

A Framework for Deciding on Vaccinations in Acute Emergencies

1. Introduction

1.1. Statement of aim

This Framework attempts to fill an existing void in the literature pertaining to acute humanitarian emergencies. Despite the recognized importance of many vaccine-preventable diseases in the emergency setting, and even though some vaccines, especially measles vaccine, have been frequently promoted and implemented as public health interventions of the highest priority in these situations, no widely accepted or generally used guidance for making decisions regarding vaccination in emergencies currently exists.

The proposed Framework is not prescriptive in that it does not give instructions as to when to vaccinate which population groups with what antigens. Instead the Framework fully recognizes that different vaccination-related decisions will be appropriate in different emergency settings. For that reason, its objective is to provide a structure for thinking through the process of deciding which vaccines would constitute high-priority public health interventions in a specific emergency context when delivered in accordance with an appropriate strategy. Case-studies and literature review conducted in conjunction with the development of the Framework show that a consistent and methodical approach to making a decision as to whether or not to vaccinate a disaster-affected population with one or more antigens would be of great benefit to those responsible for coordinating the overall response to the acute phase of an emergency.

Users of the Framework should bear in mind that acute emergencies are often associated with political instability, unusual societal stress, and a generally turbulent and even chaotic environment. The ultimate goal of public health interventions and resources in emergency settings is to save lives by whatever means necessary; the urgency of food delivery and distribution, water and sanitation measures, the provision of adequate shelter, and other health sector interventions must all be taken into consideration in the prioritization process. Principles of equity, human rights, and distributive justice must be respected. Accordingly, steps must be taken to document decisions and to ensure that the affected population or its representatives understand the need for vaccination, why certain groups are receiving specific vaccines, and why limited resources are being allocated as they are. The Framework is intended to provide assistance in making the right decisions, but the interventions that result from the decision-making process must be implemented in an ethically sound manner. For this reason, the Framework is accompanied by a document that clearly defines the key ethical concerns that need to be taken into account during the processes of decision-making and vaccine delivery.

The Framework proposed here is composed of three essential components: 1) a process for assessing the epidemiological risk posed by each potentially important vaccine-preventable disease within a given context; 2) guidance for considering the properties, biological and programmatic, of each vaccine to be considered for intervention; and 3) guidance for deciding how to prioritize the importance of vaccination in a context where there might be equal or greater urgency to implement of other public health interventions and interventions in other sectors (water and sanitation, nutrition, etc.) that might also contribute to reducing disease and death.

Accordingly, the aim of this document is to assist the user to thoughtfully, deliberately, and rationally determine whether or not the delivery of one or more vaccines to specific target populations during the acute phase of an emergency would result in an overall saving of lives, a reduction in the population burden of disease, and in a generally more favorable outcome than might otherwise be the case.

1.2. Intended audience

The Framework should be used by anyone involved in making decisions about public health programming in emergencies. In almost all cases, the final decisions should lie with appropriately designated officials of the Member State in which the emergency is occurring, usually a combination of those overseeing emergency response and those involved in the implementation of vaccination programs.

However, it has frequently been the case that emergencies occur in countries that do not possess the capacity to optimally respond to a relatively sudden change in the size or distribution of its population caused by either an influx of refugees or by the internal movement of its own citizens. In addition, the vulnerability of a population can be vastly increased due to natural events – earthquakes, floods, and the like, that require a surge in human, financial, and technical resources that may not be readily available. In these cases, one or more agencies of the United Nations system have frequently been recognized as partners in policy-making. Since the initiation of the UN Humanitarian Reforms, a “cluster system” has been implemented, in which WHO, in conjunction other UN agencies, health authorities of the country concerned, and/or a representative of the local or international non-governmental relief agencies, work together to develop, promote, and implement appropriate health policies and programs as an integral part of the emergency response. In general, vaccination programs in these circumstances are decided upon by consensus. This Framework is meant to guide the discussions that result in that consensus.

1.3. Definition of acute emergency

The scope of the Framework is comprehensive – it applies to all age groups affected by an acute emergency and to all vaccine-preventable diseases. Because so many different kinds of emergency occur in so many different settings and in so many different circumstances, it is important to be clear as to when the proposed Framework should be applied. Accordingly, all mentions of the term “acute emergency” in this and in the accompanying documents should be understood to signify a situation meeting one or more of the following conditions that might arise as a consequence of either man-made or natural events:

1. **Sudden unplanned displacement** of a large proportion of the population away from the place(s) of habitual residence and into any settlement, e.g. refugee or internally displaced persons’ camps, urban environment, or any unorganized area;
2. Direct exposure of a civilian, non-combatant population to **new or exacerbated and sustained episodes of armed conflict** resulting in reduced access to health care, disrupted water supply and sanitation, food insecurity, and/or any other breakdown of critical state function;

