

BRITISH COLUMBIA CENTRE ON SUBSTANCE USE

Networking researchers, educators & care providers

Observational Substance Use Epidemiology: A case study

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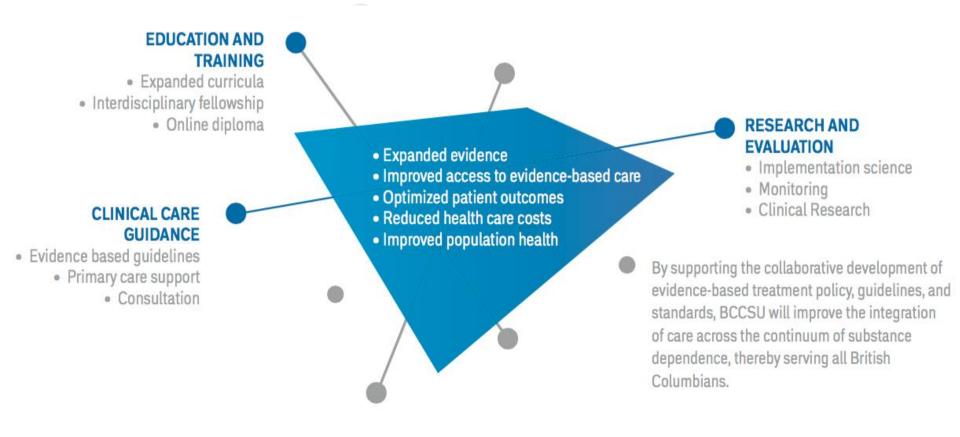
Research in Addiction Medicine Scholars (RAMS) webinar Monday, January 22, 2018



HEALTH CARE HOW YOU WANT to be treated



Core Functions



Outline

- 1. Basic concepts in observational epidemiology
- 2. A case study
- 3. Some notes on publications

 Please put down phones and other distractions as this will be very interactive!

What is the definition of Epidemiology?

Definition of Epidemiology:

- The study of the distribution and determinants of disease frequency in human populations...
- (usually through the interpretation of <u>statistical</u> <u>associations</u>)

What 4 things can explain a statistical association?

1. Chance: We assess chance by...

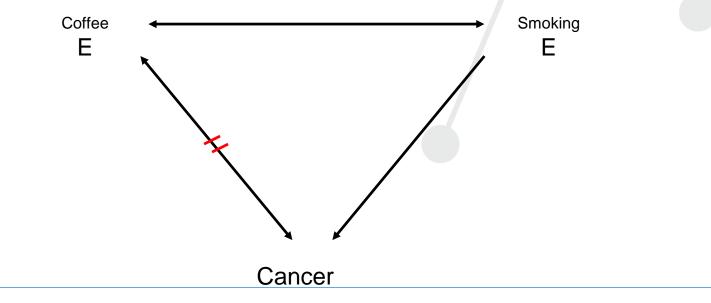
- The *p*-value. You often get a statistic such as an 'odds ratio' that reports the strength of the association between exposure and disease
- In medicine, we generally allow a 5% probability that our findings are due to chance

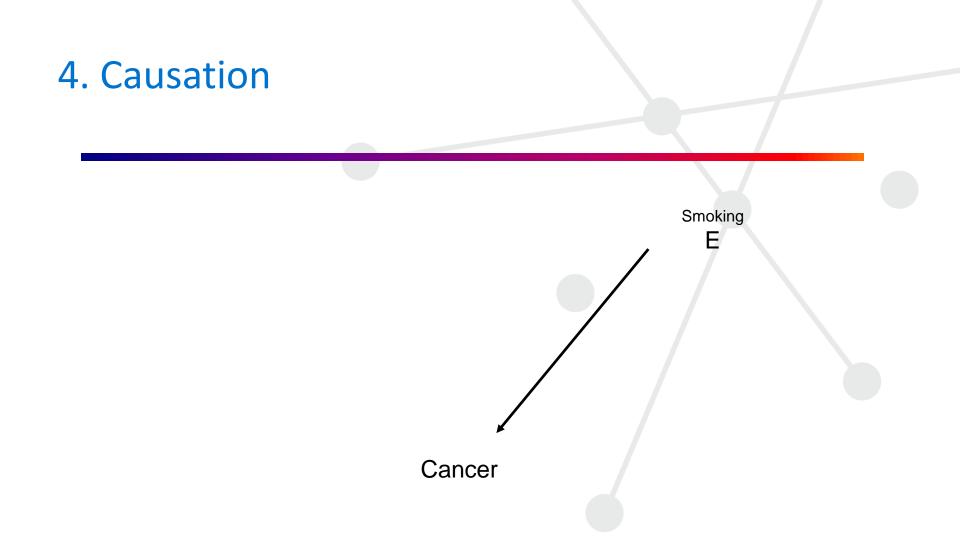
2. Bias

 Any systematic error in an epidemiologic study that results in an incorrect estimate of the association between exposure and risk of disease

3. Confounding

 A mixing of effects between the exposure of interest, the disease, and a third factor that is associated with the exposure and independently affects the risk of developing the disease





For bonus marks: What are some types of confounding?

