoria), an independent review of the MSIR has been conducted. An independent MSIR Review Panel (the panel) was appointed by the Victorian Government Minister for Mental Health to conduct the review. The panel, chaired by Professor Margaret Hamilton AO, reviewed the initial two-year trial period in 2020, with their full report released on Friday 5 June 2020. The report provides a comprehensive overview of the context, history and operation of the trial, including the panel's findings, and can be accessed here: https://www2.health.vic.gov.au/about/publications/researchandreports/review-med-supervised-injecting-room-report.

The MSIR provides services to clients seven days a week. For many people, the MSIR is more than a medically supervised setting to inject drugs. The service is a space where people can connect without judgement with their peers and healthcare providers and access vital health and social support services. The MSIR was carefully designed to provide onsite rapid intervention to prevent overdose deaths. At the same time, within a harm reduction framework, the service aims to holistically respond to individual risk factors for fatal overdose, comorbidities associated with non-fatal overdose, and support people to address their physical, mental and psychosocial health needs.

ICER – population

Based on our experience in Melbourne, we suggest where possible including Indigenous people as a subpopulation in the focus for the ICER review. In our first two years of operation, between 10 and 15 per cent of MSIR service users have identified as Aboriginal and Torres Strait Islander people. Our registration form is voluntary to complete and about one-third of MSIR service users choose to do so

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upon registering to access the facility. It is likely that the proportion of Indigenous service users accessing the MSIR is higher than reported and likely be in the magnitude of around 20 per cent. We consider it is important to understand this subpopulation of service users in the Australian setting, as well as in settings overseas like Canada, as an example.

ICER – interventions

We consider it is necessary to analyse the comparative effectiveness of interventions according to variations in concept, design and models of care *between* supervised injecting facilities (SIFs), rather than grouping all SIFs together as the same intervention. Most SIFs around the world are designed to operate as linear models, whereby service users access the facility and progress through the service in a linear fashion, e.g. Zone 1 (the Entry Zone), Zone 2 (the Injecting Zone) and Zone 3 (the Aftercare Zone).

Our facility in Melbourne was co-designed with NRCH local service users (people who inject drugs) as a mixed service model, which includes the addition of a Zone 4/Consulting Area space with three private consulting rooms. To this end, in addition to the standard SIF components of our service, we have implemented and operate a low threshold, non-appointment-based Consulting Area as an extension to the MSIR. MSIR service users can access the Consulting Area from Zone 3 after receiving monitoring for a supervised injection, or from Zone 1. Being able to access the Consulting Area from Zone 1 means that service users can access the health and social services on offer in the Consulting Area that day without the prerequisite of a supervised injection, which aims to maximises utility for our clients.

Comparators

As above, in addition to comparing SIFs to not having a SIF and syringe service programs (SSPs), we recommend undertaking a between-SIF comparison to account for variations in concept, design and models of care on intervention effectiveness.

In particular, we propose there are differences between SIFs with onsite health and social services and those that, by virtue of design, rely on referring service users to offsite providers for the care and/or treatment they may be seeking. Opportunistic, low threshold services and interventions enable people who inject drugs and access SIFs to receive the right care for their needs at the right time in the right place. This means that that service users do not have to:

- plan transport and travel
- navigate complex health and social service systems
- overcome service unfamiliarity
- bear the additional costs of referral
- deal with health and social service system delays
- experience potential fear, stigma and discrimination in other health and social service system settings.

From practical experience, when considering access to health and social services we suggest making a distinction between those SIFs that offer easily accessible onsite services and those that refer to external services. Our experience has been that onsite service delivery is a very effective means of boosting service uptake in the PWID population and that referrals are less effective.

Outcomes

We welcome the outcomes of interest proposed in the draft background and scope paper.

In addition to the proposed outcomes of interest, we suggest including a range of onsite services for individuals to determine potential benefits as part of the evidence on clinical effectiveness. In particular we suggest the following for **individual outcomes**:

- Pathology – onsite testing
- Blood borne virus treatment – onsite medications for HIV, and hepatitis B and C, etc.
- Wound care – onsite wound dressing and antibiotic provision
- Take-home naloxone programs – where naloxone is provided onsite
- Dental care and oral health related quality of life – onsite provision of silver diamine fluoride
- Medication assisted therapy – onsite prescription and administration of the long-acting buprenorphine injections
- Mental health – onsite specialist mental health clinician for care coordination.

