

## Political Points

Dr. Lang, a public health epidemiologist, is interested in the use of sterile needle exchange programs (NEPs) to reduce the rates of HIV in injection drug users. She designed a study that provided the data about the seroprevalence of HIV among injection drug users in Capitol City (a city not studied previously) and tracked seroprevalence over time in a population that used NEPs and a group that did not. The study design did not allow Dr. Lang to assign subjects randomly to the groups of NEP participants or nonparticipants.. She recruited the NEP participants at the exchange. To recruit the nonparticipants, she placed an ad in the local paper and hung fliers in community centers, shopping galleries and free health clinics throughout the city. She collected demographic and HIV risk behavior data through a written survey and administered HIV tests to obtain seroprevalence data at the beginning and end of the study period.

Upon completion of the study, she finds surprising results: NEP participants showed higher HIV infection rates over the study period than nonparticipants. This finding contradicts all the research she has read on the subject, which indicates in controlled studies and across cities that needle exchange programs significantly reduce rates of HIV infection among injection drug users, without increasing drug use.

On analyzing her results, Dr. Lang observes that they may have been biased by the fact that the NEPs she studied were located in inner-city neighborhoods, serving a population at higher risk of infection. Those who did not accept the needles at the exchange tended not to need them because they could afford to buy them on the black market or travel across state lines to buy them in drugstores. Moreover, she found that the nonparticipants were less likely to participate in the riskiest activities. She included these observations and explanations in her draft paper.

While Dr. Lang is confident that her colleagues will understand (although not necessarily agree with) her interpretation of her results, she also knows that needle exchange is a hotly debated political issue that has recently been taken up by people she considers to be religious extremists. She fears that they could misrepresent her results as support for their political goals—ensuring that the government refuse to approve NEPs and shutting down existing programs, including the one where she does her research. She is afraid to circulate her draft paper to colleagues for comments because she knows that even an unpublished study could be cited by activists or discussed in the media.

Although she is not directly involved in the NEP, she knows the activists well because of her research with them, and because she was present at the site on many occasions to gather data and interact with the study participants. The exchange is in a precarious position due to the state's drug paraphernalia laws, and the fact that research is done on site has helped the activists achieve a policy of tolerance from local law enforcement. She fears the misrepresentation of her research may lead to the closing of many NEPs and more new, preventable cases of HIV in those areas.

She also fears that if her findings are cited by lobbyists against needle exchange, her reputation may be tarnished both among her colleagues in the public health field who may not take the time to read her article and among the activists, study participants and clients of the needle exchange. On the other hand, she has spent three years designing and conducting this study, and if she doesn't publish soon, she will have nothing to show for years of hard work and thousands of funding dollars.

### **Discussion Questions**

1. Who has an interest in Dr. Lang's research (including Lang herself)? What are her obligations to each interested group? How should these obligations affect her decision to publish?
2. What are researchers' responsibilities in experimental design and implementation of research on politically charged issues? What are their responsibilities in presenting their results to the scientific community and to the public at large? What is the appropriate course of action when a researcher discovers a flaw in her experimental design?
3. What are the responsibilities of the media and politicians in distributing and interpreting the results of such a study?
4. Should Dr. Lang publish her study? Why or why not?

## Commentary

This case is based on real studies that were conducted in Vancouver and Montreal (Bruneau et al., 1997; Strathdee et al., 1997a, b; Archibald et al., 1998). When researchers found that needle exchange did not reduce the spread of HIV among their subjects, congressional leaders in the United States and conservative Christian groups like the Family Research Council demanded an end to NEPs, (E.g., Maginnis [1998a] specifically cites the Bruneau et al. [1997] and Strathdee et al. [1997a] studies). Though some may find the reference to “religious extremists” biased and even inflammatory, it reflects the political environment in which needle exchange and needle exchange research take place. (See Maginnis, 1996a-c, 1997a-d, 1998a-c for Family Research Council articles on the topic). Relevant policy research necessarily hits on such hot-button issues.