Types of confounding:

"Pure confounding": estimate goes from 6.0
(95% CI: 3.0 – 9.0) in unadjusted analyses to 1.0
(9%% CI: 1.0 – 1.0) after adjustment

Types of confounding:

What if estimate goes from 6.0 (95% CI: 3.0 – 9.0) in unadjusted analyses to 3.0 (9%% CI: 1.5 – 4.5) after adjustment?

Types of confounding:

If estimate goes from 6.0 (95% CI: 3.0 – 9.0) in unadjusted analyses to 3.0 (9%% CI: 1.5 – 4.5) after adjustment this could be "Partial confounding" (e.g. gender) or "Residual confounding" (e.g. smoking)

What are observational studies?

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What are observational studies?

An **observational study** seeks to draw statistical inferences from a sample to a population where the independent variable(s) is not under the control of the researcher

- From a sample to a population (? Generalizability)
- Natural history rather than active manipulation (e.g. not an RCT)

Why do we do observational studies?

Why do we do observational studies?

When not ethical to control a variable (e.g. with something helpful or offer something dangerous), limited resources, secondary data analysis

For instance, is it ethical to randomize individuals to accessing a supervised injecting facility or not?

What is the classic observational study and what is are the main limitations on doing cohort based research? What is the classic observational study and what is are the main limitations on doing cohort based research?

Classic study would be the cohort study

Most common limitation is cost

A Case Study





Vancouver's raging HIV epidemic most rampant in developed world

Nearly half the 6,000 to 10,000 addicts in Downtown Eastside are infected, AIDS expert says.

MARCARST MUNICIPALITY

The HPV epidemic routing in the boart. of Mastermayers in terms contrakilly out the last the mater campoont in the Acceloped works.

Close to nall the 5.000 to 10,0001 addicts which frequents the words, periods and back alleys in the Dramtoner Electride are believed to be reflected avoly the All Gammarig visue, which passes from drig user to drug user unthe tipe of igent systemet

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"Basically, I don't think or gets any netwood," and nervous-state-states Dr. Martin Scheethiet, where many itcommenting have a printing manager of drops, despan and powerty is faelling the spademic.

According to yndies at the B.C. Cenno for Excellence in HIV/AADO, the in-Rection is said assessing indecision drug assess in Vancouver has been running or cleanto 20 per land per year. "What that more a that out of every 1,000 people. to free part of expansive an infor herpitations of the year, 200 will become inducted by the



GRIM WARRING: Dr. Dave Parriets, who is charting the HW. Main and Nextings where sign of door size, if all Reads 50 appliants; in vancisives, stands befored Carregia Centre at percent of anen's injection drag users are believed infected.

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exand, will go on to develop AIDS 40 tion his birgeigen.

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JAIDS Journal of Acquired Immune Deficiency Syndromes 32:2–8 © 2003 Lippincott Williams & Wilkins, Inc., Philadelphia

Rapid Communications

The Potential Public Health and Community Impacts of Safer Injecting Facilities: Evidence From a Cohort of Injection Drug Users

*†Evan Wood, ‡Thomas Kerr, *†Patricia M. Spittal, *Kathy Li, *Will Small, *†Mark W. Tyndall, *†Robert S. Hogg, *§Michael V. O'Shaughnessy, and *†Martin T. Schechter

Potential Impacts of SIF?

- During a observational study (VIDUS) follow-up, participants were asked if they would use a medically supervised SIF if one were available
- Those that expressed willingness were compared to those that did not

What type of study is this?

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What type of study is this?

Cross sectional study

Logistic regression analysis* of factors associated with willingness to attend Safe Injection Facilities were one available.

Variable	Adjusted Odds ratio	95 % Confidence Interval	p-value
Hard to get Clean Needle (Yes versus No)	s 2.07	(1.35 – 3.17)	<0.001
Requiring Help Injecting (Yes versus No)	1.52	(1.01 – 2.30)	0.045
Heroin use Frequency (<u>></u> 1 daily Daily versus <1) 1.81	(1.22 – 2.68)	0.030
Public Injection Drug Use (Yes versus No)	2.00	(1.27 – 3.16)	0.003
Sex-trade work (Yes versus No)	2.02	(1.31 – 3.12)	0.001

* Model was adjusted for age, and frequency of cocaine injection.

Wood et al. J AIDS [FT] 2003;32(1):2-8.



THE VANCOUVER SUN

www.vancouversun.com

THURSDAY, NOVEMBER 21, 2002 FINAL

Drug plan waste of resources, city told

More drug users will come here, U.S. official warns

By FRANCES BULA

American drug czar John Walters says Vancouver's proposed safe-injection sites for drug users are a waste of resources that should go to helping addicts get clean.

