NAOMI RESEARCH SURVIVORS: EXPERIENCES AND RECOMMENDATIONS

By: The NAOMI Patients Association and Susan Boyd

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The NAOMI Patients Association (NPA)
Participant Support and Advocacy

In January 2011, Dave Murray organized a group of participants from the North American Opiate Medication Initiative (NAOMI) heroin-assisted treatment clinical trials from 2005 to 2008 in the Downtown Eastside of Vancouver (DTES), B.C., Canada.

The NAOMI Patients Association (NPA) is an independent group that currently meets every Saturday at Vancouver Area Network of Drug Users (VANDU). Currently, all members of the NPA are former participants in the heroin stream of the clinical trials. The NPA is associated with the British Columbia Association of People On Methadone (BCAPOM). The NPA offers support, education, and advocacy to its members. The NPA has reached out to all former NAOMI participants in the heroin stream of the clinical trial. Although attendance at weekly meetings varies, the highest attendance at a meeting was 44 members. On average, 15 members gather each week.

NPA Mission Statement

We are a unique group of former NAOMI research participants dedicated to:

- Support for each other
- Advocacy
- Educating peers and the public
- Personal and political empowerment
- Advising future studies (heroin and other drugs) and permanent programs

- Improvements in consent and ethics
- The right to a stable life and to improvement in quality of life

Our goal is to have alternative and permanent public treatments and programs, including heroin assistance programs.

NAOMI Patients Association Study

In May 2011 the NPA decided to undertake their own research about their experiences as NAOMI research participants. They were particularly interested in recording their experiences during and following NAOMI and making recommendations for other heroin and drug substitution research experiments and programs. They met with Susan Boyd, a drug policy researcher and activist, in the spring of 2011 and decided to work together to conduct focus groups, individual interviews, brainstorming sessions, and writing workshops with NPA members. NPA members also wished to write a report about their experience.

This Report draws from the brainstorming sessions and focus groups that were conducted in the summer of 2011 and writing workshops conducted in the fall of 2011. In addition, NPA members submitted writing at meetings from April to November 2011. At the NPA writing workshops that were held during weekly meetings, members wrote poems and short essays about their lives. The research project received ethics approval from the University of Victoria, B.C. All NPA participants were granted confidentiality and anonymity and signed a consent form prior to participating in the focus groups. However, all NPA members insisted that their first name be included on their written work included in this Report. At the first focus group, the NPA members identified

several topics they wanted to discuss in later focus groups. Each focus group was audiotaped and transcriptions were made. After careful reading and coding of the transcripts, five primary themes were identified:

- Beneficial outcomes of being a participant in NAOMI
- Problematic outcomes of being a participant in NAOMI
- Ethics and Consent
- Creative writing/Everyday life
- Recommendations for other research projects and programs

This Report highlights the experiences of the NPA members in their own words. The themes identified above are expanded upon in these pages. The stories in this Report provide a lens to understand how people addicted to narcotics navigate their lives in and outside of the DTES and how becoming a research subject for the NAOMI project impacted their lives, both positive and negative. The first section of the Report introduces readers to the DTES and a number of ethical issues, including the impact of research conducted in the area. This section is followed by guidelines and principles created by VANDU and NPA members for researchers working in the DTES and elsewhere, and for future drug substitution studies and programs . The next section provides a brief history of heroin-assisted treatment and the circumstances that led to the NAOMI clinical trial. Following are stories, quotations, and poetry through which the NPA provides insight into the lives of their members during the NAOMI research project both within and outside of their role as drug users and research subjects. Finally, this Report concludes with the hope that future research will benefit from the experiences and reflection of the NAOMI participants.

The Downtown Eastside, Research and Ethics

NPA meetings take place at VANDU, on East Hastings Street in the DTES. The NAOMI clinic was also located in the DTES. Although it was not always so, today the Downtown Eastside of Vancouver is Canada's poorest urban neighbourhood. About 16,000 people live there. It is a racially diverse population of Aboriginals, Asians, Latinos/as and Caucasians. The DTES has a number of single-room occupancy (SRO) establishments and a visible street scene. The street scene is directly related to cutbacks at the federal, provincial, and local levels, leading to poverty and a lack of social housing and private space. Gentrification of the area has also made it more difficult for long-time residents to find safe, permanent, and affordable housing. For women, the DTES is also the site of much violence, often linked to the sex trade, but more generally, to everyday life. The negative outcome of drug prohibition, the criminalization of heroin, cocaine, and other drugs, is played out on the streets daily. Prohibition fuels an illegal market and, unlike in more privileged neighbourhoods, drug use and selling is more visible on the street in the DTES instead of hidden behind closed doors. This situation makes people more vulnerable to unwanted police attention and prison time, and sometimes drug-related violence.

It is well documented that drug prohibition, a reliance on the criminal law to eliminate illegal drug production, selling, and use, has worsened the health and well-being of drug users. The results of prohibition include increased imprisonment and the undermining of health services, including prevention and treatment services that would

more effectively counter HIV and Hepatitis C epidemics and drug overdose deaths.[1] Effective countermeasures are undermined. (For example, Insite, the safer injection site in Vancouver, was challenged by the federal government which actively sought to close it down and challenged its legitimacy in court despite scientific evidence demonstrating its effectiveness.) Meanwhile, prison and police/RCMP budgets expand. Prohibition also fuels social and legal discrimination and stigma, and the marginalization of people who consume illegal drugs. Law enforcement and civil initiatives over the last 100 years have led to increased incarceration, prison building, and the infringement of human rights. Recently in Canada we have seen a rush by the Conservative federal government to enact mandatory minimum sentencing for some drug offences. The individual and social costs of this bill will be immense: families will be torn apart when parents are sentenced to prison; children will be apprehended by the state; and the loss of income for families will leave many destitute. At the NPA we see daily that it is the poor and marginalized who suffer the most under prohibition; they, not an imagined "drug king pin," are arrested, convicted, and sent to prison. Yet, prohibition is not uncontested. In the 1990s activists in the DTES came together to challenge the status quo.

The DTES gained national and worldwide attention in 1997 when a public health emergency was declared in response to the growing rates of HIV, Hepatitis C, and overdose deaths in the area. Stemming from those events, community activists played a major role in a social movement for change in the DTES, demanding an end to drug

[1] Room, R., & Reuter, P. (2012). How well do international drug conventions protect public health? *Lancet*, *379*, 84-91.

prohibition, more social supports, and the establishment of more harm reduction services, such as a safer injection site.

