1.1 Executive Summary

1.1.1 Health Issues Related to Injection Drug Use

An estimated 15,000 British Columbians inject illicit drugs (Millar, 1998). This estimate is likely conservative as it fails to include hundreds, perhaps thousands, of occasional users. An estimated 10% to 20% of these 15,000 live in Vancouver’s Downtown Eastside (DTES). Injection drug use is associated with an array of severe health and social consequences for drug users, their families, and their communities. Rates of disease, death, and the accompanying costs are distressing indicators of drug-related harm experienced within our society (Fischer, Rehm, & Blitz-Miller, 2000). Over the past decade, problems resulting from injection drug use have grown exponentially.

In a report to the Vancouver Medical Health Officer, Dr. Elizabeth Whynot (1996) lists the major impacts of injection drug use on the Vancouver health system:

- Increasing incidence and prevalence of symptomatic infectious diseases, including HIV/AIDS, hepatitis A, B, and C, skin and blood-borne infections, and endocarditis;
- High frequency of drug overdoses resulting in significant morbidity and mortality;
- Increased hospital and emergency service utilization: treatment for HIV-related disease, sepsis, and endocarditis; emergency room visits; ambulance responses (including approximately 2,048 ambulance responses to drug overdoses in the Downtown Eastside in 1998);
- Fetal exposures with both short-term and long-term consequences (an estimated 30% of infants born to mothers living in the Downtown Eastside live with effects of fetal exposure to illicit drugs);
- Increasing pressure on all community-level outreach, nursing, and medical services;
- Increasing need for community-level hospice palliative care; and
- Worsening consequences of associated conditions such as mental illness.

1.1.2 The Supervised Injection Site Intervention

A supervised injection site (SIS) is a controlled health care setting where drug users inject drugs under supervision and receive health care, counselling, and referral to health and social services, including drug treatment. Vancouver’s SIS will address the following objectives:

- To improve the overall health of drug users, including reducing the incidence of overdose and disease transmission;
- To reduce the harm associated with illicit drug use (e.g., crime, discarded needles, public drug use) that affects communities;
- To increase appropriate use of health and social services by drug users; and
- To reduce health, social, legal, and incarceration costs associated with drug use.

The SIS will provide the following services:

- Supervision of injections including emergency response to drug overdoses;
- Injection-related first aid (such as wound and abscess care);
- Assessment and referral to primary health care and service providers;
- Harm reduction teaching and counseling; and
- Exchange of needles, condoms and other injecting equipment.
1.1.3 The Evaluation

The evaluation has been designed to achieve the following objectives:

- To provide information to the program's management and staff that is useful in improving services and planning additional services;
- To determine the impact and cost-benefit of the intervention;
- To provide information—practical lessons learned—that will be useful to other organizations planning to start similar services elsewhere in Canada; and
- To increase understanding of the dynamics of IDUs’ health status changes in relation to their health services utilization.

The evaluation will have three foci. It will examine the implementation of the SIS services as sites are established, focusing on the processes of service delivery. The main purpose of the process evaluation is to assist staff to carry out a program as planned, or if the plan is found to have significant flaws, to modify it as needed. The process evaluations will also be useful for providing practical information to other organizations that may want to establish a similar program and for generating contextual information that can be helpful in interpreting results from outcome and cost-benefit evaluations.*

As the SIS builds a user base, tracking will begin to provide the information about health-related and other outcomes. Throughout the intervention’s pilot phase, cost data will be recorded to facilitate a cost-benefit analysis.

Process evaluation questions and their corresponding indicators address the following:

<table>
<thead>
<tr>
<th>Clientele</th>
<th>The evaluation will describe the SIS clients and their needs as well as the group within the target population who are not being served.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utilization of Services</td>
<td>The degree to which the intervention can potentially produce health outcomes with its clients depends, in part, on the nature and frequency of their service utilization.</td>
</tr>
<tr>
<td>Service Quality and Adherence to the SIS Management Protocols</td>
<td>The potential impact of the intervention also depends, in part, on the adherence to practices that are expected at the outset to be beneficial.</td>
</tr>
<tr>
<td>Client &amp; Staff Satisfaction</td>
<td>Clients, management and staff will have many ideas about how to improve the intervention.</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>Although the number of adverse events within the SIS such as overdoses is expected to be relatively low, based on experience in Australia and elsewhere, it is important to monitor these with a view to reducing their occurrence.</td>
</tr>
<tr>
<td>Linkages with Other Drug-Related Services</td>
<td>The SIS is part of a continuum of services within the DTES directed towards prevention, primary care, harm reduction and treatment for IDUs. Improvements in health status of SIS clients are, in part, a result of the successful operation of the full system of services they access. As part of the process evaluation, it is important to examine the functioning of the linkages between the SIS and these other services.</td>
</tr>
</tbody>
</table>

* Every individual who enters the site for the purpose of assessment, treatment and/or injection will be a participant enrolled in the process evaluation, regardless of eligibility or consent to enroll in the outcomes evaluation.
The outcome evaluation will address the following:

<table>
<thead>
<tr>
<th>Public Health</th>
<th>The effect on the number of overdose events and overdose deaths in the program’s service area as well as new notifications of blood-borne virus infections—HIV, hepatitis B and C.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client Health</td>
<td>The likelihood that SIS clients will access primary and enter drug treatment programs, as well as improvements in injecting practices and injecting-related health.</td>
</tr>
<tr>
<td>Neighbourhood Environment</td>
<td>The impact of the SIS on the surrounding neighbourhood, e.g., reduction in discarded injecting equipment, the incidence of drug injecting in public places and associated public nuisance.</td>
</tr>
<tr>
<td>Drug-Dealing and Other Crime</td>
<td>The effect of the SIS on drug related loitering and criminal activity in the vicinity of the site, specifically property crime as well as local community perceptions of on public drug use and drug dealing.</td>
</tr>
</tbody>
</table>

The economic evaluation will provide a cost analysis conducted from the perspective of the VCHA and a cost-benefit analysis using both a VCHA and societal perspectives.

The evaluation uses an open cohort design. Where possible, comparisons will be made between SIS clients and other injection drug users who are non-clients, adjusting for demographic and other differences.

Data will be collected at regular intervals through interviews with clients, VIDUS cohort members, staff, and community members. Many external data sources will also be used including, Coroners’ and Ambulance Service records as well as Centre for Disease Control, hospital and SIS operational databases.

Process evaluation reports will be provided to SIS management and staff as well as other stakeholders at 2, 6, 12, 18, 24 and 36 months after start-up. The outcome and economic evaluation reports will be delivered within six months of the end of the SIS pilot phase.
1.2 Background

1.2.1 Health Issues in Vancouver’s Downtown Eastside Related to Injection Drug Use

An estimated 15,000 British Columbians inject illicit drugs (Millar, 1998). This estimate is likely conservative as it fails to include hundreds, perhaps thousands, of occasional users. An estimated 10% to 20% of these 15,000 live in Vancouver’s Downtown Eastside (DTES). Injection drug use is associated with an array of severe health and social consequences for drug users, their families, and their communities. Rates of disease, death, and the accompanying costs are distressing indicators of drug-related harm experienced within our society (Fischer, Rehm, & Blitz-Miller, 2000). Over the past decade, problems resulting from injection drug use have grown exponentially.

1.2.1.1 Overdoses and Drug-Induced Deaths

Among Canadian provinces, British Columbia has the highest number of drug-induced deaths per capita (4.7 per 100,000 population). Drug-induced deaths in BC have increased dramatically in the last twelve years, rising sharply from 39 in 1988 to 412 in 1998. There were 202 overdose deaths in the first nine months of 2000 (BC Coroner’s Office, 2000).

In 1993, deaths due to illicit drugs reached epidemic proportions in BC (Millar, 1998), with illicit drugs becoming the leading cause of death among adults 30 to 49 years of age (Cain, 1994). The Chief Coroner’s report of 1993 suggested that the sharp rise in accidental overdose deaths could be attributed to unpredictable shifts in heroin purity and the increased tendency among injection drug users (IDUs) to combine drugs (particularly heroin and alcohol).

In the 1999 Vancouver Injection Drug Users Study (VIDUS), the 10% mortality rate among the study’s participants was accounted for primarily by drug-induced deaths, and 15% of the study’s participants reported at least one non-fatal overdose in the previous six-month period.

1.2.1.2 HIV/AIDS, Hepatitis C and Other Diseases

Risk behaviours among injection drug users are common and are associated with the spread of diseases such as HIV/AIDS and hepatitis C. These behaviours include, but are not limited to, the sharing of needles and other injection equipment (e.g., filters, spoons, cookers) and unprotected sex (including unprotected commercial sex). The increasing use of cocaine has contributed to an escalation in risk behaviour, since many cocaine users inject frequently—often up to twenty times per day.

Prior to 1993, injection drug users accounted for less than 3% of new HIV infections in Canada. In 1993-94, for the first time, IDUs outnumbered men who have sex with men among those testing newly positive for HIV. In BC today, IDUs account for 38% of new HIV infections (Fischer et al., 2000). The groups now considered most at risk for HIV infection include First Nations peoples (composing 17% of new infections), women who inject drugs (80% of whom work in the sex trade), persons living with mental illness, persons injecting cocaine, street youth, and homeless persons (Parry, 1997). According to the Point Project (cited in Millar, 1998), other factors most commonly associated with HIV infection among IDUs are unstable housing, frequent injecting, history of sexual abuse, and depression.
Hepatitis C is a blood-borne viral hepatitis transmitted easily through needle sharing, and less easily through unprotected sex (McLean, 2000). Recently, more than half of all hepatitis C cases reported in Canada were in British Columbia (Millar, 1998). This is attributed primarily to a higher rate of injection drug use in BC compared to other parts of the country. For the last four years, approximately 2,000 new cases of hepatitis C have been reported annually in Greater Vancouver. Injection drug users currently account for an estimated 80% of new cases of hepatitis C. According to the 1998 VIDUS project, 88% of injection drug users in Vancouver have hepatitis C (cited in McLean, 2000).

While HIV/AIDS and hepatitis C are the diseases most frequently associated with injection drug use, many other diseases and medical conditions often result from injection drug use and accompanying behaviours. For example, hepatitis B is an infectious disease that peaked in incidence in 1995 in part because of injection drug use, and although immunization programs have been effective in reducing the incidence of hepatitis B, this disease will remain a problem for years to come (Millar, 1998). Tuberculosis, syphilis, and hepatitis A also occur at epidemic rates within the IDU population. For example, in 1998, the VIDUS project reported a 38% prevalence rate of tuberculosis among Vancouver injection drug users. Other medical conditions common among drug users are severe abscesses, endocarditis, and septicemia, all of which require hospitalization for treatment.

1.2.2 The Economic Costs of Illicit Drug Use

It is evident that injection drug use leads to an array of health, legal, and social consequences that have an immense impact on the economy of British Columbia. According to Single et al. (1992), illicit drugs cost the BC economy more than $207 million per year. This figure does not take into account transfer payments for income assistance or the costs associated with a number of drug-related crimes (such as property crimes). The cost of income assistance alone may be as high as $67 million annually (Millar, 1998). One Ontario study (cited in Millar, 1998) found the annual costs for an untreated opiate user to be as high as $33,761 per year ($29,164 for law enforcement and $4,597 for health care).

