

ADVISORY REPORT: PUBLICATION OF DATA
COLLECTED THROUGH UNETHICAL MEANS

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ADVISORY REPORT: Publication of data collected through unethical means

To: Colonel Stephanie Boyd

From: Director, Center of Disease Control and Prevention

By exposing patients to a lethal infectious disease without their consent, USAMRIID medical officer Major Pena breached numerous moral and legal principles. Although his actions deserve the severest reprimands and those repercussions deemed fit by the law to restore justice, no benefit arises from refraining to publish the data collected through the heinous experiment. No foreseeable further damage can result from publication of the results – in fact, allowing medical researchers access to the information may help mitigate future suffering through improved disease control and prevention. When conducted with appropriate sensitivity, publication may act as a method of acknowledging and sympathizing with the suffering of the victims while openly denouncing unethical practices. As the data cannot be replaced with information obtained through ethical means, increased access to the collected results may help prevent a repeat incident of the crime. Although it does not validate Major Pena's actions, the victims of the unwarranted experiment may value the small solace offered by the assurance that their past suffering will be directed towards the avoidance of future transgressions and infections.

The consequences of actions taken in similar past circumstances provide a frame of reference from which to judge the current situation. Previously, controversies have arisen in regards to the publication of scientific data based on either concern for public safety or outrage surrounding unethical investigative practices. As a response to the severely immoral research conducted under Nazi rule, international guidelines for ethical research involving human subjects were established in the Nuremberg Code and the Declaration of Helsinki.¹ Publication of data collected through unethical means is discouraged in the Declaration of Helsinki, which states that, "reports of research not in accordance with the principles of this Declaration should not be accepted for publication."² Major Pena's research unquestionably violates all codes of ethical research; however, in this specific situation, the benefits of publication appear to outweigh the potential harm. Although this route of action may not comport with the position endorsed by

¹ Sade RM. *Publication of Unethical Research Studies: The Importance of Informed Consent*. *Ann Thorac Surg* 2003;75:325-328

² World Medical Association, "WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects." Last modified 2008. Accessed October 25, 2012. <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>.

the Declaration of Helsinki, publication of these particular data offers an opportunity to prevent future suffering through an improved understanding of the disease and through a public denouncement of unethical practices.

In their Code of Medical Ethics, the American Medical Association (AMA) includes a supportive opinion on the publication of data collected through unethical means.³ The position states that publication with a disclaimer is warranted if the data are necessary to saving lives and cannot be replaced through ethical practices. In the present situation, the data cannot be obtained through morally-sanctioned practices. Although publication cannot guarantee saving future human lives, the intention is to assist in the diagnosis and prevention of a poorly-understood and lethal disease. The AMA provides comprehensive guidelines for the disclaimer to appear with the publication of data collected through unethical research and states that "such disclosure would by no means rectify unethical conduct or legitimize the collection of data gathered from unethical experimentation."⁴ Among other suggestions, the guidelines for the disclaimer include acknowledgement of the ethical violation, endorsement of better ethical standards, and expression of sympathy for the harmed victims. Following these guidelines produces a publication sensitive to the suffering endured by victims of the experiment and can act as a public denouncement of future unethical practices.

The legacy of infamous precedents suggests that Major Pena's actions are likely to have long-lasting impacts. The victims of this unfortunate experiment bear resemblance to those of the infamous Tuskegee experiment, in which the progression of syphilis was observed in African American subjects in rural Alabama over 40 years without providing access to reliable, developing cures.⁵ In a similar experiment conducted from 1946 to 1948 in Guatemala, prisoners were intentionally infected with syphilis.⁶ Apologies for this ethical violation were made by the U.S. government in 2010, after 64 years had passed.⁷ In these examples of unethical experimentation, outrage appropriately continues to focus on the direct unjust experience of the victims. The data collected from these experiments garners little attention

³ American Medical Association, "Opinion 2.30 - Information From Unethical Experiments." Last modified 1998. Accessed October 23, 2012. <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion230.page>.

⁴ Ibid.

⁵ James H. Jones, *Bad Blood: The Tuskegee Syphilis Experiment, New and Expanded Edition*, (New York: The Free Press, 1993).

⁶ U.S. Department of Health and Human Services, "Fact Sheet on the 1946-1948 U.S. Public Health Service Sexually Transmitted Diseases (STD) Inoculation Study." Accessed October 23, 2012. <http://www.hhs.gov/1946inoculationstudy/factsheet.html>.

