

Ethical Considerations for Vaccination Programmes in Acute Humanitarian Emergencies

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Summary

Humanitarian emergencies lead to a breakdown of critical healthcare services and result in vulnerable communities who are often dependent on external agencies for care. In resource constrained settings this may occur against a backdrop of extreme poverty, malnutrition, insecurity, low literacy levels and limited infrastructure. Under these circumstances the provision of food, water and shelter and limiting communicable disease outbreaks become primary concerns. Where effective and safe vaccines are available to mitigate the risk of disease outbreaks, their potential deployment is a key consideration in meeting emergency health needs. Decision-making on vaccine deployment should include ethical deliberations, as they are pertinent to multiple issues including vaccine availability, target groups, delivery strategies, surveillance and research during acute humanitarian emergencies. Ethical considerations central to these public health activities include autonomy and consent, beneficence (duty of care and the rule of rescue) and distributive and procedural justice.

Introduction

During acute humanitarian crises complex ethical issues arise that vary depending on the nature of the crisis, the interventions required, the geographic location of the crisis, pre-existing infrastructure and prevalent infectious diseases. In describing the key ethical issues, general ethical principles have been applied that need to be tailored to specific situations. Humanitarian crises lead to a breakdown of critical healthcare services or occur in places where existing healthcare services are inadequate, resulting in vulnerable communities that may require urgent healthcare and who are dependent on external agencies for this care.¹

In resource constrained settings this could occur against a backdrop of extreme poverty, malnutrition, low literacy, insecurity and limited infrastructure, which creates an environment of extreme dependency on external assistance and health care, potentially compromising individual autonomy.

Infectious disease outbreaks occur commonly during humanitarian emergencies and complicate response and recovery. Measures to mitigate the risk of communicable disease outbreaks, such as effective and safe vaccines, must be seriously considered in the initial response. This must occur simultaneously with other interventions, like food, water, sanitation, and shelter, as the disruption of infrastructure, environmental contamination, crowding and population migration accentuate the risk of outbreaks for affected communities. Disease severity can be extreme in these settings, for example, the measles case fatality ratio can be as high as 3:1 during a humanitarian crisis.²

Important factors that must be considered before deploying vaccines during emergencies include weighing up the potential burden of disease compared to the often minimal risk of vaccination, the desirability of disease prevention compared with treatment, duration of protection, cost, population effects (herd immunity) in addition to

individual protection and the logistical feasibility of rolling out quality large-scale vaccination programs. For some diseases, such as meningitis and measles, vaccination is the only available means of protection. Unlike many medical or surgical therapies, the recipients of vaccines do not require ongoing related care and some vaccines have long-term benefits which will outlast the crisis. Scarcity will however influence decisions about the resources available for allocation to vaccination programmes and other public health measures.

The World Health Organisation and a number of humanitarian non-governmental organisations recognised the need for a framework to systematically guide decision-making on vaccination in emergency situations.³ This framework addresses epidemiologic, ethical and vaccine-specific considerations. The ethical issues explicitly focused on in this framework include assuring a vaccine supply, distributive and procedural justice in allocating limited vaccine supplies, balancing benefits and harms, acquiring informed consent and appropriate research. Although each acute humanitarian emergency will differ depending on the nature of the emergency and the threat posed, the pre-existing situation in the affected community and the agencies involved, this paper highlights ethical concerns that should be addressed when considering vaccination during the emergency response without necessarily providing specific, prescriptive guidance.

Beneficence and a Human Rights approach to vaccine access

The international community has a collective duty of care to ensure that effective affordable measures are available to those most in need. As the risk of communicable diseases during humanitarian emergencies is often extreme, the duty of care based on the principle of beneficence demands that effective vaccinations against these disease threats should be available to those at risk. A special obligation in addition to the duty of care is the rule of rescue; “the imperative that people feel to rescue identifiable individuals facing avoidable death”.^{4,5} Humanitarian emergencies occur frequently enough⁶ to warrant timely access to an assured vaccine supply as certain vaccine preventable diseases have severe outcomes including increased mortality.⁷ An obligation falls on global and local communities, including governments and non-government organisations, to facilitate this access.