In a report to the Vancouver Medical Health Officer, Dr. Elizabeth Whynot (1996) lists the major impacts of injection drug use on the Vancouver health system:

- Increasing incidence and prevalence of symptomatic infectious diseases, including HIV/AIDS, hepatitis A, B, and C, skin and blood-borne infections, and endocarditis;
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- Increased hospital and emergency service utilization: treatment for HIV-related disease, sepsis, and endocarditis; emergency room visits; ambulance responses (including approximately 2,048 ambulance responses to drug overdoses in the Downtown Eastside in 1998);
- Fetal exposures with both short-term and long-term consequences (an estimated 30% of infants born to mothers living in the Downtown Eastside live with effects of fetal exposure to illicit drugs);
- Increasing pressure on all community-level outreach, nursing, and medical services;
- Increasing need for community-level hospice palliative care; and
- Worsening consequences of associated conditions such as mental illness.
In a 1996 report, the City of Vancouver stated that in 1992 an estimated 30,799 in-patient hospital days were attributed to drug and alcohol problems (primary and secondary diagnoses). At a base rate of $873 per day (for in-patient beds), the total cost of these drug-related hospitalizations was approximately $27 million. In 1999 alone, 1,002 injection drug users accounted for 9,483 in-patient days at St. Paul’s Hospital (St. Paul’s Hospital, 2000).

1.2.2.1 HIV / AIDS

The National Task Force on HIV, AIDS and Injection Drug Use declared that Vancouver has the highest reported rate of new HIV infections among injection drug users in all of North America (Canadian National Task Force on HIV, AIDS and Injection Drug Use CNTF – 1997 pp. 2-3). Care for individual IDUs with incurable diseases such as HIV/AIDS and hepatitis C may continue beyond twenty years. The average age of persons newly diagnosed with HIV in 1998 was 23 (Bognar, Legare, & Ross, 1998).

Treatment costs for HIV/AIDS in British Columbia in 1999-2000 are projected to be $72.3 million (Hanvelt et al., 1999). In the long term, local estimates of the lifetime expense of medical treatment for an IDU living with HIV/AIDS is $134,559 (Hanvelt et al., 1999). Estimates for the cost of lost productivity are $471,650 per individual. Therefore, if only five to seven of every 100 HIV infections were prevented each year, the long-term saving for that one year alone would be approximately $3 million for treatment and $38 million for lost productivity.

1.2.2.2 Hepatitis C and Other Infections

Annually, the cost of healthcare and prevention of hepatitis C in B.C. is $100 million. Of the 40,000 chronically infected HCV patients in the province, 15 – 25% will require liver transplants within the next 10 – 40 years (Krajden, 2003). The costs of Hepatitis C in terms of loss of employment and other social effects are not yet known, but are substantial as many patients are unable to carry on employment as a result of the disease. Currently, only 10 - 15% of those affected can be cured with existing drug treatments. This means that prevention of HCV transmission is still the most cost-effective intervention.

Abscesses are one of the most common health care problems for people who inject. They often do so under unhygienic circumstances, using unclean paraphernalia and water that is not sterile. The costs of abscess care are very high as infections must be treated with antibiotics and other types of medications and occupy a large proportion of the services provided by doctors, nurses, outreach workers and other health practitioners in the Downtown Eastside.

Other common infections from injection can include endocarditis, an acute infection of the heart valves that is not commonly seen among young adults (Centre for Disease Control 1998).

1.2.2.3 Drug Overdoses and Drug-Induced Deaths

The cost of calling an ambulance is approximately $460 per call if an individual is taken to hospital (BC Ambulance Service). In 1998 there were 2,048 ambulance responses to overdoses in the Downtown Eastside (Whynot, 1996). This resulted in a cost of $942,080 for that area.
1.2.3 Drug-Related Crime

The relationship between illicit drug use and crime is complex and difficult to assess. While it is generally accepted that people using drugs commit many crimes, a large portion of these crimes do not directly involve drugs and therefore are not recorded as “drug offences.” Furthermore, while many writers have attempted to reduce to a simple formula the causal role drug use plays in crime (e.g., users commit crimes to get money to buy drugs to feed their habit), comprehensive reviews indicate that there is currently no viable singular explanation (Brochu, 1995). In discussing the relationship between drug use and crime, Brochu (1995) noted that 80% of offenders within the correctional system reported using illicit drugs during their lifetime, and 30-50% of prison inmates showed signs of illicit drug dependence. Approximately 50-75% of these offenders showed traces of drugs in their urine at the time of arrest, and almost 30% reported being under the influence of illicit drugs when committing the crime for which they had been arrested. There are approximately 131,000 people incarcerated in Canada (Correctional Services of Canada, 1999), and another 113,000 are in non-custodial care such as full or day parole or statutory release (City of Vancouver, 1998).

Easier to assess are the crime statistics directly involving drugs. The Vancouver Police Department (McLean, 2000) reported the following counts of illicit drug-related offences for 1998 (adults only): Cocaine, 1,178; Heroin, 328; and Marijuana, 313. It is important to note that these statistics are for Vancouver only, and do not include drug offences involving other common illicit drugs such as amphetamines or methamphetamine (speed).

In 1998, Single et al. reported an estimated 56,000 charges attributable to violations of drug laws in Canada. Given this figure and the various crimes related to but not directly involving violations of drug laws, it is fair to assume that the statistics cited by the Vancouver Police Department capture only a fraction of the crimes committed in Vancouver that are associated with drug use.
1.3 The Intervention

In the past decade there have been many efforts by health providers, community organizations, police and governmental bodies in B.C. to provide services for people with addictions and for people who use injection drugs. A new process of expanding and improving appropriate addictions services as part of a comprehensive primary health care strategy has been initiated under the Vancouver Coastal Health Authority (VCHA).

Primary health care is generally the first point of contact for the public with the health system. It is at this entry level that most health conditions are identified and where services are mobilized and coordinated to respond to people’s needs. Placing alcohol and drug interventions within a primary health care framework is essential to enhance delivery and integration of new and existing services through a coordinated and comprehensive health care system.

Critical to the success of a comprehensive system is the provision of a range of low, medium and high threshold services for drug users including first contact settings like supervised injection sites (SISs) and needle exchange as well as opiate replacement, withdrawal management, counseling and prevention services.

For marginalized people who inject drugs, the point of first contact with the health care system is extremely important. The actual act of injection is the most precarious moment for those individuals from a health point of view, particularly if they are injecting on the street. The act of public injection also provides one of the most problematic behaviours from a community point of view. Interventions like needle exchange and street outreach do not address the fact that these people have no place to go to safely inject. Experience from other countries has shown that supervised injection sites form an important part of the health care continuum.

Public health efforts for injectors in European and Australian cities, as well as in many major cities throughout the United States and Canada, typically include a range of street-based outreach services, needle exchange programs, HIV-test counselling centres, drug treatment / drug-substitution programs, and broad-based, multi-targeted educational initiatives (Kerr, 2000; Normand, Vlahov, & Moses, 1995). As such, safe injection sites are clearly additions to, but still only parts of, much larger comprehensive public health approaches to reduce drug-related harm. (Broadhead et al, 2002).

1.3.1 Supervised Injection Sites

A supervised injection site is a controlled health care setting where drug users inject drugs under supervision and receive health care, counselling, and referral to health and social services, including drug treatment. Evidence from Europe suggests that supervised injection facilities provide a cost-effective means of engaging the most marginalized and at-risk drug users and help to address the following aims:

- Improving the overall health of drug users, including reducing the incidence of overdose and disease transmission;
- Reducing the harm associated with illicit drug use (e.g., crime, discarded needles, public drug use) that affects communities;
- Increasing appropriate use of health and social services by drug users; and
- Reducing health, social, legal, and incarceration costs associated with drug use.
A SIS should address service delivery gaps and work in conjunction with the police, drug assistance agencies, related community organizations and all levels of government health authorities. SISs target three significant problems that have not been adequately addressed by other existing services: injection in public spaces, inadequate IDU contact with the primary care system and the community burden of illicit drug use.

1.3.1.1 Reducing Rates and Risks of Drug Injection in Public Spaces

Needle exchange and street-based outreach services work to provide injectors with harm reduction materials and education, but there is no evidence that such services lead to a reduction in use of public spaces for injection. In order to prevent the onset of withdrawal symptoms, or to get high as fast as possible, injectors commonly consume drugs close to where they are purchased (McCoy & Inciardi, 1995). Doing so results in injectors frequently injecting drugs in public and quasi-public spaces, such as restaurant and public restrooms, abandoned buildings, cars, stairwells, parks, and alleys.

Injectors’ use of public spaces to inject drugs creates a number of risks to their health and well-being:

- It increases their risk of being assaulted and robbed by street predators, or confronted by the police. In reaction, injectors are prone to rush when injecting in public spaces, which leads to mistakes and carelessness.
- Cutting-corners in order to save time increases risks, especially when drugs are injected quickly (e.g., not tested for strength) and when injection equipment is re-used but not properly cleaned (increasing the likelihood of bacterial and viral infections). Carrying out risk reduction measures takes time and resources. For example, cleaning a used syringe with bleach requires that it first be flushed several times with clean water, then filled entirely with bleach at least 3 times, and leaving the bleach in the syringe for at least 30 seconds. After removing the bleach, the syringe then needs to be flushed several more times with clean water. All other used injection equipment, such as spoons or cookers, must also be cleaned with bleach and rinsed with clean water (Normand, Vlahov, & Moses, 1995). The pressures and anxieties of injecting in public spaces work against users’ ability to adhere calmly and carefully to these risk-reduction procedures.
- In addition, when injecting outdoors, injectors are more likely to lack the supplies needed for safer injection. For example, injectors are often reluctant to carry injection equipment when they are out and about town, usually from fear of the police (Grund, Broadhead, Heckathorn, & Anthony, 1995). Not being able to obtain sterile injection equipment increases injectors’ risks of using contaminated equipment, either by borrowing someone else’s syringe or using one that has been discarded.
- Finally, just as the risk of fatal drug-overdose increases when drug users inject by themselves, research indicates it also increases when they inject in public spaces. There are frequently no telephones on-site to call for help; many spaces, such as alleys, abandoned buildings and parked cars have no real address to guide emergency workers to; some spaces are difficult to reach with emergency equipment; and competent bystanders are less likely to be available in many spaces, such as alleys, abandoned buildings, and highway and railroad underpasses, to help or seek assistance (McGregor, Darke, Ali & Christie, 1998).
1.3.1.2 Creating Opportunities to Work with IDUs

SISs are seen as providing a far greater opportunity for health workers to connect meaningfully with injectors than conventional public health services and programs. First, needle exchange and street-outreach workers make frequent contact with injectors, but it normally happens when injectors are working to cop drugs or get the money needed to buy them. The great majority of these interactions, therefore, tend to be cursory and on-the-run (Broadhead & Fox, 1993; Murphy, Sales, Choe, McKearin, & Murphy, 2000). As the Drugs and Crime Prevention Committee (1999) of the Victoria Parliament found, “In contrast to needle exchange outlets where clients generally visit briefly, [SISs] allow for a more prolonged interaction between health-care staff and client” (p. 16). This is because SISs place trained staff in direct proximity with injectors while they are waiting to consume their drugs, as well as after they have done so and have returned to the waiting room to stabilize.

As noted above, once inside an SIS waiting room, clients must sign-up to gain admission for the injection room and then wait their turn. While they are waiting, clients and staff have the opportunity to connect with one another, discuss problems, or make arrangements to see a counsellor or a health provider. If nothing else, clients have the opportunity to relax and reflect in a non-threatening environment. When clients finish in the injection room, they are encouraged to return or go to a waiting room and stay for a half-hour or so until they have stabilized. This gives staff a further opportunity to monitor clients' condition and connect with them at a time when they are not agitated, stressed-out or dope-sick. Because many people inject drugs simply to “get straight” and feel “normal,” one of the best times for staff to interact with clients can be in the post-injection area after using the injection room (Rosenbaum, 1981; Siegel, 1989; Waldorf, 1973).

In general, an SIS's waiting room is the most opportune space for staff to engage clients, either as a group in terms of presentations, videos, and announcements; or as individuals, in terms of getting to know them as persons, enrolling them in counseling or medical and drug treatment, or consulting with them about any number of things. Still, this optimum situation should not be over-drawn; connecting meaningfully with active drug injectors is still a challenge. While waiting to shoot-up in an SIS, some injection drug users (IDUs) are anxious or dope sick, and not in the mood to communicate. After shooting-up, they may go on the nod for a half hour or so before stabilizing. Yet, despite these obstacles, SISs appear to provide much better opportunities to interact with active IDUs than do street outreach or needle-exchange programs, in order to help injectors deal with, and take responsibility for, any number of problem they may be facing. This includes outpatient methadone programs as well, since they typically discourage “patients” from hanging out after they have received their dose.

