Advocacy Research in Harm Reduction Drug Policies

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Harm reduction now has a strong foundation in scientific evidence and is widely accepted in many countries as national policy and much of the world's scientific community, including leading U.S. and international public-health, e.g. The US National Academy of Medicine, the American Medical Association, the European Union, and the WHO. Nonetheless its impact in official U.S. policies and practices remains minimal. In this chapter, two harm reduction case studies are presented: one about needle-exchange programs for intravenous drug users and the about methadone treatment programs for heroin addiction. These studies suggest how, in order to improve impact, research questions must be strategically chosen and presented. Such research should support our ability to implement HR policies in practice and make public-health officials more accountable for their opposition to HR, using the mounting body of evidence supportive of HR to support changing those positions. Both of these cases demonstrate the possibilities (and limitations) of advocacy research where science speaks truth to political power.

The effective treatment of drug addiction and the reduction or prevention of the many collateral damages associated with it, most famously HIV/AIDS, are central concerns of modern public-health conceptions—now widely practiced under the model of harm reduction (Drucker, 2011). While The United States has done over 85% of the world's research on drugs and addiction, new AIDS cases related to drug injecting and related sex work continue to be a persistent problem—about a third of the nations estimated 56,000 new HIV infections each year (over half a million in the last 10 years) can be linked to drugs and failed drug policies (Drucker, Apetrie, Heimer, & Marx, 2007). In addition our approach to drugs is also linked to a fearsome mortality rate—the United States had over 20,000 drug overdose deaths in 2010, increasingly by prescription opioids, sedatives, and tranquilizers (Brooks, 2010). Despite this carnage both clinical and public-health practices in the United States have remained refractory to the massive body of

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research and clinical evidence showing the efficacy of harm reduction methods such as needle exchange and methadone treatment.

Harm reduction now has a strong foundation in scientific evidence and is widely accepted in many countries as national policy, by much of the world’s scientific community, and by the leading U.S. and international public-health bodies—that is, the US National Academy of Medicine, the American Medical Association, the European Union, and the WHO. Nonetheless its impact in official U.S. policies and practices remains minimal. This is because U.S. national drug policies (despite some recent reforms under Obama) have for decades been dominated by the war on drugs—with its strong ideological opposition to harm reduction (portrayed as “tolerant” of drug use) and as a dangerous threat to the nations commitment to drug prohibition policies (zero tolerance), the criminalization of drug use, and the mass arrest and imprisonment of drug users (Drucker, 2011). But we can now also see signs of positive change—for example, the spread of medical marijuana (in 16 states) and full legalization in two others. In the early months of his second term President Obama has called for a shift in U.S. drug policies from the war on drugs to new policies premised on public health.¹

This collection of papers proposes impact validity as “a new framework” for reimagining research as a source of “usable knowledge” and the needed goal of meeting SPSSI’s stated mission “of bringing theory and practice into focus on human problems” (Massey & Barreras, 2013). We could find few better examples of this need (and the price we pay for failing to meet it) than the subject of drugs and addiction. The fact that our U.S. drug policies and its clinical and public-health practices continue to be refractory to decades of research supporting harm reduction, while no surprise given the ideologies behind them, confirms the basic premise of this collection of papers on impact validity—strongly suggesting that it is more effective advocacy, not more research, that is what is most urgently needed.

In this article I want to share the experience of over 30 years of doing such research—at considerable public expense under NIH and other grants that I have collaborated in. The United States’ failure to produce meaningful changes in its own drug policies to date also reminds us that such work must ultimately be translated into concrete actions based on these ideas and findings to serve as a basis for better clinical and public-health practice.

Harm Reduction: Two Case Studies

In the area of drug use and addiction the most striking cases involve the responses to research on needle and syringe exchange (a new innovation in response to the HIV epidemic) and the liberalization of the use of methadone

¹USONDCP 2013.
and other forms of opiate substitutions treatment (OST) for the care of chronic opiate addiction—an approach that is over 100 years old and still the most effective form for treating it. My experience is that these two examples demonstrate the issues of impact validity very well. Each can be understood best as we directly address the public-health issues associated with drug use today and both illustrate many of the ways that advocacy research can be aimed at altering these restrictions of practice.

