Justice and Fairness in the Kennedy Krieger Institute Lead Paint Study: the Ethics of Public Health Research on Less Expensive, Less Effective Interventions

David R. Buchanan, DrPH, and Franklin G. Miller, PhD

The Kennedy Krieger lead paint study stirred controversial questions about whether research designed to develop less expensive interventions that are not as effective as existing treatments can be ethically warranted. Critics questioned the social value of such research and alleged that it sanctions a double standard, exploits participants, and is complicit in perpetuating the social injustice.

In response, we demonstrate the propriety of conducting research on interventions that can be extended to the population in need by stipulating the limited conditions in which it is ethically warranted and providing fair terms of participation. We contend that the failure to conduct such research causes greater harm, because it deprives disadvantaged populations of the benefits of imminent incremental improvements in their health conditions. (*Am J Public Health.* 2006;96:781–787. doi:10.2105/AJPH.2005.063719)

THE CONTROVERSIAL KENNEDY

Krieger lead paint abatement study raised serious questions about the ethics of public health research and the relation between research and policies aimed at improving population health.[1–4] This study tested low-cost lead abatement procedures in housing in Baltimore to determine their effectiveness in reducing blood lead levels in children living in these houses. An impassioned debate has ensued about the role of public health researchers in improving health outcomes, reducing health inequalities, and promoting social justice.[5–10] Critics have questioned whether attempts to find interventions that are less expensive than the current standard of care, but also less effective than existing treatments, sanction a double standard, exploit participants, and are ultimately counterproductive by sapping the political will to provide the best health care possible.[11,12] However, research that seeks to discover less expensive interventions may be ethical under certain carefully defined conditions, and the failure to conduct such research is contrary to the interests of those most in need.

The goal of public health is to improve the health of the population as a whole.[13,14] Because of the robust relation between socioeconomic status and the full spectrum of health indicators, many people have argued that significant improvements in population health can be achieved only by effecting substantial redistributions of wealth and access to social resources.[15–17] Programs that attempt to ameliorate conditions within the existing structure of social inequalities have often been faulted as Band-Aid solutions that merely perpetuate injustice. Thus, it is important to place the debate about the ethics of public health research in the context of a wider debate about competing conceptions of social justice and to sort out carefully the links between research ethics and the ethical obligations of society to reduce socioeconomic inequalities in order to improve the health and welfare of the poor.

The Kennedy Krieger Institute (KKI) case is particularly instructive because it extricates controversial debates relating to standards of care that are now prominent in international health research from those confounding ethical concerns associated with delivering medical care in the context of doctor–patient relationships.

BACKGROUND

The KKI, a children's health facility and research institute affiliated with Johns Hopkins University in Baltimore, Md, conducted research investigating low-cost partial lead abatement procedures to prevent lead poisoning in children living in public housing in inner-city Baltimore between 1993 and 1995.[18] When the research idea was being originated, an estimated 95% of low-income housing in identified neighborhoods in Baltimore was contaminated with lead-based paint.[18] Studies at the time showed that 40% to 50% of the predominantly African American children living in these high-risk neighborhoods had elevated blood lead levels (>20 micrograms per deciliter [μg/dL] of blood), deemed "moderate" blood lead elevation by contemporary Centers for Disease Control and Prevention (CDC) standards.[18] However, because of the high costs of implementing the recommended total lead abatement procedure

(approximately $20 000 per house), little was being done about the problem.[19–21]

The health hazards of exposure to lead have been known since the late 1800s. The use of lead-based paint was banned in the United States in 1978. Yet the most recent CDC data show that in the United States from 2000–2001, 2.2% of all children aged 1 to 5 years and 9.6% of African American children of the same ages had blood lead levels that were above the recommended maximum of 10 μg/dL of blood.[22] According to the Alliance to End Childhood Lead Poisoning, an estimated 5 million preschool children still live in houses with significant lead hazards.[23] In the current situation, what should public health researchers do?