Arguments against introducing levels of care, including vaccinations, which do not usually exist in the specific crisis settings, include the doctrines of developmental relief and sustainability. There is a concern that introducing higher levels of care than existed prior to the emergency will result in aid dependency. However, in the acute humanitarian crisis setting, where administering a vaccine will provide immediate protection against a substantial disease threat (high mortality or morbidity rates and transmissibility), this argument does not have legitimacy and could be criticised as denial of international responsibility.⁸ Public health crises require a higher standard of care due to their immediate life-threatening nature and it is ethically reasonable for standards of preventive care to return to pre-existing levels after crisis resolution when the heightened threat has subsided. Establishing a vaccination programme differs from many other medical interventions in the wake of an acute humanitarian emergency, which may require some level of ongoing care or rehabilitation. Vaccinations may, in addition, provide long-lasting benefits. The sustainable provision of some vaccines will

be limited by the availability of local and global resources in a context of other global crises occurring concurrently or in close succession.

Over the past two decades there has been a shift from viewing humanitarian assistance as charity (based on the principle of beneficence) to adopting a human rights approach, with international emergency response considered an obligation incurred by those who can help, to ensure that the rights of affected individuals and populations are respected and promoted.⁹ The Humanitarian Charter in the Sphere Handbook¹⁰ “defines the legal responsibilities of states and parties to guarantee the right to assistance and protection.” It draws on the Universal Declaration of Human Rights, International Humanitarian Law (the Geneva Conventions), and the Convention on the Status of Refugees, to establish a legal framework guiding humanitarian action.

A human rights approach argues for access to vaccination to equitably promote and protect public health. Article 25 of the Universal Declaration of Human Rights¹¹ states that:

Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, and medical care ... [and that] every individual and every organ of society ...shall strive ... by progressive measures, national and international, to secure [its] universal and effective recognition.’

Irrespective of whether humanitarian assistance is justified on the basis of beneficence or human rights, donations of vaccines may form part of the strategy for timely access to vaccines in emergencies. Although WHO and UNICEF have noted five requirements to achieve "Good Donations Practice", including suitability, sustainability, informed key persons, supply and licensing, their joint statement¹² recognises that in exceptional circumstances, including emergency situations, these minimum requirements may not all be possible or even justified. The most important consideration is that the vaccine is responsive to the needs of the population from the public health perspective.

Balancing Benefits and Risks

Balancing the principles of beneficence (doing good) and non-maleficence (avoiding or minimising harm) are integral to all humanitarian decision-making. Vaccines that are likely to be considered in the acute phase of a crisis usually have established efficacy and safety track records in routine use. In addition to the benefits they offer to individuals who are directly protected against specific diseases, many vaccines confer additional community benefit through herd immunity that decreases the likelihood of outbreaks where vaccination coverage is high.

Vaccines are generally administered to individuals prior to their exposure to a targeted disease, and administering unnecessary vaccines incurs attendant opportunity costs and needless risks of side-effects. It is therefore essential that the risk of illness justifies vaccination. Risk is the product of four variables: nature (epidemiological and environmental), probability, severity and duration.¹³ Where a disaster occurs in a location with existing high vaccination coverage or low rates of a specific infectious disease, the benefits of additional emergency vaccinations may be minimal. For example the introduction of a measles vaccine following an earthquake in Sichuan

Province in China 2008 would have been inappropriate given that a province wide preventive measles campaign with high coverage had just been completed.¹⁴

Like benefits, harms may occur at the individual and collective level. Individual harm includes the side effects of a specific vaccine. Adverse events range from the relatively common, such as inflammation and pain at an injection site, to the very serious but rare. Established vaccines, which are most likely to be used in emergency settings, have well-known side-effect profiles within routine vaccination programmes. However, there is less knowledge about the risk of adverse events in emergency situations where people may be malnourished or have other medical conditions as a result of the crisis.¹⁵