"

And, he told reporter speech to the Vancouv of Trade Wednesday, at that makes life easier users will only attract m users.

Walters' speech on America's drug policy was punctuated by frequent booing and heckling from a table of people that included B.C. Marijuana Party leader Marc Emery.

Look at U.S. experience, Walters says

From A1

Use the resources — they're always going to be scarce to make people well, to reintegrate them into society."

He said he doesn't even buy the argument that safe-injection sites reduce the spread of disease.

"Even the best sites, the usual safe-injection site argument is for the prevention of

The Vancou Board of Ti

...state-sponsored suicide ... "

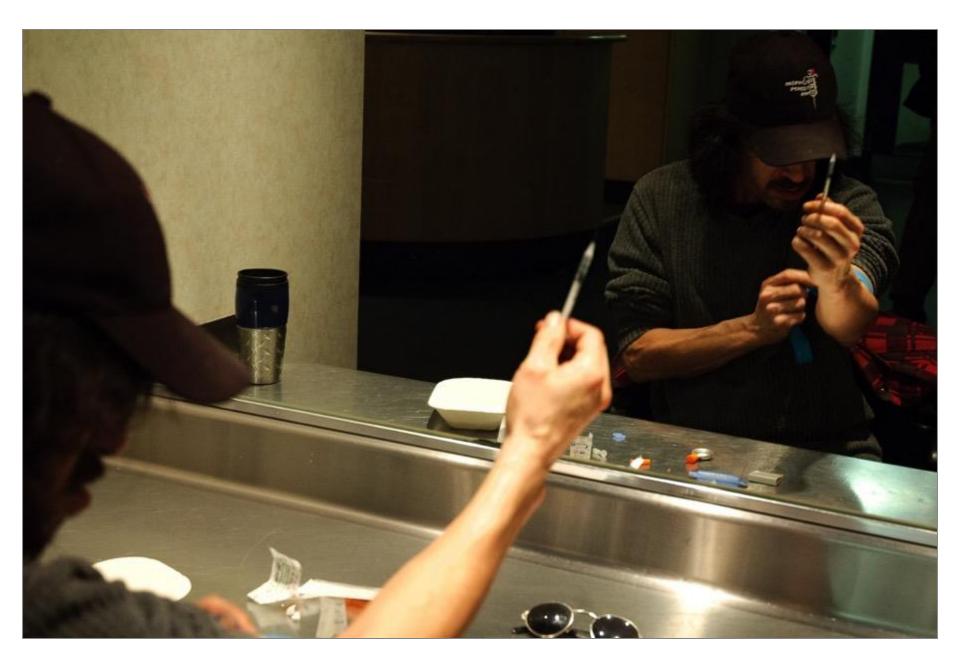
areas still have many times the number of people converting than those who get effective treatment.

"Again, hepatitis and HIV

BILL KEAY/VANCOUVER SUN

John P. Walters, White House Office of National Drug Control Policy director, speaks to Vancouver Board of Trade meeting.











Findings from the Evaluation of the Vancouver Supervised Injecting Facility



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Harm Reduction Journal

Methodology



Open Access

Methodology for evaluating Insite: Canada's first medically supervised safer injection facility for injection drug users Evan Wood*^{1,2}, Thomas Kerr^{1,3}, Elisa Lloyd-Smith¹, Chris Buchner⁴, David C Marsh^{1,4}, Julio SG Montaner^{1,2} and Mark W Tyndall^{1,2}

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This article is available from: http://www.harmreductionjournal.com/content/1/1/9

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SEOSI = Scientific Evaluation of Supervised Injecting Cohort

Safe Fixing Site will share confidential information about YOU with police

The Safe Fixing Site to be opened on the Downtown Eastside will be stalled by Vancouver Coastal Health Authority nurses who have a proven track record of sharing client information with police. Below are examples of abuse one DES woman has suffered as a result of Coastal nurses working with police. If Coastal nurses treat you the way they treated this woman – and they are likely to since they have refused to change their policy – you are almost certain to experience some of the following abuses at the Safe Fixing Site:

· Nurses will work with police to harass you by creating a mental

health file on you when evidence can't be found to arrest you When police found "nothing untoward" about the conduct of a female activist on the DES and had nothing with which to charge her, they recruited Coastal nurse Don Getz to harass her by creating a mental health file on her. Gets windled the woman and told her he knew she had no mental health history. He said "You seem fine to me." But he created a file on her anyhow because police had instructed him to. Getz wrote in the file that she had been targeted for an "Assessment" as she had made requests for information under the Freedom of information Act

- Nurses will aid police in using your file to harass you in future When Constable 2010 discovered that this DES activits was lodging a complaint against him with the Police Complaints Commission, his notes reveal that within minutes he had recruited a Coastal nurse to help him use her bogus mental health file against her. The two arranged a harassment visit to her home by police "Car 87", which contains a pych nurse and a constable. The constable and nurse were aware that they were harassing and suscaring this DES woman. Car 87 is to be reserved for people who are an imminent risk of physically harming someone and may require "apprehension." Previous notes made by the constable and his partner comtain 15 comments confirming that there was "no evidence to substantiate [her] being a physical threat."
- · Nurses will fabricate information on you for your file

Getz located a 14-year old medical file on the DES woman and altered entries in it when transferring them to his new file. He fraudulent/velaimed that she had attended an appointment al Strathcong Mental Health and been presenbed medication there. He was aware when making this entry that SMH had confirmed in writing that she had never been to their facility.

