When Science and Politics Collide: The Federal Response to Needle-exchange Programs

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Among the avalanche of statistics about the acquired immunodeficiency syndrome (AIDS), two stand head and shoulders above the rest: (1) AIDS is the leading cause of mortality among Americans aged 25 to 44 years,[1] and (2) the great majority of new human immunodeficiency virus (HIV) infections are occurring among injection drug users (IDUs), their sex partners, and their offspring.[2] Combined, these two observations require that the federal government act expeditiously to prevent HIV infection and that it focus its efforts particularly on IDUs.

This article will assess whether the federal government has put the implications of these scientific findings into practice. It describes the events surrounding the preparation and publication of a three-volume, 700-page report on needle-exchange programs (NEPs) prepared for the Centers for Disease Control and Prevention (CDC) by the author of this article and 11 other researchers at the University of California (the UC report).[3,4,5] It chronicles how the study began, describes its methods and findings briefly, and relates the circumstances surrounding its release. Finally, the article details how internal federal government reviews of the scientific merits of the UC report were not released by the government, presumably because the conclusions conflict with present federal policy, and how the reviews eventually became public.

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Study Origins

In the 1980s, the UC report would not have been possible. A series of federal laws precluded the use of federal funds for both NEP research and services. While a ban on the use of federal funds for NEP services remains in effect (the details of this restriction are described below), a provision preventing federally funded NEP research last appeared in the 1991 budget.[6] The first federally funded NEP study was conducted by Yale University researchers, who, beginning in 1992, used funds provided by the National Institute on Drug Abuse (NIDA) to refine a syringe tracking and testing system to evaluate the New Haven NEP.[7]

The UC report was the second federally funded study. In early 1991, following discussions between Dr. William Roper, Director of CDC, and Robert Martinez, Director of the Office of National Drug Control Policy (ONDCP), researchers at the University of California, San Francisco were approached by the CDC to review all existing data on NEPs. The study was funded by the CDC through a Cooperative Agreement with the Association of Schools of Public Health.

The study occurred amidst great controversy over NEPs. Whereas NEP proponents asserted that the programs could reduce HIV transmission and provide IDUs with a bridge to public health services including drug treatment, opponents claimed that NEPs disrupt local business and residential communities and lead to an increase in drug use.[8,9] Some critics went so far as to equate NEPs with genocide.[4] At least three dozen arrests of NEP workers have occurred since the first US NEP opened in 1986.[4]

In this heated climate, some NEP critics accused researchers who reported positive findings in NEP evaluations of bias; thus only researchers who had not gone on record as favoring or opposing NEPs were included in the UC study team. The original Principal Investigators were Dr. Philip R. Lee and Dr. Arthur L. Reingold. On July 2, 1993, when Dr. Lee was appointed Assistant Secretary for Health, he was replaced as Principal Investigator by the author of this article, who had been the study's Project Director.

Study Methods

The study was conducted between April 1992 and September 1993; it consisted of four principal activities, described in detail elsewhere.[10] First, some 2,000 written documents were reviewed, including published articles, conference abstracts, unpublished manuscripts, book chapters, internal NEP documents, and newspaper articles. Second, site visits to 23 NEPs in 15 cities in four countries were conducted. At those visits, the NEPs were observed and individuals central to the evolution of the local NEP, particularly those who actively opposed or supported the NEP, were interviewed. These included elected public officials, IDU researchers, public health officials, business people, neighborhood residents, and representatives of religious and ethnic minority groups. Focus groups were also conducted with IDUs who were using the NEP and those who were not. In sum, 239 individuals were interviewed. Third, the investigators conducted a mail survey of NEPs in the United States that the team was unable to visit. Finally, the findings of the New Haven research were reviewed in detail, and additional mathematical models were developed to estimate the cost-effectiveness of NEPs in preventing HIV infection.