1.3.1.3 Reducing the Burden of Illicit Drug Use on the Community

SISs are described in the available literature as reducing the nuisance, costs, and risks to the larger community caused by drug injection in public spaces. Injecting in public spaces results in large amounts of litter that is unsightly and costly to collect. Such litter, particularly discarded syringes, pose a health risk of accidental needle sticks and the transmission of blood-borne pathogens, especially to municipal workers and custodians who collect such litter, and trash haulers and sorters who separate and process it. Needle exchange programs endeavor to collect as many needles and syringes...
as they dispense, however many needles come from sources other than needle exchange. There is an additional real cost in collecting other associated litter and discarded needles.

Just as important as the problem of drug-related litter, congregations of injectors are widely regarded by the public-at-large as a nuisance and a threat. Moreover, some inner-city areas have been de facto expropriated by injectors, including whole sections of municipal parks, street corners, vacant lots, sidewalks, and alleys. Vancouver’s Downtown Eastside contains an open drug scene that is well known in Canada and North America. SISs are seen as offering an innovative way to reduce significantly the expropriation of such public spaces, as well as the nuisance and fear that public drug use creates, by giving injectors a sanctioned, alternative space that accommodates the needs and sensibilities of both injectors and the larger community. As the State of Victoria Drug Policy Expert Committee (2000) reported, “Overseas experience suggests that communities find a well run [SIS] more acceptable in their neighbourhood than the intense street-using situations that preceded them” (p. 17).

Conversely, there is no evidence in the available literature that indicates that the establishment of a SIS results in an increase in improperly discarded injection equipment, an increase in drug users congregating in public spaces and becoming a greater nuisance, or an increase in drug dealing and other forms of drug-related crime within a community (Broadhead, Kerr, Grund and Altice, 2002 pp.337-342).

1.3.2 Evidence about Operations and Impacts of SISs in Other Countries

1.3.2.1 European Research

Supervised injection sites have operated in the Netherlands, Switzerland, and Germany for up to 20 years (Dolan, Kimber, & Fry et al., 2000). There is currently only a small literature on injection centres (with limited English publications making comprehensive review difficult). Moreover, as European injecting centres have generally not been subjected to impact evaluations there is limited research evidence of their outcomes (de Jong and Weber 1999).

The evidence reviewed here is based primarily on five studies of injection centres conducted in Basel, Bern, Frankfurt, Hannover and Zurich. These studies were all observational, typically employing cross-sectional designs without follow-up and based on various sources of data including operational statistics, and quantitative and qualitative surveys of clients and staff. They provide the following information.

Operation and Service Delivery

The acceptability and substantial uptake of injecting centres by the target group is evidenced by a high frequency of use and constant throughput (Ronco, Spuhler et al. 1996; Jacob, Rottman et al. 1999). For example, most German centres average between 100 and 200 visits per day (Kimber 2000). Supervision of drug use appears to be well tolerated by clients (Jacob, Rottman et al. 1999). The main reasons given by clients for using these centres are: the opportunity to consume ‘in peace’; the needle and syringe program; availability of advice and counselling; and as a meeting place or place to spend
time during the day (Geense 1997; Jacob, Rottman et al. 1999; Kemmesies 1999). Conversely, the main reasons given for continued public drug use, in spite of the availability of an injecting room, are: limited opening hours; waiting time; and the distance to the Centre from the point of drug purchase (Kemmesies 1999). The most common suggestions made by clients for improvement of injecting centres are to extend opening hours, to make available a smoking area for heroin and cocaine, and permission to smoke tobacco in the injecting room (Jacob, Rottman et al. 1999).

Public Health

Immediate intervention in the case of overdose appears to be the most significant function of injecting centres (Ronco, Spuhler et al. 1996; Jacob, Rottman et al. 1999). There have been no overdose deaths at any injecting centre in Europe to date, and the risk of staying in hospital for one night is ten times greater for a street-based overdose compared to an injecting centre overdose (Integrative Drogenhilfe 1997). Moreover, the number of non-fatal overdose events relative to the number of injections supervised is very low. Reported rates of overdose events or complications per number of injections include: two per 1000 (Kemmesies 1999), one in 520 (Happel 1999), one in 648 (AIDS-Hilfe Frankfurt e.V. 1998) and one in 498 (Jacob, Rottman et al. 1999). Some cities, such as Frankfurt, have reported substantial reductions in overdose deaths (Weber and Schneider 1998). It is difficult to be certain how much of this reduction is attributable to the operation of injecting centres, given concurrent changes in drug policy and increased availability of substitution treatments (Kemmesies 1999).

Changes in needle sharing and condom use are widely reported by injecting centre clients and suggest a reduction in BBV risk behaviours (Nejedly and Bürki 1996; Ronco, Spuhler et al. 1996; Warner 1997; Jacob, Rottman et al. 1999). Although not solely attributable to injecting centres, surveys of injecting centre clients in Switzerland point to the contribution of these services in the stabilisation of HIV prevalence (Ronco, Spuhler et al. 1996) and a decreased rate of new infections especially in younger users (Nejedly and Bürki 1996).

Client Health

Contact with health and counselling services at injecting centres appears to contribute to a stabilization or improvement in injecting related and general health, and the social functioning of clients. The demand for medical services at a Basel injecting room diminished so much over time due to the radically improved health status and living situation of attendees that a restructuring of medical services was required (Ronco, Spuhler et al. 1996).

Injecting centres act as a contact point and place of referral to other treatment and social welfare services. It is difficult, however, to draw conclusions about the number of referrals made at any given injecting centre, as there is no comparison group or benchmark for number of referrals. There are also no available studies investigating the outcomes of any referrals made. Client reported changes in drug consumption behaviour include greater awareness and practice of hygienic consumption, less stressful consumption, consuming less, being more in control of drug use, entering methadone treatment, undertaking detoxification, and trying to consume only when at the injecting centre (Jacob, Rottman et al. 1999). The attainment of stable living arrangements was found to be a significant predictor for individuals ceasing to visit an injecting centre (Kressig, Nydegger-Lory et al. 1996).
Neighbourhood Environment and Safety

A shift from public drug use to using injecting centres has been observed during their hours of operation (Sozialamt der Stadt Zurich 1995; Ronco, Spuhler et al. 1996; Jacob, Rottman et al. 1999). There are also reports of a general reduction in the visibility and public nuisance of the drug scene (Kemmesies 1995; Kemmesies 1996). In the evaluation of Basel injecting centres, only 10% of attendees came outside the Basel area. The authors concluded that the unequivocal local demand demonstrated that the room did not attract injecting drug users from other areas (Ronco, Spuhler et al. 1996).

There is little available information on the impact of injecting centres on drug dealing and other crime. In a study of the Frankfurt drug scene, Kemmesies (1999) found that individuals surveyed in the injecting room were significantly less likely than individuals surveyed in the open scene to source their income from drug dealing, and significantly more likely to have paid employment. Sale of illegal drugs by clients of a Swiss centre decreased significantly from 65% of respondents to 28% over a five year period, and self-reported criminal activities such as theft, burglary and robbery decreased from 27% to 16%. However, approximately 60% of clients stated that they did obtain drugs from dealers in the vicinity of the centre (Nejedly and Bürki 1996).

Community Attitudes

Available studies do not report explicitly on community attitudes, however, the extensive community consultation process typical in the establishment and ongoing operation of European injecting centres can be viewed as an indication of community support for the facilities. Related to this, 98% of injecting centre clients surveyed in Hannover reported having not encountered a negative experience with residents in the area, and 94% of clients had not encountered a negative experience with police in the area (Jacob, Rottman et al. 1999).

Conclusions

The available evidence from Europe suggests that supervised injecting centres are acceptable to the target group and contribute to improvements in public health, client health, and public amenity. Comprehensive evaluation into the impact of an injecting centre is, however, limited.

1.3.2.2 Australian Research

In May, 2001 a SIS was established in the Kings Cross district in Sydney with the following objectives:

- To decrease overdose deaths;
- To provide a gateway to treatment; and
- To reduce the problem of discarded needles and users injecting in public places.
The service model used included the following features:

- Direct oversight and supervision by a medical director and nurses;
- Direct linkages to drug and alcohol counselling and assessment services;
- Opportunities for drug users to access health services including medical consultation and assessment, health education and drug treatment;
- Direct linkages to services for testing for blood borne and sexually transmissible infections at the facility;
- Provision of a needle and syringe program on the premises; and
- Provision for referral services for young people under the age of 18 years or children accompanied by parents.

An evaluation of the 18-month pilot phase of this project is currently being completed, and a full report of the outcomes cost-effectiveness and other findings will be published in April, 2003. To date, several process evaluation reports have been published. The following results were reported after 18 months (Kaldor et al., 2002):

- During the first 18-months of operation, 3,818 individuals were assessed and registered as clients to use the services at the SIS.
- Registered clients made 56,861 visits to the SIS during which their injection of drugs was supervised.
- The majority of these registered clients were male (73%), and less than one-third were female (26%). Male clients accounted for majority of visits (64%).
- Heroin was the drug most frequently injected at the SIS (61% of visits) followed by cocaine (30% of visits).
- Clients made an average of 15 visits in the 18-months with a range of 1 to 641 visits. The average time spent in the SIS per visit was approximately 28 minutes.
- On approximately one in every four visits, a health care service was provided to the clients (in addition to the supervision of their injecting). Over half of the occasions of service were injecting and vein-care advice (56%).
- Approximately one in 41 visits resulted in a referral for further assistance. Among the 1,385 referrals for further assistance, 43% were for the treatment of drug dependence, 32% were to primary health-care facilities and 25% were to social welfare services.
- Four hundred and twenty-four drug-overdose related incidents occurred at the SIS requiring clinical management, a rate of 7 overdoses per 1000 visits. These comprised of 337 heroin-related overdoses, 60 cases of cocaine-related toxicity, and 16 benzodiazepine overdoses and 11 other opioid-related overdoses.
- There were 243 occasions where individuals who sought use of the SIS did not gain entry. On 151 occasions, the registration and/or entry criteria were not met, and there were 93 occasions where individuals expressed the wish to use the SIS but did not proceed to register at that time.
1.3.3 Vancouver’s Supervised Injection Site

1.3.3.1 Target Population

It is difficult to talk about Vancouver’s injection drug users (IDUs) without focusing on the Downtown Eastside where by far the highest concentration of users resides. It is for this reason that a first focus on implementing these sites would be in the Downtown and Downtown Eastside areas. However, injection drug users reside in many parts of Vancouver and the Lower Mainland and live with the same health and social issues.

The Downtown Eastside (DTES) of Vancouver is an area of the city characterized by poverty and low health status. There is a high rate of addiction, mental illness, HIV infection, hepatitis infection and tuberculosis. The population of the area has the following characteristics, as compared with other populations in Vancouver and B.C.:

- Shorter life expectancy at birth for both males and females
- High proportions of:
  - Single parent families with children under 18
  - People with income below Low Income Cut-off
  - People aged 15 and older with less than grade 9 education
  - People with a diagnosed mental illnesses
- High mortality due to:
  - Alcohol-Related Causes
  - Drug-Related Causes
  - Smoking-Related Causes
  - Lung Cancer
  - Infectious/Parasitic Disease
  - AIDS
  - External Causes

There are currently epidemics of syphilis and tuberculosis in the area. These communicable diseases are endemic to the population here and pose a serious public health threat to the rest of the region.

The Downtown Eastside is estimated to have about 4500 resident IDUs. The total population of injecting drug users in all of British Columbia is about 15,000 (Fischer et al, 2000).