Within the crisis-affected community there are individuals who are more vulnerable to vaccine preventable diseases due to their biological status (nutritional status, pregnancy, age, immunosuppression, pre-existing health conditions). Certain sub-groups in a community may have contraindications or not be eligible for certain vaccines, for example children under two years for inactivated typhoid vaccine. The entire community may be extraordinarily vulnerable due to environmental conditions such as crowding and lack of access to hygienic measures. Noting this, individual harm can result for a child whose parents refuse vaccination on the child's behalf. Collective harm may result from adults' choices not to be vaccinated or parents' decisions not to vaccinate their children. If the level of refusal results in a large pool of susceptible individuals that compromises herd immunity, then devastating outbreaks can result. In these settings there may be a moral obligation to accept vaccination in order to prevent harm to others.¹⁶

Distributive Justice

Distributive justice requires the fair allocation of limited resources. This applies to basic items such as shelter, food and potable water, as well as vaccines that are in limited supply. One arguably equitable way of distributing a limited supply of vaccine would be a lottery, but this does not take into account groups who are most vulnerable to illness or those who contribute most to transmission. Decision-making and priority setting in acute crises differs from routine situations or protracted crises. The "best possible" way to distribute resources is often not perfect, as humanitarians can only do the "best they can" in the context of imperfect information, exceptional and unique circumstances.⁷ This challenge of allocating resources fairly and legitimately is exacerbated in humanitarian crises due to the enormous disjunction between constrained resources and accentuated need.

Where resources, particularly human resources, are limited, decision-makers often explicitly or implicitly consider cost-effectiveness when determining the relative focus on various interventions to achieve maximum benefits. Vaccination is widely recognised as highly cost-effective. Additional considerations include the extent and urgency of the need met by vaccination, and the feasibility of quickly providing vaccination compared with other interventions in the specific emergency situation. There should be explicit consideration of targeting distribution to high risk or high transmission groups. Vaccination is often highly relevant in emergency settings, as it can mitigate serious infectious disease risks. It is also possible to vaccinate large numbers of people in a timely fashion.

Allocation decisions are relevant to all countries regardless of socioeconomic status or past experience of humanitarian emergencies. There is a shared global vulnerability to humanitarian emergencies, although this is more pronounced in poor countries and regions because poverty hampers resilience. As described below, allocation decisions require striking a balance between promotion of utility (maximising the good to the community, smooth economic and societal functioning) and the achievement of equality and fairness. This is essential to promote public trust in vaccination programmes during crises. Egalitarian considerations require that allocation decisions should not be discriminatory and everyone should have a fair chance of receiving vaccination.¹⁷ Utilitarian considerations require that allocation decisions achieve maximal benefits in terms of aggregate wellbeing, i.e. achieving "the greatest good for the greatest number". It is perhaps unclear whether utility considerations require maximally reducing the burden of disease, for example in terms of Disability Adjusted Life Years (DALYs) versus saving the most lives. These two goals might sometimes conflict with one another. In any case, utility can conflict with equality or fairness because it may sometimes be possible to achieve the greatest health gains, in terms of lives saved or DALYs averted, by allocating vaccines to urban rather than rural areas, with greater impact and cost-effectiveness of implementation due to population density in urban areas.¹⁷ If rural populations are systematically excluded, however, this would be considered inequitable. Occasionally physical security risk to health workers in areas of conflict will determine which groups are able to be vaccinated.

The goal of maximising utility may conflict with the egalitarian idea that justice requires efforts to maximally improve the situation of those who are worst-off. Improving the situation of worst-off groups implies that these populations receive priority allocation of limited supplies even if less health utility is achieved overall.

From a pluralistic perspective, we should aim to strike a balance between utilitarian and egalitarian considerations rather than according absolute priority to either. Fortunately when it comes to vaccination, it is often the most socioeconomically marginalised groups that will gain the greatest utility from vaccination, with limited conflict between utilitarian and egalitarian aims.