For **health system utilisation**, in relation to EMT/paramedic calls/responses, we strongly suggest examining the difference between impact during the hours of SIF operation and those when the SIF is closed. The independent review of the MSIR found significant differences in ambulance callouts with naloxone according to our SIF's hours of operation. We consider that this likely to be the best way to separate the true impact of SIFs from changes in overdose frequency over time.

Summary

In summary, the MSIR welcomes ICER's supervised injecting facility (SIF) draft background and scope paper as part of the evaluation the health and economic outcomes of SIFs. We suggest including Indigenous people as a sub-population in the evaluation where possible, analysing the comparative effectiveness of interventions between SIF models of care (particularly between SIFs that provide onsite services compared with SIFs that rely on referrals to external providers), including a range of individual outcomes from SIFs that provide a range of onsite health and social services, and examining overdose data in relation EMT/paramedic calls/responses during and outside SIF hours of operation.

We thank ICER for the opportunity to provide feedback to the draft background and scope paper. We would welcome the opportunity to discuss our submission with ICER should there be a need for further clarification and detail. Please feel free to contact me at nicoc@nrch.com.au.

Yours sincerely

Dr Nico Clark

MSIR Medical Director

Appendix 1: The MSIR model of care

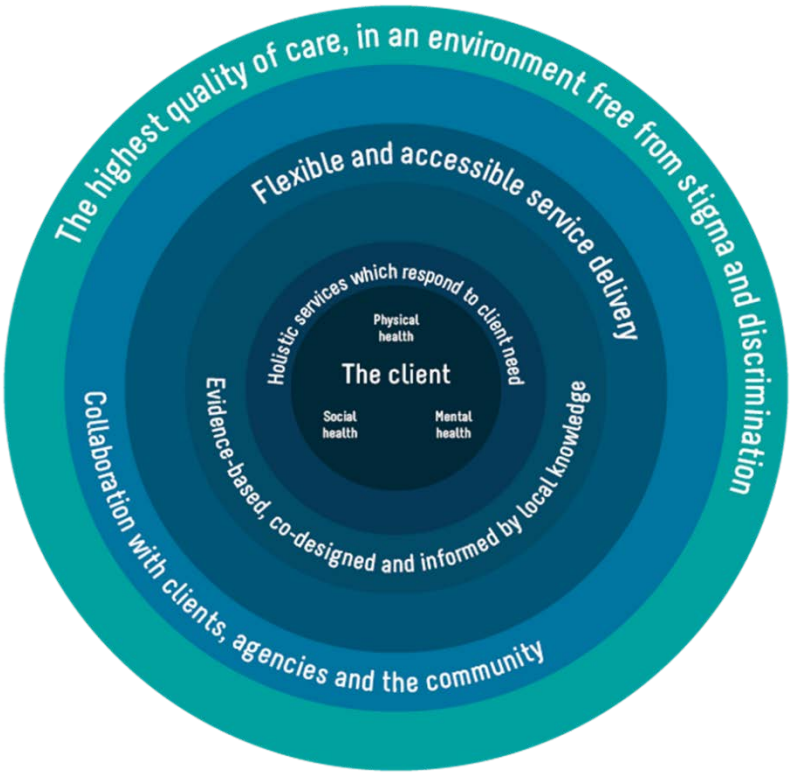
The Medically Supervised Injecting Room model of care – a person centred model

The MSIR uses a person-centred model which:

- treats the client as an equal partner in their care
- puts the client and their needs at the centre of all care
- respects each client and their choices
- communicates openly and transparently with clients about their health
- acknowledges that physical health, social health and mental health are all key components of a client's health and wellbeing.

It achieves this through:

- providing holistic services which respond to client need
- providing care which is evidence-based, co-designed and informed by local knowledge
- using flexible and accessible service delivery
- collaborating with clients, agencies and the community
- a commitment to provide the highest quality of care, in an environment free from stigma and discrimination.



Holistic services which respond to client need

The MSIR recognises that each person has physical, social and mental health needs. These are not distinct categories. Each element of a client's health interacts and has an impact on their overall health outcomes.

