COMMENTS

An ethical appraisal of the choice of vaccines against Poliomyelitis

T JACOB JOHN, DHANYA DHARMAPALAN

Abstract

Medical ethics is invoked for immunisation of children as it involves an interaction between a healthcare professional and the child. Immunisation under the national immunisation programme is a public health intervention and the common belief is that ethics is not relevant.

Two vaccines with contrasting safety and efficacy profiles were available against polio before the national immunisation programme was launched: the inactivated poliovirus vaccine (IPV) and the live attenuated oral poliovirus vaccine (OPV). India chose OPV and excluded IPV. We carried out an ethical appraisal of that choice. Principles of medical ethics comprising four elements—non-maleficence, beneficence, autonomy and justice—was already in vogue at the time. Applying each of them, a head-to-head comparison between IPV and OPV is made. The results clearly show that the choice of vaccine was made without using ethical principles, resulting in serious adverse effects in hundreds of thousands of children. We recommend that medical ethics must be applied to all choices of public health interventions.

Background

Medical ethics is applicable in both healthcare practice and research involving human participants (1). The application of and adherence to ethical principles are crucial to guiding such transactions where one party is more influential than, or has power over, the other. An example of such a transaction, where abiding by ethics ensures accountability, is one between a civil servant holding a high post and the general public (2: p xxviii).

In public health interventions, the focus is on the community—consisting of ill and well individuals—and not on the patient as an individual. Human subjects are involved collectively, during investigations or interventions relevant to an outbreak and in health promotion or disease prevention settings. For example, to prevent mosquito breeding, all houses may be visited and all residents, treated alike, may be asked to prove the absence of breeding in any water receptacle. Here, an intrusion into the privacy of a residence is assumed to be for the common good and individual autonomy is restricted. However, the conflict that emerges between individual good and common good is greatly heightened when it comes to a public health intervention like vaccination, thereby raising an intense ethical debate.

Sound ethical principles are crucial to justify any immunisation programme. Biomedical ethics, framed in the 1970s by Beauchamp and Childress, has the following four elements: non-maleficence, beneficence, autonomy and justice (1, 3). Ethics in public health evolved in the early 2000s. It largely addresses the issues of interdependence, autonomy, justice and human rights. In 2004, Verweij and Dawson (4) proposed seven ethical principles for the design of collective immunisation, which were further developed by David Isaacs in 2012 (5) as:

i) The programme should benefit individual and community;
ii) It should be monitored for risks of adverse effects;
iii) It should be monitored for effectiveness of the programme;
iv) It should be cost effective and justly made available for vulnerable and disadvantaged groups;
v) Autonomy and informed decisions for vaccine recipients/care providers of children should be ensured;
vi) Reciprocity including no-fault compensation schemes must be available for those who suffer serious consequences of vaccination;
vii) Mutual trust must be built and decisions made by public consultation.

These principles were designed in view of rising concerns regarding the emergence of new and future vaccines.

WHO's Strategic Advisory Group of Experts (SAGE) on Immunization developed a framework for decision-makers on the use of life saving vaccines during emergencies (6). It advised, targeting the most susceptible population with high rate of transmission, using a tool that can give maximum speed of coverage, while overruling parental objection to the child's vaccination if disease risk is high. But for regular vaccination policies, ethical ambiguity continues on issues pertaining to communication, mandatory implementation, safety, and compensation for adverse effects, and resolution is largely dependent on local rules and regulations.

In this paper, we focus our discussion on an important topic—the ethics behind selection of vaccines against poliomyelitis (polio) in the Government of India's (GOI) Universal

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Immunisation Programme (UIP). This debate is carried out in light of traditional ethical principles of non-maleficence, beneficence, autonomy and justice. We present our assessment of the choice against each element and argue that the choice was vitiated due to the non-application of ethics.

Under the UIP, a trained health worker vaccinates all children eligible by age and place of residence. The worker implements a job assigned by the government under its national policy and there is little or no personal choice. A paediatrician immunising a child in their clinic, is involved in a one-to-one transaction with the vaccine recipient and most often the caretaker of the minor vaccine recipient. While the paediatrician may be called to justify the choice of a vaccine in case of a dispute, the health worker immunising children is protected from such disputes as the worker is fulfilling national policy. In case of injury to the child due to a vaccine, the parent apparently has no recourse to compensation under UIP (7). Parents have to accept the government policy under UIP with regard to the choice of vaccines. Since parents bring children to the worker, consent for giving immunisation is taken for granted. When the worker is instructed to go into houses and immunise children, a guardian's non-refusal is taken to be consent.