Getz further falsified his report by inserting a 23-word quote which at attributed to the DES woman. How could be quote her accurately when he had taken no notes while speaking to her?

Getz lied by omission in his report by claiming that the DES woman had "strong body odour" and "poor hygicae." He avoided mentioning that he had met her just once, when she was sweaty after a 90-minute workout and had told him she could not talk as she was going to take a shower.

Getz also made false claims about the nature of the DES woman's written communication. The recipient of this communication later confirmed in writing that it had never been released to Getz, with the exception of one document which Getz admitted notiaving read.

Nurses will dictate "details" of your file to police over the telephone to be used in a police report

Constable St, Amant admitted in VPD report #2002-307063 that he had relephoned Coastal nurses to "obtain details" of the DES woman's file. The DES woman was shocked to see the contents of her Coastal file quoted extensively in this police report. Even, Getz 'libel about her having "body odour" and "poor hygiene" appeared in the police report. Material from the 14year old medical report Getz claimed to have obtained from Strahcona Mental Health also appeared. The Supreme Court has prohibited police from telephoning a health facility to obtain information about a "suspect" as it is a violation of the Search & Sezure section of the Charter.

 Constal will attempt to prevent you from protecting DES residents Coastal Director Ida Goodreau attempted to intimidate the DES woman into not spreading the word about this nurse-volice pact. She sent the DES woman a letter threatening letal action.

The Safe Fixing Site is not Safe fPlease post



Brief Reports

Do Supervised Injecting Facilities Attract Higher-Risk Injection Drug Users?

Evan Wood, PhD, Mark W. Tyndall, MD, ScD, Kathy Li, MSc, Elisa Lloyd-Smith, BSc, Will Small, MA, Julio S.G. Montaner, MD, Thomas Kerr, PhD

Background: In Western Europe and elsewhere, medically supervised safer injection facilities (SIFs) are increasingly being implemented for the prevention of health- and community-related harms among injection drug users (IDUs), although few evaluations have been conducted, and there have been questions regarding SIFs' ability to attract high-risk IDUs. We examined whether North America's first SIF was attracting IDUs who were at greatest risk of overdose and blood-borne disease infection.

Wood et al, American Journal of Preventative Medicine, 2005

What type of study is this?

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What type of study is this?

Prospective observational cohort study

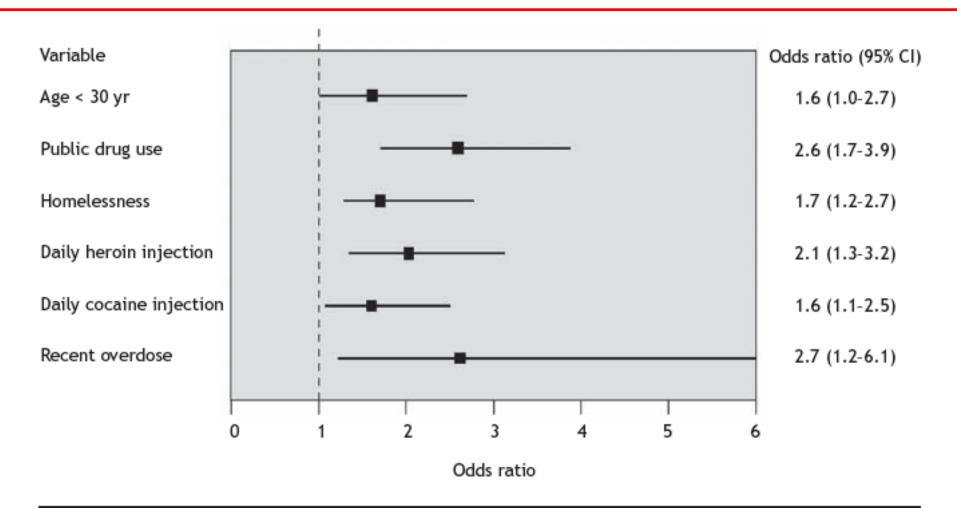


Fig. 2: Characteristics of injection drug users (IDUs) measured in the community before the Vancouver safer injecting facility opened, which predicted subsequent initiation of facility use.