Five peer reviewers, including opponents and supporters of NEPs, and the CDC Project Officer reviewed the full report. In addition, two mathematical modelers reviewed the portions specific to their expertise, and selected chapters were circulated to university, CDC, and other government researchers for further comment.

The Role of the "Drug Czar's" Office

While the UC report was being prepared, other federal agencies entered the NEP debate. In June 1992, the ONDCP (known colloquially as the "Drug Czar's Office") released a report entitled "Needle exchange programs: are they effective?" The report, published in the *ONDCP Bulletin,* concluded that "there is no getting around the fact that distributing needles facilitates drug

use and undercuts the credibility of society's message that using drugs is illegal and morally wrong."[11] The report concentrated in large part on the results of the New Haven evaluation, which had concluded that NEPs decreased the incidence of HIV infection among participants in the program by 33%.[12] The ONDCP, long an opponent of NEPs, criticized various aspects of the study, including study retention rates, data on syringe sharing, and generalizability of results. These criticisms have never been subjected to peer review and have been addressed in detail in a peer-reviewed journal by the principal investigator of the New Haven study.[13]

Nonetheless, the *ONDCP Bulletin* continues to play a role in the evolution of NEPs. Its release generated significant media attention[14] and it was cited by California Governor Pete Wilson when he vetoed a 1992 bill that would have permitted NEPs in California jurisdictions that wanted them.[15] ONDCP Director Martinez also sent copies of the *Bulletin* to the mayors of cities with NEPs.[16] More recently, the *Bulletin* has figured prominently in debates over NEPs in Tacoma, WA and Sacramento, CA, where a county supervisor opposed to establishing a local NEP sought to portray the *Bulletin* as the actual New Haven study.[17]

ONDCP also contracted with Abt Associates, Inc., a Cambridge, MA health-consulting group, to conduct telephone interviews with the staff of more than a dozen NEPs in the United States. However, the results of the survey were never made public, prompting an exchange of letters between the Drug Policy Foundation, a critic of federal drug policies, and ONDCP. In a letter to ONDCP Director Martinez, the Foundation's vice-president, Kevin Zeese, wrote: "Honest debate requires the release of research conducted with federal tax dollars."[18] ONDCP Chief of Staff Terence Pell replied that the study was "never intended for public dissemination" and that "Possibly, when the study is finalized, we will release our findings in an ONDCP Publication."[19] Three years later, these data have not been made public. As discussed further, this would not be the last time that the government would decline to release scientific information on NEPs.

The election of Bill Clinton as President in November 1992 seemed to usher in a new phase in the history of NEPs in the United States. Candidate Bill Clinton promised, as did the Democratic Party platform,[20] that he would convene a task force to "rapidly review and implement the recommendations of the National Commission on AIDS,"[21] which had endorsed NEPs in its 1991 report.[22]

The General Accounting Office Report

The General Accounting Office (GAO), a nonpartisan research arm of Congress, also became involved in the evaluation of NEPs.[23] In 1991, Rep. Charles Rangel (D-NY), Chairman of the House Select Committee on Narcotics Abuse and Control and a strong opponent of NEPs, requested that the GAO review existing research on NEPs, particularly those studies cited by the National Commission on AIDS.[22] The GAO report, a 33-page document drawing largely on published studies and consultation with legal and mathematical-modeling experts, concluded in March 1993 that "research [on NEPs] suggests promise as an AIDS prevention strategy."[24] Specifically, the report concluded that most studies did not show increases in drug injection among IDUs using the NEP, that some studies showed decreases in syringe sharing among those IDUs, and that many NEPs had successfully linked IDUs to drug treatment and other public health services. It described the New Haven mathematical model as "credible" and concluded that "Existing statutory authority does . . . permit use of federal funds for studies or demonstrations of needle exchanges, which might involve provision of needles."[24] To date, the authority to fund demonstration NEPs has not been exercised. (Demonstration projects of new interventions are used to provide services accompanied by evaluation.)