In the late 1980s, the KKI had tested alternative, less expensive lead reduction methods in empty properties and demonstrated that these techniques reduced ambient lead paint dust by 80% or more.[24,25] They then proposed a follow-up study to determine if the reduction in lead paint dust in housing that had been abated with these processes would result in lower blood levels in children living in these houses. The study included 108 houses in 5 comparison groups: 3 treatment groups that used the new lead abatement procedures, costing $1650, $3500, and $6500, respectively, and 2 comparison conditions, composed of housing that had been abated by the city of Baltimore and housing built after 1978 that was presumably free of lead paint. By design, the researchers chose not to include a control comparison of existing housing that had received no abatement procedures, because they considered it unethical to follow children who were being exposed to a known health hazard without remediation, despite the fact that this was the condition of the majority of children living in these neighborhoods. The study was designed to collect blood samples at baseline, 6 months, and 24 months; children whose blood lead level exceeded 20 μg/dL or whose blood lead level increased by 5 μg/dL or more were to be referred for medical and environmental attention.

The results of the research showed significant reductions in lead dust in all study conditions. Overall, the blood lead levels of children residing in the KKI-treated homes stayed constant or went down, although there were a few cases of increases.[26,27]

Two families later sued KKI, stating that they were not fully informed of the risks of participation for their children and that KKI failed to inform them in a timely manner of test results. In *Grimes v Kennedy Krieger Institute, Inc,* the Maryland Court of Appeals (Maryland's highest court) overturned a lower court's initial ruling to dismiss and reinstated the families' lawsuits.[28] In August 2001, the court of appeals issued a scathing 96-page ruling comparing the research study conducted by KKI to the Tuskegee syphilis study and Nazi research on prisoners.[28] The judges called it a callous scientific experiment that put children in harm's way, saying they were being used merely as "measuring tools." The court's remand focused on 3 main issues: (1) informed consent, declaring that parents cannot give consent for their children to enroll in "nontherapeutic" research; (2) a duty to warn because of the "special relationship" between the researchers and participants; and (3) the inadequacies of the institutional review board's review, referring to the Johns Hopkins institutional review board as "in-house organs" who were not "as sufficiently concerned with ethicality of the experiments they review as they are with the success of the experiment."[29(p12)]

The judges' remarks made national headlines and spurred a contentious debate about the ethical acceptability of this research. Although concerns were raised about the adequacy of the informed consent process and the timeliness in informing families about blood lead levels, the case was eventually dismissed with prejudice by the lower court (Joanne Pollak, general counsel, Johns Hopkins University. Personal telephone communication, October 20, 2005.) Setting aside these important ethical concerns, we discuss the fundamental question of whether research designed to test less costly interventions that might not be as effective as existing treatments can ever be ethically justified. Although the KKI case may raise other issues that deserve further ethical attention and analysis, we focus here on the ethical warrants for research on interventions that are likely to turn out to be not as efficacious as existing (albeit expensive) treatments.

ETHICAL CRITIQUE

Since the Maryland Court of Appeals judges' ruling, many commentaries on the case have appeared in public health, legal, medical, and bioethics journals. Critics have questioned the social value of the research and have further questioned whether such research undermines efforts to enforce just social policies.[11] In addition, the critics claim that the research is unfair, because it treats different population groups unequally by providing the research participants with an intervention that is less effective than the best-known treatment available.[12] Finally, they contend that the research exploits the participants by sacrificing their welfare to accomplish the goals of the research.[29]

The first major criticism concerns the social or scientific value of the research, one of the primary ethical requirements for conducting research.[30] Because of the inherent risks of research on human subjects, research that has no counterbalancing social or scientific value can never be ethically justified. According to critics, the conditions that the research was designed to ameliorate should have been remedied not by conducting research aimed at finding a more cost-effective alternative but by providing the most effective extant intervention to those who had not yet received it. Spriggs, for example, charged that the lead abatement research "lacked

importance and value."[11(p176)] He concluded,

> Knowing how to get rid of lead or reducing exposure was not as much of a problem as getting someone to pay for it. . . . [The] dominant value of the lead paint study seems to be that it is not acceptable for landlords to lose out financially but it is acceptable for children in low income housing to face the continuing risk of lead poisoning.[11(p180)]