VANDU also emerged in 1997, the first drug user union in Canada. VANDU has long advocated for their members and for change in the DTES and to Canada's drug laws and policy. Due to these efforts and those of other community activists, the DTES has witnessed some changes since 1997. VANDU secured a permanent site and offers support, education, and advocacy for group members. Needle exchange expanded; the first safer injection site, Insite, opened its doors in 2003 and a heroin prescription trial, NAOMI, opened its doors in 2005. Yet, for many residents, especially people who consume illegal drugs such as heroin and crack, the social conditions of their lives barely changed. Lack of housing, poverty, criminalization, violence, drug prohibition, and discrimination continue to shape the lives of people living in the DTES.

At the same time that activists in the DTES have striven to improve the conditions of people's lives in the area and to advocate for change, health and social science researchers began to conduct studies in this area and many of the residents became research subjects. Many of these studies made clear empirically what the residents already knew: a myriad of health and social factors detrimentally shape the lives of people in the DTES.

NPA members wanted to conduct their own research, in part because they had participated as research subjects in the NAOMI trial. However, for many NPA members, the NAOMI trial was not the first study in which they had participated. In the Downtown Eastside of Vancouver, one of the only ways to access services or to make ends meet is

to become a research subject. Research honorariums, bus passes, and stipends, and for a short period, access to unadulterated legal heroin, are now familiar exchanges in the DTES.

In 2005, the Canadian HIV/AIDS Legal Network published, "*Nothing About Us Without Us" – Greater, Meaningful Involvement of People Who Use Illegal Drugs: A Public Health, Ethical, and Human Rights Imperative*. This booklet responded to the negative impact of programs and research studies on people who use illegal drugs, including the participants' exclusion from the development of studies, programs, and services. This booklet includes a manifesto by people who use illegal drugs: the authors recommend greater involvement of people who use drugs in the programs and services that affect their lives, as well as in broader policy and advocacy work on HIV/AIDS and Hepatitis C.

The issues surrounding research, ethics, and exploitation have long interested drug user groups and activists because they have themselves become research subjects or witnessed others participating in trials and studies. Dara Culhane, a researcher and long-time resident in the DTES, also critiques the ethics of some of the research conducted in the DTES. She is critical of "data-mining," which she defines as "researchers using research subjects principally as means to researchers' ends." She argues data-mining has become a "central dynamic in everyday encounters between research*ers* and researche*d*" in the DTES even though residents have strongly protested against these interventions. In the section below we draw extensively from Dara

Culhane's recent 2011 article published in *Anthropologica*.[2]

Culhane notes that the DTES has become an "internationally renowned centre for medical and pharmaceutical research on HIV/AIDS and addiction" dating back to the public health crises in 1997. She explains that along with harm reduction services came clinical trials (including NAOMI) and studies to prove their effectiveness and thus, "a research industry expanded dramatically" in the DTES. Yet the social conditions of people's lives there have for the most part worsened.

Culhane questions the role of many marginalized people in the DTES "to serve as research subjects" in varied social science studies, clinical trials, and art projects. She argues that for marginalized people, "access to public support and private philanthropy increasingly demands performing" and telling one's story in exchange for "food, housing, health care, attention, affection, compassion and belonging." Researchers, of course, benefit from "grants, publications, tenure and promotion." Culhane writes that the stories told are true and the pain they reveal is real. Many DTES researchers try hard to be ethical; however, the conditions of poverty and exploitation in which studies take place challenge researchers to find ways to support research subjects' autonomy and self-determination within projects themselves and within society as a whole.

Because people living in the DTES need income and services, these needs shape how their stories are told to researchers. Responding to these events in the DTES, the

[2] Culhane, D. (2011). Stories and plays: Ethnography, performance and ethical engagements. *Anthropologica, 53*, 257-274.

NPA decided to conduct their own research, to tell their own stories, in their own words. The issues of participation, ethics, and consent were discussed by the NPA. In these pages the NPA asks their readers: how can there be consent to participate in studies, to tell one's story, including the NAOMI clinical trial, when the social conditions of people's lives are so compromised? How can research be initiated and guided by the experiences and knowledge of those most affected by drug prohibition? The NPA members speak to these issues and others in the following pages. In the fall of 2011, VANDU, including members of the NPA, created further guidelines and principles for researchers working with VANDU and the NPA. VANDU's guiding principles are followed by NPA's recommendations for future experimental drug maintenance studies and programs.

Research and Drug User Liberation

Research and the Drug War:

- The drug war didn't start because of a lack of research or "bad" research and we don't think it will end because of "good" research. The active struggle of people oppressed by drug war policies and fighting for their liberation will be the decisive factor in ending the drug war. Researchers can play a positive role when they act as supporters, allies and partners of this movement for liberation.
- Research is political. Research is shaped by funding, by the career aspirations of researchers, by the political tendencies of research institutions, by government funding and intervention, by peer pressure and by class, racial and gender biases.
- The relationship between the researcher and the researched is not in and of itself empowering or liberating. It only becomes so when organized movements of the oppressed group play an active role in shaping and carrying out the research.
- Researchers should leave the organizations of oppressed people that they work with stronger than when they came in; if they don't, they are part of the problem and not part of the solution.

Principles for Researchers Working with VANDU:

1. Research should be consistent with our principles of achieving social justice.
2. If researchers want to work with us they should really become allies of our movement. That means supporting our movement with your research but also as a citizen!
3. Please familiarize yourself with the VANDU website, mission statement and other materials to try to understand our work before you ask us to participate in your research project.
4. We (VANDU Board) want to know where every cent of funding is coming from and where it is going (financial transparency).
5. VANDU members must be included whenever research we were involved in is presented.
6. VANDU representatives who participate in research should be supported to develop research skills and know-how. Please make an effort to include VANDU members in various ways consistent with their unique capacities.
7. Where the "peer" involved in the research has capacity, try to involve them in all aspects of the research, not just one small part.
8. Researchers should make an effort to democratize the language you use, by using plain language and respecting that people who use drugs are whole human beings, not just research subjects.
9. We want to see the research – in progress – to give feedback.
10. Present us with an explanation and action plan on how the research will contribute to the empowerment and liberation of people who use drugs.
11. If you are a researcher and you say that you are on the side of the oppressed and that you want to make positive changes, your first responsibility (as a researcher) is to meet with the most representative, democratic and active organization of the oppressed group to make sure that your research supports their work, or ask how it can.
12. Being involved in the research should move more people into action and strengthen the existing organizations of the oppressed.