Citizens assume that the government would have carefully chosen the vaccines to be included in the UIP based on epidemiological need, safety and efficacy of the vaccine and economic feasibility. All expenses on vaccine delivery are covered by public funds at the disposal of the government. Best practices are defined and ensured by staff-training and supervision. There is a general perception that the programme is in the best interest of society and ethics is either not relevant, or, if relevant implicit in the transaction.

For many diseases like tuberculosis, diphtheria, tetanus, pertussis and measles there is one globally accepted vaccine each, and for that reason there was no need to choose between products when the policy was enunciated. In case of polio, however, two types of vaccines with highly contrasting properties have been available since the 1960s. In 1978 when the National Immunisation Programme was launched as a public health intervention, the GOI chose one for exclusive use and the other was disallowed by non-licensure.

The two polio vaccines

The inactivated polio vaccine (IPV) and live attenuated oral polio vaccine (OPV) were both created in the USA during the mid-1950s and early 1960s. The Expanded Programme on Immunisation (EPI) was launched by the World Health Organisation (WHO) in 1974, in which OPV was recommended. India established EPI in 1978 and introduced OPV in 1979-80 (8). EPI was revised as the UIP in 1985 (9).

In the USA and in Europe, OPV was highly efficacious with no vaccine failure documented. However, globally OPV was shown not to be totally safe, with children developing polio caused by vaccine viruses, called vaccine-associated paralytic poliomyelitis (VAPP), the frequency of which varied from country to country (10,11). In 1982 the WHO strongly recommended that all countries using OPV should establish surveillance to monitor the frequency of VAPP (11). The EPI in India did not comply and data on VAPP emerged only years after active polio surveillance was started in 1997 as part of the National Polio Surveillance Project (12). Before India established EPI, data from within the country had shown sub-optimal vaccine efficacy of OPV (13-16). As per information from multiple sources on the comparative parameters of both vaccines, which the GOI had access to, India faced problems with both efficacy and safety of OPV. Experiences from other countries using IPV had shown complete safety, unparalleled by almost any other vaccine (11). Studies on IPV in India—limited in number because IPV was not licensed or available to the public—had shown very high vaccine efficacy, on par with results in other countries (16,17).

Application of ethical principles

Non-maleficence

The first ethical principle is to do no harm. OPV carried a small but definite risk of VAPP (10,11). After comparing one completely safe (IPV) and another not completely safe (OPV) vaccine, choosing the latter fails the test of non-maleficence, unless there was any overriding reason to choose the former. No such overriding reason was stated. The USA had also chosen to use OPV exclusively, but set up a mechanism for compensation for VAPP victims through the National Childhood Vaccine-Injury Compensation Act of 1986 (18). India ignored the problem of VAPP until their numbers were counted; 181, 129 and 109 VAPP cases were reported in 1999, 2000 and 2001 respectively (19).

Moreover, with OPV, many children with primary immunodeficiency developed polio. Others became chronically infected with vaccine viruses and shed them in the stools for long periods of time. With such chronic shedding of vaccine viruses there existed the potential threat of polio in contacts as the viruses became increasingly neurovirulent with time (20).

Although the per-dose cost of OPV was lower than that of IPV, it did poorly on account of both vaccine safety and vaccine efficacy. A health economics evaluation was apparently not done since only one was licensed. Hence, the issue of costs could not be considered as a reason to overrule non-maleficence.

Further, from 1984 a new generation IPV was available whose production cost was substantially lower than that of the older IPV. Considering that the number of units of IPV required are relatively less than OPV, probably the overall cost per protected child would have been lower with IPV (16).

Beneficence

On the face of it, both vaccines appeared to satisfy beneficence, as both prevented paralytic polio. However, there is reason to question if OPV satisfied fully the test of beneficence.

OPV, given under a national policy of 3 doses, protected only about two-thirds of vaccinated children in India. Consequently, many children developed polio in spite of the EPI-stipulated dosage of 3-4 in the first year of life (12-14). USA had also chosen a policy of exclusive use of OPV, but had one supporting argument that OPV was completely effective in preventing polio while, according to the original IPV efficacy trial, the IPV available then was not (21). However, that was only a matter of the number of doses—3 doses of the original IPV were not a 100% efficacious (21). The old IPV contained thimerosal, a mercury-containing preservative that reduces polio antigenicity. When IPV was made without this preservative, it was 100% efficacious (21). Globally, 3 doses of the old IPV without preservative and 2 doses of modern IPV, given at appropriate age and interval, are completely efficacious. No child is recorded as having had polio after the recommended number of doses in the first year of life.

EPI did not evaluate either vaccine for efficacy, but the sub-optimal efficacy of OPV and consequent cases of polio vaccine failure had been recognised and were widely known when EPI was launched (12-16). By the mid-1980s about half of the cases of polio were seen in children who had been given all the EPI-recommended doses of OPV (16).