Similarly, Farmer, commenting on health interventions in developing countries, noted, "Projects [should be] striving for excellence and inclusiveness, rather than, say, 'cost-effectiveness' or 'sustainability.'"[31(p240)] As he and his colleagues indicated elsewhere, "In short, since we can, we should. . . . [But], though we can, and should, do right, we choose not to. This is the core ethical problem."[12(p247)]

Spriggs expanded on the point about the social value of the research by raising the question of whether a successful experiment would truly help anyone: "Reducing lead exposure in children is certainly desirable, but there is no indication that the lead paint study was going to achieve this. . . . Nothing in the research suggests that the study would lead to the enforcement of more lead reduction."[11(p179)] Under these conditions, without a commitment to implementing the results of the research (if successful), any potential benefits of the study are strictly theoretical and should not be considered in institutional review board deliberations about the respective risks and benefits of the research.

In questioning the value of the research, opponents go even further in alleging that it is a form of capitulation or collusion with status quo conditions of gross social injustice. Several commentators[19,32–34] assert that what is needed in these situations is not more knowledge aimed at testing a "feasible" but less costly intervention but the political will to transfer resources to supply a known effective treatment. They say that by diverting attention to peripheral issues, such research merely serves to reduce pressure on the government to provide the needed treatment and thereby interferes with achieving the equitable service provision that is owed to citizens as a matter of justice. Critics thus charge the researchers with bad faith and an insincere or indifferent commitment to equality. As Farmer and Campos[12] stated, these researchers, by their actions, tolerate inequalities and endorse an unacknowledged consensus that in fact not all human beings are created equal.

Critics also state that this type of research is not fair.[29] These critics assert that by seeking to develop an intervention that may well turn out to be less effective than a currently known treatment, such research creates a double standard that violates the rights and the dignity of disadvantaged populations. Accordingly, research must conform to principles of equity: all people deserve the same treatment, nothing less than the best. As Farmer put it, "Efficiency cannot trump equity in the field of health and human rights."[31(p241)]

Finally, critics have charged that the welfare of the research participants is being subordinated to social and scientific goals. Echoing critiques by Angell[35,36] with respect to the conduct of international health research, the plaintiffs[37] have charged that their children were used as "guinea pigs," and others pronounced, "KKI and [Johns Hopkins University] researchers put their efforts to advance medical knowledge before the protection of a susceptible population."[29(p478)] These critics assert that, because any attendant morbidities could have been prevented by providing the highest standard of care, the participants were being exploited perforce from the outset. According to Kantian principles, the research is inherently unethical because it treats the subjects merely as a means to an end; the rights and well-being of the individual participants must always take precedence over the goals of the research.

JUSTIFICATION FOR LESS EFFECTIVE RESEARCH

In response to these significant ethical concerns, the general question that we discuss is whether research that is designed to test less expensive interventions that might not be as effective as existing treatments can ever be ethically justified. In the KKI case, the issue is did the fact that it is possible to treat houses to eliminate the risk of lead poisoning make research on the effectiveness of less expensive means of partial lead abatement invariably immoral?

SOCIAL VALUE OF THE RESEARCH

Spriggs[11] and others[12,29,31] have claimed that this type of research has no social value because an effective solution to the problem is already known. But this is a non sequitur. If complete lead abatement or the provision of lead-free housing is not likely to occur, then there is a clear social value in finding a less expensive means of partial abatement that may actually be implemented. The social value of this type of public health research lies in developing an intervention that can provide relief to potentially millions of children who are alive today, rather than the theoretical possibility of providing the highest standard of care to children someday in the distant future—a more ideal world, to be sure, but one that will not help today's children.

Debates about the nature and meaning of justice in society arise precisely because social resources are limited and therefore must be distributed according to some rule or patterned conception that people consider fair.[38,39] At this time, US society has not determined that justice demands the provision of safe housing for all its citizens or the guarantee of a minimal standard of living to which everyone is entitled. Rather, a libertarian conception of justice that would leave social betterment to market forces appears to prevail.[40] Thus, even

though the technical capacity for complete lead abatement is available, the slow rate of progress in providing lead-free housing for all children makes research aimed at finding more cost-effective methods to alleviate this serious, widespread public health problem a potentially positive contribution to improving the social conditions of the least well off and is therefore ethically warranted in terms of its social value.