NPA Recommendations for Future "Experimental" Drug Maintenance Programs

The NPA recommends:

When experimental drug maintenance programs are over, clients (research subjects), for compassionate reasons, should receive the drug they were on as long as they need it.

An ideal study would provide an umbrella of support and services:

- Housing (most important)
- Access to medical treatment all under one roof (nurses, family doctors, dentists, etc.)
- Access to welfare workers (who are familiar with the area and the people who live there) and Ministry representatives
- Access to nutritious food for self and family
- Support to move life forward (school, trade, family unification)
- Access to lawyers
- Education/advocacy skills and access to advocates
- Diverse routes of administration available—oral, smoking form, injection. Not all people want to inject their drug.

An ideal study would utilize the time clients (research subjects) spent on site, three times a day. Use the time to support, educate, and advocate.

All future studies and programs should include NPA and other heroin users as part of the team from the beginning.

The NPA has adopted the words below to further guide their own research. They are written by long-time DTES activist Sandy Cameron from his poem, *Telling Stories*.

Telling Stories

We need to tell our own stories.
If we don't tell our stories,
people with power
will tell our stories for us.

It is from this place that the NPA began their own research, to tell their own story in their own words.

A Brief History of Heroin-assisted Treatment

All of the NPA members were research subjects in the NAOMI clinical trial in Vancouver. The following section outlines briefly the history of drug maintenance therapy and the circumstances that led up to the NAOMI trial, followed by a summary of the research findings of the NAOMI trial.

Prior to the criminalization of narcotics in Canada in the early 1900s, opiate (and opiate derivatives) use was acceptable in society to treat a wide range of illnesses. Opium is made from the opium poppy. It is one of the oldest drugs recorded, the parent of all other narcotics. It was an important item of commerce and used widely for medical purposes. In the 1700s and 1800s, settlers to Canada brought opium remedies, patent medicines, and elixirs to treat illness. Most settlers could not afford the services of a doctor; nor were doctors available in rural areas, which made up most of Canada

then. Although Aboriginal healers had their own array of remedies, the practices of colonization led white settlers to eventually reject Aboriginal medicines and to use drugs with which they were already familiar, including a wide array of oral patent medicines that were made available at stores and through mail order at Eaton's and Sears, Roebuck and Company. Doctors heralded these drugs (opium, cocaine, and marijuana) in liquid form for their healing properties to control coughing, address gastro complaints, and treat severe pain. Opiates were advertised to appeal to women as caregivers to their families. In Canada, Britain, and the U.S., it was quite common for households to contain patent medicines and remedies that included opiates. In fact, prior to the criminalization of opium and heroin, the typical persons using opium or its derivatives, such as Laudanum, were law-abiding middle and upper class white women. However, what was once considered a personal matter shifted in the late 1800s and early 1900s. In 1803, morphine was isolated from opium. This was the first time in history that a chemical compound was extracted from a plant. This event led to other scientists and pharmacists experimenting with an array of plant compounds, and eventually to the creation of synthetic drugs and our modern day pharmaceutical and chemical industry. Heroin is a derivative of morphine. It is more potent than morphine in that it produces the same effect but with smaller doses. Heroin was marketed by Bayer Pharmaceutical Products in 1898. Early on, it was popular as a cough suppressant; its popularity and medical applications were illustrated by the advertisements for its use that appeared in medical journals in the early 1900s.

For the purpose of this Report, we only wish to point out that opiates and opiate derivatives were in common use in Canada prior to Canada's first narcotic legislation, the Opium Act of 1908 and the Opium and Narcotic Act of 1911. The Opium Act was not enacted because of evidence that opiates caused physiological harm; rather it was enacted to control the Chinese Canadians in western Canada, and its original focus was on the sale and manufacture of smoking opium and not the array of liquid-based opiate drugs that white settlers consumed. From their inception, Canada's drug laws have been racist, class-based, and gendered in their formation and application. It was assumed that the Opium and Narcotic Act, for example, would not be applied to white middle-class citizens. The Act was passed and subsequent amendments criminalized other drugs. As the schedule of prohibited drugs expanded, so did penalties and police/RCMP budgets over the years. The most prominent feature of Canada's drug policy over the last century has been a reliance on the criminal law, also called "prohibition."[3] These laws were enforced by the RCMP and other police forces in Canada. Police and RCMP also became key initiators of harsh drug policies.

Following the criminalization of opium, heroin, and a number of other drugs in the early 1900s, a new group of citizens became criminals and they had few options for obtaining legal and illegal narcotics. Unlike doctors in the U.K., Canadian doctors did not retain the right to prescribe narcotics for maintenance purposes and no publicly funded drug maintenance programs were set up. In the 1920s, the police focused on arresting

[3] Oscapella, E., & Canadian Drug Policy Coalition Policy Working Group (2012, February). *Changing the frame: A new approach to drug policy in Canada*. Vancouver, B.C.: CDPC. Retrieved February 10, 2012, from http://www.drugpolicy.ca

and deporting Chinese Canadian residents convicted of possessing opium in smoking form and closing down opium dens. Eventually police attention shifted to white narcotic users, especially those who were poor and working class. As the opium dens closed, narcotic users switched to other drugs such as heroin bought on the illegal market. Prison time was often their fate as Canada's drug laws became more and more harsh. In the 1940s the RCMP coined the phrase "criminal addict" to describe people addicted to illegal drugs. They wanted to make clear that first and foremost, these people were criminals; the RCMP promoted the idea that addiction was secondary and stemmed from having a "criminal lifestyle." The RCMP were vehemently opposed to drug maintenance therapy. Abstinence and prison time were touted as the solution to addiction to narcotics. By the 1950s medical doctors gained new ground and psychiatric treatment in prison emerged as one response for new narcotic users.

