Medical Ethics

Ethical Issues in Public Health Policy

K. ANAND, N. BARIDALYNE, D. MOORTHY, S. K. KAPOOR, R. SANKAR, C. S. PANDAV

ABSTRACT
Ethics in public health policy is given the least importance and rarely discussed. Resolving ethical issues in public health is often an arduous task as these are complicated and require careful handling. Using four case studies, we discuss issues pertaining to pertussis and brain damage, water fluoridation and dental caries, infection with the human immunodeficiency virus and the right to marriage, and the debate surrounding universal salt iodization. The core issue in all these examples pertains to the relevance of ethics in public health policy.


CASE STUDIES
1. The link between pertussis and permanent brain damage has been the subject of a heated medical controversy. In England and Wales, coverage of the vaccine dropped from >78.5% in 1971 to 37% in 1974 as a result of the fear of neurological side-effects. These low rates coincided with the largest epidemic of pertussis in 20 years. In 1985, some parents of the allegedly affected children moved the British High Court for compensation. As a result, about £6 million have been paid out to children who have been accepted as having brain damage due to the pertussis vaccine.

2. From the 1930s, an inverse correlation between the levels of fluoride and occurrence of dental caries has been noted. This initiated a preventive policy of fluoridation of water in areas with a low fluoride level. There were objections on the basis of undesirable side-effects of fluoride such as Down syndrome and various cancers. The ethical objection was that adding fluoride to the water supply is a compulsory medication and, therefore, a violation of individual rights.

3. In its judgment on the rights of a patient with contagious venereal disease to marry, the Supreme Court of India decided that the law would recognize marriage of a person with HIV/AIDS to be an offence. Such a marriage would have the effect of spreading the disease and putting the life of the partner in jeopardy.

4. On 13 September 2000, the Government of India lifted the ban on the sale of non-iodized salt. When the ban, which was enforced in November 1997, was lifted, the reason given was that food consumption is a matter of individual choice and cannot be forced upon people.

What is ethics?
Ethics is a set of philosophical beliefs and practices concerned with the distinction between right and wrong. While ethical issues in medical research and practice are discussed and debated, ethics in public health policy is rarely discussed and given very little importance. The core issue in these examples pertains to ethics in public health policy. Resolving ethical issues in public health is an arduous task. Using these case studies, we discuss a framework to address these issues.

Four basic principles of ethics
Medical ethics has four principles: (i) non-maleficence; (ii) beneficence; (iii) respect for autonomy; (iv) justice or equity.1 In the 1960s, medical ethics was predominantly associated with not harming the patient (non-maleficence). This was derived from the ancient medical maxim, primum non nocere (first do not harm), which is relevant even today. The principle of doing good (beneficence) has been unquestionably recognized as being important. In the 1970s, the principle of respect for autonomy was added and concerned human dignity and freedom and respect for the fundamental rights of an individual. Justice (equity), in the ethical sense, means natural and distributive justice—a concept of fairness and impartiality. It not only means ensuring that all persons are entitled to equal shares in the distribution of healthcare (equality) but, more importantly, priority is to be given to those who are in need, in proportion to their need (equity). This is particularly relevant to public health. The concept of rationing of health services and resources is an important fall-out of this concept.