Individuals who develop alcohol and other drug addictions are still stigmatized in Canadian society. Canadians who inject drugs are even more stigmatized, as they are, by and large, rejected by society because of the illegal nature of their behaviour, their sometimes disorganized lives and their vulnerability to diseases. They are often labeled as difficult to manage, disruptive and manipulative. A significant portion of society views them as lesser persons – criminals and derelicts. These attitudes and misconceptions have resulted in a variety of harms, including public apathy, undiagnosed mental illness and inaccessible treatment and rehabilitation programs (Federal / Provincial / Territorial Advisory Committee on Population Health, February 2001).

An estimated 30% of our addicted population is also diagnosed with mental illnesses (concurrent disorders). These people comprise one of the most vulnerable and challenging client groups. It is often difficult for them to come into contact with appropriate services and to have consistent health
care. They are particularly vulnerable to pressure from drug dealers and have a great deal of difficulty within the criminal justice system when they are apprehended for their behaviours.

The Downtown Eastside has a large Aboriginal population. Aboriginal Canadians are at a high risk of substance misuse and injection drug use as they experience many of the disadvantages associated with drug misuse such as poverty, low education, unstable family structure, physical abuse and poor social support networks (F/P/T Advisory Committee on Population Health, 2001). It is estimated that approximately 80% of the females sex trade workers in Vancouver of Aboriginal descent.

Female sex trade workers represent a large proportion of the drug using population in the area. In addition to their vulnerability to disease, women who inject drugs face other unique challenges. They are often hesitant to enter treatment programs out of fear that their children will be taken away from them. They experience difficulties finding safe and suitable child-care while in treatment and so are less likely to stay in programs.

Many IDUs in this area are homeless or live in housing that is so substandard it is equivalent to homelessness (a complete lack of facilities such as kitchens and washrooms) (O’Shaughnessy 1997). For example, in the single occupancy hotels in the Downtown Eastside there is often one toilet for up to 40 rooms. It is for these reasons that provision of health care for these people includes the need for amenities like toilets, showers, laundries and kitchens where people can help themselves in the most basic ways. An obvious other need for people who inject drugs is to have a safe and sterile place to do so.

1.3.3.2 Objectives of the SIS

The objective for the SIS include the following:

1. To improve the overall health of drug users, including reducing the incidence of overdose and disease transmission;
2. To reduce the harm associated with illicit drug use (e.g., crime, discarded needles, public drug use) that affects communities;
3. To increase appropriate use of health and social services by drug users; and
4. To reduce health, social, legal, and incarceration costs associated with drug use.

1.3.3.3 Services to be Provided

The proposed SIS will provide the following services:

1. Supervision of injections including emergency response to drug overdoses;
2. Injection-related first aid (such as wound and abscess care) and primary health care;
3. Assessment and referral to primary health care and service providers;
4. Harm reduction teaching and counseling; and
5. Needle, condom and other injecting equipment distribution.
The program logic model shown in the following figures link the SIS’s services with the needs of clients and the community on the one hand, and with the expected outcomes on the other.

### Client-based SIS Logic Model

<table>
<thead>
<tr>
<th>Client Needs</th>
<th>Activities</th>
<th>Outputs</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment for health problems</td>
<td>Direct Primary Care Referrals to care</td>
<td>Uptake of primary care treatment</td>
<td></td>
</tr>
<tr>
<td>A place to inject drugs safely</td>
<td>Trained supervision of injection</td>
<td>Regular use of the facility</td>
<td>Improved health status</td>
</tr>
<tr>
<td>Medical assistance if overdose occurs</td>
<td>Medical care if overdose occurs</td>
<td>Increased use of clean equipment</td>
<td>Reduced risk of overdose</td>
</tr>
<tr>
<td>Clean injection equipment</td>
<td>Provision of clean supplies &amp; facility</td>
<td>Increased knowledge of safe practices</td>
<td>Reduced risk of BB infections</td>
</tr>
<tr>
<td>Information and / or counselling</td>
<td>Education on safe practices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment when ready</td>
<td>Counselling</td>
<td>Increased motivation to reduce risk</td>
<td></td>
</tr>
<tr>
<td>Social support</td>
<td>Referral to treatment &amp; other services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food, shelter, clothing etc.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Community-based SIS Logic Model

<table>
<thead>
<tr>
<th>Community Needs</th>
<th>Activities</th>
<th>Outputs</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe community environment</td>
<td>Direct Primary Care Referrals to care</td>
<td>Increased proportion of IDUs using SIS</td>
<td>Decreased rate of overdose deaths</td>
</tr>
<tr>
<td>Improved population health</td>
<td>Trained supervision of injection</td>
<td>Regular use of the facility</td>
<td>Decreased rates of BB infections</td>
</tr>
<tr>
<td>Optimal use of care resources, e.g., ERs</td>
<td>Medical care if overdose occurs</td>
<td>Increased use of clean equipment</td>
<td>Decreased drug-related hospital use</td>
</tr>
<tr>
<td></td>
<td>Provision of clean supplies &amp; facility</td>
<td>Increased use of SIS for primary care</td>
<td>Reduced public drug use</td>
</tr>
<tr>
<td></td>
<td>Modifying services to increase responsiveness</td>
<td>Increased knowledge of safe practices</td>
<td>Reduced drug-related litter on streets</td>
</tr>
<tr>
<td></td>
<td>Building relations with community partners</td>
<td>Increased motivation to reduce risk</td>
<td>No adverse effect on business in SIS area</td>
</tr>
</tbody>
</table>
1.4 Overview of the Evaluation

1.4.1 Objectives of the Evaluation

The evaluation has been designed to achieve the following objectives:

- To provide information to the VCHA management and program staff that is useful in improving services and planning additional services;
- To determine the impact and cost-benefit of the intervention;
- To provide information—practical lessons learned—that will be useful to other organizations planning to start similar services elsewhere in Canada; and
- To increase understanding of the dynamics of IDUs’ health status changes in relation to their health services utilization.

The specific process-, outcome- and cost-related questions the evaluation will address are outlined later in this section. Also included are the methods that will be used to answer these questions. The focus is on descriptions of the main indicators, data collection processes and the nature of the core analyses. Some challenges in interpreting the findings are also described. A timeline for data collection throughout the project is included. In Section 1.6, issues concerning ethics, data management and reporting of results are addressed.

1.4.1.1 Three Foci—Implementation/Process, Outcomes and Cost

The evaluation will have three foci. It will examine the implementation of the SIS services as sites are established, focusing on the processes of service delivery. As the SIS builds a user base, tracking will begin to provide the information about health-related and other outcomes. Throughout the intervention’s pilot phase, cost data will be recorded to facilitate a cost-benefit analysis.

A process evaluation is an ongoing check of the implementation of the plan for an intervention / service. Its main purpose is to assist staff to carry out a program as planned, or if the plan is found to have significant flaws, to modify it as needed. Process evaluations are also useful for facilitating accountability for meeting service delivery (output) objectives, for providing practical information to other organizations that may want to establish a similar program and for generating contextual information that can be helpful in interpreting results from outcome and cost-benefit evaluations.

The process evaluation will be primarily formative in nature. Data collection and analysis will be ongoing, and findings will be reported frequently to program management and staff to enable them to adjust program operation if necessary. Evaluators will document these changes and monitor their effects as part of a quality improvement cycle. A full assessment of the value or worth of the intervention—part of a summative evaluation—will require the outcome data.

As part of the process evaluation, the evaluator(s) will keep a journal documenting potentially important events in the community that could have an effect on the operation and outcomes of the program. Examples of such events include the following: changes in law enforcement policies and practices, changes in the supply of drugs, actions of community groups with an interest (positive or negative) in the operation of the SIS, opening / closing / modification of other services used by the target group etc. The evaluator will also keep a log of media stories related to the SIS project, letters
to newspaper editors, VCHA communications initiatives etc. These notes will be used, in part, in (1) formulating interview questions used with SIS management and staff, SIS clients and others and (2) interpreting other evaluation findings. In addition, VCHA will establish a telephone feedback line to respond to questions and concerns from users and the community. Leading up to the launch of the new site, VCHA will develop an education program targeting potential users and engage in advertising to communicate the site’s opening date and purpose.

During the first six to 12 months of the pilot, the major portion of evaluation work will be focused on setting up and implementing the process evaluation. As SIS operations stabilize, the emphasis will shift to the outcome and cost-benefit evaluations. Of course, some ongoing data collection and management procedures for the outcome and cost-benefit evaluations will be established at the outset of the pilot. A significant amount of the required outcome data will be obtained from sources external to the project, e.g., records of Emergency Room visits from St. Paul’s and Vancouver Hospitals.

The outcome evaluation aims to determine whether or not there were any reliable and meaningful changes in health-related and community impact indicators, and if so, whether changes can be attributed to the operation of the SIS. As explained later, some of the indicators chosen are more sensitive for detecting change than others.

### 1.4.2 Process Evaluation Questions

#### 1.4.2.1 Clientele

In examining the delivery of the intervention, it is important to carefully describe its clients and their needs as well as the group within the target population who are not being served.

P1 To what extent are SIS services reaching the target population(s)?

P2 How aware of the SIS are potential clients in the DTES?

P3 Who is not using the services and for what reasons?

P4 How many refusals of entry to the SI room occur for each of a specified list of reasons? What types of referrals are made for people who are refused entry?

The methodology for addressing these questions is outlined in section 1.5.2.1.

#### 1.4.2.2 Utilization of Services

The degree to which the intervention can potentially produce health outcomes with its clients depends, in part, on the nature and frequency of their service utilization.

P5 How frequently do SIS clients use the different services provided at the site? Are target levels of utilization achieved?

P6 To what extent do SIS clients make use of services provided by the VCHA and other organizations following a referral by SIS staff? To what extent do SIS clients use other VCHA services without a referral by SIS staff?

P7 How much injecting equipment is supplied each month to SIS clients as part of the SI room service and as part of the needle exchange service?

The methodology for addressing these questions is outlined in section 1.5.2.2.
1.4.2.3 Service Quality and Adherence to the SIS Management Protocols

The potential impact of the intervention also depends, in part, on the adherence to practices that are expected at the outset to be beneficial.

P8 To what extent are the requirements in the SIS Management Protocols being fulfilled?
P9 What difficulties, if any, have arisen in relation to fulfillment of the Management Protocols requirements? What modifications have been proposed / implemented?

The methodology for addressing these questions is outlined in section 1.5.2.3.

1.4.2.4 Client and Staff Satisfaction

Clients, management and staff will have many ideas about how to improve the intervention.

P10 To what extent are SIS clients satisfied with the services they receive? What improvements do they suggest?
P11 What do SIS staff think about the operation of the service, their work there, their needs (e.g., for training and support) and possible service improvements?

The methodology for addressing these questions is outlined in section 1.5.2.4.

1.4.2.5 Community Attitudes

There is concern in some quarters that the operation of a SIS may create an impression that illicit drug use is being condoned (i.e., ‘send the wrong message’) and encourage initiation of injecting drug use. A further concern is that the operation of a SIS would have a negative impact on businesses in the nearby vicinity. The evaluation will address the following questions:

P12 What are local residents attitudes toward the operation of the SIS and illicit drug use?
P13 What are businesses attitudes toward the operation of the SIS and illicit drug use?

The methodology for addressing these questions is described in section 1.5.2.5.

1.4.2.6 Adverse Events

Although the number of adverse events within the SIS such as overdoses is expected to be relatively low, based on experience in Australia and elsewhere, it is important to monitor these with a view to reducing their occurrence.

P14 What is the frequency of each type of adverse event within the SIS? What changes in practice might be effective in reducing the risk of future occurrences?