Dr. Lang and the real-world researchers on whom this case is based are indeed needle exchange advocates (Bruneau and Schechter, 1998b), but it is up to the reader to decide whether theirs is a well-researched, rational, professional opinion or the view of passionate activists. It is important to address the issue of bias in research head on. What are the limits to the objectivity of science? Relevant to the issue of needle exchange and HIV/AIDS in particular is the role that social injustice plays in disease, which is increasingly recognized by the public health and medical communities. How researchers deal with bias varies across and even within fields.

Is bias something to be minimized, avoided and downplayed, or is it something to be named in order to contextualize the work and help others understand it? Is it possible to be a competent, well-read researcher on such a hot-button issue and not have an opinion on the efficacy of NEPs? Does having no opinions in this environment reflect a kind of bias against the existing research? How confident is Dr. Lang in her explanation of confounding variables in her study? What if she is wrong? What if needle exchange really does increase HIV through some as yet unknown mechanism? What is her responsibility as a scientist to report her results as she finds them, and where is the line between experienced interpretation of results and unfounded argument?

What are researchers’ obligations in the process of policy making and politics? In the Montreal and Vancouver studies, the misrepresentation of results in the public arena was so significant that the studies’ authors published an op-ed piece in the *New York Times* about the distortion of their findings by American policy advocates, politicians and journalists (Bruneau and Schechter, 1998a). Local government in Canada responded to the studies by expanding needle exchanges and adding other health services for injection drug users. In the United States, however, the Clinton administration upheld the federal ban on funding for needle exchanges, which had a chilling effect on many less established local needle exchanges (Freedberg, 1998; Neal, 1998).

One might ask if Dr. Lang is obliged to be similarly active in communicating her results in the political sphere; while Bruneau and Schechter responded only after damage had been done, Dr. Lang anticipates the misrepresentation of her results and has the option to act preventatively. Where does Dr. Lang's role as a researcher meet the ethical responsibilities of journalists reporting on science and health policy issues or the responsibilities of policy advocates and public servants to accurately represent research findings?

This case raises further questions about the social consequences of scholarly research and the responsibilities of researchers to various communities with which they interact. What should be done when these interests and responsibilities conflict? On the one hand, Dr. Lang's finding that needle exchange did not aid HIV prevention could result in the shutdown of the exchange and any future research she had planned there. On the other hand, she is under pressure from her funders to publish, and findings that so blatantly contradict the dominant belief in her field could be her ticket to fame or notoriety, depending on whether she is right.

One might explore the possible alternatives Dr. Lang faces in her choice to publish. She might, for example, choose to present her results in the best light possible, perhaps falsifying or omitting some of her data. She might delay publication, wanting to collect more data that might alter her findings. What are the implications of these decisions for each party involved in and affected by the research?

The nature of Dr. Lang's relationship with the NEP's activists and clients is a key issue. There is a strong possibility that the trust the exchange had established with clients would be eroded by articles in the paper against needle exchange that used Dr. Lang's findings for support. To what extent are the needle exchange activists and clients partners in research? What kind of role would they ideally play in such a project?

Because injection drug users have so little access to health care, needle exchange can be their only bridge to health care services (including, in many cases, drug treatment). Might access to certain forms of medical care such as free HIV testing serve as a coercive inducement to participation in research? How might Dr. Lang address the concerns of some community members who view needle exchange as part of a racist effort to bolster the influx of drugs to poor, African-American communities? What are the ethical issues involved in a research project that monitors the spread of HIV through the voluntary use of and refusal of needles? For example, what follow-up care should be planned for those who do contract HIV during the course of the study? With a disease like HIV for which effective treatment is not an option in poor communities, what is the researcher's responsibility to disseminate information about HIV prevention? Does this responsibility compromise the "objectivity" of the study? How can such a conflict be resolved?