COMPETING CONCEPTIONS OF JUSTICE

It is misguided and unfair to charge researchers with indefensible ethical standards when the crux of the critics' argument rests on legitimate questions about competing conceptions of justice in society. Clearly, if new or refurbished public housing had been or was imminently about to be provided to all those in need, the issue of conducting research on new lead abatement processes would be moot. However, blaming researchers for the lack of social consensus on the right to safe housing for all is misplaced indignation.

Critics then allege that by diverting intellectual and political energy from the drive for social justice, such research is counterproductive.[31] Although some might question the propriety of researchers engaging in political advocacy, it is clear that there are important questions about the nature of justice in society that must continue to be debated. This debate, however, needs to proceed in a domain appropriate to its resolution. The apparent injustice of existing social conditions does not in itself make any and all efforts that are not designed to effect significant redistributions in wealth complicit in perpetuating conditions of gross social injustice. A clear distinction needs to be made between applications of the principle of justice in macrolevel distributions of social resources and the principle of fairness in the microlevel conduct of research.[41]

Taking a position that completely rejects the value of research that seeks to benefit literally millions of children sacrifices the welfare of those children to the presumption that a particular conception of justice will eventually prevail. It also sacrifices the health of those children to the glacial pace of social change.[42] However much we may agree with concerns about inequities in American society, and more broadly, the global community, the invocation of powerfully appealing egalitarian principles cannot be regarded as a sufficiently compelling reason to totally shut down research that offers a realistic prospect of improving conditions for those without access to an extant standard of care or to what many might consider a minimally just standard of living. In contrast to standing on principles that call for far-reaching changes that are unlikely to occur in the foreseeable future, we contend that it is the failure to conduct such research that causes the greater harm, because it limits health interventions to the status quo of those who can afford currently available options and deprives disadvantaged populations of the benefits of imminent incremental improvements in their health conditions. This type of research, however, can be ethically justified only in carefully circumscribed conditions.

CONDITIONAL WARRANTS

To justify public health research aimed at developing less expensive yet less effective interventions, 4 conditions must be met. There must be (1) a large population in need, (2) the existence of a higher standard of treatment that is more effective yet substantially more expensive than a lower standard that would be cheaper but still hypothesized to be significantly effective, (3) resource or political constraints that do not allow full or extensive provision of the higher standard, and (4) a high degree of likelihood that the less costly intervention can and will be implemented on a large scale. Under these conditions, research on less expensive, less effective interventions can be ethically warranted by giving due moral consideration to the feasibility of providing universal public health protections and by the offer of fair terms of cooperation, as follows.

FAIRNESS AND EXPLOITATION

To respond to the critics' charges that participants have been treated unfairly and exploited, it is important to see how the debate about the responsibilities of researchers toward research participants has evolved from within 1 particular stream of thinking regarding the ethics of clinical medical research. An ethical position that has gained considerable currency states that the conduct of clinical research should be governed by the same moral norms that govern the practice of medicine.[43–46] From this perspective, which draws on tenets originally affirmed in the Hippocratic oath, physicians have a therapeutic obligation to provide the best medical care possible for their patients. Therefore, when conducting research, clinical investigators should fulfill the research's purported therapeutic obligation by ensuring that the conditions of equipoise are satisfied. In equipoise, both arms of a trial—the experimental intervention under investigation and the comparison condition—must be seen to be equivalent, such that it precludes the possibility of patients being randomized to a condition known to be inferior. Accordingly, failing to provide anything less than the best medical care possible should be considered exploitive because physicians are obligated to treat their patients with undivided loyalty. Thus, the failure to provide anything less than the highest quality of care is considered a prima facie indication of clinicians putting the goal of advancing medical science ahead of the needs of their patient-subjects.