These four principles are upheld as far as possible in the field of healthcare. Sometimes, however, a conflict arises in the application of these principles. At times, we need to restrict individual freedom (autonomy) in the interest of justice. In this context, the differences between a clinician and a public health specialist need to be highlighted. A clinician is in a one-to-one relationship with a patient who has approached her/him because of a particular need. Here, imparting adequate information to the patient and respect for the patient's autonomy is more important from the ethical point of view. However, a public health specialist neither has a specific patient nor receives any request from a patient and deals with population groups and societies rather than individual patients. Therefore, for a public health specialist the emphasis is on the greater good of larger numbers and the principle of justice plays a more important role. He, therefore, has to make a decision regarding what is in the interest of the people; the consequences of making such a choice are broader and its implications are more sociopolitical than medical.
Immunization for pertussis
Since 1933, there have been reports of neurological complications after immunization for pertussis. The inconclusive nature of this complication has resulted in considerable debate in the media, particularly in Britain, and left both doctors and parents anxious and confused about the safety of the vaccine. The rate of immunization halved from >78.5% in 1971 to 37% in 1974. An epidemic of pertussis was reported in a community of 360 000 people where the pertussis acceptance rates had fallen to 9.5%. In addition, under the Vaccine Damage Payments Act, £10 000 each has been paid to over 500 children whose parents have proved on the balance of probabilities that the vaccine caused the handicap. In 1981, a case-control study, named the National Childhood Encephalopathy Study (NCES), was initiated in England to assess the association between serious neurological illness and the pertussis vaccine. In 1988, in the famous Vaccine Court trial, 17-year-old Susan Loveday sued Dr George Benton, the general practitioner who gave her the vaccine, alleging negligence because he had given her the second and third doses despite reactions to the first dose. A four-month trial followed and the final judgment read that there was no evidence that the vaccine had caused the brain damage. In the same year, the NCES concluded its study of 1182 cases. They did not report any significant association between encephalopathy and the pertussis vaccine. The High Court vindicated the use of the vaccine and observed that far from causing encephalopathy the pertussis vaccine probably protects against it.

In this example, beneficence was observed by the administration of pertussis vaccine to all eligible children as it protected them against the disease. On the other hand, considering the probable neurological side-effect of the vaccine, the principle of non-maleficence was not respected, as universal immunization makes children susceptible to potentially dangerous side-effects. At an individual level, parents can exercise the freedom not to immunize the child. However, if all parents are allowed to take such a decision, the immunization programme will fail. It is a known fact that a population can be successfully immunized even without achieving 100% coverage. Effective protection can be achieved by immunizing a large part of the population; the remaining would be protected because of herd immunity. The actual proportion to be covered varies from disease to disease based on its epidemiology. In such a situation, there will be a small percentage of children who will be protected against a disease without getting exposed to the risk of side-effects of the vaccine. This group would enjoy the ‘best of both worlds’. This is the best group to be in and everyone would like to be included in this group. If this were to be implemented, who are the children who should be excluded from immunization and how is this to be decided? One process could be a natural selection—some children may not be immunized due to various reasons, including inaccessibility and non-availability of health services, lack of information, etc. As long as the selection of the non-immunized group is random, there is no violation of human rights by the deliberate inclusion or exclusion of any child.

A similar example is rubella immunization. Rubella per se is a self-limiting disease occurring in children or young persons. However, when it occurs in early pregnancy, it causes serious harm to the foetus resulting in abortions or severe congenital deformities including mental retardation (congenital rubella syndrome: CRS). An effective vaccine exists against the disease which is potentially eradicable. However, for it to be eradicated, the coverage has to exceed 90%. It is obvious that immunizing men is of no benefit to them but is essential for the community. Also, if the vaccine uptake is around 50%, the median age at infection increases. This means that the disease instead of affecting children affects adults. Paradoxically, this increases the chances of the disease occurring during pregnancy and, therefore, the incidence of CRS, which is diametrically opposite to the expected outcome of the immunization. Therefore, for the vaccination programme to succeed, there would have to be an element of compulsion.

Fluoridation of water
From the 1930s, it was noted that there was an inverse relationship between the levels of fluoride in drinking water and the occurrence of dental caries. This suggested a preventive policy of adding fluoride to water with a low fluoride level. There were objections on the grounds of undesirable side-effects such as Down syndrome and cancer. However, in Britain, the Report of the Working Party on Fluoridation of Water and Cancer (1985) found no evidence for such claims and other scientific groups have also reached the same conclusion. The suspicion that excess fluoride leads to the development of cancers is justifiable as an objection to compulsory fluoridation (non-maleficence). However, it was not based on scientific fact. The second objection was related to it being a compulsory medication. This illustrates the principle of autonomy conflicting with the positive community effects of fluoridation (beneficence).