While they have still not fared well in the United States in attempts at overcoming some of the limitations imposed on access to safe injections, the federal ban on funding for needle and syringe exchanges, and liberalizing the use of methadone in the United States in the face of a worsening AIDS epidemic and rising drug fatalities and expansion of the most dangerous forms of drug use, they continue to grow in acceptance worldwide. Accordingly, this is a mixed tale that illustrates both the possibilities and limitations of advocacy research that attempts to scientifically speak truth to political power.

Drug control policies must be based on scientific evidence. Yet international drug control strategies and regimes based almost exclusively on prohibition (i.e., on the use of criminal penalties to regulate the sale and use of certain drugs) have been largely unsuccessful in containing injecting drug use in most regions and are now associated with generalized HIV epidemics in the United States, Russia, and several other countries. Throughout the 35 years of epidemic HIV spread, despite massively increased interdiction and drug enforcement activities, worldwide heroin and cocaine production have tripled, with comparable increases in the prevalence of injecting and addiction. In addition, prohibitionist drug policies also affect patterns of drug use in ways that increase individual and public-health risk. The necessarily clandestine life of the (criminal) addict fosters several specific patterns of behavior known to increase HIV transmission, most important among these the sharing of scarce injection equipment and increased sex work to get money for drugs. Stigmatizing and marginalizing the drug user also acts as a barrier to access to medical and social services, isolating the drug user from education, prevention, and drug treatment that might ameliorate AIDS and other health risks (e.g., overdose). In this context, the major test of the public-health efficacy of specific AIDS prevention measures is, therefore, not their impact on the prevalence of drug use per se (which is a function of drug markets) but, rather, of our drug policies based on absolute prohibition and their effects within the current environment of no effective regulation of these drugs.

**Needle and Syringe Programs**

Needle and syringe programs (NSP) are one of the hallmarks of public-health innovation for AIDS prevention among drug injectors. These programs not only
provide sterile injecting equipment to active injectors, they also offer sex education
and prevention materials, referrals to medical care, legal and social services, and
drug treatment. And, by reducing the marginalization of drug users, they increase
the likelihood that even active injectors who continue to use drugs will do so more
safely. The hundreds of studies done over the last 30 years all confirm and extend
the evidence of NSP efficacy and the lack of associated adverse effects—such as
the initiation or increase of injection use. The combination of NSP with efforts
to increase syringe availability by modifying restrictive laws and regulations and
outreach to increase pharmacist involvement in syringe sales holds great promise
for reducing the toll of HIV infection (Des Jarlais, 2000). Considering NSP as
part of a national risk-reduction strategy, if NSP are established early, in sufficient
quantity, and are part of an overall drug policy which simultaneously promotes
a range of other prevention and treatment services such as drug treatment, their
effects on local and regional AIDS outbreaks can be dramatic (Wodak & Cooney,
2006).

The timely initiation of needle exchange has played a significant role in ef-
effectively restricting HIV spread among drug injectors in Australia, the United
Kingdom, and a score of other countries. But political obstacles to expanding NSP
remain significant. And while scientific demonstrations of NSP impact have been
sufficient to lead more than 20 countries to adopt NSP as part of their national
AIDS prevention strategy, U.S. federal health authorities have been unyielding
in their opposition to NSP. Until 2010, the United States banned the use of fed-
eral funds for NSP despite the many U.S. studies demonstrating their safety and
efficacy, and the clear and repeated recommendations of two National AIDS Com-
missions, the National Academy of Science's Institute of Medicine, and leading
U.S. government experts calling for federal support of NSP. In 2010, the Obama
administration lifted the ban but, in the face of the 2008 economic crisis this
resulted in no increase in access to federal funding support for such programs
(which continue to be funded only by states and localities).