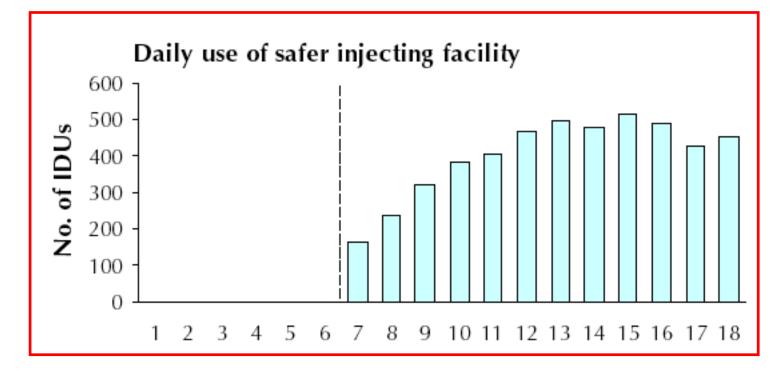
Research

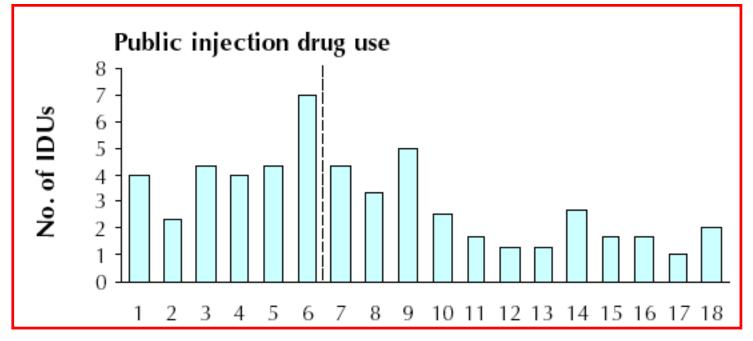
Recherche

Changes in public order after the opening of a medically supervised safer injecting facility for illicit injection drug users

Evan Wood, Thomas Kerr, Will Small, Kathy Li, David C. Marsh, Julio S.G. Montaner, Mark W. Tyndall

Canadian Medical Association Journal. 2004





What are potential sources of bias in this study design and how might you assess for bias?

What are potential sources of bias and how might you assess for bias?

Bias on the part of the person counting public drug use and discarded needles

Ideally, secondary data sets could be used to confirm observations (could not blind)

Table 1: Predicted daily mean measures of public order problems during the 6 weeks before and the 12 weeks after the opening of Vancouver's safer injecting facility*

	Predicted dai (and 95	1
Measure	Before the facility opened	After the facility opened
IDUs injecting in public Publicly discarded syringes	4.3 (3.5–5.4) 11.5 (10.0–13.2)	2.4 (1.9–3.0) 5.4 (4.7–6.3)
Injection-related litter	601 (590–613)	310 (305–317)

When the number of syringes discarded in the neighbourhood's 6 outdoor safe disposal boxes were examined, the mean number per box per week was significantly higher before than after the safer injecting facility opened (30.9 v. 9.4; p < 0.001).

Safer injection facility use and syringe sharing in injection drug users

Thomas Kerr, Mark Tyndall, Kathy Li, Julio Montaner, Evan Wood

Lancet 2005; 366: 316-18 Published online March 18, 2005 http://image.thelancet.com/ extras/04let9110web.pdf See Comment page 271 British Columbia Centre for Excellence in HIV/AIDS, St Paul's Hospital,

Safer injection facilities provide medical supervision for illicit drug injections. We aimed to examine factors associated with syringe sharing in a community-recruited cohort of illicit injection drug users in a setting where such a facility had recently opened. Between Dec 1, 2003, and June 1, 2004, of 431 active injection drug users 49 (11.4%, 95% CI 8.5-14.3) reported syringe sharing in the past 6 months. In logistic regression analyses, use of the facility was independently associated with reduced syringe sharing (adjusted odds ratio 0.30, 0.11-0.82, p=0.02) after adjustment for relevant sociodemographic and drug-use characteristics. These findings could help inform discussions about the merits of such facilities.

Kerr et al, The Lancet, 2005

What type of study is this?

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	Adjusted odds ratio (95% CI)	р
Age (per year older)	0.95 (0.92–0.98)	0.01
Use of safer injection facility	0.30 (0.11–0.82)	0.02
Need for help injecting	2·95 (1·57–5·55)	0.01
Binge drug use	2.04 (1.02-4.08)	0.04
Intercept (constant)	(-0.79)	0.19

Model adjusted for all variables shown.

Table: Multivariate logistic regression of factors associated with syringe sharing

Kerr et al, The Lancet, 2005

What might explain this association?

How might you ensure your study sample is representative?