Contagious venereal disease
In the third example, the Supreme Court of India’s first ever judgment on the right of a patient with contagious venereal disease to marry, ruled that ‘so long as a person is not cured of the disease, his right to marry is suspended’. This judgment came in the wake of a Nagaland doctor’s petition seeking compensation from the Chennai-based Apollo hospital, which had found that he was HIV-positive, and disclosed it to his would-be bride’s family. The marriage was immediately called off. In such a case where there is a clash of two fundamental rights, namely the patient’s right to privacy and the bride’s right to lead a healthy life, the right which would advance the public morality or public interest would be enforced through the process of court, the court said. Many non-governmental organizations (NGOs) and human rights activists have come out against this judgment. This case illustrates the conflict between principles of beneficence and respect for autonomy. It is in the public interest (beneficence) that the spread of HIV should be contained by all means. However, the right of a person to marry is violated by the prohibition to do so. Thus, respect for autonomy is not being observed here.

Universal iodization of salt
As a preventive measure against iodine deficiency disorders, the fortification of salt with iodine has also invited much controversy. The issues involved include:

1. Beneficence: Iodine deficiency disorders comprise a spectrum ranging from abortion to hypothyroidism. The most serious and irreversible consequences of iodine deficiency are abortions, stillbirths, congenital malformations, mental retardation and cretinism. Fortification of salt with iodine can be considered as a ‘vaccine’ for ensuring the proper physical and mental development of a child. India has been a pioneer in testing the effectiveness of iodized salt in community trials conducted in the Kangra Valley in the late 1950s and 1960s. Besides, a recent economic evaluation of the disease from the state of Sikkim found that the benefits of the programme far exceeded its cost (more than four-fold).
2. **Non-maleficence**: No untoward effect of excess iodine consumption has been reported from countries that were previously iodine sufficient. A small, transient and self-limiting increase in the incidence of thyrotoxicosis occurs generally among adults above 45 years of age, when large doses of iodine are given to a chronic and severely iodine-deficient population over a very short period of time. It occurs only in the early phases of an iodine fortification programme. Allergy to iodine in the fortified salt has not been reported in the medical literature, though it is possible.9

3. **Justice (equity)**: This means that priority should be given to those who are in need, in proportion to their need. In the case of iodine deficiency, the communities that are deficient in iodine are the ‘needy’ communities. Though most of the studies show that iodine deficiency exists in all parts of India, it may be possible that there are some iodine-sufficient areas. However, equity demands that areas deficient in iodine should get iodine supplementation. There is evidence from other countries such as the Commonwealth of Independent States (formerly part of the USSR) and Germany (where the control of iodine deficiency disorders through universal salt iodization was squandered because of slackening due to sociopolitical reasons).10,11 Anecdotal evidence from the past suggests that this is true for India as well.

4. **Autonomy**: Universal salt iodization can be looked upon as a compulsory medication and, therefore, a violation of an individual’s rights.

**THE CONFLICTS**

With the issues outlined, we are faced with the conflicts. Lack of any maleficence and proof of beneficence clearly vindicate the intervention of salt iodization. The conflict seems to be between equity and autonomy. The best option is obviously to have a salt iodization programme only in iodine-deficient areas. This approach is beset with problems, the foremost being how to identify iodine-deficient areas. A countrywide survey has not been done. Is it necessary for each district to be studied? Of the 275 districts surveyed in 29 states and 6 union territories till now, iodine deficiency disorders are a major health problem in 235 districts where the prevalence is more than 10%.12 Is this not enough proof that iodine deficiency disorders are almost universal in India? Also, the fact that a district is iodine sufficient at present does not mean that it will remain so by itself. There is evidence that due to repeated leaching from the soil, in the absence of an intervention, iodine deficiency will occur over a period of time in most ecosystems. Under the purview of preventive medicine, need we wait till deficiency occurs or act before it does so?