Social health	**Physical health**	**Mental health**
Legal Financial Housing Education Employment Inclusion and participation Cultural safety	BBV and sexual health Veins Wounds and injuries Oral health Mobility and motor skills Overdose Acquired brain injury Nutrition	Domestic and family violence Stigma and discrimination Grief and trauma Sexual assault Anxiety and depression

The program strives to provide access to services which address each element of a client's health. This includes:

Social health	**Physical health**	**Mental health**
Legal aid Financial counselling Housing support Literacy program Employment services Group activities Aboriginal Health services Casework	**Pathology – onsite blood testing** **BBV treatment – onsite medications for HIV/hepatitis** Vein care **Wound care – onsite wound dressing with a specialist wound care nurse** Harm reduction education NSP **Take-home naloxone program** – naloxone provided onsite Overdose response **Oral health care** – onsite silver fluoride treatment Occupational therapy Dietetics Podiatry **Opioid agonist treatment** – onsite prescribing and administration of long-acting buprenorphine injection Neuropsychology Primary care Acute care Pre- and post-natal care	Counselling Men's and women's groups Relationship counselling Psychology Domestic and family violence support Grief and trauma counselling

Evidence-based, co-designed and informed by local knowledge

All care provided by the MSIR is underpinned by three principles:

- *Evidence*: using the best available research from a range of disciplines, and constantly seeking new research to inform practice
- *Co-design*: actively involving clients and the local community in both design and delivery through consultation, research and peer workers
- *Local knowledge*: using local expertise to support a nuanced understanding of clients' needs, aspirations and circumstances.

Flexible and accessible service delivery

The MSIR is designed to be responsive to the way clients live. Clients at NRCH have identified ways to improve their access to services, including:

- a "one stop shop" where clients can access a range of services at a single place
- improved case management, to help clients navigate health, social and welfare systems
- improved referral pathways, to help clients connect with service providers
- low barriers to access
- a drop-in space which allows clients to access services without appointments
- a workforce which is respectful and engages with clients and their needs.

Clients can access services through the MSIR in the following locations:

- the MSIR
- the NSP, which is incorporated into the MSIR
- at NRCH, beyond the MSIR
- in the community
- at other agencies or organisations.

The MSIR will facilitate access to services using methods including:

- onsite provision and outreach
- collocated services
- "warm" referral, or accompanying clients to services
- casework and formal referrals.

Collaboration with clients, agencies and the community

To achieve the best outcomes for clients and the community, the MSIR is committed to collaborating with a range of partners. This includes:

- sharing knowledge and expertise with other organisations committed to harm reduction
- working with all of NRCH to provide an integrated service
- consulting with the community about their priorities, experiences and needs
- co-design of services and resources with people who use drugs
- seeking feedback from clients about their experience with the program
- employing staff with a lived experience of drug use

- transparent communication with clients about the way we provide care
- actively working with external organisations to provide the best care for clients.

The highest quality of care, in an environment free from stigma and discrimination

NRCH believes all members of the community deserve the highest quality of care, provided in a respectful, safe and inclusive environment.

To achieve this, the MSIR relies on a workforce which is:

- experienced
- knowledgeable
- diverse
- passionate about the health and wellbeing of the client group.

The MSIR recognises the impact of stigma and discrimination on access to services and health outcomes for people who use drugs. The MSIR is committed to advocating for people who use drugs, both within NRCH and in the wider community.

To promote an environment free from stigma and discrimination, the MSIR fosters a culture which is:

- collaborative
- inclusive
- respectful
- non-judgemental
- culturally safe.

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Tuesday, June 16, 2020

C/O: Catherine Koola, MPH
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Re: ICER SIF Review: Draft Scoping Document

Dear Ms. Koola,

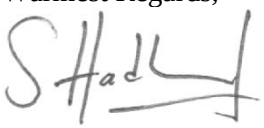
Thank you for the opportunity to speak to you earlier regarding your forthcoming review of supervised injection facilities (SIF). I have two comments I would like to offer with regard to language used in the document:

1. In the *Background* section, SIFs are described as "controversial". However, they are not controversial by a majority of addiction and public health experts when considered from the viewpoint of asking whether they are an effective intervention. They may be 'politically' controversial and a subject of ongoing debate among communities. Thus, I would recommend removing the term "controversial" altogether, or qualifying that they are 'controversial from the perspective of certain policymakers'.

2. The term "medication-assisted treatment (MAT)" is used in the document. This term is increasingly considered outdated and I would recommend replacing it with the updated, commonly used term "medications for opioid use disorder (MOUD)". (Use of the term "medication-assisted treatment" suggests that mainstream treatment for opioid use disorder might not otherwise include medications. Such terminology is not used in the treatment of other medical conditions. For example, use of insulin in diabetes mellitus is simply referred to as "treatment", rather than "medication-assisted treatment".)

Thank you for this effort. I would happy to discuss these recommendations further if that would be helpful.

Warmest Regards,



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