Perhaps Dr. Lang's situation could have been avoided entirely with a more appropriate research design. Discussions of this case may include brainstorming about

what kinds of designs might have eliminated or minimized the flaw in Dr. Lang's work. Could she have foreseen this problem? What should scientists do when they make such mistakes?

## References

- Archibald, C.P., M. Ofner, S.A. Strathdee, D.M. Patrick, D.Sutherland, M.L. Rekart, M.T. Schechter and M.V. O'Shaughnessy. "Factors Associated with Frequent Needle Exchange Program Attendance in Injection Drug Users in Vancouver, Canada." *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* 17 (2, 1998): 160-66.
- Bruneau, J., F. Lamothe, E. Franco, N. Lachance, M. Desy, J. Soto and J. Vincelette. "High Rates of HIV Infection among Injection Drug Users Participating in Needle Exchange Programs in Montreal: Results of a Cohort Study." *American Journal of Epidemiology* 146 (12, 1997): 994-1002.
- Bruneau, J., and M.T. Schechter. "The Politics of Needles and AIDS." *New York Times*, April 8, 1998. (1998a).
- Bruneau, J., and M.T. Schechter. "Needle Exchange Programs Do Work." *Chicago Tribune*, April 23, 1998; Sec. 1, p. 22, sol. 3. (1998b).
- Freedberg, L. "White House Needle Swap Surprise: A Refusal to Lift Ban on Program Funding." *San Francisco Chronicle*, April 21, 1998, Sec. A., p. 1, col. 5.
- Maginnis, R.L. "Will Exchanging Needles Save America's Future?" Insight, Family Research Council, May 1996. <http://www.frc.org/insight/is96e1dr.html>. (1996a).
- Maginnis, R.L. "Government Should Not Encourage Newest Heroin Epidemic," Perspective, Family Research Council, September 1996. <http://www.frc.org/perspective/pv96i2dr.html>. (1996b).
- Maginnis, R.L. "'Harm Reduction' an Alternative to the Drug War?" Insight, Family Research Council, October 1996. <http://www.frc.org/insight/is96j1dr.html>. (1996c).
- Maginnis, R.L. "An Update: Free Needles for Junkies?" Insight, Family Research Council, June 1997. <http://www.frc.org/insight/is97f2dr.html>. (1997a).
- Maginnis, R.L. "Swiss Heroin Giveaways, Media and National Security," Insight, Family Research Council, July 1997. <http://www.frc.org/insight/is97g1dr.html>. (1997b).
- Maginnis, R.L. "America Assesses Needle Exchange Programs," Special Publication,

- Family Research Council, August 1997. <http://www.frc.org/misc/nep>. (1997c).
- Maginnis, R.L. "Voters Reject Free Needles for Addicts," Article, Family Research Council, October 1997. <http://www.frc.org/articles/ar97j2dr.html>. (1997d).
- Maginnis, R.L. "1998 Update: Free Needles and Politics," Insight, Family Research Council, March 1998. <http://www.frc.org/insight/is98c1dr.html>. (1998a).
- Maginnis, R.L. "Religious Voters Assess Drug Policy," In Focus, Family Research Council, March 1998. <http://www.frc.org/infocus/if98c2dr.html>. (1998b).
- Maginnis, R.L. "Needle Exchanges are Bad Medicine," At the Podium, Family Research Council, June 1998. <http://www.frc.org/podium/pd98f1dr.html>. (1998c).
- Neal, T.M. "Drug Policy Chief is Facing Some New Foes; McCaffey's Tactics on Needle Exchange Program Prompt Anger Among Advocates." *Washington Post*, May 18, 1998, Sec. A, p. 15, col. 1.
- Strathdee, S.A., D.M. Patrick, S.L. Currie, P.G. Cornelisse, M.L. Rekart, J.S. Montaner, M.T. Schechter, and M.V. O'Shaughnessy. "Needle Exchange is Not Enough: Lessons from the Vancouver Injecting Drug Use Study." *AIDS* 11 (8, 1997a): F59-65.
- Strathdee, S.A., D.M. Patrick, c.p Archibald, M. Ofner, P.G. Cornelisse, M.L. Rekart, M.T. Schechter, and M.V. O'Shaughnessy. "Social Determinants Predict Needle-sharing Behaviour among Injection Drug Users in Vancouver, Canada." *Addiction*, 92 (10, 1997b): 1339-47.