Another problem is the way in which the salt is manufactured and traded. It is made in a few states (Gujarat, Rajasthan and Tamil Nadu account for more than 80% of all salt produced in India) and sent to different parts of India. Therefore, with salt manufacture and iodization being centralized, it would be logistically difficult to transport salt differentially to neighbouring districts, because we are likely to have iodine-deficient and -sufficient districts adjoining each other. Past experience has shown that it is administratively impossible to effectively supply iodized salt separately for the high risk areas. Thus, both iodized and non-iodized salt would be available in the market. Non-iodized salt is cheaper than iodized salt, and invariably people would go for a cheaper option if both were available in the market. Thus, people in iodine-deficient areas would be deprived of the iodine that they need.

In summary, universal salt iodization will expose the iodine-sufficient areas to additional levels of iodine, without any likely benefit or adverse effect. Efforts aimed at withholding iodized salt from certain iodine-sufficient areas would be likely to result in people in iodine-deficient areas consuming non-iodized salt. This goes against the principle of justice/equity because, based on the probability of adverse effects to the people in iodine-sufficient areas, we would expose the population in iodine-deficient areas to the potential risk of iodine deficiency disorders.

**Decision-making**

We support the policy of universal iodization of salt though we are not and should not be the decision-makers. As with many other public health issues, ethical decisions may not be so unequivocal. **Beneficence and maleficence** can be quantified since the risks and benefits can be measured objectively. Hence, if decisions are to be made based on these two principles, a simple equation of the two will give the answer. An economic analysis can also be factored into the equation. Another concept proposed by Calman is the concept of utility—maximizing the total benefits for the population involved.13 Utility commits us to evaluate outcomes, set targets and audit everything that can be audited. In that sense, it gives us a comprehensive view of the quantifiable nature of the issue with the societal perspective.

However, what is not measurable tends to be regarded as unimportant. **Respect for autonomy and equity** (justice) is more subjective, and hence difficult to measure. Equity can be measured to some extent, whereas respect for autonomy is impossible to measure. Similarly, ‘quality’ of healthcare or life is not measurable. However, ethical decisions in public health policy need to be taken. The question is, who should take the decisions and on what basis?

We believe that three principles must be followed in arriving at any decision on ethical issues in public health. The process should ensure that the decision would be:

1. Taken by a representative body
2. An informed consent
3. By consensus.

All three points are equally important and difficult to achieve. First, public health issues concern the interest of the public at large and, ideally, society should take such a decision. However, it is not practical to consult the public each time such an issue is raised. The resources required for doing so are prohibitive and issues relating to representation will also arise. The representation should be such that minorities who normally do not have a voice should be equally represented. The next obvious method could be a ‘representative’ sample of citizens, which is empowered to take decisions on behalf of the rest. We already have one such body in the country—our Parliament. Parliament should be responsible for taking such decisions on behalf of the people. We also have a Central Council of Health consisting of State Ministers of Health. These fora may not be the most ideal way to represent our country, but they have the advantages of availability and acceptability. If one feels strongly that they are ‘unfit’, a new forum will have to be created. The scope of the National Human Rights Commission (NHRC) can also be expanded to include this role.