The National Commission on AIDS praised the GAO study as "consistent with the Commission's own findings that needle exchange programs do not lead to more drug use, and they do result in behavior change likely to lead to reduced transmission of

HIV."[25] In an apparent (and successful) attempt to minimize media attention,[26] Rep. Rangel released the GAO report on a Friday (a slow news day), and described the report as "inconclusive".[27]

The Release of the University of California Report

Even before its release, the conclusions of the UC report were the subject of considerable media speculation.[28,29,30] Newly appointed national AIDS policy coordinator Kristine Gebbie told reporters in June 1993 that she supported NEPs and that "we're looking forward to a major review of needle exchange programs due out in a very short period of time."[31]

On September 30, 1993, the report was released at a press conference in San Francisco. The release was extensively covered in the national media, including National Public Radio, the Cable News Network (CNN) and a number of major newspapers, including the *New York Times* and the *Los Angeles Times*.[32,33,34,35]

The report came to two major policy-relevant conclusions. First, it concluded that multiple lines of evidence (biological plausibility, decreased syringe sharing among NEP participants, protection against hepatitis B infection, several mathematical models including that from New Haven) made it "likely" that NEPs decrease HIV seroconversion rates. Second, it stated that "available [data] provide no evidence that [NEPs] increase the amount of drug use by [NEP] clients or change overall levels of non-injection drug use."[3,4] Based on these findings, the UC report recommended that the ban on federal funding of NEP services be lifted, and that state prescription and paraphernalia laws that restrict the availability of sterile syringes to IDUs be revoked or modified. Over 12,000 copies of the various volumes of the report have been distributed.

The UC Report was released shortly after a California bill, similar to the one vetoed by Governor Wilson in 1992, passed the State Senate. On October 4, three members of the UC report team traveled to Sacramento and conducted a 2-hour briefing of senior members of the Governor's staff.[36] However, Governor Wilson

and his staff were not persuaded and on October 8, 1993 the Governor once again vetoed the NEP legislation,[37] indicating in his veto message that the UC report had not demonstrated a reduction in HIV transmission to his satisfaction. "In blunt terms," he stated, "is it worth reducing the risk of infection to intravenous drug users at the potentially far greater cost of undermining all our other preventive anti-drug efforts and suffering as a result an enormous increase in the number of young people who make a wrong choice that leads to an enormous increase in addicts?"[37]

Federal Government Reviews of the UC Report

Federal officials were evasive when the UC report was released. CDC officials declined to be interviewed by CNN reporters, claiming that they had not read the report.[38] CDC's official response to the report was: "We plan a detailed review of the report and its findings and will be in a position to comment after that is done."[39] On October 15, 1993, Jo Boufford, Principal Deputy Assistant Secretary for Health in the Office of the Assistant Secretary for Health, requested that CDC review the UC report and provide recommendations for federal policy on NEPs.

Over the next 2 months, CDC consulted with all federal agencies with expertise relevant to NEPs: the National Institutes of Health (principally NIDA), the Substance Abuse and Mental Health Services Administration (principally the Center for Substance Abuse Treatment), the Health Resources and Services Administration, and the Food and Drug Administration. The completed 42-page review was signed by CDC Director David Satcher, MD, and forwarded to the Office of the Assistant Secretary for Health on December 10, 1993.[40]

The CDC review endorsed the conclusions and recommendations of the UC report. It described the report as "careful and scientifically sound" and characterized it as "the most extensive and comprehensive study of needle exchange ever published."[40] The review concluded that "Several findings strongly support the conclusion that NEPs reduce HIV transmission" and that "No

data exists indicating increases related to NEPs in either drug use or in the number of discarded syringes."[40] Finally, the review stated: "We conclude that the ban on Federal funding of NEPs should be lifted to allow communities and States to use Federal funds to support NEPs as components of comprehensive HIV prevention programs."[40] Even NIDA, long skeptical about the efficacy of NEPs, stated in an attachment to the CDC review that, "With respect to the [federal] funding of services, it appears reasonable, as the [UC] Report suggests, that the ban on funding be lifted."[41] *The federal government has never made the results of its own review of the UC report public,* although a copy was provided by the Office of the Assistant Secretary for Health to Representative Henry Waxman's (D-CA) office in November 1994 on the condition that it not be distributed further.[42]