Another perspective began to emerge in Canada in the 1950s, a drug treatment movement centred in Vancouver. Doctors, social workers, politicians, and concerned citizens rallied for change, including the setting up of drug maintenance programs for people addicted to narcotics. Although they were not completely successful at that time, a number of small programs were later set up in Canada. These programs included limited methadone maintenance programs and some drug treatment programs in prisons, the most famous at Matsqui prison in B.C. It was not until the early 1970s that publicly funded methadone maintenance programs and drug treatment programs and other services became available throughout Canada, and even then rural areas did not have services.

Narcotic users have long questioned why heroin is illegal and why it is not offered as a choice for drug maintenance. From the 1970s on, methadone became the standard treatment in Canada for people addicted to narcotics and this treatment was expanded in B.C. in the late 1990s. Yet right from its inception, it was clear that methadone maintenance does not work for everyone. Research and later drug user groups made it clear that many narcotic users do not benefit from methadone therapy and many participants drop out or are kicked out of treatment for not complying with rigid regulations. Rather than methadone maintenance, people who participated in these programs requested heroin. But their requests fell on deaf ears.

However, heroin prescription is not unusual: the U.K. has long had heroin prescription as part of their addiction treatment services, and in the U.S., a number of heroin/morphine clinics were opened following prohibition. These public clinics were eventually closed down as the U.S. moved towards a more prohibitionist and criminal law model of drug policy and, at that time, little else was put into place to help people addicted to narcotics except prison programs such as Lexington.

In the early 1950s, the *Senate Special Committee on the Traffic in Narcotic Drugs in Canada* visited Oakalla prison farm in Burnaby, B.C. This committee noted in its report that "without exception" all of the former narcotic users in the prison group advocated for the "legalized provision of drugs." [4] The report also pointed out how medical and professional "addicts" were treated differently in Canada. From 1928 to the early 1970s,

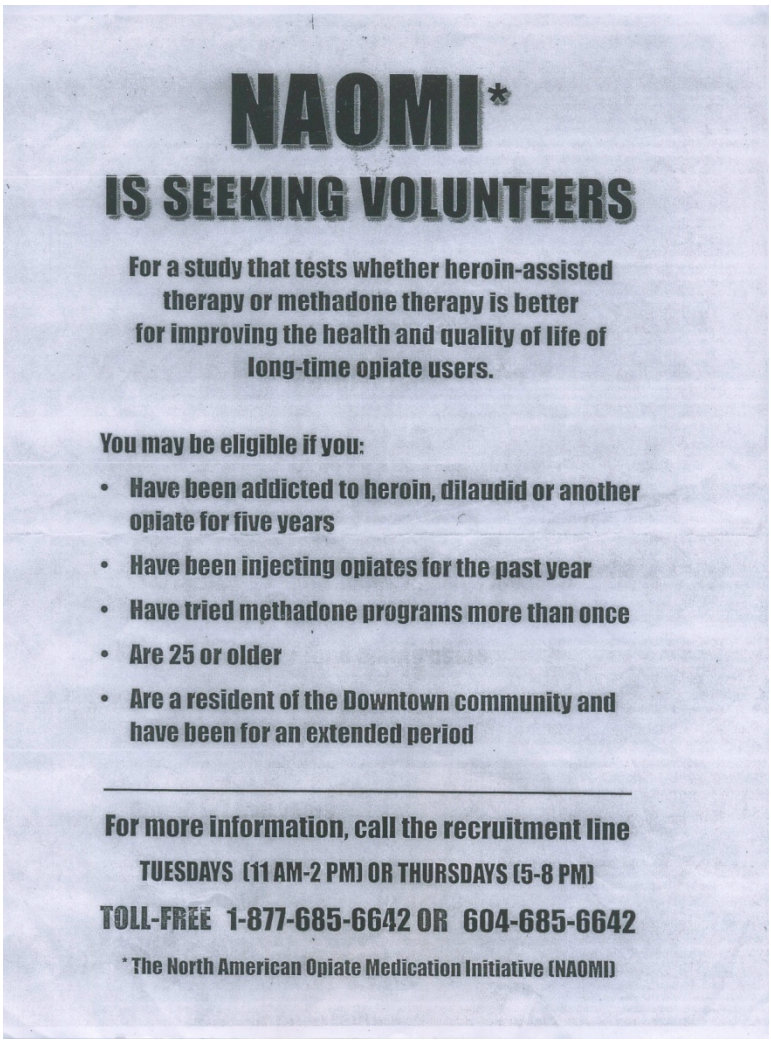
[4] Senate (1955). *Proceedings, Special Committee on the Traffic in Narcotic Drugs in Canada*, p. 244.

the Division of Narcotic Control (within the Federal Department of Health) kept a registry and case files on every known illegal drug user in Canada, whom they referred to as "criminal addicts." Each file contained police reports, photos, criminal records, and memos and letters from doctors, prosecutors, and parole boards. Every arrest for narcotic possession or trafficking was noted in the files. The police also included notes from drug trials to inform the RCMP and special prosecutors about testimony and trial outcomes. Whenever the department found out that a known drug user was obtaining drugs from a doctor, they set out to investigate. A separate filing system was kept for medical professionals (doctors, nurses, pharmacists) known to use narcotics; yet to date, these files are unavailable and no researcher has been able to access them.[5] Most significant for the purposes of our Report, the two categories of narcotic user were treated differently: prison time was handed out to those labelled criminal addicts, and at the same time, medical professionals received private treatment and cautions.

There is a long history of advocating for people who use criminalized drugs, including legalizing narcotics in Canada and setting up alternative drug maintenance programs, such as heroin therapy. In the 1990s, Switzerland implemented heroin-assisted treatment (HAT) in several cities. The success of the Swiss program led to many other countries adopting similar models, including Germany, the Netherlands, Spain, Belgium, and Denmark. There is now a "rich data set on the feasibility, efficacy, safety

[5] Carstairs, C. (2006). *Jailed for possession: Illegal drug use, regulation, and power in Canada, 1920-1961*. Toronto: University of Toronto Press.

and effectiveness of HAT."[6] In 1998, the first North American Opiate Medication Initiative (NAOMI) Working Group was formed to conduct a HAT trial in the U.S. and Canada. Because it was not possible to get a U.S. site for the trial, Canadian investigators applied for a 3-site study in Canada. Full funding approval was granted by the Canadian Institutes of Health Research (CIHR) in 2002 and NAOMI eventually opened its doors in only Vancouver and Montreal.