Questions concerning the fair distribution of limited vaccine supplies came into sharp focus in the context of pandemic influenza preparations. Particular categories prioritised in this situation for special consideration were those people at greatest risk of infection such as school children and health care workers, those most likely to suffer severe consequences from the disease if infected, including individuals with chronic illness or immunosuppression and those most likely to spread infection including children; and emergency service providers.¹⁸

During humanitarian emergencies characterised by displacement of affected populations, communities neighbouring those that have been displaced by the emergency, also merit consideration. In most circumstances, host communities should have access to services provided to refugees in camps, and refugees should have access to government services available to host communities.¹⁹ Refugee or displaced populations should not be regarded as separate from the host community²⁰ and assistance programmes, including vaccination, should be planned to support the area as a whole. The guiding principle should be equitable access to vaccination for equal

risk. Other considerations for an inclusive approach include efficiency of providing programmes to two communities with the available resources; and the benefit of fair and equitable approaches to minimise hostility and jealousies between host and displaced communities.¹⁰

On a utilitarian and equity basis children often deserve prioritisation as they are more vulnerable to vaccine-preventable illnesses¹⁷ and saving a younger person's life will usually result in a larger reduction in disease burden, as more years of healthy life are lost when a young person dies. Furthermore, parents and caregivers will often prioritise the needs of children over themselves. Some communities place a greater importance on the roles of the elderly or pregnant women, however, and may thus prioritise access to healthcare, and vaccines in particular, differently.

From a utilitarian perspective preventing illness in frontline health workers, who are in the business of saving lives, will have indirect health benefits for the community, particularly where there are limited numbers of health workers. The principle of reciprocity suggests that it is fair to prioritise vaccination to health care workers exposed to increased infection risks due to their professional commitment to care for society. In addition, as health care workers have contact with particularly vulnerable individuals they have a duty to accept vaccination so that they do not place patients at risk of infection.²¹

Procedural Justice

Procedural justice requires transparent decision-making and participation of communities that are affected by the decisions.²² The current paucity of publicly available guidance to assist in transparent decision-making regarding introducing vaccination programmes in emergencies is of concern. It is preferable to have a legal framework or explicit guidance, in this instance in the form of guidelines, to ensure procedural justice. Guidelines are of particular value in situations where: large numbers of people receive treatment or a preventative therapy (for example through mass vaccination campaigns); emergency situations where delays or sub-optimal approaches could result in severe detrimental outcomes; and health conditions, if poorly managed, have a high mortality rate or cause large-scale epidemics in vulnerable populations.

Although guidelines do not have mandatory status i.e. they are not legislated policy, if they are evidence-based and contextually appropriate they should be considered normative practice against which behaviours by authorities and health practitioners are judged.

National legal systems should guide the implementation of vaccination programmes in individual nation states; however they do not frequently accommodate humanitarian emergencies. In instances where national legislative frameworks are absent or dysfunctional, international human rights law dictates a duty of care to protect those in need of assistance. In these settings implementation should ideally be guided by legitimate international health guidelines. WHO vaccination guidelines²³, which are developed with consideration of a broad range of factors including the: epidemiologic features of the disease, clinical characteristics of the disease, vaccine characteristics, economic considerations, health system infrastructure, social impacts, legal and ethical

considerations, are a legitimate tool for WHO member states, focusing both on the strength of evidence and the context in which the guidelines will be applied.²⁴

There have been many initiatives to improve accountability during humanitarian emergencies, at state, operational agency, and donor level. These include Sphere, the Humanitarian Accountability Partnership and the Active Learning Network for Accountability and Performance in Humanitarian Action.²⁵ These include involving beneficiaries in the planning and implementation of aid programmes, codes of conduct for responding agencies, technical standards and the use of performance indicators and impact assessments.

Applying these approaches during humanitarian crises is challenging⁷ with constraints on information dissemination, cultural awareness and time available. Affected populations are often disenfranchised and less able to defend their interests. As a minimum the factors considered during the decision-making process regarding the introduction of a vaccination programme should be well-documented and publicly available to donors, community leaders, local staff and governments. There should also be opportunity for concerns to be raised directly by affected communities with the responding agencies.