If a study followed a random sample of Insite users forward to see who got into detoxification programs... and you did an analysis of <u>time</u> to first enrollment... what type of study design would this be? In epidemiology, "time to event" (e.g. death) are often referred to as "survival analyses"

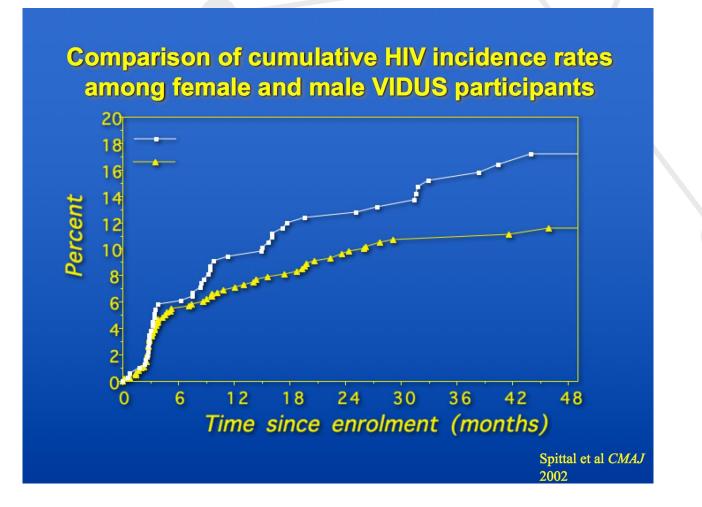


Table 1. Univariate and Multivariate Cox Proportional-Hazards Analysis of the Time to Entry into a Detoxification
Program among 1031 Users of Injection Drugs after the Opening of a Supervised Injecting Facility (SIF).*

Variable	Unadjusted Relative Hazard (95% CI)	P Value	Adjusted Relative Hazard (95% CI)	P Value
Homelessness (yes vs. no)†	1.43 (1.07-1.91)	0.02	1.42 (1.06-1.90)	0.02
Binge drug use (yes vs. no)†	1.44 (1.05-1.97)	0.02	1.35 (0.98-1.85)	0.06
Ever in treatment (yes vs. no)‡	2.70 (1.56-4.65)	<0.001	2.43 (1.41-4.22)	0.002
Weekly use of SIF (yes vs. no)§	1.84 (1.34–2.52)	<0.001	1.72 (1.25–2.38)	0.001
Addictions counselor (yes vs. no)†§	2.41 (1.55–3.77)	<0.001	1.98 (1.26–3.10)	0.003

* Use of a detoxification service was identified on the basis of database linkage. The model was adjusted for all variables that were significant (P<0.05) in unadjusted analyses, including all variables shown, as well as residence in the neighborhood of the supervised injecting facility (yes vs. no). Time zero was the date of recruitment, and participants who remained persistently out of a detoxification program were censored as of March 1, 2005. CI denotes confidence interval.</p>

- †The variable refers to activities during the previous six months.
- ‡ The "ever in treatment" category refers to current or historical use of addiction-treatment services.
- Solution of the "weekly use of SIF" category were derived from the database of the SIF, and weekly use was determined according to the average use before the censoring or event date.

Reduction in overdose mortality after the opening of North America's first medically supervised safer injecting facility: a retrospective population-based study

Brandon D L Marshall, M-J Milloy, Evan Wood, Julio S G Montaner, Thomas Kerr

Summary

Background Overdose from illicit drugs is a leading cause of premature mortality in North America. Internationally, more than 65 supervised injecting facilities (SIFs), where drug users can inject pre-obtained illicit drugs, have been opened as part of various strategies to reduce the harms associated with drug use. We sought to determine whether the opening of an SIF in Vancouver, BC, Canada, was associated with a reduction in overdose mortality.

