



NAOMI—Her Time Has Come

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Illicit opiate use is a significant public health problem in North America and elsewhere around the world. The affected population is estimated to be around 600,000 in the United States and 60,000–90,000 in Canada. Untreated opiate addiction can lead to overdose, infectious diseases such as human immunodeficiency virus (HIV) and hepatitis, loss of regular social and economic functioning, and extensive engagement in both drug-related and drug acquisition crime. At a societal level, there are the respective costs to the public health, health care, and welfare and criminal systems contending with these risk and harm phenomena. A recent Canadian study¹ on cost of illness found a total social cost burden of US \$30,000 per untreated user per year due to lost productivity, health and health care, and crime and criminal justice costs. The North American Opiate Medication Initiative (NAOMI) is meant to help address this major health problem.

Methadone maintenance therapy (MMT), the mainstay of opiate addiction treatment, has proven effective for some, but not all, opiate users. It is well established that while MMT can be beneficial to many opiate users, a considerable subset will not be attracted into MMT for a variety of reasons or will not be retained in such programs even if initially attracted. Complementary and alternative treatment modalities are thus needed for those opiate addicts who cannot be reached by, attracted into, or productively retained in conventional forms of opiate addiction treatment.

For these reasons, attention has turned in recent years to the use of medically prescribed heroin as an adjunctive therapy for treatment-refractory opiate users. An uncontrolled study² conducted in Switzerland since 1994 has shown very promising results. A report on a much-anticipated Dutch trial involving both injectable and inhaled heroin is due this year, and in Germany, a multisite heroin-assisted treatment trial will start in 2002. There are two protocols in Spain for heroin trials that have recently been approved by federal authorities. But not all initiatives go forward as planned. In Australia, a protocol for a heroin trial was approved by the Ministerial Council on Drug Strategy in 1997, but was subsequently blocked by political decision makers. A trial protocol was submitted to French health authorities as far back as 1999 and is still awaiting a decision.

So who (or what) is NAOMI? NAOMI is a collaborative effort of a team of addiction medicine specialists, epidemiologists, clinical trial specialists, social scientists, and health economists from across the continent; its aim is to conduct a rigorous randomized controlled trial of heroin-assisted therapy in the North American setting. In essence, the trial will compare an optimized MMT program with a medically prescribed injectable heroin program. Primary outcomes will include examination of treatment retention as well as treatment response based on the Addiction Severity Index on an intent-to-treat basis. A comprehensive health economics component will examine the cost-effectiveness of the treatment options. NAOMI was

first reviewed by an expert independent panel, and their recommendations were incorporated into the final protocol.

Regrettably, a number of factors unrelated to the science of the study have hindered the conduct of the trial in American sites. In 2001, NAOMI was submitted to the Canadian Institutes of Health Research (CIHR) for review and was rated in the high excellent category (upper sixth percentile). In February 2002, the Canadian government announced full funding of the study involving 470 volunteers in Vancouver, Toronto, and Montreal. It is hoped that US sites may be able to join in time, but the critical importance of this public health problem makes the need to proceed imperative. At long last, NAOMI's time has come.

REFERENCES

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2. Uchtenhagen A, Dobler-Mikola A, Steffen T, Gutzwiller F, Blattler R, Pfeifer S. Prescription of narcotics for heroin addicts: main results of the Swiss national cohort study. *Medical Prescription of Narcotics* vol. 1. Basel: Karger, 1999:44-table11.