The methodology for this component is described in section 1.5.2.6.
1.4.2.7 Linkages with Other Drug-Related Services

As discussed in Section 1, the SIS is part of a continuum of services within the DTES directed towards prevention, primary care, harm reduction and treatment for IDUs. Improvements in health status of SIS clients are, in part, a result of the successful operation of the full system of services they access. As part of the process evaluation, it is important to examine the functioning of the linkages between the SIS and these other services.

P15 What are the perceived challenges in coordinating services among agencies for SIS clients, and what strategies are viewed as feasible for improving the overall impact of services on client health?

The methodology for addressing this question is outlined in section 1.5.2.7.

1.4.3 Outcome Evaluation Questions

1.4.3.1 Public Health

The operation of the SIS is expected to have a positive impact on public health, specifically on reducing the number of accidental overdose events and reducing the spread of blood-borne viruses resulting from the use of non-sterile injection equipment. The evaluation will examine the following questions:

O1 What is the effect of the SIS on the number of overdose events and overdose deaths in the program’s service area(s)?
O2 What is the effect of the SIS on new notifications of blood-borne virus infections—HIV, hepatitis B and C—in the program’s service area(s)?

The methodology for addressing these questions is described in section 1.5.3.1.

1.4.3.2 Client Health

It is expected that the operation of the SIS can increase the likelihood that IDUs will access primary care and enter drug treatment programs, and contribute to improvements in injecting practices and injecting-related health. The evaluation seeks to examine the following questions:

O3 How many safe injections occurred at the SIS each month? How did the median of individual clients’ monthly numbers of safe injections change over time?
O4 How many and what kinds of referrals are made to drug treatment, primary health care and social welfare agencies?
O5 What are the referral outcomes associated with SIS client referrals to drug treatment?
O6 What is the relative utilization of drug treatment between SIS clients and other IDUs living in the DTES?
O7 What is the effect of the SIS on injecting practices and injecting-related health of clients?
O8 What is the effect of the SIS on the incidence of HIV and hepatitis C and B virus in the 14 to 18 year old subgroup of the SIS client group?

The methodology for addressing these questions is described in section 1.5.3.2.
1.4.3.3 Neighbourhood Environment

It has been argued that the SIS may have a positive impact on the neighbourhoods surrounding the facility through a reduction in discarded injecting equipment, the incidence of drug injecting in public places and associated public nuisance. The evaluation will address the following questions:

O9 What is the effect of the SIS on discarded injecting equipment in the site’s vicinity?
O10 What is the local community’s perception of injection equipment discarded in public?
O11 What is the local community’s perception of public drug use?

The methodology for addressing these questions is described in section 1.5.3.3.

1.4.3.4 Drug-Dealing and Other Crime

Concerns have been expressed by citizens and businesses that the operation of a SIS may contribute to a congregation of drug users in the area (the so-called ‘honey-pot’ effect), lead to an increase in drug-dealing, and opportunistic street and property crime. Some fear that the operation of a SIS may lead to an increase in individual drug use. The evaluation will provide evidence in relation to these issues:

O12 What is the effect of the SIS on drug related loitering?
O13 What is the effect of the SIS on criminal activity in the vicinity of the site(s), specifically property crime?
O14 What are local community perceptions of public drug use and drug dealing?
O15 What is the effect of the SIS on IDUs’ frequency of public / private injection?

The methodology for addressing these questions is described in section 1.5.3.4.

1.4.4 Economic Evaluation Questions

This component of the evaluation is concerned with an economic assessment of the SIS. The primary research questions for the economic evaluation are:

CE1 What are the start-up costs and the ongoing operational costs of the SIS?
CE2 Are there any cost-offsets or cost-additions related to the 36-month operation of the SIS? Do the benefits derived from SIS outweigh the associated costs?

The methodology for addressing these questions is described in section 1.5.4.
1.5 Methodology

1.5.1 Evaluation Design

The process and outcome evaluations both will be open cohort studies. New SIS clients will enter the cohort of intervention subjects throughout the three-year pilot and will have varying degrees of exposure to the safe injection service. The outcome evaluation will include a nested case control study. SIS clients who develop a particular outcome during the evaluation period—e.g., having an overdose event—will be considered cases, and clients who do not will be considered to be controls. In the between-group analyses of the outcome data, adjustments will be made for differences in utilization of the intervention and other inter-client differences.

An additional cohort, partially overlapping with the evaluation cohort, is available for use in some components of the evaluation—the participants in the Vancouver Injection Drug User Study (VIDUS). Some VIDUS cohort members will become SIS clients at different times during the pilot, and others will not. Comparisons will be made between SIS non-users’ and SIS users’ outcomes, statistically adjusting as much as possible for client differences that may affect self-selection into the SIS user group.

All SIS users will provide core data as part of their registration to receive services, but only those clients who consent to provide additional data for evaluation purposes will be asked for more comprehensive information at initial intake and in follow-up interviews. Therefore for some of the indicators, the sample size could be quite limited. Experience in the VIDUS study suggests, however, that up to 90% of clients may consent to provide full information.

The evaluation staff will ask each client whether they would consent to permitting their data to be linked with hospital and physician service records for the purposes of evaluation, given assurances that only evaluators will see the linked data, identifiers will be removed from the files after linkage and only aggregate results will be reported.
### 1.5.2 Process Evaluation Indicators, Data Collection and Analysis

#### 1.5.2.1 Clientele

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Collection</th>
<th>Core Analysis &amp; Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI1 Client Profile</td>
<td>Source: Client Intake Form, completed by staff for each individual on first visit and results of baseline blood tests for HIV/HVC/HVB on samples provided by consenting clients. Storage: Evaluation Database / Primary Access Regional Information System (PARIS).</td>
<td>Frequency distributions, means, SDs for each variable will be presented monthly. Cross-tabulations and sub-group mean differences will also be presented. Trends will be plotted. Profiles will be compared with client profiles from other VCHA drug-related services. User counts will be compared with the estimated size of SIS’s target population.</td>
</tr>
<tr>
<td>PI2 Target Population’s Program Awareness</td>
<td>Sources: Brief informal interviews by evaluator with samples of IDUs attending the VCHA’s DTES clinics. Regular interviews with VIDUS clients. Storage: Evaluation database.</td>
<td>Evaluator will review notes from informal conversations with IDUs and compute the proportion who know about the SIS. Proportion of non-using VIDUS IDUs who know about the SIS will be computed. Trends will be plotted. IDUs’ sources of information about SIS will be described.</td>
</tr>
<tr>
<td>PI3 SIS Non-user Profile</td>
<td>Source: Regular interviews with VIDUS clients. Storage: VIDUS database.</td>
<td>Presentation of frequency distributions, means, SDs etc. for each variable. Cross-tabulations and sub-group mean differences will also be presented. User and non-user profiles will be compared.</td>
</tr>
<tr>
<td>PI4 SIS Non-user Reasons</td>
<td>Source: Interviews with VIDUS sample members who know of the SIS but have not used it. Storage: VIDUS database.</td>
<td>Proportions of non-users stating each type of reason will be computed.</td>
</tr>
<tr>
<td>PI5 Refusal of Entry to SI Room</td>
<td>Source: Injection Room Log, recorded by SIS staff whenever an IDU is refused entry to the SI room. Storage: Evaluation database / PARIS.</td>
<td>The total number of refusals and the proportion for each reason will be computed monthly.</td>
</tr>
<tr>
<td>PI6 Referrals for Refused IDUs</td>
<td>Source: Injection Room Log, recorded by SIS staff whenever an IDU is refused entry to the room. Storage: Evaluation database / PARIS.</td>
<td>The proportion of refused IDUs who are referred to each type of service will be computed monthly.</td>
</tr>
</tbody>
</table>
### 1.5.2.2 Utilization of Services

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Collection</th>
<th>Core Analysis &amp; Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PI7</strong></td>
<td><strong>Client SIS Service Utilization Profile</strong>&lt;br&gt; The number and proportion of clients using the following SIS services: (1) the injection room; (2) primary health care; (3) counselling; (4) referral and (5) the needle exchange.</td>
<td>Source: For each client visit, staff record core facts about delivery of each type of service, e.g., time of day, nature of primary care provided, referral destination etc.&lt;br&gt; Storage: Evaluation database / PARIS.</td>
</tr>
<tr>
<td><strong>PI8</strong></td>
<td><strong>Client Non-SIS Service Utilization Profile</strong>&lt;br&gt; The number and proportion of SIS clients’ service use events in VCHA and other health care agencies.</td>
<td>Sources: Records in PARIS for VCHA services; Medical Services Plan (MSP) database for physician services; hospitalization from hospitals’ discharge abstracts and Emergency Room(ER) databases.</td>
</tr>
<tr>
<td><strong>PI9</strong></td>
<td><strong>Referral Volume</strong>&lt;br&gt; The number and proportion of SIS clients referred to drug treatment, primary health care and social welfare agencies.</td>
<td>Sources: Referral Log, completed by staff at the time of the referral. Referral types will be categorized.&lt;br&gt; Storage: Evaluation database / PARIS.</td>
</tr>
<tr>
<td><strong>PI10</strong></td>
<td><strong>Referral Follow-through</strong>&lt;br&gt; The proportion of referrals made by SIS staff that clients follow through on.</td>
<td>Sources: Referral follow-up cards. When SIS clients are referred to a non-VCHA service, they are given a postage-paid card (identified using only their SIS client ID number) to turn in at the referral destination, e.g., a methadone maintenance program. Staff there stamp the card with the service name and follow-through date and mail it to the evaluator.&lt;br&gt; Follow-through at VCHA services is recorded in PARIS.&lt;br&gt; Storage: Evaluation database.</td>
</tr>
<tr>
<td><strong>PI11</strong></td>
<td><strong>Injection Equipment Volume</strong>&lt;br&gt; Number of needles, syringes and other equipment (e.g., swabs) issued by staff in (1) the injecting room and (2) the needle exchange. Number of needles and syringes returned to the exchange.</td>
<td>Source: Equipment Log Sheets and monthly stock inventories.&lt;br&gt; Storage: Evaluation database.</td>
</tr>
</tbody>
</table>
### 1.5.2.3 Service Quality and Adherence to the SIS Management Protocols

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Collection</th>
<th>Core Analysis &amp; Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI12</td>
<td><strong>Protocol Implementation Checklist</strong>&lt;br&gt;A summary of the key elements of the SIS Management Protocol that are / are not being implemented as written.</td>
<td>Sources:&lt;br&gt;Notes from structured interviews with SIS manager / staff to review compliance with each element in the protocol.&lt;br&gt;Notes from evaluator’s systematic observations of service delivery processes (at randomly-chosen times).&lt;br&gt;A written description will be provided at 1, 6, 12, 24 and 30 months after start-up that summarizes SIS operations with regard to compliance with and discrepancies from the Protocol.</td>
</tr>
<tr>
<td>PI13</td>
<td><strong>Procedural Difficulties and Modifications Record</strong>&lt;br&gt;A summary of reported difficulties staff have in implementing the original Protocol and approved / unapproved modifications that have been implemented.</td>
<td>Sources:&lt;br&gt;Interview notes (see PI12).&lt;br&gt;Modifications to procedures will be classified as approved if they have been given approval by the SIS Steering Committee.&lt;br&gt;The description of compliance (see PI12) will be supplemented with a description of changes that staff have made to the procedures covered by the protocol and the rationale for the changes.</td>
</tr>
</tbody>
</table>