3. Consistent and reliable evidence from food security and/or nutritional indicators suggesting that **a sudden deterioration of nutritional status is impending or has already occurred**, above and beyond known seasonal fluctuations or situations of chronic poor nutritional status and/or food insecurity;
4. **Natural or industrial (including nuclear) disaster** resulting in temporary homelessness, disruption to critical public services, increased risk of injury and/or exposure to the elements for a substantial proportion of the population;
5. **Sudden breakdown of critical administrative and management functions**, within the public and/or private sector, due to any reason, resulting in large scale disruption of public health and/or other critical public functions.

The following notes assist in applying the above definition:

- a. The size of the affected population is not *per se* a criterion for defining an acute emergency, and relatively small populations should receive appropriate consideration. Nevertheless, it is to be expected that emergencies involving relatively small populations, such as communities affected by a localised event such as a landslide, result in limited epidemiological risk and can usually be addressed by available services.
- b. Whether an emergency does or does not occur against a background of chronic crisis is irrelevant for the purposes of the above definition. However, this circumstance is explicitly taken account of in the Framework, as different vaccination interventions may be warranted in different settings with different epidemiological risks. For example, in long-term crisis situations, background vaccination coverage may be particularly low.
- c. The severity of acute emergencies is commonly defined by estimates of excess mortality. If credible evidence shows that over a recent period the crude death rate and/or under-5 years death rate in a population is/are in excess of the non-emergency baseline by at least double, use of the framework to determine if special vaccination programs should be implemented is warranted, even if the causes of the increase in mortality are not immediately clear.
- d. The occurrence of an epidemic of infectious disease in the absence of any one of the above criteria does not constitute an acute emergency.
- e. In keeping with (d), pandemics of influenza and HIV/AIDS or possible future pandemics due to other diseases are not within the scope of this framework, unless the population experiences one or more of the above specified conditions.
- f. Terrorist attacks are likewise outside the scope of this framework, unless they lead to one or more of conditions 1, 2, 3, 4 or 5 above.
- g. The definition is believed to encompass the large majority of potential scenarios, but there may be cases in which data and available information are imprecise, incomplete or controversial. In such instances, application of the definition should err on the side of caution; i.e., it is preferable to assume that an emergency is taking place.
- h. While it may be relatively straightforward to decide when an acute emergency has begun, it is often difficult to determine when one has ended. For the purposes of this framework, an acute emergency may be considered to have ended or to be moving into a chronic phase if conditions that resulted in a suddenly increased risk of vaccine-preventable diseases have attenuated.

Typically, this will occur when routine basic preventive and curative health services and other essential public services that impact public health, particularly water and sanitation provision, have been restored, food security has returned to pre-emergency levels, and shelter conditions are acceptable. Obviously, the restoration of routine vaccination services will obviate the need for using this Framework to a large extent.

1.4. Beneficiary populations

In many large emergencies there are a number of different groups that require assistance. Some of those affected by the emergency may be living in urban areas, others in rural areas; some may be displaced, while others remain in situ; some may be sheltered in camps, others may be living in unorganized settings. The epidemiological risks, the vaccine-specific characteristics such as doses required to induce immunity and cold chain requirements, and the contextual setting may be different for each of these emergency-affected populations. Accordingly, in many emergencies the Framework may need to be applied a number of times, the decision to proceed with a specific vaccination program may be different for different populations, and the details of any vaccination program that is implemented may vary. As the situation dynamically evolves, it is appropriate to apply the Framework repeatedly, as many times as is necessary.

In addition, the question of how to deal with populations that are not directly affected by an emergency but that live in close proximity to those that have been affected has often raised issues. Whether it refers to populations that are hosting refugees or to people exposed to a higher risk of vaccine-preventable disease because the circumstances around them have changed, it has become generally accepted policy to provide neighboring populations with the benefits of any public health interventions that are designed for and implemented in emergency-affected populations. Accordingly, the benefits of vaccination programs designed to save lives and to reduce the risk of disease in emergency-affected populations should be extended to surrounding populations as well, to the extent that this is possible financially, logistically, and operationally.

A difficult issue may arise where vaccines and supplies necessary for a successful vaccine campaign, or human resources, are limited. In this situation, where some groups deemed appropriate for vaccination may have to be prioritized above others, the principles of distributive justice should be respected. In respect to vaccination programs in response to acute emergencies, ethical issues are discussed at greater length in the ethics briefing document that accompanies the Framework.