The Federal Government Reviews of the UC Report Become Public

Through much of 1994, the federal response stalled in bureaucratic limbo. In January, Clinton Administration national AIDS policy coordinator Gebbie told the US Conference of Mayors that the Clinton administration was studying whether to lift the ban on federal NEP funding, but that the nation's mayors could proceed to implement NEPs without a decision from the administration.[43] Otherwise, the government was noticeably silent on the issue. In March 1994, the first national public opinion poll on the issue revealed that 55% of the 1,001 respondents supported NEPs.[44] In July, an Institute of Medicine study on AIDS behavioral research described NEPs as "highly promising" and advocated lifting the federal ban on NEP funding.[45]

The failure of the government to release its review of the UC report was first raised publicly in an oral presentation by the author of this article at the Tenth International Conference on AIDS in Yokohama, Japan on August 11, 1994.[46] Press attention was limited to a segment on CNN, in which CDC Director Satcher confirmed the existence of the government review but declined to

divulge its contents, and a brief mention in the *San Francisco Chronicle*.[47] On December 6, 1994, a front-page *Chronicle* story noted the existence of the review, but provided no details as to its contents.[42] An anonymous Public Health Service source quoted in the *Chronicle* article described the matter as "officially still under review."[42]

In fact, shortly before the *Chronicle* story, the CDC had been directed by the Office of the Assistant Secretary for Health to conduct a second review of NEPs, summarizing information that had become available since the UC report. The second review, which was only seven pages long and made no recommendations with respect to federal NEP policy, was completed on November 22, 1994.[48] The review included summaries of three new studies with beneficial NEP effects on syringe sharing and one that provided further evidence of the protective effect of NEPs on IDU risk for hepatitis B and C, which was described in the review as demonstrating "more clearly than any previous research that use of NEPs is associated with decreases in blood-borne infections."[48] It also made reference to an unpublished Montreal study in which the HIV seroconversion rate was higher among NEP participants than among other IDUs.[49]*

On February 3, 1995, Assistant Secretary for Health Philip Lee, the former Principal Investigator of the UC Report, was in San Francisco to give the closing address at the 7th Annual AIDS Update Conference. A copy of his prepared remarks indicate that he planned to refer briefly to studies from Montreal, San Francisco and the Netherlands (all of them unpublished and some the subject of great controversy) as well as the government's "thorough review of the published literature" and would conclude: "Based upon the evidence now available to me, and in light of the explicit nature of the restriction, we cannot say that Needle Exchange programs decrease HIV transmission. As a result, the requirement in the statue [sic] is not met at this time."[50]

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* This finding could well be the result of selection bias, particularly in a city where the NEP is relatively small and only open at night, and where there is widespread availability of syringes through pharmacies, a circumstance unlike any in the United States.

The statute he specifically referred to was the Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Act. The Act makes it clear that the administration has the authority to lift the ban on federal funding for NEP services if the Surgeon General determines that NEPs "are effective in preventing the spread of HIV and do not encourage the use of illegal drugs, except that such funds may be used for such purposes in furtherance of demonstrations or studies authorized in the ADAMHA Reorganization Act." Nowhere in Dr. Lee's prepared speech was there reference to the UC report, the two CDC reviews, the GAO report, or any other restriction on federal funding of NEPs. However, when delivering the speech, he omitted the entire section dealing with injection drug use at the last moment and discussed the Administration's health-care reform plans instead.