Conversely, we contend that an ethical standard based on fulfilling a perceived therapeutic obligation is inappropriate for

assessing the conduct of medical research and, *a fortiori*, public health research.[47–49] In establishing suitable ethical standards for evaluating public health research, it is crucial to recognize that different societal contexts generate different moral obligations. In *Jacobsen v Massachusetts* (1905),[50] the US Supreme Court upheld a Massachusetts law that authorized the state board of health to require all citizens to be immunized against smallpox, citing the state's authority to legislate "for the common good, for the protection, safety, prosperity, and happiness of the people."[50(p208)]

The *Jacobsen* verdict demonstrates that, outside the doctor's office, the ethical need to protect the population as a whole should take precedence over the individual's right to exercise autonomy. In the context of conducting public health research, there are other valid moral considerations, such as the just distribution of limited resources and equity in access to populationwide protections, that, albeit only under the limited conditions enumerated previously, may supercede an individual's interest in receiving nothing less than the best. As we have argued elsewhere,[49] it is not compelling to assert that health research can or should be conducted without giving ethically apposite weight to the goal of gaining new knowledge that will benefit society; hence, in the context of conducting public health research, the ethically relevant question is not how an alleged therapeutic obligation can be fulfilled but how the participants can be protected from harm and exploitation.

Although it is beyond the scope of this article to provide a definitive exposition of the concept of exploitation in research with human subjects, Wertheimer[41] has identified the key terms for discussion. In Wertheimer's analysis, exploitation is defined as one person taking unfair advantage of another, where fairness is understood in terms of the propriety or right-ordering of the distribution of benefits and burdens in social transactions. According to this standard, both parties can benefit from a defined arrangement and it can still be exploitive; it is not necessary for one party to harm another, only that the benefit to one side is disproportionate compared with the benefit to the other. To determine whether the participants in the KKI study were treated unfairly, one must decide whether the potential benefits to the researchers, research institution, research sponsors, or society in general were inequitable, imbalanced, or excessive relative to the potential benefits to the participants.

If it could be anticipated that the participants would be harmed or made worse off, then the terms of research participation would be undeniably unfair and exploitive. Contrary to statements made by the court of appeals judges and others, however, the KKI research cannot be properly characterized as "a non-therapeutic study that promises no medical benefit to the child whatever."[28(p3)] Because the participants stood to benefit directly by an environmental intervention hypothesized to effect reduced blood lead levels, the court's assertion reflects a deep misunderstanding of the nature of public health research. Unlike nontherapeutic research designed solely for the sake of advancing medical science, there can be no question that an outcome intrinsic to the KKI research design was the projected benefit to the research participants of lower blood lead levels.

UNEQUAL TREATMENT AND THE DOUBLE STANDARD

Finally, it is important to examine the issue of whether the participants were being harmed and treated inequitably by being deprived of a known beneficial treatment. On this point, Wertheimer[41] makes an important distinction between taking advantage of people who are in an unfair situation and unfairly taking advantage of them in that situation. The latter is exploitive; the former is not necessarily. For example, a person who is seriously ill and lacks health insurance may be more likely to agree to participate in a clinical trial than someone who is not, but that does not necessarily mean that the researcher is exploiting or unfairly taking advantage of the person's circumstances.[51] Questions surrounding who should be considered the appropriate reference group for making comparisons about unfair treatment are what are important.

Critics charge that the KKI participants were treated inequitably,[11,29] but the comparison is relative to those better-off individuals who have access to new or refurbished housing. The comparison is made on the basis of the assumption that the feasibility of universal provision is unproblematic and hence irrelevant. The conduct of public health research, however, introduces valid, ethically germane consideration of the feasibility of universal coverage. From a public health perspective, if it is not feasible to extend the current standard of care to the population as a whole, then the appropriate comparison group with respect to the question of inequitable treatment is those who do not now have access to the current standard of care. In the KKI case, it is important to be clear that the children were not being exposed to a risky home environment as a result of their participation in the research. Rather it was the injustice of social conditions that caused their exposure, conditions that the research itself was intended to alleviate. As there was no reason to think that the abatement interventions would increase the lead exposure of the research participants compared with unabated housing, the institutional review board could reasonably conclude that the participants would not be made worse off as a result of their participation relative to the decision not to participate.