1.5. Vaccine-preventable diseases

Diseases are considered to fall within the scope of the Framework if the following conditions are met: 1) a vaccine exists that has been licensed by an appropriate regulatory authority and that has been shown to be safe and at least partially protective against the disease; and 2) the disease burden may be increased as a result of an acute emergency. These diseases are shown in Table 1.

Table 1. List of vaccine preventable disease

Anthrax	Japanese encephalitis	Rotavirus gastroenteritis
Cholera	Measles	Rubella
Diphtheria	Meningococcal disease	Influenza
Hepatitis A	Mumps	Tetanus
Hepatitis B	Pertussis	Typhoid fever
Hepatitis E	Pneumococcal disease	Varicella
H. influenza type b	Poliomyelitis	Yellow fever
HPV	Rabies	

These diseases represent a fairly comprehensive list of vaccine-preventable conditions that should be considered in an acute emergency. Some will receive greater consideration than others. For example, there is strong evidence that emergency-affected populations are at great risk of outbreaks of measles unless pre-emergency vaccination coverage is especially high, and mass measles vaccination campaigns are frequently among the earliest of public health interventions. On the other hand, it is unlikely that cervical cancer would be addressed in most responses to acute emergencies, although the risk of exposure to human papillomavirus in some circumstances, for example where sexual violence is a particularly prominent feature of the crisis, may warrant consideration. The Framework is intended to prompt discussion of issues of this nature.

There are other diseases for which vaccines are in various stages of development and are anticipated to become available in the next decade, such as malaria and dengue. As new vaccines are developed, their target diseases should be added to this list. The Framework, while providing specific guidance for existing vaccines, also provides a general approach that will be applicable to the use of any vaccine in an emergency, including new ones as they emerge.

2. Overall Structure of the Framework

2.1. Guiding Principles

Certain general principles have been borne in mind while developing the Framework:

- The Framework is not intended to supersede or contradict existing WHO guidance on the use of specific vaccines and WHO guidance has been taken into account at all times.
- Nevertheless, the Framework recognizes that acute emergencies pose specific challenges for which guidelines developed for routine vaccination programs may not apply. For example, acute emergencies may result in sudden changes in the burden of vaccine-preventable diseases, either in their incidence or their case-fatality ratio or both, as well as in an increased risk of epidemics and changes in the usual age-distribution patterns.
- Addressing acute emergencies exacerbates already competing priorities -- acute emergencies cause important disruptions in the delivery of all routine health services, and many of these, routine vaccination programmes among them, need to be re-established as quickly as possible in order to minimize excess preventable mortality.
- Security issues as well as logistic challenges are likely to be much more important during an acute emergency, with important implications for population access to health services and for health provider access to the population as well as for the safety of health providers. Among other things, this may affect the ability to deliver a recommended full series of vaccinations and forces a consideration of viable alternatives.
- Acute emergencies are often characterized by political overtones. Vaccination programs which may seem to public health authorities to be of obvious benefit may be used as, or be seen to be used as, a tool to advance a political agenda. A careful and accurate contextual analysis should always be undertaken before deciding on a course of action that may have unintended consequences.
- During an acute emergency vaccine—related research is usually inappropriate as communities and individuals are vulnerable and not be able to give informed consent. However, there may be research questions which can only be answered during an emergency and consideration may be given to such interventions, for example the evaluation of vaccine effectiveness when offered outside the normal schedules, or operations research to evaluate interventions used specifically during an emergency.
- The primary objective of vaccination programs in an acute emergency is not to ensure the progressive increase of population immunity that would result in long-term protection against a given disease, but rather the rapid reduction of risk from a disease in order to protect a population during a period of extreme vulnerability. An acute emergency should not be seen as an opportunity to rapidly achieve the goals of a routine vaccination

program. To the contrary, the use of vaccines in acute emergencies should have the following objective: to limit the occurrence of serious illness and the number of excess preventable deaths for which the emergency might be responsible. For these reasons, strategies such as mass vaccination campaigns, expanded target age groups, and reduced courses for certain vaccines warrant greater consideration in acute emergencies than they might in other circumstances, whether or not routine vaccination services remain functional. The one possible exception to this principle is where the occurrence of an emergency may pose a threat to the success of a global eradication program. Where this is the case, and the disease that is the object of the eradication program also poses a threat to the population, vaccination should be strongly considered.

- For the most part, however, the Framework is applicable only from the time that planning for or responding to the onset of an emergency is occurring until the time that routine vaccination programs can be re-established. The Framework would be best used as early as possible as undue delays in decision-making should be avoided.

In summary, the Framework provides depth to a systematic, qualitative decision-making process that could be sketched as illustrate in Figure 1.

Fig. 1 Decision making flow chat