⁷ Fox, Maggie. "U.S. apologizes for syphilis experiment in Guatemala." *Reuters*, October 1, 2010. <http://www.reuters.com/article/2010/10/01/us-usa-guatemala-experiment-idUSTRE6903RZ20101001> (accessed October 23, 2012).

and is overshadowed by anger directed at the researchers and sympathy towards the victims. The disservice done to the victims lies entirely in the manner in which the experiment was conducted and not in the publication of the results.

As recently as early 2012, concerns for public safety were voiced in an unsuccessful attempt to dissuade researchers from publishing potentially dangerous information on highly-virulent, engineered forms of the H5N1 flu.⁸ Analysis of this incident may help predict the popular reaction expected to follow a choice to publish Major Pena's data. The H5N1 research itself met ethical standards; however, the controversy centered on the hypothesized dangers of making valuable information publicly available. Ultimately, the paper was published on the basis that the benefits of increased access to information outweighed the dangers of potential bioterrorism. In the present situation, appropriate measures have been taken to abort the experiment and administer legal action to restore justice. Therefore, as in the situation with the H5N1 flu, the remaining controversy exclusively concerns whether the data should be published.

In contrast to the direct global health risk posed by publication of information on the flu virus, sharing Major Pena's results bears minimal risk while adding to the information base necessary for treatment and prevention of a particular disease. Judging from the subsidence of the controversy surrounding the H5N1 situation and the fortunate avoidance of perceived dangers, public opinion highly values disease prevention and offers exceptions to controversial publications if they benefit human health. Outrage should continue to focus on the conduct of the experiment and appropriate reparations must be provided to the wronged individuals, but from a forward-looking perspective, publication carries no potential for future harm.

Sadly, in the eyes of the researchers, the patients' rights were overlooked in the name of science — reducing them to sources of raw data without concern for their human suffering. This abhorrent lack of sympathy for the victims deserves severe censure; however, it is important to note that this attitude of impersonality also guarantees that the data under consideration for publication will consist purely of objective observations that bear no sensitive or private information about the victims. Reaffirming the humanity of the offended individuals lies in recognizing that their wellbeing takes precedence over their potential role as scientific subjects. This process needs to address their past suffering, but due to the detached nature of the objective data, no further harm or dehumanization stems from publication.

⁸ Yong, Ed. "Mutant-flu paper published: Controversial study shows how dangerous forms of avian influenza could evolve in the wild.." *Nature*. 485. no. 7396 (2012): 13-14. <http://www.nature.com/news/mutant-flu-paper-published-1.10551> (accessed October 23, 2012).

Before publishing the data, the following two concerns require consideration: (1) Will publication deeply offend victims and (2) will publication validate further unethical practices? As publication of data on disease progression, symptoms and transmission does not directly reveal information of a personal nature regarding the victims, sharing the information cannot be seen as personally offensive to harmed individuals. Furthermore, restricting access to the data does not erase the harm done. By acknowledging the ethical violation in the publication, attention is drawn to human rights issues and increased public concern can act as a deterrent to future perpetrators. The most important disincentive to future unethical practices, however, comes from the manner in which violators are dealt with in the court of law. If adequate repercussions are administered to Major Pena and other transgressing researchers, these should act as sufficient preventative measures. In the minds of researchers tempted to violate ethical codes, it is unlikely that the allurements of publication would outweigh fears of legal repercussions. In other forms of wrongdoing, individuals may commit crimes with little reference to the possible consequences based on hopes of avoiding detection. However, the transparency associated with publication makes it impossible for researchers involved in unethical experimentation to simultaneously achieve the validation of their peers while avoiding detection and censure.

Despite the blatant ethical violations of Major Pena's study, the collected data should be published to acknowledge the suffering of victims, publicly denounce immoral investigative practices and to ameliorate future suffering through improved disease prevention, treatment and control. Judging from previous controversies regarding research ethics and scientific publication, sharing the collected results is unlikely to endanger society, validate future transgressions or increase the suffering of the victims harmed in the experiment. If the data are published with proper disclaimers that reflect public disapproval of unethical human experimentation and sympathy for the harmed study participants, publication offers an opportunity to prevent future suffering without condoning unethical human experimentation.