Consent

Obtaining valid consent from individuals prior to offering medical intervention is an obligation created by the principle of respect for the autonomy of persons. Under non-emergency circumstances, the consent process is often comprehensive and therefore time consuming. The nature of the consent process during an emergency will differ from a routine health setting. Time permitting; information on risks and benefits must be communicated to target populations in sufficient depth, given the severity of the situation, to facilitate an informed decision on receiving the vaccine, while recognising that health literacy levels, including a basic understanding of germ theory and immunology, will be limited in some affected communities. Vaccination is often offered in a setting where the recipients of humanitarian services will be desperate for some services, for example food, but may not have an inherent understanding of other services, for example vaccination. Furthermore, in some developing countries deference to decision-makers remains common, which is in clear tension with individual autonomy.

The amount of information provided will need to be tailored if the process places others at risk by creating avoidable delays. However, any questions raised should be adequately and accurately addressed. This implies that those immunising should be able to answer common questions relating to the diseases targeted, benefits offered, potential adverse events, follow up and alternative options available if vaccination is refused. They should also have the ability to refer undecided individuals with additional legitimate questions to others with particular expertise, although this requirement may not always be feasible and should not prevent programme implementation in an emergency setting. Group education prior to vaccination roll-out, or in the waiting space or line, using visual aids and other appropriate media may assist in providing necessary information in a more time efficient manner.

Vaccination should be voluntary unless compulsory vaccination is essential to “prevent a concrete and serious harm”.²⁶ The degree of risk to communities will determine the extent to which individual rights may be limited. Where there is an imminent threat of infectious disease that poses a significant risk of substantial harm to a large number of persons individual liberties may be justifiably curtailed.²⁷ The Siracusa Principles²⁸ endorsed by the United Nations Economic and Social Council state that: “Public health may be invoked as a ground for limiting certain rights in order to allow a State to take measures dealing with a serious threat to the health of the population or individual members of the population. These measures must be specifically aimed at preventing disease or injury or providing care for the sick and injured.” It may thus be permissible for those in authority to limit the autonomy of some in order to prevent harm to others. Although traditional public health law has argued that this approach is limited to immediate or direct threat, it should arguably be extended to what is “reasonably foreseeable”²⁹, based on epidemiology and historical occurrence. It would be inappropriate to allow individuals to compromise group protection³⁰ and group rights under the threat of great danger.^{31,32}

Liberty restriction to protect public health should be based on evidence that the measure is: effective, the least restrictive (i.e. least liberty-infringing) alternative, proportional to the risk, used in an equitable and non-discriminatory manner, minimally burdensome, involves due process, and those whose liberty is violated should, where appropriate, be compensated in return, particularly if they experience vaccine-associated adverse effects.^{33,34}

Respecting the autonomy of persons implies that individuals may exert their choice to decline vaccination even though public health policy may encourage widespread vaccination. The right to autonomy is however not absolute. When an individual’s decision to refuse vaccination may endanger others, mandatory public health measures, proportional to the public health threat, will sometimes be appropriate.²⁸ Some vaccines, such as rabies and tetanus, only benefit the individual recipient while other vaccines, such as measles, additionally contribute to herd immunity and protect communities. It is for this latter class of vaccines that conflict between individual choice and the common good may arise. When members of a community decline to participate in a vaccination programme, they are risking not only their own health but also the health of others who either may not have access to vaccination or are unable to be vaccinated for medical reasons. Even if herd immunity is achieved, such people may be considered “free riders” because they benefit from herd immunity without contributing to herd immunity themselves. This places an unequal burden of the risks of adverse events from vaccination on those who participate.

Children are at particularly high risk in humanitarian crises, being more susceptible to the severe consequences and complications of infection, particularly if malnourished, and health systems have a limited capacity to cope with the demand for acute paediatric care during crises. Under five-year mortality is generally two to three-fold greater than crude mortality in most emergencies.³⁵ In addition, as children are often a sub-group in which epidemics are initiated and perpetuated, immunising children could reduce mortality in all age groups.³⁶ As parents assume decision-making authority for young children, parental vaccine refusal should be accepted where risk of disease is low or

where the disease is mild. However, where there is substantial risk of significant harm to the child, parental authority may be overruled on the basis of the child's best interests.^{16,37} In emergency settings a parent or guardian may not be available, in which case health care workers should be empowered to make rapid decisions about immunising a child, provided this is believed to be in the child and community's best interests.