In late 2012 (after Obama's re-election) the ban on federal funding of NSP was
reinstated as part of a larger financing bill—receiving little attention and having
little impact since no significant federal funding of NSPs had occurred in the
brief window that opened in 2011. In the meantime, the U.S. posture has been the
most important influence in sustaining hostility to NSP in some other countries
(e.g., Russia, Sweden) that are enthusiastic supporters of the United States led
war on drugs. Yet it is this U.S. national policy that is a landmark failure of our
public-health approach to drugs. As regards NSPs, several important studies had
clearly demonstrated the effects of using NSPs as a public-health intervention to
contain the spread of HIV among IDUs, but has had little effect on US policies.
It seemed clear that we need not more research on the efficacy of NSPs but rather
a greater focus on the resistance to the employment of these research findings in
the determination of public policies in the United States.
In 1997 Peter Lurie and I conducted a study designed to assess the impact of this policy on AIDS rates in the United States and to fashion it from the outset as a tool for both national and local advocacy in the United States. Hoping to reach a wide audience in medicine and public health, we published our study in The Lancet under the title "An opportunity lost: HIV infections associated with lack of a national needle-exchange program in the USA" (Lurie & Drucker, 1997).

Our study's aim was to estimate the number of HIV infections that could have been prevented had needle exchange programs been implemented during the early stages of the AIDS epidemic in the United States. We also estimated the cost to the U.S. healthcare system to treat these preventable HIV infections. The formula we used to calculate the annual number of preventable HIV infections accounted for the effectiveness and level of use of needle-exchange programs, as well as sexual transmission to injection drug users, and secondary transmission to their sexual partners and children. Data for the model were obtained from epidemiological and mathematical studies in peer reviewed published research, government reports, and consultations with experts.

Using data from Australia as a model, we calculated the number of HIV infections that could have been prevented by a national needle-exchange program in the United States between 1987 and 1995. Cost calculations were based on the current U.S. government estimate of the discounted lifetime cost of treating an HIV infection ($55,640). Our conservative calculation of the number of HIV infections that could have been prevented ranged from 4,394 (15% incidence reduction due to needle exchanges) to 9,666 (33% incidence reduction). The cost to the U.S. healthcare system of treating these preventable HIV infections is between $244 million and $538 million, respectively. If current U.S. policies are not changed. We estimate that an additional 5,150–11,329 preventable HIV infections could occur by the year 2000. These data determined the cost of the failure of the federal government in the United States to implement a national needle-exchange program, despite six government-funded reports in support of needle exchanges. They indicate that these policies may have led to HIV infection among thousands of IDUs, their sexual partners, and their children.

One of the unanticipated results of this advocacy approach to research was that harm reduction activists in many cities and states in the United States contacted us and began using our methodology to advocate for NSPs locally (Barreras & Torruella, 2013). In addition to spelling out our methods in the Lancet article, we made worksheets and data forms of our analytic and data handling methodology readily available to these activists, and offered technical assistance to calculate the data on their own HIV epidemics and the potential impact and economic cost of their own cities or states failures to institute NSPs at adequate levels relative to their AIDS problems. While the impact of this approach had traction locally, it had no effect on revoking the U.S. government ban on funding for needle-exchange programs until 2010, when Obama agreed to lift the ban. But still we
see the persistence of failure in financial support for the growth of harm reduction programs in the United States, which continues to be an urgent public-health priorities.

Methadone Maintenance Treatment of Opiate Addiction

The treatment of heroin addiction by opiate substitution therapies (OST) using methadone and other medications—including buprenorphine, morphine, codeine, and injectable heroin already has a better prognosis than many other chronic medical or psychiatric conditions. But widespread ideological hostility and professional ignorance, therapeutic nihilism, and frank medical malpractice regarding treatment of opiates (e.g., the common use of subtherapeutic dosages or the clinical goal of termination of OST) are still the norm throughout the United States. Indeed, much of America's addiction treatment policies and practice have only the most tenuous relation to scientific evidence—this is especially the case with the use of drug-free programs to treat heroin addiction. Despite the mass of decisive evidence on the efficacy of methadone in treating opiate addiction, it is still treated as a pariah drug in many parts of the world. Some nations (e.g., Russia and many states of the former Soviet Union) still forbid its use in addiction treatment. In the United States (where methadone was first employed for addiction treatment) eight states still prohibit its use.