According to Wendler et al.,[52] judgments about feasibility turn on the question of whether the development of less-than-the-best

methods has a better chance of being implemented than the currently best available methods that will be provided to those in need in the absence of such research. If it is reasonable to conclude that the provision of the "best methods" is not feasible under existing economic or political constraints, than the researchers and research participants can agree that social conditions are unfair and can engage in research conducted in a fair and socially responsible manner. To avoid exploitation in these limited circumstances, the research participants should have a reasonable prospect of benefit, despite not being offered the best available option. As noted earlier, the participants in the KKI study were not exposed to a no-treatment condition without any lead abatement intervention. In research aimed at finding clinically valuable but less expensive, less effective interventions, the question of whether placebo-controlled trials can be justified under conditions of gross social injustice will continue to raise complex contextual issues that at a minimum require stringent justification based on scientific necessity.[52]

According to the preceding analysis, the KKI study offered a favorable risk–benefit ratio both in terms of potential benefits to the participating children, who lived in safer housing, and in terms of the social value of knowledge to be gained regarding cost-effective means of lead abatement. The justification for public health research on less expensive, less effective interventions is based on giving due moral consideration to the issue of the feasibility of providing populationwide or population-in-need public health protections, provided that the risks to the research participants are reasonable and proportionately balanced in relation to the prospective health benefits to them and the value of the knowledge to be gained.

The position outlined here provides a principled framework that permits socially valuable research to be conducted on the basis of a fair social contract that includes ethical constraints that respect participants as persons and protect them from undue risks of harm. We emphasize that introducing moral consideration of the potential benefits to society that may result from public health research does not diminish the ethical responsibility of the researchers to prevent the participants from being harmed and exploited. As the KKI researchers demonstrated, the ethical conduct of public health research must always incorporate principled protections, such as provisions for referrals to treatment services for those whose blood lead levels might rise or exceed a predetermined cutoff point.

CONCLUSIONS

With a range of challenges facing the field of public health—from responding to emerging infectious diseases, to the growing threat of ozone depletion (and consequent cancers), to the possibility of new genetic screenings, to treating the growing epidemics of diabetes and hypertension—public health researchers will continue to be confronted with difficult questions about what should be done in situations in which the discovery of a new technology, new drug, or new intervention costs more than it is currently reasonable to expect taxpayers to pay in order to provide populationwide protection. There can be little question that the universal provision of the most effective intervention—the idea that public health infrastructure could, and therefore should, provide nothing less than the best to everyone—will not always be feasible. In such circumstances, when providing the highest quality of health care to each and every individual is not possible, public health research designed for the purpose of generating alternatives that can realistically be extended to those in need is ethically warranted. The search for interventions that can be provided to substantially greater numbers of people in turn advances a pragmatic understanding of justice.[53] If a less expensive treatment that can reach a greater number of people can be developed, it would yield a net improvement in the health of the population as a whole, and thus it represents substantial progress over status quo conditions that would be likely to persist without a mitigating intervention. Dogmatic stances that preclude research aimed at evaluating cost-effective interventions on grounds of egalitarian justice will result in research paralysis and policy stagnation, thus guaranteeing the continuing neglect of the needs of disadvantaged populations. ■

About the Authors

David R. Buchanan is with the School of Public Health and Health Sciences, University of Massachusetts, Amherst. Franklin G. Miller is with the Division of Research Ethics, Center for Clinical Bioethics, National Institutes of Health, Bethesda, Md.

Requests for reprints should be sent to David Buchanan, DrPH, Professor of Community Health Education, 306 Arnold House, School of Public Health and Health Sciences, University of Massachusetts, Amherst, MA 01003 (e-mail: Buchanan@schoolph.umass.edu.)

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Contributors

Both authors jointly developed the concept and original outline for the article. D.R. Buchanan drafted the initial version of the article. F.G. Miller provided extensive revisions to each subsequent draft until the final article was completed.

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