Research

The acute setting following disasters presents a unique opportunity to conduct research that can be extremely beneficial in providing a better understanding of the health and humanitarian consequences of disasters, establishing the safest and most effective health interventions, and evaluating service delivery models for specific disaster settings.^{38,39} However, it is imperative that medical care and service delivery take precedence over research in resource limited settings during an acute humanitarian emergency.⁴⁰ Research in disaster settings is often conducted by people who are also involved in providing aid, thus research "rightly takes second place to the provision of life-saving assistance".⁴¹ Ideally a local research ethics committee should establish that care needs have been met before such personnel are permitted to conduct research,⁴² however if there is no appropriate local expertise the research should be referred to another Institutional Review Board. In countries where research governance structures are not functioning then researchers must use credible international ethics review boards.

Research must be distinguished from disease and programme surveillance.⁴³ Surveillance is essential for assessing vaccination coverage and informing programme planning, evaluating vaccine effectiveness, and monitoring safety in the population as a whole and in sub-groups where less safety information may be routinely available.⁴⁴ Sensitive surveillance allows rapid detection of disease cases that may demonstrate programme failure requiring remediation. As surveillance activities have an opportunity cost, it is imperative that the data collected is analysed and used to direct public health action.⁴⁵

The principle of justice dictates that communities that carry the burdens of research must stand to benefit. Research protocols should be relevant, methodologically sound and should make the benefits or potential harms for participants explicit. They should also contain clear plans for returning results to participants recognising that they may relocate in the months following the humanitarian crisis.⁴⁶ Important in the context of humanitarian emergencies is that the research should not detrimentally affect the provision of health services and that any research commenced should continue until completion.

Although most non-medical research conducted during disasters is observational, including surveys, social science and mental health research, it should nevertheless undergo ethics review to ensure that individual and societal benefits outweigh any risks. The level of review should be proportional to the risk associated with a specific project, with expedited review of low risk research and full committee review for higher risk research. Full review of generic protocols for anticipated projects that may occur in the setting of an acute humanitarian emergency should be considered. Adequate provision

should be made for counselling or debriefing should participants experience research interviews as traumatic or emotionally distressing.⁴⁷

The decisional capacity of potential research participants may be impaired following an acute humanitarian emergency, with many communities meeting the UNAIDS (Joint United Nations Programme on HIV/AIDS) criteria for “vulnerable communities”: limited economic development, inadequate human rights protection and discrimination based on health status, inadequate community/cultural experience and understanding of scientific research, limited availability of healthcare and treatment options. This poses a particular concern for the research consent process, as individuals in these communities may have a limited ability to provide voluntary individual informed consent.¹ Empirical research in developing countries has shown that even under usual non-emergency circumstances, obtaining informed consent from study participants is challenging. Acute humanitarian crises add an additional layer of complexity and thus decisional-capacity must be carefully assessed.^{48,49,50,51,52} Given the need for medical care in acute crises, patients may falsely believe that a research intervention has already proven effective. This should be actively guarded against in the consent process. Participants need to be made aware that they are consenting for research only and no expectations of extra care should be created.

Conclusion

Ethical considerations are vital to decision-making on vaccine deployment in acute humanitarian emergencies. A human rights commitment and application of the rule of rescue places an onus on wealthy countries to ensure the availability of life-saving vaccines for poor communities affected by humanitarian emergencies. Justice and ethics require improving the situation of those who are worst off and thus allocating resources accordingly.^{53,22}

National health authorities have a moral obligation to take all reasonable measures to implement evidence-based guidelines to avert preventable harm if they have the ability to do so and the implementation does not impose an excessive burden.⁵⁴

Decisions on allocating limited vaccine resources demand a fine balance between promotion of utility and the achievement of equality and fairness. Accountability demands that decision-making is explicit, documented, and open to review.

Vaccination should usually be accompanied by informed consent even in emergencies, however the process may be reasonably adjusted to ensure that protection for vulnerable communities is not delayed. Autonomy is not absolute and where the health and well-being of others is threatened then authorities may be required to mandate vaccination and intervene on behalf of minors against parental wishes.

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