Autonomy

There is a common belief that the principle of autonomy applies only when the patient or research subject has a choice. The government had a choice – to include or exclude a vaccine from UIP and the choice could have been applied autonomously or made according to recommendations of international organisations. There is no evidence, direct or circumstantial, that autonomy was applied in the choice of OPV to be used exclusively. Many member countries of WHO autonomously chose IPV over OPV – mainly for safety from the risk of VAPP. India did not monitor the frequency of VAPP in spite of the recommendation by WHO in 1982. Eventually investigators from the US CDC counted 181 VAPP cases in 1999 in India (12). One can only imagine and lament over the enormous numbers of children who were paralysed by VAPP, for want of an ethical choice between OPV and IPV.

The national policy did not give parents of children a choice between the two vaccines and thus autonomy of choice was denied. They were obliged to accept OPV and face the consequences of VAPP as well as vaccine-failure polio.

Sweden autonomously chose to use IPV exclusively and OPV was never allowed in the country (22). Norway began with IPV, switched to OPV and when faced with VAPP (at the rate of one case per 100,000 children), switched back to IPV (22). France gave the freedom to choose between OPV and IPV to parents and their paediatricians. In 1987, when only a small minority of children were getting OPV, as they were choosing IPV over OPV, France discontinued OPV altogether (23). Thereafter in France there was no polio either due to vaccine virus or wild virus importation from North Africa.

Countries like the USA and UK had chosen OPV autonomously. Information on VAPP was available in public domain in the US but victims were monetarily compensated. In the UK, information was not in the public domain (21). Both USA and UK have abandoned the use of OPV and use IPV exclusively since 2000 and 2004 respectively.

Justice

There was global inequity in the choice of vaccines, with OPV being promoted in the low-income countries where its efficacy was low and the rich countries choosing IPV (24).

For the period that OPV was in use in the USA and Japan, families of children with VAPP were monetarily compensated, thereby fulfilling the ethical principle of justice. On the other hand, no compensation was offered to the affected families in India.

Discussion

To the best of our knowledge, ethical issues in the Indian UIP's vaccine choice to the exclusion of IPV have rarely been discussed in any forum. On account of existing ethical principles, we have argued that the decision to exclusively use OPV was faulty. It would have been better if both vaccines were licensed so that experts could gain experience and insights from using both of them. If the policymakers wanted only one vaccine licensed in India they should have made an informed decision.

Over time it became apparent that global polio eradication can be achieved only when IPV is used universally to the exclusion of OPV. Ultimately, in 2006, India licensed IPV. India had an opportunity to lead the rest of the low- and middle-income countries, which was forfeited for want of the application of ethics in the choice between two products for use in public health.

Two moral principles are possible in public health, the utilitarian and deontological (25). The former accepts an intervention if it benefits the majority, while harm may occur in a minority. The latter does not accept an intervention if it harms the individual. There could be situations where a choice between utilitarian and deontological principles may be impossible but the choice of one vaccine from the two available vaccines ie, OPV and IPV was clearly unethical, the utilitarian principle that was apparently applied, was inappropriate.

We draw an important lesson from this historical national experience: ethical principles must be applied in all public health policies. People on whom public health interventions are applied may not be clients of any transaction, but they are human beings and the application of ethics is essential.

We have used only the four principles of biomedical ethics that had been enunciated before the choice of one vaccine over another was made. Ethical principles specifically pertaining to national immunisation programmes that were evolved later

have not been applied in our assessment of OPV versus IPV (4,5). Suffice to say that adverse reactions due to OPV were not monitored in spite of specific recommendations by the WHO for countries using OPV (11) and no compensation was offered to those who suffered serious health problems due to such immunisation.

While we cannot retrace our steps, we must learn from the past and consider the value of applying ethics to vaccine choice. Traditionally, epidemiology and economics have guided vaccine choice, but we recommend that ethics should also be a critical element. As actions under a national policy may be non-justiciable, in order to ensure ethics and preservation of human rights India's policy leaders must conduct an ethics assessment/review of every national health programme.

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Medical Council of India's new guidelines on admission of persons with specified disabilities: Unfair, discriminatory and unlawful

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Abstract

The Medical Council of India (MCI)'s recent guidelines on admission of persons with specified disabilities into the medical course under the disability quota has escalated into a huge controversy. Multiple litigations have been initiated against MCI by successful National Eligibility cum Entrance Test candidates with disabilities across the country. In light of our new Rights of Persons with Disabilities Act, 2016, and the United Nations Convention on the Rights of Persons with Disabilities, I argue in this essay that these guidelines are unfair, discriminatory and unlawful. I quote Supreme Court judgments on reasonable accommodation, equality and discrimination and highlight the exclusion of doctors with disabilities in policy making.

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Introduction

India ratified the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) in 2007, which made