

Review of: "Relevance of Medical Ethics in Public Health: Case Study of Polio Eradication"

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Relevance of Medical Ethics in Public Health: Case Study of Polio Eradication

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This is an interesting reflection and a challenging analysis of the ethical implications of WHO strategy aimed at eradicating poliomyelitis through a global vaccination programme. The authors' passion and conviction emerge clearly, and it is obvious they have done a considerable amount of research.

The authors represent it as a case study illustrating the importance of ethics to public health. The idea that this is an illustration of something more general adds a layer of complexity to a piece that already has several dimensions. It seems to me unnecessary and I would re-frame the piece simply as ethical analysis of an important issue: 'OPV and polio eradication: unethical in practice ?' or something like that. The issue is important and interesting enough to stand on its own merit.

As I understand it, the argument the authors want to make can be represented as follows:

1. Globally, OPV has caused more harm than benefit, whereas IPV would have offered more benefit than harm.
2. Ethics should protect the individual against exploitation by those who are more powerful
3. Use of the OPV represents such exploitation because either:
 - a. Those instigating it did not know that OPV would be harmful, in which case it was a trial and 'patients' were in fact participants who should have given informed consent before having the intervention or
 - b. Those instigating it did know, in which case they knowingly inflicted unnecessary harms on large numbers of people
4. According to either of those arguments, use of OPV represents unethical practice
5. If individuals are harmed by unethical medical practice, they should be entitled in law to compensation

I do not think that argument emerges clearly from the current draft of the paper. The case against the OPV appears piecemeal in a series of assertions scattered throughout the article. Many of those assertions are well-evidenced, but some are not. Overall I therefore found the argument unconvincing, even though I was sympathetic to the case the authors wanted to make.

I would suggest re-writing the paper so that the argument appears in the form I have set out above:

1. Globally, OPV has caused more harm than benefit, whereas IPV would have offered more benefit than harm.

This is a strong assertion and needs careful evidential support. The authors suggest (if I've understood correctly) that there is no meaningful transmission of long-term immunity as a result of faecal-oral transmission of the vaccine in OPV. That is a big claim; the hypothetical benefit of patients being able to 'catch' immunity without needing to take the OPV is almost incalculable, especially in areas where those at risk find it difficult to access medical services.

Needle-sticks also represent a harm, especially to children. The pain they cause may even be instrumental in dissuading some families from having a child vaccinated at all. The benefits of a vaccination that does not require a needle must also be factored into the benefit/harm calculus. They might be outweighed by the risk of VAPP but the authors need to show that.

2. Ethics should protect the individual against exploitation by those who are more powerful

I think most ethicists and clinicians would agree. This would be the place to set out the authors' hypotheses regarding the benefit that WHO and those advising it would gain from using OPV instead of IPV. It would be worth checking that these accusations do not transgress libel laws.

3. Use of the OPV represents such exploitation because either:

- a. Those instigating it did not know that OPV would be harmful, in which case it was a trial and 'patients' were in fact participants who should have given informed consent before having the intervention or
- b. Those instigating it *did* know, in which case they knowingly inflicted unnecessary harms on large numbers of people

At the moment these two possibilities are not clearly distinguished in the paper, which as a result is rather confusing to read. The arguments are in reality very different from one another and they need to be set out separately and consecutively rather than (as now) enmeshed with one another.

In passing, I am not sure argument a) is correct here. The risk of VAPP is small and it seems to me quite plausible that it was not apparent until large numbers of patients had been treated; more than could reasonably be expected to participate in trials before OPV was released. Under those circumstances it would be quite reasonable for doctors to prescribe OPV on the basis that it was an established therapeutic intervention, rather than a clinical trial.

The authors could argue that there was a point at which it became clear that the risk of VAPP was so great that its harms outweighed its benefits and argument b) began to obtain. Again, that claim is very significant and, in my view, would need careful evidential support. Is there evidence that OPV offers more harm than benefit? If so, is there evidence that WHO continued to endorse OPV while in possession of that knowledge?

4. According to either of those arguments, use of OPV represents unethical practice

If the authors have convincingly argued points 1, 2 and 3, then I think they are on secure ground at this point. It is unethical if it is BOTH true that OPV has done more harm than good (or, at least, that the alternative IPV would have done less harm and/or more good and was available) AND that the people who caused it to be used were aware of that at the time they did so. The reason it is unethical is that it fails to protect individuals from exploitation.

5. If individuals are harmed by unethical medical practice, they should be entitled in law to compensation

The move from what is ethically desirable to what should be legally mandated is not always straightforward. My own feeling is that, in this paper on ethics, the section should go no further than arguing in the name of justice that the law should ensure those who have been harmed as a result of unethical practice have some redress. I would not try and set out a legal argument unless one or more of the authors is a lawyer.

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