By this point, federal policy on HIV prevention among IDUs was rapidly moving away from NEPs toward a less controversial policy in which IDUs would be exhorted to use a syringe only once before discarding properly. This was the subject of a conference at Johns Hopkins University on February 15 and 16, 1995. Dr. Eric Goosby, Designated Director of the National AIDS Policy Office, gave an address that, in the portions addressing federal NEP policy, was markedly similar to the one that Dr. Lee had decided not to give in San Francisco two weeks earlier. Dr. Goosby cited the same three unpublished studies, describing their findings as "explainable," but said that they raise "big enough questions to preclude [lifting the federal ban] at this time." "[One] cannot say that NEPs decrease HIV transmission," he concluded.

Unlike Dr. Lee, Dr. Goosby also referred to the Health Omnibus Programs Extension of 1988, which requires the Surgeon General to determine that an NEP "would be effective in reducing drug abuse and the risk that the public will become infected with the etiologic agent for acquired immune deficiency syndrome." This law is more restrictive than the law cited in Dr. Lee's written remarks (it requires that the Surgeon General certify a reduction, rather than no increase, in drug abuse related to NEP

use), and had not previously been cited by the administration as an obstacle to federal NEP funding. Dr. Goosby did not take questions from the audience and left immediately after his address. The administration's position was now official: there would be no federal NEP funding.

The day after Dr. Goosby's address, the *Washington Post* ran a prominent story revealing the contents of the two CDC reviews for the first time.[51,52] Reached for comment, Dr. Lee cited the existence of unpublished studies and the restrictiveness of federal law.[51] Three weeks later, the Drug Policy Foundation released the actual documents to the press and held a Congressional Forum on NEPs, generating a further round of press coverage.[53–59] By this point, the administration was increasingly emphasizing the more restrictive language contained in the Health Omnibus Programs Extension. A spokesperson for the Department of Health and Human Services even conceded that the UC report "does offer conclusive evidence of the effectiveness of needle exchange for curbing the transmission of HIV," but stated that it failed to demonstrate a reduction in drug abuse.[56] Although there is still debate over which statutory language applies, no one has challenged the GAO's assertion that federally funded demonstration NEPs could be established today without a finding of any sort by the Surgeon General.[24] There has been little public debate over federal NEP policy since the events described here, and no evidence of an imminent change in federal policy.

Discussion

In summary, the federal government funded a comprehensive study of NEPs that recommended lifting the federal ban on funding NEPs; its most senior scientists endorsed the study's conclusions and recommendations, but the government instead elected to suppress the internal reviews and then cite unpublished, often inaccurate studies when called upon to justify its inaction. There is no other example in the 14-year history of the HIV epidemic where government scientists determined a preven-

tive intervention to be effective, and then the government elected to deny it to the group at highest risk for this fatal infection.

This is, of course, not the first time that federally funded AIDS prevention and behavioral research has become a casualty of the political process. Other examples are an amendment by Senator Jesse Helms (R-NC) rescinding funds for a survey of adult sexual behavior,[60] the revocation by Health and Human Services Secretary Louis Sullivan of a National Institutes of Health grant for a survey of adolescent sexual behavior,[61] a $20-million congressional appropriation to the US army (skirting peer review) to conduct an efficacy trial of a specific HIV vaccine after intense lobbying by the manufacturer,[62] and federal opposition to a study of the potential efficacy of inhaled marijuana in reducing nausea and wasting in HIV-infected persons.[63]

What can be learned from these events? First, although government officials may pay lip service to science, they will at times ignore results inconsistent with their policies, regardless of the quality of the research that generated those results. In this case, they have selectively cited studies with known limitations that have never been published or survived peer review. Researchers simply cannot count on the good graces of government to deliver the policies that science would mandate. Rather, scientists have a responsibility to become actively engaged in the political debates generated by their work to minimize the kinds of distortions of science that occurred here.