Published Online April 18, 2011 DOI:10.1016/S0140-6736(10)62353-7

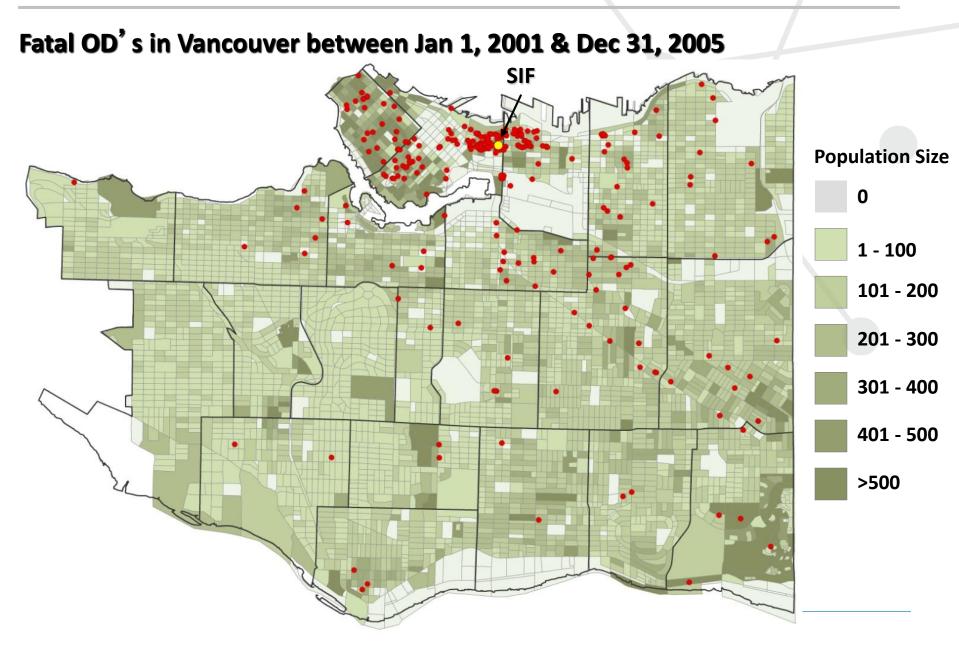
Se Online/Comment

Marshall et al, Lancet, 2011

Methods

- Location of death estimated using six-digit postal code
- Geocoding: ArcGIS using the Statistics Canada Postal Code Conversion File
- Area of interest: all blocks within 500 metres of the SIF
- Quasi-control: blocks >500m from the SIF
- Outcome: rate difference in OD mortality between the pre-SIF (Jan 1, 2001 – Sep 20, 2003) and post-SIF (Sep 21, 2003 – Dec 31, 2005) periods

Results



	ODs occurring in blocks within 500 m of the SIF*		ODs occurring in blocks farther than 500 m of the SIF*		
	Pre-SIF	Post-SIF	Pre-SIF	Post-SIF	
Number of overdoses	56	33	113	88	
Person-years at risk	22 066	19991	1 479 792	1271246	
Overdose rate (95% CI)*	253.8 (187.3-320.3)	165.1 (108.8–221.4)	7.6 (6.2–9.0)	6.9 (5.5–8.4)	
Rate difference (95% CI)*	88·7 (1·6–175·8): p=0·048		0·7 (-1·3–2·7): p=0·490		
Percentage reduction (95% CI)	35.0% (0.0%-57.7%)		9·3% (-19·8% to 31·4%)		

SIF=supervised injection facility. Pre-SIF period=Jan 1, 2001, to Sept 20, 2003. Post-SIF period=Sept 21, 2003, to Dec 31, 2005. *Expressed in units of per 100 000 person-years.

Table 2: Overdose mortality rate in Vancouver between Jan 1, 2001, and Dec 31, 2005 (n=290), stratified by proximity to the SIF

Overdose deaths declined by 35% in the area around Insite

Marshall et al, Lancet, 2011

Summary of findings from the evaluation of a pilot medically supervised safer injecting facility

Evan Wood, Mark W. Tyndall, Julio S. Montaner, Thomas Kerr

∞ See related article page 1395

Abstract

In many cities, infectious disease and overdose epidemics are occurring among illicit injection drug users (IDUs). To reduce these concerns, Vancouver opened a supervised safer injecting facility in September 2003. Within the facility, people inject pre-obtained illicit drugs under the supervision of medical staff. The program was granted a legal exemption by the Canadian government on the condition that a 3-year scientific evaluation of its impacts be conducted. In this review, we summarize the findings from evaluations in those 3 years, including characteristics of IDUs at the facility, public injection drug use and publicly discarded syringes, HIV risk behaviour, use of addiction treatment services and other community resources, and drug-related crime rates. Vancouver's safer injecting facility has been associated with an array of community and public health benefits without evidence of adverse impacts. These findings should be useful to other cities considering supervised injecting facilities and to governments considering regulating their use.

CMAJ 2006;175(11):1399-404

federal government that allowed operation of the facility was limited to 3 years and was granted on the condition that an external 3-year scientific evaluation of its impacts be conducted. Given the controversial nature of the program,¹⁴ stakeholders agreed that all findings from the evaluation, including this report, should be externally peer-reviewed and published in the medical literature before dissemination. In this review we report on the 3 years' findings.

REVIEW

Program and evaluation methods

As described previously,¹³ the Vancouver safer injecting facility has 12 injection stalls where IDUs inject pre-obtained illicit drugs under the supervision of nurses. Nurses respond to overdoses and address other health needs (e.g., treating injection-site abscesses), and the facility has an addiction counsellor and support staff who seek to meet the needs of IDUs or refer them to appropriate community resources (e.g., housing services, addiction treatment).¹³

Although the best strategy for evaluating the safer injecting facility would be to randomly assign IDUs to either full access or no access to the program, interventional study de-





PRINT

A Critique of Canada's INSITE Injection Site and its Parent Philosophy: Implications and Recommendations for Policy Planning Colin Mangham, PhD

Director of Research Drug Prevention Network of Canada

Key Words: Injection Rooms; Harm Reduction; Program Effectiveness; Drug Policy; IV Drug Use; Canada

Abstract

This report provides a critical analysis of the evaluations done on INSITE, the drug injection site in operation in Vancouver, British Columbia, and billed as North America's first medically supervised injection facility. In doing so, it provides a documented historical discussion laying

The Institute on Global Drug Policy :: Volume 1, Issue 1





PRINT

A Critique of Canada's INSITE Injection Site and its Parent Philosophy: Implications and

"The Institute is charged with creating and strengthening international laws that hold drug users and dealers criminally accountable for their actions. The institute supports efforts to vigorously oppose policies based on the concept of harm reduction."