NAOMI*

IS SEEKING VOLUNTEERS

For a study that tests whether heroin-assisted therapy or methadone therapy is better for improving the health and quality of life of long-time opiate users.

You may be eligible if you:

- **Have been addicted to heroin, dilaudid or another opiate for five years**
- **Have been injecting opiates for the past year**
- **Have tried methadone programs more than once**
- **Are 25 or older**
- **Are a resident of the Downtown community and have been for an extended period**

For more information, call the recruitment line

TUESDAYS (11 AM-2 PM) OR THURSDAYS (5-8 PM)

TOLL-FREE 1-877-685-6642 OR 604-685-6642

*** The North American Opiate Medication Initiative (NAOMI)**

[6] Blanken, P. et al. (2010). Heroin-assisted treatment in the Netherlands: History, findings, and international context. *European Neuropsychopharmacology*, *20* (Supplement 2), S105-S158

NAOMI

In 2005 posters went up on telephone poles and walls throughout the Downtown Eastside of Vancouver, with a telephone number to contact the NAOMI research people. The North American Opiate Medication Initiative (NAOMI) was a clinical trial that tested whether heroin-assisted therapy benefits people suffering from chronic opiate addictions who have not benefited from other treatments. The clinical trial was funded by the Canadian Institutes of Health Research (CIHR) and approved by Health Canada. The study enrolled participants in Vancouver and Montreal.

The NAOMI trial began enrolling people in February 2005 in Vancouver, B.C.

The target population for NAOMI included men and women over the age of 25 who were "chronic, opioid dependent, daily IDUs" and who had previously been unsuccessful with methadone maintenance and other treatment modalities. Participants in the NAOMI study were randomized into one of two groups: one received injections of heroin or Dilaudid (hydromorphone), and the other received oral methadone. The NAOMI study provided heroin/Dilaudid for 12 months, followed by a 3-month transition period. When they entered the study, participants were not currently on methadone maintenance therapy (MMT) and had to be off MMT for at least six months prior to participating in NAOMI. Apparently this criteria for entering the study was added after response from Canadian health authorities and MMT providers who were worried that their patients would drop out in order to participate in NAOMI.[7] This is the opposite of

[7] Garty, C., Oviedo-Joekes, E., Laliberte, N., & Schechter, M. (2009). NAOMI: The trials and tribulations of implementing a heroin assisted treatment study in North America. *Harm Reduction Journal*, *6*(2).

participant criteria in other countries that actively recruited MMT patients. In fact the criteria of these other trials made clear the participants "must" currently be on MMT. Recruitment ended in April 2007 and the last participants left the program in 2008.

NAOMI Study Results:

1. Heroin-assisted therapy proved to be a safe and highly effective treatment for people with chronic, "treatment-refractory" heroin addiction. Marked improvements were observed including decreased use of illicit "street" heroin, decreased criminal activity, decreased money spent on drugs, and improved physical and psychological health.

2. The NAOMI trial attracted the most chronic and marginalized heroin users who were outside the treatment system and continued to use heroin despite numerous previous treatment attempts. Both heroin-assisted therapy and optimized methadone maintenance treatment achieved high retention rates and remarkable response rates in this difficult-to-treat group.

3. Contrary to pre-existing concerns, the treatment clinics appeared to have no negative impacts on the surrounding neighbourhoods.

4. Participants on hydromorphone [Dilaudid] did not distinguish this drug from heroin. Moreover, hydromorphone appeared to be equally effective as heroin although the study was not designed to test this conclusively. If this were proven to be true, hydromorphone-assisted therapy could offer legal, political and logistical advantages over heroin and could be made more widely available.[8]

After a year of receiving heroin (or hydromorphone), participants entered a 3-month transition period. During this period, all NAOMI participants were offered a range of traditional treatments, including methadone maintenance and detox. After the 3-month

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[8] The NAOMI Study Team, October 17, 2008. *Reaching the hardest to reach – Treating the hardest-to-treat: Summary of the primary outcomes of the North American Opiate Medication Initiative (NAOMI)* retrieved from http://www.naomistudy.ca/ documents.html, p. 18.

transitional period, the research participants were no longer part of the study and no further treatment or supports were offered. A number of research participants had difficulty transitioning back to currently available treatments in Vancouver. The NAOMI findings demonstrated that heroin-assisted therapy was an effective treatment that improved physical and psychological health. The NPA participants questioned why such a successful trial would close down. Outside Canada, heroin-assisted therapy is offered in a number of countries and none of these programs shut down following their study stage; due to the fact that study results were positive, these programs continued on a permanent basis and/or participants were granted further HAT on compassionate grounds. The Netherlands HAT randomized trial conducted over four years demonstrates that the longer a patient is offered HAT, the better is the chance of continued good health (in contrast to those patients with only one year of HAT).[9] Continuation of HAT is thus essential. **The Canadian NAOMI project is the only heroin-assisted study that failed to continue offering HAT to its participants when the study ended in Vancouver.**[10] In 2007, Health Canada refused compassionate use of heroin for NAOMI participants. In Canada, the views of prohibitionist politicians outweighed the beneficial evidence, and the result was a lack of government support for the implementation of HAT.

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[9] See footnote 6.

[10] See footnote 6. The SALOME website states that: "Canada will be the only country that has ever terminated the treatment after showing success. The Canadian study team applies for research funding to continue investigating effectiveness of licensed injectable opioids (the SALOME trial)." (Salome, 2012). Timeline: From Opium to Salome. Retrieved January 29, 2012 from http://www.providencehealthcare.org/salome/timeline.html

NAOMI from the Perspective of the NPA

The preceding sections outlined some of the findings of the NAOMI trial from the perspectives of researchers involved in this study. This section of the Report is drawn from what the research participants said about their experience in the NPA focus groups and in their writing about NAOMI. It highlights the experiences of the NPA members when they were NAOMI research subjects.

Why Participate in NAOMI

NPA members discussed why they chose to become NAOMI research subjects. Two members expressed their views:

> ***Well, we all wanted heroin. Everybody wanted the heroin*.** (female NPA participant)
>
> ***That's why we went through it all.*** (male NPA participant)

Participants expressed how full consent becomes problematic when researchers have something that participants wish to obtain.

The Setting of NAOMI in Vancouver: The Corner of Hastings and Abbott

NPA members discussed the physical space of the NAOMI clinic over the study period. Participants in the study were expected to arrive at the clinic on the corner of Hastings and Abbott Streets three times a day (morning, afternoon, evening) with about four hours between each dose.