### 1.5.2.4 Client and Staff Satisfaction

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Collection</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI14</td>
<td><strong>Client Satisfaction</strong>&lt;br&gt;Clients’ ratings of the SIS services they have received, comments and suggestions for improvement.</td>
<td>Source: Client Opinion Questionnaire.&lt;br&gt;At 2, 6, 12, 18, 24 and 30 months after start-up, a random sample of 150 SIS users will be selected. Those who consent to be interviewed will be asked to rate several features of services they have used.&lt;br&gt;Storage: Evaluation database.&lt;br&gt;Ratings of SIS services will be described in relation to intensity of service use, client demographic characteristics and injecting behaviour.&lt;br&gt;Trends will be graphed.&lt;br&gt;The analysis of trends in satisfaction will be supplemented by descriptions of changes in the operation of the SIS that have been made in response to client suggestions.</td>
</tr>
<tr>
<td>PI15</td>
<td><strong>Staff Views</strong>&lt;br&gt;Staff opinions about the operation of the SIS, work environment, work tasks, workload, professional relationships, support and career development.</td>
<td>Source: Notes from focus groups conducted by an evaluator with managers and staff (separately) at 2, 6, 12, 18, 24 and 30 months after start-up.&lt;br&gt;Content analyses of notes will be conducted, and a summary of major themes and suggestions will be written.&lt;br&gt;The analysis of trends in satisfaction will be supplemented by descriptions of changes in the operation of the SIS that have been made in response to staff suggestions.</td>
</tr>
</tbody>
</table>
### 1.5.2.5 Attitudes and Opinions of Local Residents and Business Owners

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Collection</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI16</td>
<td>Source: A telephone panel survey of 150 randomly selected residents conducted by a contracted market research firm at start-up and 2, 12, 21 and 30 months after start-up. Storage: Community Survey database.</td>
<td>Responses will be tabulated and related to residents’ demographic characteristics. The size and significance of any changes in respondents’ views between survey occasions will be examined.</td>
</tr>
<tr>
<td></td>
<td><strong>Local Residents’ Perceptions of SIS.</strong> The proportions of residents in the neighbourhoods surrounding the SIS sites selecting each response category in a series of opinion survey questions about SIS operations and their immediate effects, e.g., on perceived street safety.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Collection</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI17</td>
<td>Source: A telephone panel survey of 150 randomly selected businesses conducted by a contracted market research firm at start-up and 2, 12, 21 and 30 months after start-up. Storage: Community Survey database.</td>
<td>Responses will be tabulated and related to business characteristics, e.g., type of business, proximity to the SIS. The size and significance of any changes in respondents’ views between survey occasions will be examined.</td>
</tr>
<tr>
<td></td>
<td><strong>Local Business Owners’ Perceptions</strong> The proportions of owners of businesses in the neighbourhoods surrounding the SIS sites selecting each response category in a series of opinion survey questions about SIS operations and their immediate effects, e.g., business volume.</td>
<td></td>
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</tbody>
</table>

### 1.5.2.6 Adverse Events at the SIS

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Collection</th>
<th>Core Analysis &amp; Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI18</td>
<td>Source: Adverse Event Log. For each adverse event of the following types, staff will record date, time, client ID, type of event, circumstances and disposition. (1) opioid-related overdose (OD) requiring oxygen; (2) opioid-related OD requiring oxygen &amp; Naloxone; (3) opioid-related OD requiring oxygen, Nalaxone and ambulance; (4) other drug OD; (5) allergic reaction; (6) anaphylactic reaction; (7) arterial injection; (8) cardiac arrest; (9) seizure; (10) ambulance transportation; (11) death; (12) act of violence or abuse; (13) malicious property damage; (14) other behaviour requiring removal from the premises; (15) other.</td>
<td>Monthly numbers of adverse events by type will be presented. In particular, frequencies of overdose events will be categorized by type and outcome. Client demographics, details of the SIS visit.</td>
</tr>
<tr>
<td></td>
<td><strong>Adverse events at the SIS</strong> The monthly count of each of a list of adverse events occurring on the SIS premises.</td>
<td></td>
</tr>
</tbody>
</table>

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1. The actual sample size needed to detect significant differences will be determined after review of findings from a trial of the proposed questionnaire.
1.5.2.7 Linkages with Other Drug-Related Services

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Collection</th>
<th>Core Analysis &amp; Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI19</td>
<td><strong>Service linkage assessment</strong>&lt;br&gt;List of challenges and potential solutions in relation to coordination and enhancement of services for SIS clients.</td>
<td>Source: Focus groups at 6 and 18 months after start-up, involving representatives of DTES drug service providers and SIS management and staff.</td>
</tr>
</tbody>
</table>

1.5.3 Outcome Indicators, Data Collection and Analysis

1.5.3.1 Public Health

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Collection</th>
<th>Core Analysis &amp; Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>OI 1</td>
<td><strong>Overdose deaths</strong>&lt;br&gt;Monthly counts of deaths from illicit drug related overdoses within the postal code areas in which the SIS sites are located, based on coroner’s data.</td>
<td>Source: Coroner’s files and B.C. Vital Statistics.&lt;br&gt;Time interval: from 3 years prior to start-up to 3 years after start-up.</td>
</tr>
<tr>
<td>OI 2</td>
<td><strong>Ambulance attendances at overdose events</strong>&lt;br&gt;Monthly counts of ambulance attendances to illicit drug-related overdoses within the postal code areas in which the SIS sites are located.</td>
<td>Source: B.C. Ambulance Service records.&lt;br&gt;Time interval: from 3 years prior to start-up to 3 years after start-up.</td>
</tr>
<tr>
<td>OI 3</td>
<td><strong>Overdose volumes at hospital emergency departments</strong>&lt;br&gt;Monthly counts of illicit drug-related overdose cases served by the St. Paul’s and Vancouver Hospitals’ emergency departments.</td>
<td>Source: Hospitals’ emergency department databases.&lt;br&gt;Time interval: from 3 years prior to start-up to 3 years after start-up.</td>
</tr>
<tr>
<td>OI 4</td>
<td><strong>Newly diagnosed blood borne virus infections</strong>&lt;br&gt;Population-based rates of newly diagnosed cases of HIV, hepatitis B and hepatitis C for Community Health Area 2.</td>
<td>Source: B.C. Centre for Disease Control (BCCDC) database.&lt;br&gt;Downloads every 6 months.</td>
</tr>
<tr>
<td>OI 5</td>
<td><strong>Blood borne virus infections in SIS youth clients</strong> (Dependent upon policy development for youth)&lt;br&gt;Incidence of HCV infection among SIS clients aged 14 to 18 tested more than once following SIS start-up.&lt;br&gt;Prevalence of HIV and HCV among tested SIS clients aged 14 to 18.</td>
<td>Source: B.C. Centre for Disease Control (BCCDC) database.&lt;br&gt;Downloads every 6 months.</td>
</tr>
</tbody>
</table>
## 1.5.3.2 Client Health

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Collection</th>
<th>Core Analysis &amp; Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>O16</strong> IDU utilization of drug treatment</td>
<td>Source: Structured interviews at 6, 12, 18, 24 and 30 months after start-up with samples of 150 SIS clients and 150 non-SIS VIDUS clients. Storage: Evaluation database, VIDUS database.</td>
<td>Self-report of current treatment for drug dependence and recent testing for HIV and HCV infection among respondents who have injected frequently at the SIS will be compared to respondents who have injected occasionally or not injected at the SIS. In addition, the proportion and characteristics of IDUs referred to treatment from the SIS will be presented.</td>
</tr>
<tr>
<td><strong>O17</strong> Injecting practices</td>
<td>Source: Structured interviews at 6, 12, 18, 24 and 30 months after start-up with samples of 150 SIS clients and 150 non-SIS VIDUS clients. Storage: Evaluation database.</td>
<td>Self-report of frequencies of recent behaviours among respondents who have injected often at the SIS will be compared to respondents who have injected occasionally or not injected at the SIS.</td>
</tr>
<tr>
<td><strong>O18</strong> Injecting-related health (A)</td>
<td>Source: Structured interviews at 6, 12, 18, 24 and 30 months after start-up with samples of 150 SIS clients and 150 non-SIS VIDUS clients. Storage: Evaluation database.</td>
<td>Self-report of occurrence of specified health problems among respondents who have injected often at the SIS will be compared to respondents who have injected occasionally or not injected at the SIS. See also Section 4.7.5</td>
</tr>
<tr>
<td><strong>O19</strong> Injecting-related health (B)</td>
<td>Source: Hospitals’ discharge abstracts databases. Downloads every 6 months.</td>
<td>Trends in monthly counts of admissions will be graphed for each diagnosis. Using records from clients who have provided PHNs, counts will be analyzed by level of use of SIS, adjusting for client characteristics that distinguish SIS users from non-users. See also Section 4.7.5</td>
</tr>
</tbody>
</table>

2 Behavioural information will include the following: type of drug most often in the past month, frequency of injecting, places of frequent injection, use of new syringes, reuse of own and other people’s syringes, reuse of other injecting equipment, frequency of use of needle exchange, pharmacies and the SIS to obtain equipment.

3 Common injecting-related health problems include the following: vein damage, limited venous access, prominent scarring and bruising, abscesses, skin and soft tissue infections, septicemia, infective endocarditis and thrombosis.
### 1.5.3.3 Neighbourhood Environment

<table>
<thead>
<tr>
<th>Indicator</th>
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<th>Core Analysis &amp; Presentation</th>
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<tbody>
<tr>
<td><strong>OI10</strong></td>
<td><strong>Publicly Discarded Syringe Count</strong>&lt;br&gt;Weekly count of discarded syringes (barrel intact) collected within five blocks of the SIS site.</td>
<td>Source: Count following daily clean-up by volunteers / evaluators.&lt;br&gt;Duration: From eight weeks prior to start-up to end of project.&lt;br&gt;Graphing of trends and time series analysis. Changes within sub-areas of the collection zone will be examined, as will the relationship between counts and proximity to the SIS.</td>
</tr>
<tr>
<td><strong>OI11</strong></td>
<td><strong>Community perception of publicly discarded syringes</strong>&lt;br&gt;The proportion of local residents and business owners who have ever observed a discarded syringe in the SIS neighbourhood; and, for those who have, time interval since the last observation of one and the number of times one or more was observed in the past month.</td>
<td>Source: A telephone panel survey of 150 randomly selected residents and 150 businesses conducted by a contracted market research firm at start-up and 2, 12, 21 and 30 months after start-up.&lt;br&gt;Storage: Community Survey database.&lt;br&gt;Responses will be tabulated and related to resident and business characteristics, e.g., proximity to the SIS. The size and significance of any changes in respondents’ views between survey occasions will be examined.</td>
</tr>
<tr>
<td><strong>OI12</strong></td>
<td><strong>Community perception of public drug use</strong>&lt;br&gt;The proportion of local residents and business owners who have ever observed public drug use in the SIS neighbourhood; and, for those who have, time interval since the last observation of it and the number of times it was observed in the past month.</td>
<td>Source: A telephone panel survey of 150 randomly selected residents and 150 businesses conducted by a contracted market research firm at start-up and 2, 12, 21 and 30 months after start-up.&lt;br&gt;Storage: Community Survey database.&lt;br&gt;Responses will be tabulated and related to resident and business characteristics, e.g., proximity to the SIS. The size and significance of any changes in respondents’ views between survey occasions will be examined.</td>
</tr>
</tbody>
</table>
### 1.5.3.4 Drug Dealing and Other Crime

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data Collection</th>
<th>Core Analysis &amp; Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>OI13 Pedestrian traffic and loitering</td>
<td>Source: twice-daily counts made by an evaluator walking a specified route.</td>
<td>Graphical presentation of trends. Time series analysis.</td>
</tr>
<tr>
<td></td>
<td>Storage: Evaluation database.</td>
<td></td>
</tr>
<tr>
<td>OI14 Property crime</td>
<td>Source: Vancouver Police Department’s Uniform Crime Reporting (UCR) database.</td>
<td>Graphing of trends and comparison of areas.</td>
</tr>
<tr>
<td></td>
<td>Downloads every 6 months.</td>
<td></td>
</tr>
<tr>
<td>OI15 Perception of trafficking and other drug-related problems</td>
<td>Source: A telephone panel survey of 150 randomly selected residents and 150 businesses conducted by a contracted market research firm at start-up and 2, 12, 21 and 30 months after start-up. Storage: Community Survey database.</td>
<td>Responses will be tabulated and related to resident and business characteristics, e.g., proximity to the SIS. The size and significance of any changes in respondents’ views between survey occasions will be examined.</td>
</tr>
<tr>
<td>OI16 Injection Frequencies</td>
<td>Source: Panel interview survey of 300 SIS clients at start-up and 6, 12, 18, 24 and 30 months after start-up.</td>
<td>Repeated measures ANOVA to compare mean frequency of injecting drugs.</td>
</tr>
</tbody>
</table>
1.5.4 Economic Evaluation Methods

1.5.4.1 Cost-analysis

Perspective

The cost-analysis will be conducted from the perspectives of the VCHA.