Elsewhere in the United States, though medically approved, methadone's clinical application is so blind to the clinical evidence (e.g., justifying systematic use of subclinical doses) irrational and downright mean-spirited and punitive that, despite its proven efficacy many patients (even those who concede that has saved their lives) have grown to hate it (Stancliff). Indeed much of the allure of the newly approved use of buprenorphine is that it is “NOT methadone.” At the center of this problem is the restriction of methadone treatment in the United States to large narcotic treatment clinics and its exclusion from routine medical practice—a model of practice that is now the norm in most other courtiers that employ methadone.

To address this problem my research group at Montefiore/Einstein embarked on a series of NIH funded studies to demonstrate the feasibility and efficacy of a new approach to methadone maintenance in the United States as a basis for advocacy for policy change. This approach was called office-based opiate treatment (OBOT) and is today in widespread use in dozens of countries elsewhere in the world. OBOT provides medically supervised maintenance treatment for opiate-dependent individuals through primary care physician practices and community pharmacies. This model is now well-established clinical practice throughout the world with hundreds of thousands of patients in care in dozens of countries. The introduction of buprenorphine and its FDA approval in the United States in 2005, now allows buprenorphine (another opiate maintenance medication similar in its
action to methadone) to be routinely employed in an OBOT model—that is, with medications prescribed by a general or primary care physician and dispensed by community pharmacists. There have been several small demonstration projects and studies of methadone OBOT in the United States over three decades and some "medical maintenance (MM)" has been available to a few very long-term patients since the 1960s. The MM patients make monthly visits to a doctor who also supplies them with 30 days of medication. In all cases both physicians and patients have been satisfied with this approach, and the results have been comparable or superior to those seen in usual care in methadone clinics.

However, OBOT with methadone is far less accessible in the United States. Despite methadone’s extensive record of clinical efficacy, simplicity of administration, ease of stabilization, and its much lower cost (methadone costs <10% of the cost of buprenorphine), methadone may only be provided through DEA approved specialty narcotic treatment programs in Methadone Maintenance Treatment Program (MMTP) clinics. Although the use of buprenorphine is now expanding, OBOT with methadone is still not a major feature of the treatment landscape in the United States. Methadone is still far and away the dominant opiate maintenance modality in the United States (with >200,000 patients in treatment) but federal and state regulations continue to limit MMTP to DEA certified NTPs, and the use of methadone in an OBOT model in the United States has been very limited.

Today about 97% of methadone maintenance treatment in the United States occurs within large MMMTs. And, although OBOT with methadone is still very limited in U.S. addiction medicine practice, federally sponsored research studies in the United States have continued and these consistently demonstrate that office-based physicians can safely manage methadone for stabilized patients (both in OBOT and in MM) and has shown that physicians can successfully integrate OBOT into their primary care practices and that community pharmacists can dispense these medications for maintenance. But each locality and state have different needs for opiate treatment and often very different conditions affecting the motivations to employ OBOT and practitioners ability to institute it successfully within the context of the existing drug treatment assets and priorities. These include the philosophy of the regulatory bodies that control methadone in each state, the culture of the primary care practitioners and addiction medicine specialists, and the attitudes of local pharmacies—all of whom must do the actual work of treating these addicted patients in this new context.

In my own and my colleagues OBOT research, we have developed and evaluated methadone OBOT programs in several localities employing different models adapted to a wide range of conditions and contexts—with trials conducted in Lancaster PA; New York City; Albuquerque and Santa Fe, NM; and in Baltimore, MD. The results of this 8 year multimillion dollar research program completely supported the OBOT model—with equal or superior outcomes for retention, reduced illicit drug use, and superior consumer and provider satisfaction in each of
these cities and demonstrations of the feasibility to initiate pilot demonstration programs of OBOT linked to each city’s MMTP programs.