## Commentary on “Political Points”

**Brian Schrag**  
**Indiana University**

This case raises a host of ethical issues, including a researcher’s responsibility to ensure good design in human subjects research, particularly for topics that are politically sensitive. The case presents issues of truth telling and deception in the reporting of findings and of the relative strength of obligations to report findings honestly as weighed against harms those findings might cause to others. Finally, it raises issues of the degree to which researchers have a responsibility to ensure their findings are not misrepresented or misused.

In this case, there are a number of stakeholders, and Lang may have moral obligations to most of them. Stakeholders include the general public, which relies on solid scientific information for making sound health policy and promoting public health; the scientific community; the needle exchange activists; the needle exchange participants; the opponents of needle exchange; the funders for Lang’s research. Lang might also consider her own self-interest.

One can start with the observation that all stakeholders are ultimately best served if Lang is doing good science. One of the scientist’s primary obligations is to design studies that have potential to provide useful results. One issue raised by this case is whether Lang has done that and consequently, whether she has results worth reporting.

Whether Lang has fulfilled this obligation depends in part on the study’s objective. The point of needle exchange programs (NEPs) is to reduce the spread of HIV by reducing needle sharing by injection drug users. Lang “designed a study that would provide data about the seroprevalence of HIV among injection drug users in Capitol City...and track seroprevalence over time in a population that used NEPs and a group that did not.” The significance of that data depends on the precise objective of her study. 1) One could do a study to determine NEPs’ effectiveness in reducing HIV transmission. Answering that question would presumably require a randomized, controlled clinical study. As described, Lang’s is not such a study but rather an observational study. So presumably her objective is not to determine NEPs’ effectiveness in reducing HIV transmission. 2) Lang may be trying to simply a) measure the level of seroprevalence among NEP participants, and b) monitor that level of seroprevalence over time compared to some other group; this objective could be achieved by an observational study. Lang appears to be doing the latter, but her objective is still not clear.

Surely she is not simply interested in measuring the initial level and continuing levels of seroprevalence among NEP participants, *simpliciter*, but rather those levels compared to some other group. One must have some context in which to make sense of the significance of measured levels of seroprevalence. For example, one could compare levels of seroprevalence among NEP participants to nondrug users, to the general

population, to drug users who are not participants in NEP programs, or to drug users who are not participants in NEPs but who are otherwise *relevantly similar* to NEP participants.

Even if this is an observational study and not a clinical trial, the nonparticipant group can be used to provide some context for interpreting the significance of the findings. In the design of a study, one always makes judgments about the criteria of relevant similarity of the observational and control groups. The very choice of the control group is always a decision about the criterion of relevant similarity of the control group to the study group.

Thus, one could compare the seroprevalence levels of NEP participants to a group of NEP nonparticipants whose only relevant similarity is that there are intravenous drug participants. They may vary completely with regard to other risk factors for HIV. Or, one could compare the seroprevalence levels of NEP participants to a matched group of NEP nonparticipants who are also relevantly similar with regard to other risk factors such as likeliness to engage in prostitution, “inject frequently, borrow injection equipment, frequent shooting galleries, share equipment with HIV positive injection drug users.”<sup>1</sup>

If the researcher ignores such well-established risk factors in the criteria for selection of nonparticipants, what has one learned by such a study? If the seroprevalence levels of the NEP participants are compared to nonparticipants, the significance of the comparison is not clear. This measurement may be an instance of garbage in, garbage out. Since the comparison is between NEP participants and nonparticipants, and since needle exchange is such a controversial issue, one can predict in advance that activists on one side or the other are likely to use the results, whatever they may be, to bolster their positions. Thus, one should at least be sure that there is a possibility of useful results. The worst outcome is to generate scientifically useless data that is still used for political agendas.