Costs

Included in the estimation of the costs of the SIS program are all of the operating costs of running the SIS site including both fixed and variable costs. Fixed costs include rent/purchase of the site, hydro and other utilities; and additional maintenance costs. Appropriate economic methods will be utilized to account for the depreciation and obsolescence of fixed equipment (computers, etc). Variable costs include staffing costs (both administrative and operative), cost of all consumables broken down by item; and additional costs dependent upon level of usage.

Costs borne by other sectors of the VCHA for this program will include offsite management and ongoing planning of the program, ambulance, hospitalization, and home care. Hospitalization includes procedures, radiographic and laboratory tests, pharmaceuticals, and counseling. Home care would include outpatient treatment of infectious/physical complications secondary to injection drug use.

Data Collection and Sources

To assess fixed and variable costs associated with operating the SIS, all financial records for the SIS will be evaluated. Complete records for the SIS will be available to the VCHA as they are the sole funder of the program.

Additional costs that occur outside the SIS will be extracted from various sources. Since consent has been obtained to obtain information on a per patient basis, it will be feasible to extract the hospital emergency department visits for any patient treated at an SIS that is subsequently admitted to an emergency department from the provincial linked health database project. Databases that exist within the two major hospital emergency departments in Vancouver (SPH and VGH) will be utilized to identify whether the admission was secondary to substance abuse. Emergency Health Service (EHS - Ambulance and Paramedic) costs will be extracted directly from the EHS. Potentially, EHS employees will be recruited to participate in the data collection process which could include the prospective collection of resources utilized for clients who have experienced an overdose.

As described, costs will be further classified and recorded for both the injecting room and the non-injecting room services. The summation of these costs provides an assessment of the SIS program costs in total. Total, average and marginal costs per client will be examined for each section of the SIS and the SIS in total. Such costs will facilitate an understanding of differences in costs per client between sections as well as identify changes in cost for each additional client utilizing the service.

Start-up costs are a significant cost component and will be separately identified. It is recognized that start-up costs may well be greater for this service than for possible subsequent services, and this aspect will be considered in the costs analysis. Since a sizeable evaluation component will be built into the infrastructure of the SIS, these variable costs (for research staff) will be excluded from the cost analysis.
1.5.4.2 Cost-Benefit Analysis (CBA)

Justification for CBA Methodology

CBA can be thought of as providing a protocol for measuring allocative efficiency. Allocative efficiency refers to a situation in which resources, such as land, labour, and capital are deployed in their highest valued uses in terms of the goods and services they create. In CBA, both costs and benefits are specified in monetary terms. CBA compares the incremental program benefits with incremental program costs; the difference between these two streams being the net social benefit of the program. In terms of the SIS, this would involve the itemization of the specific benefits and costs related to the overall performance of the project.

The impetus for utilizing CBA methodology vs. cost-effectiveness methodology is multifactorial. Policy-makers may find the results of cost-effectiveness analyses difficult to operationalize (an incremental cost per outcome avoided) whereas the monetary outcomes associated with CBA lend to easy interpretation and comparability with alternative programs competing for VCHA funding. Whereas some of the outcomes of the SIS (i.e. human life) are inherently difficult to monetize, there are numerous sources of published data where these values have been estimated.

Perspective

The CBA will be conducted from the perspectives of the VCHA and from society. Thus, the societal perspective will result in a more comprehensive mix of costs and benefits whereas the VCHA perspective will look at items that specifically impact on their bottom line.

Comparator

The SIS program will be compared to the status quo that exists without the program.

Benefits

Specific health-related benefits provided by this program would include overdose deaths averted, overdose complications averted, hospitalizations averted, EHS service emergency room visits averted, reduced transmission of infectious diseases (HIV, hepatitis, etc), increased recruitment opportunity for drug counselling programs.

Non-health related benefits include increased productivity, a reduction in crime through the decentralization of the drug trade. These will be included in the CBA from the societal perspective.

In analyzing benefits that can be attributed to SIS operation, particular attention will be given to health care and other costs that have been avoided.
Costs

The specific cost categories to be considered have been previously detailed in the cost analysis section.

Data Collection and Sources

Most of the health-related benefits and the costs will be captured through the evaluation plan and will not require additional data collection. Non-health related benefits and some of the health-related benefits (reduced transmission of infectious diseases) would require modeling from data sources in the literature to estimate their impact and costs.

Discounting

Since the SIS will be piloted for a three-year period, some of the costs and benefits will be restricted to that time frame. However, others will be realized over several years (such as a reduction in infectious disease transmission). Both costs and benefits will be discounted at a generally accepted rate of 3% (however, a full range of sensitivity analysis will be employed to test these rates).

Sensitivity Analysis

To explore the impact of assumptions and uncertainty in the analysis, sensitivity univariate, multivariate and probabilistic analyses will be employed to ensure the robustness of the outcome.
### 1.5.5 Description of Data Sources

#### 1.5.5.1 Forms and Event Records Used in Operations

<table>
<thead>
<tr>
<th>Data Collection Tool</th>
<th>Types of Data Provided</th>
<th>Relevant Indicators</th>
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</thead>
<tbody>
<tr>
<td>Full Intake Form</td>
<td>Individuals seeking to register to use the SIS for the first time and who consent to participate in the outcome evaluation will be assessed by a trained interviewer—part of the evaluation team—who will complete this form. Content areas include a unique identifier (e.g., first name and first three initials of family name, date of birth, and gender), demographic details, general health and injection-related health information, injecting history and practices, drug and alcohol treatment history including previous overdose experiences. Blood samples will be taken from consenting clients at intake. These will be analyzed to provide baseline measures of HCV/HBV/HIV status. The unique ID number (SIS ID) is quoted by the client on subsequent visits and is used to monitor individual client use of services within the SIS. Clients will have the option of consenting (or not) to allowing the evaluators to link their data with data from specified other health data sources. Those who consent will be asked for their Personal Health Number (PHN).</td>
<td>P11</td>
</tr>
<tr>
<td>Short Intake Form</td>
<td>Individuals seeking to register to use the SIS for the first time and who do not consent to participate in the outcome evaluation will be assessed by the intake worker—part of the SIS staff—who will complete this form. Content areas include a unique identifier (e.g., first name and first three initials of family name, date of birth, and gender), demographic details, and general health information including HCV/HBV/HIV status if known. These participants will be part of the process evaluation only.</td>
<td>P11</td>
</tr>
<tr>
<td>Visit Form</td>
<td>Data are collected on every registered client wishing to use the injecting room. Fields include SIS ID Number, date, time arrived, postcode/suburb slept last night, admission outcome (i.e., admitted, refused, left premises), refusal reason (e.g., intoxicated, other unacceptable behaviour, on a 'Time Out'), referral (i.e. drug treatment service, social welfare agency, health service etc.), last drug injected, hours since last use, alcohol use today and number of drinks, pill use today and number of pills, drug(s) to be injected at SIS, needles in, and adverse events.</td>
<td>P17, P15</td>
</tr>
<tr>
<td>Injection Room Log</td>
<td>Fields recorded include: SIS ID, date, time in, time out, drug injected at SIS, supplies provided.</td>
<td>P17</td>
</tr>
<tr>
<td>Services &amp; Referral Log</td>
<td>Fields include: SIS ID, date, time, types of services provided at the SIS, relevant health history, referral destination(s).</td>
<td>P16, P19</td>
</tr>
<tr>
<td>Supplied Equipment Log</td>
<td>Fields include: SIS ID, date, time, number of needles provided.</td>
<td>P111</td>
</tr>
<tr>
<td>Adverse Event Log</td>
<td>Fields include: SIS ID, date, time, event category, outcome.</td>
<td>P118</td>
</tr>
<tr>
<td>Referral Follow-up Card</td>
<td>This is a tear-off portion of a referral letter to an external agency. It is stamped and addressed to the evaluation office. The only identifying data it contains is the client’s SIS ID. Agency staff stamp it with an agency stamp and record the date that the client arrived.</td>
<td>P110, P118</td>
</tr>
</tbody>
</table>
### 1.5.5.2 Instruments Used Primarily in the Evaluation

<table>
<thead>
<tr>
<th>Data Collection Tool</th>
<th>Types of Data Provided</th>
<th>Relevant Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIS Client Satisfaction Questionnaire</td>
<td>Ratings of service quality in terms of the 5 SERVQUAL dimensions: Tangibles (e.g., the appearance of the physical facilities); Reliability (e.g., the ability to perform the service dependably); Responsiveness (e.g., the willingness to help clients and provide prompt service); Assurance (e.g., security, credibility and courtesy); and Empathy (e.g., ease of access, approachability and effort taken to understand clients’ requirements).</td>
<td>PI14</td>
</tr>
<tr>
<td>VIDUS Questionnaire Supplement</td>
<td>Answers to items on awareness on SIS availability, frequency of use of the SIS, reasons for non-use, participation in drug treatment, recent injection behaviours, knowledge of safe practices, and injection-related health problems.</td>
<td>PI2, PI4, OI6, OI7, OI8</td>
</tr>
<tr>
<td>Injection Practices &amp; Health Questionnaire</td>
<td>Answers to items on recent injection behaviours, knowledge of safe practices and injection-related health problems.</td>
<td>OI7, OI8, OI16</td>
</tr>
<tr>
<td>Staff / Management Focus Group Protocol</td>
<td>Recorded comments about the operation of SIS, the work environment, work tasks, professional relationships, support and career development.</td>
<td>PI15</td>
</tr>
<tr>
<td>Inter-agency Focus Group Protocol</td>
<td>Recorded comments about difficulties and potential solutions in relation to coordina- tion of drug-related services for SIS clients.</td>
<td>PI19</td>
</tr>
<tr>
<td>Protocol Implementation Checklist</td>
<td>Responses to questions about the degree to which each area of the Protocol was being followed during a specified time period and suggestions about improvement of the protocol.</td>
<td>PI12</td>
</tr>
<tr>
<td>Local Resident Interview Protocol</td>
<td>Responses to questions about attitudes drugs, the social effects of drug use, (public) drug use in the DTES, possible solutions, perceived effects of SIS operation and ratings of neighbourhood safety, level of crime, drug-related debris, and trafficking.</td>
<td>PI16, OI11, OI12, OI15</td>
</tr>
<tr>
<td>Local Business Interview Protocol</td>
<td>Similar to the Local Resident Interview data with additional information on perceived effects on local businesses of (a) public drug use and drug-related debris and (b) the SIS.</td>
<td>PI17, OI11, OI12, OI15</td>
</tr>
<tr>
<td>Loiterer Observation Record</td>
<td>Results from two standard 30 minute ‘walks’ along a pre-determined route in the vicinity of the SIS designed to produce a twice daily count, both before and after the establishment of the SIS, of: (a) ‘loiterers’ at two sites typically frequented by drug users (identified by police and health workers) in the vicinity of the SIS (b) loiterers directly outside the front and back of the SIS; and (c) pedestrians. One of these walks would take place inside the opening hours of the SIS and one outside the opening hours. Beyond this constraint the precise walking times would be at different times so as to remove any temporal bias in the counts. To ensure objectivity, counts of all pedes- trians and loiterers are made. Exemptions from the counts of loiterers are: Tourists as indicated by carrying a camera or large backpack, or reading the currency exchange board; elderly people, clearly over age 65; children under 10 years, babies/toddlers in prams; and people sitting in cafés. To ensure the reliability of the counts, an independent researcher, separate to the team doing the counts, does ‘spot checks’ twice a week. These spot checks are to: (1) check that counts are being done; (2) check that procedures are being followed; and (3) obtain a measure of inter-rater reliability.</td>
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<td>Drug-Related Debris Record</td>
<td>Counts of needles collected within a specified geographic zone, date and time of count.</td>
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### Database Types of Data Provided Relevant Indicators