(see: http://www.dfaf.org/globaldrugpolicy.php)

Harm reduction' doesn't work

Last week, it was announced that the Conservative government will soon unveil a new national anti-drug strategy. The plan is said to feature a get-tough approach to illegal drugs, including a crackdown on grow-ops and drug gangs. And while it will also (wisely) include tens of millions for rehabilitation of addicts and for a national drug prevention campaign, it is said to retreat from safe-injection sites and other fashionable "harm-reduction" strategies introduced by the previous Liberal government.

To which we say: Good. This

last fall, the RCMP told Health Canada it had "concerns regarding any initiative that lowers the perceived risks associated with drug use. There is considerable evidence to show that, when the perceived risks associated to drug use decreases, there is a corresponding increase in number of people using drugs."

That has certainly been the case in Europe. Currently there are more than three dozen major European cities on record against SISs. Most have had such facilities and closed them because they found that drug prob-

National Post, May 29, 2007

Safe injection site leads to detox

Results of study published in New England Journal of Medicine

BY FRANCES BULA VANCOUVER SUN

VANCOUVER | The more a drug user visits Vancouver's experimental supervised-injection site, the more likely that user is to go into detox, according to a study published Wednesday in the New England Journal of Medicine.

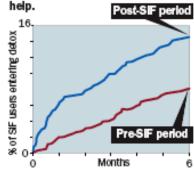
Those were the surprising findings that researchers studying the site discovered.

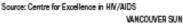
"If you use the site at least weekly, you are two times as likely than others to enter detox," said Dr. Thomas Kerr, a Centre for Excellence in HIV/AIDS Research who co-wrote the journal paper. He said that finding was not something researchers expected.

"We weren't surprised that the site had resulted in less public disorder or syringe sharing. But

Drug users seek help

Repeat users of Vancouver's supervised-injection facility (SIF) are now twice as likely to seek





we were kind of astounded actually that the more you use this facility, the more likely you are to enter treatment."

Of 1,031 randomly selected repeat users of Insite, which is near the city's notorious Main and Hastings intersection, 185

See EVIDENCE APPEARS B4

SITE AWAITS FATE



PETER BATTISTONI/VANCOUVER SUN

Brightly-lit booths line a wall at the Insite safe-injection site on Hastings Street, where drug users can be supervised.

said results from the site show the exchange of dirty needles and syringes is down in the district, and that people who use the site tend to seek rehabilitation more than people who don't.

"I can't see any reason why it wouldn't go forward unless we had a decision based on ideology and not science," Kerr said.

As well a applition of Down

Study indicates deaths and health costs cut

BY NICHOLAS READ VANCOUVER SUN

Vancouver's safe-injection site

"We have busy emergency rooms to be concerned about, and there are substantial savings here," Kerr said.

The east of calling an ambu

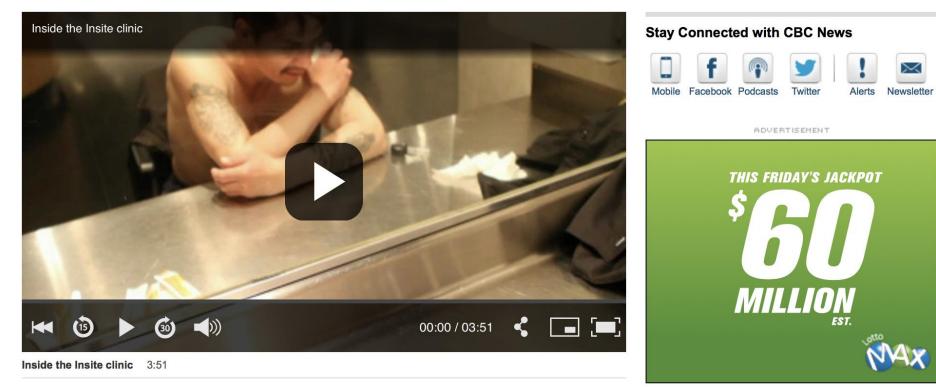
71 per cent, followed by cocaine (13 per cent), speedballs, which are a mixture of heroin and cocaine (10 per cent), morphine (two per cent) and other drugs



Vancouver's Insite drug injection clinic will stay open

Top court rules on clinic's exemption from federal drug laws

CBC News Posted: Sep 30, 2011 2:08 AM PT | Last Updated: Sep 30, 2011 5:01 PM PT





Vancouver's controversial Insite clinic can stav open, the Supreme Court

A couple of thoughts on publication

- Have healthy writing practices
- Consider all journal sections and range of journals
- Be open to concise reports rather than full length articles
- Be aware that journals like review articles and when you cite articles from their journal
- Don't be deterred by rejection
- When addressing reviews, the reviewer is always right
- Consider an appeal but don't waste time
- You will learn more about epidemiology by doing than by just studying the concepts
- There are ethical and career implications of not being productive with peer-reviewed publication

Questions & Discussion

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