The people who received heroin came in the entrance on Abbott St., and the people receiving methadone entered on Hastings St. The two groups remained physically separate during the study. When the heroin participants arrived, they had a 10-minute window for their appointment. They were not allowed to arrive early or to be late.

> ***They didn't want people lining up*.** (male NPA participant)
>
> ***Okay? Not 10 minutes and 10 seconds. You had 10 minutes . . . . The computer would not allow you to be logged in if you were past that 10-minute window*.** (female NPA participant)

Participants were buzzed though a double door that had security cameras; the doors were continuously locked. People then had to be buzzed through a second door. Patients were then logged on to a computer and they entered a waiting room for a 15-minute observation prior to injecting their dose of heroin or Dilaudid. After being observed for 15 minutes, on a first-come-first-served basis, participants were brought into the injection area (similar to Insite) where a nurse sat behind a glass partition and

supplies were handed to people in a tray, including a prepared syringe that was scanned to match your name.

Then they had seven minutes to inject, followed by a half-hour observation period following their dose (3 x day). Participants sat in a lounge during this observation period.

> ***You were given seven minutes to inject your heroin***. (male NPA participant)

There were nurses and social workers observing people, and a doctor was on site. Every two weeks the participants met with the doctor to discuss their dose. They could also arrange for a meeting in between that time.

The NAOMI participants spent a lot of time at the clinic waiting for their medication and being observed before and after their dose. In that time, they talked with one another, formed friendships, and created activities to fill in the time. One NPA member wrote about her time waiting at NAOMI with other participants:

> ***Supper at NAOMI***
>
> ***It's 5pm, time to go to my regular evening medication of heroin. All done with the medical part. Now to the fun stuff. Dave brought a Maple Leaf roast pork and gravy dish, fed about 8 people, the 4 at our table and then as many as we can. I brought bread and salad. So dinner tonight is:***
>
> ***"Hot Pork Sandwich – with gravy, Caesar Salad and Vanilla pudding with Strawberries"***
>
> ***Supper's over, I got fed and now it's time to relax and do our crosswords.***
>
> ***Bye! See you for breakfast.***
>
> By Dianne, NPA member

NPA members noted that by abiding by the protocols and regulations set up by NAOMI for their attendance, they spent a lot of their day at the clinic and it was difficult to do anything outside the clinic.

One NPA member said:

> ***Well, you couldn't do anything in between***. (male NPA participant)

NAOMI Benefits

The NPA members spoke about the benefits they experienced during their time as participants in the NAOMI trial:

> ***They helped me get a room at the Empress Hotel and from there everything started to move forward. I didn't have to worry about having to get up every morning and run all over hell's half acre just like a chicken with my head cut off wondering where I was going to get the money to get better.*** (female NPA participant)

> ***And life improved, I suppose. It was kind of a blurry year but all in all I think it was better. I don't know. I was happy, at least I think I was happy. You know, I wasn't miserable a lot. I wasn't sick, you know, I wasn't running around trying to get $10 all the time. Yeah, so I mean it was good.*** (male NPA participant)

> ***I am glad I did go through it even if we did get dropped because it was, it was the best years of my – couple of years in my life. I really learned how to be myself without having to be looking for money all the time. I learned how to do normal things, and be a good president [at VANDU] and stuff.*** (female NPA participant)

> ***I was in a bubble for 15 months, but I mean, I hit those doors at 72 pounds and, you know, here I am now and it's not – NAOMI. I had a hell of a good time. I was helped with housing. When I got an abscess on my hip the nurses from NAOMI were pulling up at Powell Place and coming and getting me and driving me without me even asking them.***

> ***I just – you know, I cried like a baby the last day I was there.*** (female NPA participant)

> ***But it changed my life a lot. I wouldn't regret doing it. I'd do it again if they would offer it again. It was a good thing for me while it lasted. It was great. It was just good for me because I just can't do methadone. It is not an option for me*****.** (male NPA participant)

> ***It would give me a huge break in my life as an addict. It would give me this huge, like, vacation, that was like going to Florida, you know, and living on the beach almost, you know, in terms of addiction. Going to Florida.*** (male NPA participant)

The NPA members reveal that the benefits of the NAOMI trial were deeply felt, as were the effects of not having to hustle every day. However, some NPA members were not able to comply with the requirements of the NAOMI trial:

> ***I was only on it for three months, but during the three months my life got a lot better and when I did get kicked off it my life was kind of screwed up because I'd forgotten how to hustle to get, you know, to get things happening***. (male NPA participant)

Others observed that they were worried about what would happen once the clinical trial ended:

> ***We were being observed, the 15 minutes and a half hour after, so there was a lot of talking going on and I think one of the big subjects was, what are you going to do when this was over? And I think that was, like, probably the thing we talked about the most.*** (male NPA participant)

> ***I mean, once you finished talking about your daily activities or whatever was going on in your life it came down to, like especially as it got closer to the end road. I think that it was helped by the fact that it was staggered, the intake, so we would always have somebody that was leaving…so we had an idea it was coming all the time…***(male NPA participant)

Consent and Expectations: What is Consent Under Drug Prohibition?

All of the NPA participants signed consent forms to participate in the NAOMI study. These forms were updated from time to time. The NPA members discussed issues of consent, ethics, and their expectations of the NAOMI trial. They also felt optimistic that the study would eventually become a permanent program.

> ***I went there with the full understanding it was a study. It was a study.*** (female NPA participant)

> ***The staff and the doctors were telling us no [the study would not continue], but they never completely extinguished that little dream that we had. . . . We were optimistic.*** (male NPA participant)

> ***I was given the impression that it would continue and then the studies that had happened in Europe that all –they'd all been on compassionate ground, so I really thought it was going [to continue] …It really kind of threw me for a loop when it didn't happen that way.*** (male NPA participant)

> ***I knew it was a study and like everybody else it was going to help the future generation. But for me it was a double-edged sword . . . . I think the thing that's flawed in this, in the ethics, was the ethics approval, like, for them to approve this study without fully – I mean, without having an exit strategy in place that was doable.***
>
> ***There's been these kind of studies done in other countries before us. So they had a good idea of what the results were going to be . . . And to go into that without having a way out that worked for the client or the participant, I think that was the -- that's the thing that wasn't right, in my opinion.*** (female NPA participant)

Several of the NPA members explained how consent is problematic when researchers control the very drug that is an integral part of their lives:

> ***Our life depends on this drug and here we're offered this drug. Well, okay, so, I mean, I always said, well, I would sign anything at that point. I would probably say which finger do you want, you know, or which arm do you want, you know.*** (male NPA participant)

The NPA members also wondered why the positive NAOMI trial findings were not fully considered by the federal government. They wondered if the failure to create a permanent program had to do with their marginalized status as illegal drug users.