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<th>Database</th>
<th>Types of Data Provided</th>
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<td>Evaluation Database / PARIS</td>
<td>The Evaluation database will be constructed to store operational data about SIS clients and their visits to the SIS. When the VCHA’s PARIS system is ready to be used for SIS client registration and recording of services provided and referrals, data will be transferred to the new system.</td>
<td>P11, P12, P15, P16, P17, O16, O17, O18, O116</td>
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<td>Ambulance Services Records</td>
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<td>VIDUS Database</td>
<td>Cohort members’ responses to questions on injection drug use, injection drug behaviours, other drug use, police activity, incarceration, sexual activity, drug / alcohol treatment, violence, service utilization and health issues.</td>
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<td>MSP Database</td>
<td>Reason for physician visit (diagnosis), type of service, specialty code, service location code, referring physician code.</td>
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<td>ER Databases</td>
<td>Date and time of service, diagnostic codes, services provided, discharge status.</td>
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<td>BCCDC database</td>
<td>Records of new infections from test results.</td>
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<td>Hospital Discharge Abstracts Databases</td>
<td>Diagnostic codes, procedure codes, physician identifiers, length of stay, discharge status.</td>
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<td>Police UCR Database</td>
<td>Date, time, location and type of crime.</td>
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1.5.6 Data Collection Timelines

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1.5.7 Further Outcome Analyses and Considerations in the Interpretation of Findings

1.5.7.1 Overdose Deaths

In determining the appropriate form of statistical analysis of overdose death data, a number of important factors need to be considered. The main issue relates to inevitable month-to-month variation in the overdose death rates (Cook and Campbell 1979). The variation is due to: (a) the continued growth of heroin and cocaine use in Vancouver; (b) the regular annual seasonal trends in heroin use and overdose events (Degenhardt, Hall et al. 2000); and (c) any random monthly variation; and (d) any independent historical events such as changes in police/heroin dealer activity, change in heroin availability, drug switching and / or change in the preferred method of drug intake, change in the operation of ‘shooting rooms’, or a change in the number of users in the area due to any “honey pot”, or other effects from the time of the introduction of the SIS.

Allowing for such variation, and given the low rate of deaths prevented by a single SIS, there may be too little an effect on opioid overdose deaths from the SIS to be observable in the raw data. Therefore, sophisticated statistical analysis will be required. An interrupted time series analysis could potentially detect a change in the rate of overdose death achieved by a SIS. However, this analysis may not successfully detect such change for a number of technical reasons. Even if the seasonal effects and other correlated variance in the death rate data could be removed, the base rate of death per monthly time period may be low. (It seems appropriate to use monthly periods for any analysis of death rates.) It may prove that the SIS cannot impact sufficiently on the heroin overdose death rate within the area of the SIS sufficiently to show a statistically detectable effect using an interrupted time series analysis, within the evaluation period.

An alternative analysis would be to employ a Poisson regression, which is indicated for rare count data, using a simple pre-post approach comparing the DTES to another part of the city. The difficulty with this approach is defining what the denominators would be, for example, the overall populations in the defined areas using census counts or PEOPLE estimates, or estimates of the number of IDUs in each area based on capture-recapture methodology.

On the basis of the foregoing reasoning, any formal statistical analysis of overdose death data for the DTES to determine the impact of the SIS needs to be informed by the possibility that the effect of the SIS on death rate will not be easily detectable. Thus, it is planned to supplement the analysis of overdose deaths with an analysis of ambulance and hospital Emergency Room data concerning overdose events (see below).

1.5.7.2 Ambulance Service Records of Overdose Events

Ambulance service data are collected whenever an ambulance is requested for a person who has experienced a drug overdose. In theory, this should be a thorough record of the occurrence of serious overdose events. There is probably an order of magnitude difference between the rate of overdose death and the rate of overdose events where ambulance officers administer naloxone after an overdose has occurred. As such, these data provide a better basis to detect a change in opioid-related overdose events than the rate of overdose death.
Assuming that data series from a sufficiently long baseline period are available—at least three years—two interrupted-time series analyses will be undertaken. The first will use a nonequivalent no-treatment control region (e.g., Surrey or Burnaby / New Westminster), and the second will be an interrupted time series with multiple replications (Cook and Campbell, 1979). The multiple replications analysis would use the SIS hours of opening and closure to look for patterns in ambulance calls.

The following variables should be collected for patients where a drug overdose and use of poisoning protocol, or administration of naloxone has occurred: ambulance case number, incident number, first crew (yes/no), date of attendance, sex, age, residential address, address of attendance, location (type of place of attendance), time booked, time out, time location, time departure, time destination, time clear, Glasgow coma scale, pupil size, all patient management variables (i.e. airway, breathing, circulation, oxygen therapy, protocols, drugs/fluids, any other consumables used) and Attending Officer level. Some of these variables will be relevant to the cost-benefit evaluation (described in Section 1.5.4.2).

The analysis should use at least a one-month period as the minimum unit of analysis, as a briefer time period will have too few events to allow for detection of change in a time series analysis. The analysis undertaken will attempt to ensure that parametric assumptions have been met, and log transformations will be carried out if these assumptions are violated.

1.5.7.3 Emergency Department Attendances for Overdose Events

Emergency Department treatments of overdoses will also be much more numerous than overdose deaths, and data may be more readily available than Ambulance Service data. (The former will be particularly useful if links can be established with SIS client records for the majority of SIS clients.)

Time series analyses will be attempted as described above.

1.5.7.4 Newly Diagnosed Blood Borne Virus Infections

It will probably be difficult to detect an effect of SIS operation on occurrences of new infections from HIV or hepatitis C for several reasons including the following:

- It is likely that most of the adult SIS users will already have contracted hepatitis C resulting in no “room” for measurable change.
- If Australian utilization patterns occur in Vancouver as well—e.g., an average frequency of use of the facility of once per month—the intervention may not be “powerful” enough to effect change in risk for many users.

An effect might be observed in a young subgroup of SIS clients, say those aged 14 to 18, but this will depend on their usage patterns. If the number of such clients is small, statistical power to detect effects will be low.
1.5.7.5  Effects on Injection Practices Bacterial Infections

Clients’ use of the SIS services—particularly counseling and education about safe injection—may lead to a measurable improvement in injection practices. Clients’ responses to survey interview questions about injection practices will be modeled in terms of extent of use of SIS services, particularly injection education, with adjustments made for differences in demographic and other factors.

Changes in injection practices may in turn result in a detectable change in the occurrence of bacterial infections such as abscesses and infective endocarditis. Trends in hospitalization and ER use for these conditions will be examined in relation to data collected on SIS utilization, and clients’ self-reports about their health conditions (and SIS staff observations of abscesses) will be modeled in relation to injection practices with adjustments for other factors.
1.6 Ethics, the Evaluation Committee, Data Management and Reporting

1.6.1 Data-Related Ethics

This evaluation plan together with copies of all questionnaires/forms and the Client Consent Form will be submitted to the Ethics Committees of St. Paul’s Hospital and the University of British Columbia for approval.

The evaluators will obtain the necessary data custodian approvals and commit to the required confidentiality agreements to use data from the following sources: the Coroner’s Office, the St. Paul’s and Vancouver Hospital Emergency Departments and Health Records Departments, the Medical Services Plan and the B.C. Ambulance Services.

Provisions of British Columbia’s Freedom of Information and Protection of Privacy Act will be followed.

1.6.2 The SIS Evaluation Steering Committee

The work of this evaluation will be monitored and assisted by a SIS Evaluation Steering Committee (SISESC). Members of this committee will include: Dr. Michael O’Shaughnessy (Chair), Drs. Michael Hayes and Ray Corrado (Simon Fraser University) Dr. John Anderson (B.C. Ministry of Health Services), Drs. Thomas Kerr and Mark Tyndall (B.C. Centre of Excellence in HIV/AIDS) and Ms Fiona Gold and Dr. Michael Rekart (B.C. Centre for Disease Control), and Chris Buchner and Heather Hay (Vancouver Coastal Health Authority).

The responsibilities of the SISESC include the following:

- Reviewing detailed plans for components of the evaluation in terms of methodological soundness and practicability;
- Monitoring implementation of the evaluation components to ensure that data collection, analysis and reporting activities progress on time and on budget;
- Resolving methodological issues and adjusting the evaluation plan as needed; and
- Reviewing and editing written reports of findings.

1.6.3 Data Management and Ownership

An Evaluation Coordinator and associated consultants and/or research assistants will be responsible for the collection, synthesis and analysis of the data for the various indicators, with the assistance and guidance of the SISESC. SISESC will permit the release of data and/or presentation of results of analyses only with the approval of the SIS project’s Provincial Steering Committee.

The Evaluation Coordinator will undertake ongoing monitoring of data quality, especially of data collected for the process evaluation. The evaluation/PARIS database will be queried weekly and checked for completeness, errors and internal coherence. Any operations-related data quality issues will be raised with SIS management and staff according to standard monitoring procedures. All such
issues raised will be consecutively numbered written memoranda. A copy will be sent to the relevant SIS or other staff member, a second will be held on the Evaluation Coordinator’s file, and a third will be lodged and registered in a central (SISESC) file. A paper trail of the resolution of these issues will be kept available for independent audit purposes. Issues should be resolved within a reasonable period, usually one week of being raised, by the SIS or other staff who collected the data. SIS staff will be oriented to the databases and data collections occurring at the SIS, and will be required to assist in these data collections and in issue resolution.

Data ownership resides with the commissioning body, the Vancouver Coastal Health Authority, which gives permission to the SISESC to use and include any and all of the data in the reports set out below.

1.6.4 Reporting

The evaluators will provide monthly updates on the process evaluation to the SIS Evaluation Steering Committee (SISESC) and SIS management and staff. These reports will include detailed information on any adverse events that may occur at the Centre.

Formal progress reports to the VCHA will be available at one, three, six, 12, 18, 24, 30 and 36 months. Interim analyses for these reports will be restricted to indicators relating to the process evaluation. No verbal or written reports of these data can be made by any party (including manager and staff of the SIS) except the SISESC without the express written permission of the Steering Committee members.

There are no planned progress reports or interim analyses in relation to the impact evaluation or economic evaluation.

The final Evaluation Report with be available within six months of end of the 36-month trial period. The final text and content of the report is the responsibility of the SISESC members. Members will have access to any and all of the data generated from the evaluation to write-up the results for a report to the Vancouver Coastal Health Authority / Health Canada and for publication in peer-reviewed journals or similar forums.

This project will generate a large amount of data. The interpretation of the data will require careful consideration and discussion by the SISESC members. It is possible there will be alternative explanations or interpretations of the results, and these will be reflected in the final report. In the event of dissenting views occurring within the Steering Committee, these views will be clearly recorded within the final report.

Staff of the VCHA / Health Canada do not have a right of veto over any of the content of the report. The Steering Committee, however, will not unreasonably ignore any requests for revision of the report, where such revision improves the clarity and content of the report.

The Steering Committee may choose to have drafts of the final Evaluation Report and any report (or a series of reports) for peer-reviewed publication, reviewed by suitable persons or organizations nationally or internationally, as a part of the writing of the reports.
1.7 References


Federal / Provincial / Territorial Advisory Committee on Population Health, (February 2001) Reducing the Harm Associated With Injection Drug Use in Canada Working Document for Consultation


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exchange and other service provision. Paper presented at the meeting of the American Society of Criminology, San Francisco, CA.


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