Second, researchers should be aware that their studies, however justifiable from a scientific perspective, may be used by policy-makers to defer decision-making on controversial topics. Particularly in the AIDS field, controversial decisions have frequently been delayed as policy-makers claim to await the results of the next study or identify the lack of some crucial piece of data that allegedly precludes immediate action. While, in certain circumstances, deferring public health decisions until definitive data become available may be justifiable, the evaluation of preventive interventions for an epidemic of a fatal, completely preventable disease primarily affecting the young is not one of them. Certainly,

other HIV prevention interventions, such as bleach disinfection of syringes and sexual abstinence outside of marriage, have been endorsed in the absence of any evidence that they reduce HIV seroconversion rates. In contrast, in the NEP debate, even a stream of endorsements of the programs by the Institute of Medicine (twice), the National Commission on AIDS, CDC, GAO, two earlier National Academy of Sciences reports,[64,65] and the UC Report, as well as a favorable public opinion poll (not to mention acceptance in most other industrialized countries[4]) have been insufficient to convince federal decision-makers who profess lingering doubts about the data. Policy-making in science should not depend on the data alone; other social, ethical, or legal concerns can also be a legitimate part of the decision-making equation. But depicting a policy as science-based when it is largely political seems disingenuous.

Third, the current emphasis on the more restrictive provisions of the Health Omnibus Programs Extension amounts to a legalistic shifting of the goalposts. The GAO's conclusion that federal funds can be used today for demonstration NEPs[24] without any finding by the Surgeon General has never been challenged. This mechanism could be used to fund large numbers of NEPs: NIDA has funded demonstration projects to evaluate the effectiveness of street-based outreach on IDU risk behaviors in 60 communities.[66]

Fourth, the federal debate over NEP policy would surely have had a different outcome had the potential beneficiaries not primarily been IDUs. California Governor Pete Wilson's 1993 veto message quoted above is a concrete expression of this, in that he explicitly balanced the benefits of NEPs to IDUs against the potential (unproven) risks to others.[37] A description of how the federal resistance to NEPs fits into the overall "War on Drugs," and its attendant stigmatization of drug users, is beyond the scope of this paper. However, it seems improbable that the federal government would deny a preventive intervention that its own scientists recommended to non-drug-using heterosexuals.

Fifth, federal policy is moving away from NEPs toward the less controversial notion of recommending that IDUs not re-use

syringes. (Indeed, the federal government essentially made such a recommendation when it stated in 1993 that bleach "is not as safe as always using a sterile needle and syringe."[67]) While this recommendation is unexceptionable and should be implemented, it will remain a hollow policy if the legal limitations to sterile syringe access are not simultaneously addressed. These legal limitations on sterile syringe access include the state prescription and paraphernalia laws, the federal Model Drug Paraphernalia Act and the federal Mail Order Drug Paraphernalia Control Act,[68] all of which should be revoked or revised inasmuch as they apply to needles and syringes. Of course, ideally the modification of these laws on syringe possession and sale would complement federal support for NEPs.

Finally, IDUs and their advocates should redeploy their resources to emphasize more state and local activism. Science that has fallen on deaf federal ears may receive a fairer hearing from state legislators, local elected officials, and judges. Despite opposition from the federal government, the number of NEPs in the US has increased from 37 at the time of the release of the UC report to 76 in December 1994.[69] Many IDUs, their sex partners, and their children may be alive today as a result of these efforts, which are a beacon of hope in a sea of governmental intransigence and irresponsibility.

Addendum

Since this article was submitted, the Institute of Medicine has completed a congressionally mandated review of the scientific data on NEPs.[70] Released in September 1995, the review concluded that NEPs reduce the spread of HIV without increasing drug use among NEP clients or in the general community. The review included data obtained at a meeting specially convened to review the unpublished studies cited by the Administration in February 1995 to justify its failure to endorse NEPs. The panel was not swayed by these studies, which remain unpublished. Of one of these studies the review stated: "In sum, based on the

panel's interpretation, we cannot say that the data justify the conclusions the researchers have reached." The panel recommended that the federal ban on NEP funding, and the state prescription laws, be revoked, and that the state paraphernalia laws be modified insofar as they apply to needles and syringes.

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