> ***If they give you a drug for – they're experimenting with a drug for cancer and it starts working. I mean, what are they – what are you going to do? Oh, no. You can't have it anymore, we're going to back off here.*** (male NPA participant)

The NPA members noted that providing legal access to heroin or any drug improves the lives of the user. However, that in itself is not enough:

> ***If you just give me the drug all the time are you improving my life? Well, you're improving my life as far as the drug goes. You're probably taking a lot of the stress out of my life, but are you actually doing these other steps?*** (male NPA participant)

The NPA members discussed how Canadian studies rarely provide necessary social and economic supports or lead to social change. Nor does drug policy change as a result of these studies. Drug prohibition continues. They noted that if social support and a change in drug policy occurred, life would be very different.

> ***And then we could move forward in our lives.*** (female NPA participant)

NPA Writing: Waiting/Creativity/Friendship/Everyday Life

The NPA members wrote about their time waiting at the NAOMI clinic and their time away from the clinic.

FROM MY HEART:

> I have been a "resident" in the DTES for 15 years now and still every day I am in some way or other shocked, surprised, stunned or confused by something I either see, hear, or experience personally. Not all bad! Please don't misunderstand—a lot of interesting, beautiful and yes sometimes flat out great things have gone on over these 15 years or so.
>
> One thing however stands out far above everything and that is how so many of us still have our "humanity" intact.
>
> Most of us have been lied to, robbed, beaten up, ripped off, blamed wrongfully, accused of, given credit for or not given credit for all sorts of stuff. Yet, here we are – still saying "Hi, how are you?' –sharing whatever we can, trusting the next "guy" and yes – trying to get that 1 hoot of hoots.
>
> For myself, dope has somehow become less and less important – probably because it has been less and less good dope. My down habit seems to be less (amount-wise) as time goes by.
>
> Maybe it has something to do with losing "friends" to dope or dope-related circumstances – who really knows? By the end of today (God forbid) there could be 1 less of us here. The survival instinct and skills we have acquired are amazing. We seem to be a bunch of "energizer bunnies."
>
> I know most of us are physical survivors of massive amounts of sugar – even though the majority of us are seriously underweight. We live on the stuff. It really should be illegal too. Just joking. Joining another important survival skill we need.
>
> At the beginning, middle and end of each day, I find myself just shaking my head –usually thinking to myself what the fuck are we

doing. I am reminded of a dog chasing its tail. Wow it hurts when you catch it! But usually you never do.

The best I can do is to keep carrying on as best I can, trying to keep my "human" self intact.

By Carol, NPA member

The excerpts below continue along the theme of friendships that have developed over time, living in the DTES and having been NAOMI research subjects and members of the NPA.

Dear Sophie,

OF LIVES AND TIMES

How often do friends leave? The immediate intensity of sadness for myself and we find ourselves to face and or to cope with the horrific news of the loss of a dear others that were close to an individual whose broken few and the toughness of the street wears even on our expression day to day.

We'll miss you Sophie.

With love,

By Mark , NPA member

A day in the life

The sun is shining. I'm going to the beach. There's families here and the waves are awesome. It smells like my Nova Scotia home. Seaside odours, fish & chips, sail boats in the harbour and tankers going to trade all over the world.

Oh no! I'm not feeling well, all of a sudden my nose is running, my bones are aching. It's the liquid hand-cuffs. Methadone. I forgot because the sun was shining, and I felt free. But I'm not. It was only a dream.

By Dianne, NPA member

Bathroom Floor

Once again I find myself
alone, contemplating
life while sitting on brick
red tiles that make the
bathroom floor. Since the
only thing that I am wearing
is a t-shirt and g-string,
the cold tiles feel so great

Pressed against my flushed
and hot skin.
Thinking, I realize that all
through my life that one
constant and comforting
thing is the hundreds of
hours that I have spent
in this tiny room shutting

Out every thing. The place
where plans are developed,
decisions made and sins
confessed. Also, where I
cry, laugh and apply the
makeup that hides the
purple/blue marks that
cover most of my body,
the red lines caused from
tears running down my
cheeks non-stop. Or the
true feelings that I spend so

much time trying to hide, the one
place that I can be my true
self and not feel the sharp
hot sting of his slap.

I, like so many women, have
learned that hiding is the
way to live. Following every
word of the man that we think loves us and for that
love we live like prisoners locked away.

By Melita, NPA member[11]

Untitled essay

When I close my eyes I see a young boy with a fishing pole walking the booms on the lake. He's surrounded by mountains, all around is clear clean water and most of all there's LIFE all around.

The water and air is busy with beings with a single purpose. That's the point, they have a purpose. All my life I've wondered what my purpose was/is. All my life I've tried everything I could to find out what my purpose is. I start out with my emotions on high then when I realize that what I'm doing isn't it. I crash hard.

Self-realization means that we have been consciously connected with our source of being. Once we have made this connection, then nothing can go wrong. No one can ask another to be healed but he can let himself be healed, and thus offer the other what he has received. Who can bestow upon another what he does not have?

And who can share what he denies himself?

That which is injurious, loses its capacity to harm.

When it is brought into the light.

By Leon, NPA member

[11] Melita's poem was printed in *Megaphone, voices of the street*, 2010, p. 20

Not all NPA members wrote about positive events in their lives, friendships, or benefits of their time in the NAOMI trial. Some NPA members chose to write about the negative outcome of being a NAOMI research subject and others wrote about NPA meetings.

"Memories at the corners of my mind"

The way we were.

NAOMI

Emotion = ANGER

Angry at myself, sometimes reminded me of being in school, being disruptive questioning authority.