Given the case description, it appears that Lang may have failed to pay sufficient attention to selection of the nonparticipant group. The candidates for the nonparticipant group were surveyed for risk behavior at the beginning of the study. At that point, Lang could have screened the nonparticipant group to include only those who matched the study group in terms of risk behavior. For whatever reason, she did not. There are several possibilities here, regarding her moral responsibility for what follows.

*Scenario 1* First, suppose there is, in fact, a clear and significant difference between the nonparticipant group and the participant group regarding these risk factors and that that difference could have been anticipated and eliminated by careful study design. In that case, Dr. Lang has just done bad science, and there is no reason to suppose any results she may obtain from her study could tell us anything about the significance of

---

<sup>1</sup> These risk factors are identified in a historically similar (but not identical) case. See J. Bruneau et al., “High Rates of HIV Infection among Injection Drug Users Participating in Needle Exchange Programs in Montreal: Results of a Cohort Study” and P. Lurie, “Invited Commentary: Le Mystere Montreal,” *American Journal of Epidemiology* 146 (1): 994-1005.

the seroprevalence data for injection drug users in Capitol City and the tracking of seroprevalence over time in a population that used needle exchanges compared to one that did not.

If that is the case, Lang has certainly acted irresponsibly as a scientist and with respect to her funding agency by using the funds for a poorly designed study. In addition, if her study produces unreliable evidence, which somehow gets publicity and is then used to undermine the work of the activists and the welfare of drug users who cooperated with her, she has harmed them as well. Finally, her unreliable results may be used to shape public policy in a way that harms the public good. All of these moral harms could have been avoided if she had taken care in the original design. Sometimes scientists need to practice “preventive ethics,” avoiding moral difficulties in the first place rather than having to resolve ethical issues afterward.

*Scenario 2* It may be the case that there is in fact a clear and significant difference between the nonparticipant group and the participant group but for some reason, Lang was not able to identify that difference during the study’s design. Perhaps the nonparticipant group misled her about their habits; perhaps some changed their behavior over the course of the three years. She may not be culpable for negligence in designing the study, but the study’s results are no less suspect. We still have no reason to believe that the results tell us anything. It is still the case that if her unreliable evidence somehow gets publicity and is then used to undermine the work of the activists and welfare of drug users who cooperated with her, they may be harmed, and her results may be used to shape public policy in a way that harms the public good. Thus, harms may result from this study although not necessarily because she did poor science. The harms may result from her efforts to publicize her results, however.

*Scenario 3* A third possibility is that some, but not all, of the NEP nonparticipant group did not share needles and some, but not all, engaged in less risky behavior than the NEP participant group and that these variations between the groups became clear only at the end of the experiment. At this point, Lang must try to determine whether the variations between the NEP participant and nonparticipant groups are sufficiently small to allow reliable conclusions to be drawn from the results.

In this last scenario, perhaps the results are indeed significant and that, for some reason, seroprevalence is higher among the study group than a relevantly similar nonparticipant group. If so, she has discharged her responsibilities as a scientist to design a good study that permits some confidence in the results. If those results run counter to the preponderance of studies, then perhaps she has identified some important factor overlooked by other studies. Consequently, our understanding of the epidemiology of the disease may be advanced.

As a scientist, Lang has an obligation to share with the scientific community. The results, if published, may indeed be used in ways that work to the detriment of the activists and NEP participants. Unlike Scenarios 1 and 2, here Lang is not morally

culpable for that harm either because of bad design or publicizing unreliable results. Neither is she culpable for the use of her results by others to mislead public policy deliberations simply because she publicized credible results that run counter to other results.