The Lancaster PA OBOT Programs

Lancaster is a small city without a methadone program that had over 100 patients traveling up to 100 miles to attend MMTPs in three other states. This example is particularly significant for its reliance on local activism and patient involvement (refs). From the outset the Pennsylvania State Department of Health’s Division of Drug and Alcohol Program Licensure—which oversees all MMTP contracts and regulatory compliance in Pennsylvania—was unwilling to support this OBOT program. They raised objections based on their interpretation of the state pharmacy board regulations and federal rules governing NTPs. Although the federal DEA office of diversion control had approved the NIDA protocol under which the Lancaster pilot would operate, and the state DEA division had explicitly approved the Lancaster pilot program. But countering the state’s objections required extensive legal review and representation. The OBOT sponsors in Lancaster mounted an aggressive campaign to gain final approval by the state methadone authorities to proceed with the pilot.

The resulting Settlement Agreement (between the State DOH and ATS—the operator of the MMTP) became the legal basis for operating the 36-month pilot program for up to 20 patients. Thereafter, the PA state Department of Health’s Division of Drug and Alcohol Program Licensure regularly challenged individual clinical decisions about patient admissions and ultimately affected the ability of the program to recruit and transfer the full complement of 20 patients—only 14 were referred and 10 admitted for the course of the program. In addition, the ownership of the Coatesville clinic changed at the end of year 1, with its acquisition by ATS—a large proprietary MMTP operating scores of clinics in the United States, many in PA.

In this period, the ATS clinic directors changed as well, and ATS was faced with a history of compliance problems with an already hostile state office, and therefore had little interest in the OBOT pilot that their predecessors had agreed to.

Although we had regular clinic/physician/pharmacy conference calls throughout year 1, the new management was unresponsive to our efforts to collaborate with them on the conduct of the program and the study. By the end of the second year, no new patients were referred and there was no regular communication with the staff at ATS/Coatesville. In July 2005, the PA state Department of Health’s Division of Drug and Alcohol Program Licensure wrote to the Coatesville clinic director challenging ATS conduct in several of the OBOT cases. They asserted that ATS had “a complete lack of compliance or regard for the terms of the Settlement Agreement” ordering that the “project must be terminated (in 60 days) and that if
ATS failed to comply the department will proceed with legal action, including an injunction to halt the program and revoke the licenses of ATS.”

There was never any warning of this action nor any prior contact by the state (or ATS) with the OBOT clinicians about the order, nor were of copies of the termination letter sent to the OBOT physician, pharmacy, or the researchers.

The order required that all OBOT patients be transferred back to the clinic within 30 days, and the clinical course or prognosis of the individual patients was not considered. Few chose the option of a return to the MMTP—with most switching to buprenorphine in Dr. Rice’s practice.

Despite the premature end of the Lancaster OBOT program, it clearly was a successful “proof of principle,” demonstrating that an equally efficacious but more humane and lower cost alternative to MMTP care is possible for stable patients. This model is well suited to a typical U.S. small city with serious addiction problems but no operating MMTP to provide care for local citizens who need it.

The community approval process demonstrates that grass roots support can be built for methadone treatment, avoiding the bitter disputes so common with large MMTP clinics and the NIMBY syndrome. Lancaster also demonstrates convincingly that it is feasible to implement OBOT with local practitioners and pharmacists, and to provide greater access and lower costs of care, with good clinical outcomes and high levels of patient and provider satisfaction. This is an easily replicated model in technical and fiscal terms, but the sponsoring clinic and state regulatory attitudes and relationship are key. Inevitably, each such initiative will have to work out the many problems that arise at the local level, so it is crucial that local advocates engage in the process to set up and operate similar OBOT programs in their own localities.

Conclusion

These tales of research aimed at having an impact on policy (and its common failure to do so) points to the need to do better—because the scientific data itself is not enough to affect policies. This is especially so in those areas affecting burning issues of public health—such as the still raging AIDS epidemic in America and the parallel epidemic of mass incarceration (so much of it associated with our wrongheaded and very self-destructive approach to our nations drugs problems) where more effective advocacy, and valid policy research to stimulate it, is urgently needed.

References

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