Second, the choice should be made on the basis of scientific information provided by experts on the subject concerned. The process of conducting research and analysing and interpreting it should be done in a scientific manner, and the implications of the results should be presented in the right perspective. We believe
that researchers have a limited role in policymaking. It is their responsibility to communicate their results effectively to policymakers and the general public. However, this should not be in the form of advocacy of a particular policy. Rothman and Poole argue that the conduct of science should be guided by the pursuit of explanations for natural phenomena, not the attainment of political objectives. The *Journal of Epidemiology* goes to the extent of prohibiting researchers from making policy recommendations in scientific articles. Third, a thorough analysis of information should be done to reach a consensus. In case a consensus cannot be reached at the outset, there should be a debate in Parliament. Consensus means going beyond the simple majority. Reaching a consensus means making efforts to satisfy the genuine concerns of affected people. For this, it is essential that the process of decision-making is transparent. If equity is to be held more important than individual autonomy, it should be done in a forthright manner and with due explanation to the concerned parties. It is possible that affected individuals and communities, when fully informed of the issues, will willingly forgo their freedom to choose.

The case studies presented can be examined in the light of the basic principles of public health. In the case of the pertussis vaccine controversy, it was the British High Court that vindicated the use of pertussis vaccine. It was supported in this effort by the availability of scientific evidence. The issue of fluoridation was resolved with the help of scientific research when it was confirmed that there is no association between cancer and fluoridation of water. However, the choice of individual freedom could not be resolved. Either equity or autonomy has to be sacrificed. Dental caries would not constitute a significant health problem and the availability of other preventive approaches meant that fluoridation never took off in a major way.

The last two cases are yet to be resolved and we can learn from the two examples given above. Often the decision is taken by a judicial court or by scientists. We, however, feel that both of them are not the right fora. The courts are not representative of the community and their decisions are not based on consensus. Therefore, it violates two of the norms laid down above. The decision may be ‘informed’ in that it gives a chance for both sides of the argument to be presented. What is more common in developing countries is decision-making by scientists. In our opinion, the role of scientists is restricted to informing the decision-making body of the issues involved. They are neither representative of the community nor are the decisions taken by them based on consensus.

In the third example, it was the court that suspended the right of HIV-infected individuals to marry. Is this too much of an infringement on such a personal issue? This brings us back to the argument that the health of society is the responsibility of the people themselves. Therefore, the right to take such decisions concerning the health and quality of life of the people should rest with them.

Coming to the example of universal salt iodization, the issue is of individual freedom versus equity. These cannot be decided without debate at a societal level. Both the initial ban on the sale of non-iodized salt in 1997 and its subsequent revocation were done without much debate. The case is now before the Supreme Court in the form of a Public Interest Litigation.

Modern technology can help in some way to provide a solution to controversial issues. As in the case of pertussis, the development of an acellular vaccine provided the answer to the problem of the whole-cell vaccine and its side-effects. However, the inhibiting factor for its widespread use is the cost. Therefore, from the safety point of view, these vaccines should be preferred; however, the cost-effectiveness of the alternative vaccine has to be studied, especially in developing countries with scarce resources. Thus, an economic issue replaces the ethical issue. In fact, India still uses the whole-cell pertussis vaccine, while many developed countries have shifted to acellular vaccines. This emphasizes the point that ethical issues have to be decided by each community based on its situation.

We have tried to outline a possible framework that is needed in India to address ethical issues in public health. Will the government take up this task as a ‘challenge’? Ethical decisions are rarely simple. What is needed now is not more rules or laws, but clear thinking and exposure of the key issues and conflicts of interest. It should be remembered that, while the decision is important, the process of arriving at that decision is of paramount importance. The public and government will have to make informed choices.

The World Health Organization speaks of public health as an ‘art and a science’. The art of public health is to persuade the public and government to adopt policies that are derived from scientific data. It is time that we moved from the *ad hoc* approach to a more rational scientific approach in solving ethical issues in public health policy.

**CONFLICT OF INTEREST**

We have been actively involved in research and advocacy in iodine deficiency disorders at the national and international levels.

**ACKNOWLEDGEMENT**

This article is dedicated to the memory of Professor V. Ramalingaswami, Former Director, All India Institute of Medical Sciences, New Delhi and Former Director-General, Indian Council of Medical Research, New Delhi.

**REFERENCES**