Some might say she is culpable for causing harm to the activists and NEP participants if she seeks to publish the results rather than to suppress them. She could refuse to publish the results. That criticism presumes that the results of the preponderance of studies are correct and that her results do not identify a factor that could improve the programs. However, if her results point to some significant factor overlooked by the other studies, suppression of the results would harm the addicts by depriving them of suitably modified programs.

There are additional moral issues regarding publicity about the results. Whether Scenario 1, 2 or 3 describes the situation, Lang is under pressure to publish for prudential reasons. Failure to publish may mean the current grant will not be renewed or future grants will not be forthcoming and her research career may be at an end.

In Scenarios 2 and 3, if she makes clear that the composition of the nonparticipant group is flawed, it is not clear that any journal would accept the paper. That may tempt her to omit the information or falsify information on the nonparticipant group in order to get published and to further or at least preserve her career in an important area of research. Lang has an obligation to the scientific community to include a full report of what she knows of the design flaws in her experiment or else not submit her paper for publication. Falsification or suppression of information regarding the nonparticipant group would not be justified by the need to publish. Deliberate suppression of information about the nonparticipant group would undermine the practice of science, undermine work in this field and undermine her own integrity. Even if she stands to gain as an individual by such an act, that is outweighed by the other considerations and is a morally unacceptable alternative.<sup>2</sup>

In Scenario 3, if she is satisfied that the match between the participant and nonparticipant groups is sufficient to produce reliable results, then she has an obligation as a scientist to publish the results, even though she is concerned that others may misuse those results for political purposes. If researchers are to engage in research in areas that are politically sensitive, they must be prepared to let the chips fall where they may in terms of honestly reporting findings. Otherwise, why bother to do the science? The fact that some harm could come from honestly reporting her results does not necessarily

---

<sup>2</sup> For a full general discussion of moral issues of lying and failing to reveal see Sissela Bok, *Lying: Moral Choice in Public and Private Life* (New York: Vintage Books, 1989) and Sissela Bok, *Keeping Secrets: On the Ethics of Concealment and Revelation* (New York: Vintage Books, 1989).

justify falsifying results or suppressing results. She owes the truth about her findings to all stakeholders, including those who oppose needle exchange programs.

One consideration is the particular good and harm that publication of these results may do to various stakeholders (e.g., pro-NEP activists, anti-NEP activists, NEP participants and Lang's credibility and her future access to these populations). But an equally legitimate concern is whether one can justify a practice of deciding to report or publish scientific findings on the basis of the impact of the findings on some ongoing political debate. It is not clear that such a practice could be morally justified in scientific research.

One can also consider the researcher's responsibilities to ensure fair and responsible reporting, interpretation and use of the researcher's findings. The researcher has these responsibilities both *qua* researcher and *qua* citizen.

At one level, the researcher cannot be held morally responsible for others' irresponsible use of the researcher's findings. If a journalist is too lazy or ignorant to do responsible reporting, that behavior is beyond the researcher's control. If politicians or activists willfully misuse findings to support a political agenda, they must be held morally accountable for that. However, if the researcher is in the best position to anticipate that her findings will be misused or to recognize they are being misused, then she has some obligation as a scientist with a commitment to the truth and as a citizen with a commitment to honest civic deliberation to take whatever steps she can reasonably take to prevent that abuse or to set the record straight.<sup>3</sup>

In Scenario 3, for example, perhaps she can alert her colleagues before publication so they are aware of the problems her findings may create in the public sphere and so they can be prepared to respond. Perhaps she could meet with journalists prior to release of the results to ensure they can place the results in the context of other research in the field.

---

<sup>3</sup> For other discussions in this series of researchers' obligations to counter misuse of their results, see the cases and commentaries in "Beyond Expertise: One Person's Science, Another Person's Policy" and "Crashing into Law" in Brian Schrag, ed., *Research Ethics: Cases and Commentaries, Volume 2* (Bloomington: Association for Practical and Professional Ethics, 1998).