By David, NPA member

Untitled poem

Still down here

can't remember how many years

had lots of laughs

and lots of tears

not sure how or when it will end

know all kinds of people can't call 1 a real friend

maybe tomorrow maybe next year

but when it is over don't shed a tear

'cause the misery is over. I hope . . .

By Kevin, NPA member

Untitled essay

I'm not sure what I'm suppose to write here, since I just occurred on the scene here late and everyone is already writing their letters I suppose you'd call this for lack of a better word. So here I sit writing.

Also just got news that a girl we all knew just passed away, she was a junkie. I suppose nobody knows why she died exactly only that she did.

I suppose life's like that, you're here one minute, gone the next. What's it all for, what's it all about, who knows? All I know for sure is one day we'll all find out.

By Mario, NPA member

Untitled essay

This is my very first meeting that I decided to attend.

I had completely forgotten that VANDU held a committee meeting every Saturday. The meeting time is usually held at the hours of 12:00 – 1:00 and $5.00 is awarded to people who decide to attend.

By Jammie, NPA member

NAOMI (TRIALS?)

How can I (we) be the lucky one? Chosen as 1st grade "A", fresh, unquestioning meat? To be lucky enough, chosen 1st to receive, FREE grade "A" dope from places and parts unknown?

Did I care?

Should I care?

If I didn't care, who could care?

Then: No one (seemed) to care.

Now: EVERYONE (seems) to care!

Raising new issues, NEVER thought of then, only thought of now?

How can this be?

Were we: so far gone, all that mattered was . . .

No! Cost . . .

No!! work . . .

No!!! MORE DRUGS (given FREE)

Back to the Grind, just like I've never left!

So . . .

Why, did I even bother to be a "trial" RAT 4 NAOMI?

To be left hanging, with No rope!

Thanks NAOMI

By Jammie, NPA member

CAUTION

This may have the ability to attain?

The path to freedom is there, if one chooses.

The tools were not given readily and the road isn't clear.

Please give us a compass, a clear day,

and a home.

NAOMI, she was a gift of freedom, a taste,

but she didn't give me her number!!!

By Steve, NPA member

Peaceful Sunshine

Peaceful Sunshine

Darkened Skies.

Cloudless Sundays

in July's Days.

The Sun so hot

While the water so cold. Just to cool down is a wondrous way to pass the time away.

One day at a time or until we have peace and happiness as well all should have with Every Sound with every Speech with everyone Listening to me all in tune all in time to only Bring out the Best in All of Us.

By Robert, NPA member

NICE

PEOPLE

USE

DRUGS

By Dave, NPA member

Following NAOMI:

Snapshot of the NPA, Where We are Today

Dave Murray gathered the following information on housing on June 11, 2011. Out of the 13 people present at the NPA meeting:

7 live in SROs
2 live in social housing (Woodward's)
4 self identify as homeless (no fixed address)

Most of NAOMI (IDU side) were housed in SROs during the study. No effort was made by the study to assist us to get better housing during or after the study. Everyone present on Saturday's meeting said they would have liked help (BC Housing, etc.) to improve their living conditions during the study (and today). The two people living in Woodward's (social housing) today were in SROs during the study.

****

Our NPA member and friend, Robert Vincent, passed away in late December 2011. His thoughts and writing are included in this Report. The NPA also wishes to honour the memory of all the former NAOMI participants who have passed away.

In December 2011, the SALOME (Study to Assess Longer-term Opiate Medication Effectiveness) study opened its doors in Vancouver. SALOME is a clinical trial. Their website describes the study as testing whether hydromorphone (Dilaudid), "a licensed medication, is as good as diacetylmorphine, the active ingredient of heroin, at benefiting people suffering from chronic opioid addiction who are not benefiting sufficiently from other treatments. This study will also test if those effectively treated with these two injectable medications can be successfully switched and retained to the oral formulations of the medications."[12]

[12] SALOME, Retrieved February 5, 2012, from http://www.providencehealthcare.org/salome/about-us.html

In order to test their hypothesis, the SALOME study will compare the effectiveness of six months injectable heroin with six months injectable Dilaudid and the effects of switching from injectable to oral heroin or Dilaudid. SALOME began active recruitment in December 2011. Utilizing a lottery system, people who registered for the trial and are deemed eligible are being contacted. Participants will be in the study for one year, followed by a 1-month transition period where participants will be encouraged to participate, once again, in conventional treatments such as methadone maintenance, drug-free treatments, and detox programs (treatments that have proven to be ineffective for these participants). The repeated failure of treatment efforts for participants is in fact part of the criteria for selection of participants in SALOME, as was the case in NAOMI.

The NPA met with SALOME researchers before the study began and provided valuable input from their experiences as NAOMI research subjects. They also shared their recommendations for future HAT trials and programs as outlined previously. However, in the end, the SALOME researchers failed to put into place the recommendations of the NPA outlined in this Report. In the pursuit of scientific evidence, important issues and recommendations by the NPA and VANDU about consent, ethics, peer support, and human rights have mostly been ignored. The SALOME study also has no exit strategy in place for its participants.[13] Thus history may repeat itself in Canada.

[13] SALOME, Retrieved January 29, 2012, from http://www.providencehealthcare.org/salome/timeline.html

Conclusion

The NPA hopes that this Report will guide future research studies and the setting up of permanent heroin and other drug maintenance programs in Canada. They also hope that the Report provides insights into the lives of the people who became research subjects when they participated in the NAOMI clinical trial. The NPA members also hope that drug prohibition will end so that other people will not be subject to the social and legal discrimination that they face daily. Nor will people feel compelled to participate in research projects in order to have essential goods, drugs, services, and supports provided to them.

Foremost the NPA encourages other groups to engage in creating their own research to tell their own stories. Here we repeat the first stanza and then include the full poem, *Telling Stories*, written by Sandy Cameron. His poem exemplifies the spirit of our research and our goals to end drug prohibition, to improve the lives of those most affected by it, and to guide future programs that offer supports and substitution drugs to users.

Telling Stories

We need to tell our own stories.
If we don't tell our stories,
people with power
will tell our stories for us.
And we won't like what they say.
When we tell our stories,
we reach out to each other
and build community.
We share our pain.
We share our hope.
We share our laughter,
and our determination.
When we tell our stories
we draw our own maps,
and we question
the maps of the powerful
Each of us has something to tell,
something to teach.
We speak the language of the heart–
here–in the Downtown Eastside–
The soul of Vancouver.