SAGE Working Group on Vaccination in Humanitarian Emergencies

Vaccination in Acute Humanitarian Emergencies: a Framework for Decision-Making

Revised Draft

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Contents

1. Executive summary

1.1 Introduction

Humanitarian emergencies result in mass population movements and resettlement in temporary locations, overcrowding, economic and environmental degradation, impoverishment, scarcity of safe water, poor sanitation and waste management, absence of shelter, poor nutritional status as a result of food shortages, and poor access to health care. These risk factors place populations affected by a humanitarian emergency at risk of high morbidity and mortality from vaccine preventable diseases, and often decision makers must decide on use or non-use of one or more vaccines. The WHO SAGE Working Group on Vaccination in Humanitarian Emergencies reviewed current literature and practice experiences relating to decision making on vaccine use in humanitarian emergencies. There was limited widely accepted or generally used guidance for making decisions regarding vaccination in emergencies.

This decision framework document aims to provide an approach for deciding what vaccines, if properly delivered, would constitute high priority public health interventions in emergencies. It will assist the user to thoughtfully, deliberately, ethically 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 generally more favourable outcomes.

The intended audience for the decision framework includes senior level government and partner agency officials who are expected to work together to reach a decision regarding the need of one or more vaccines in a given humanitarian emergency. It is not intended to be used by community level health workers given the level of detail and complexity included in the document.

1.2 Decision making process and organization of the document

Figure 1 provides a schematic representation of the decision making process that consists of three essential steps: 1) an assessment of the epidemiological risk posed by each potentially important vaccine preventable diseases within a given context; 2) a consideration of the properties of each vaccine to be considered for intervention; 3) prioritization of the importance of vaccination in relation to other urgent public health interventions; and careful consideration of key ethical principles and prevailing contextual factors.

1.2.1 Epidemiological risk assessment

In this section epidemiological risk of a vaccine preventable disease (VPD) is defined and a systematic, desk-based process for conducting a risk assessment for each VPD included within the scope of the framework following an acute emergency is presented. The risk assessment process considers both key cross-cutting risk factors (e.g. overcrowding, acute malnutrition) that have an effect on various VPDs, and other risk factors that have a very specific effect for each VPD (e.g. immunization status, geography, climate and season).

At the end of the assessment, depending on the level of risk attributed to the above factors, a decision is arrived at for each VPD: "Definitely", "Possibly", or "Do Not" consider for vaccination. The first two categories result in application of the next steps in the framework (Chapters 3 and 4) to reach a decision on a vaccination intervention. Furthermore, a characterization of the threat posed by these VPDs should be made (e.g. likelihood and timing of an epidemic, age groups affected).

1.2.2 Vaccine characteristics

Key vaccines characteristics that should be considered to reach a decision whether a vaccination intervention should be implemented include determination of vaccine efficacy using the recommended full schedule and efficacy using less than the full schedule; course of vaccine administration; contraindication and vaccine safety considerations; WHO prequalification status; formulation of the vaccine (e.g. most freeze-dried vaccine should never be kept longer than 6hrs after reconstitution and optimal use may require more staff training); vaccine presentation (e.g. multi-dose presentation); storage and cold chain requirements; cost of the vaccine; and whether sufficient quantities can be purchased locally or in the global market.

Other characteristics that assist in delivering successful high quality mass vaccination campaigns include a reasonably accurate estimation of target population, including age range, and prioritization of high risk groups or geographical areas. Other key considerations for optimal implementation include planning, logistics, social mobilization, informed consent and monitoring.

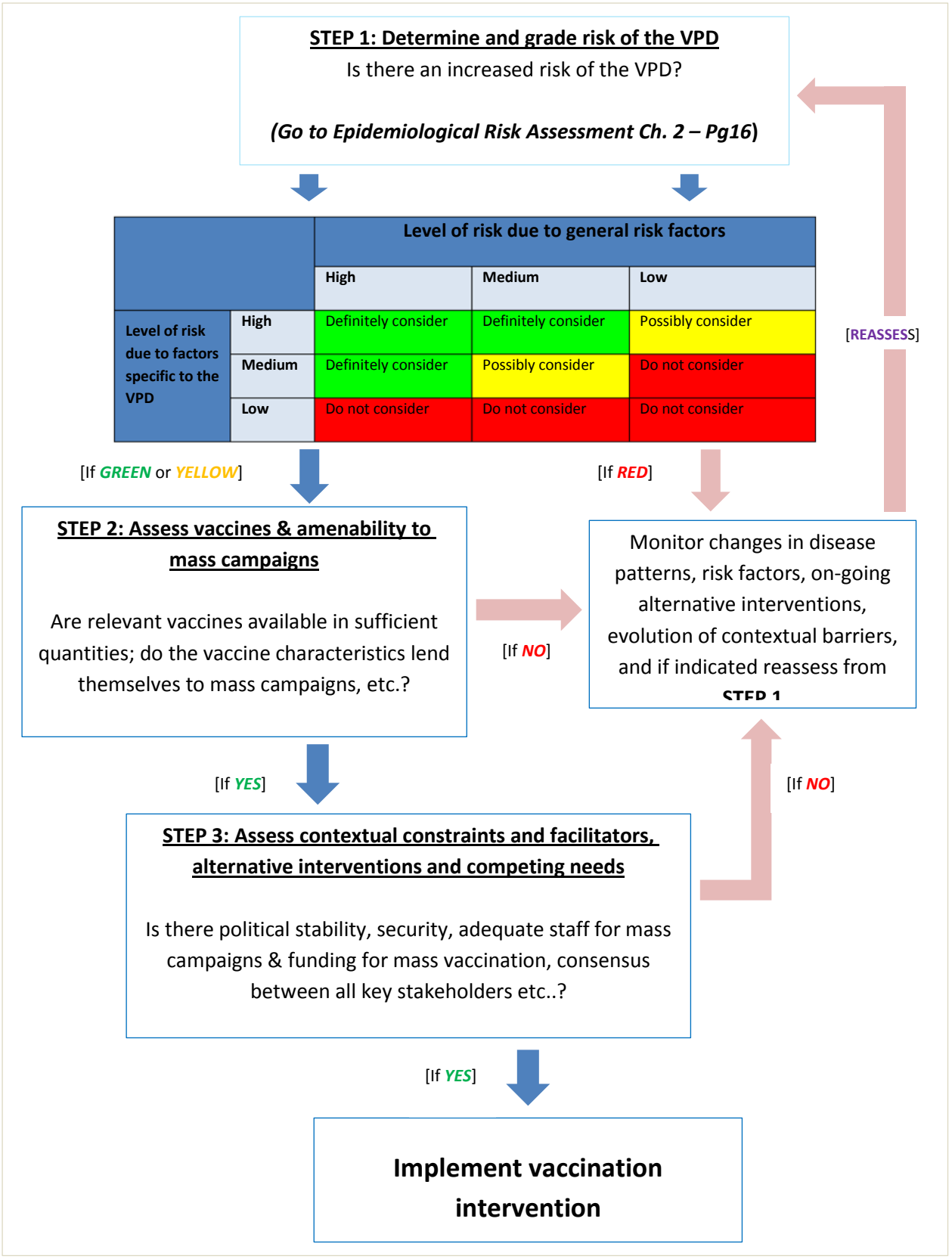
1.2.3 Contextual factors

Even if it is determined that a disease poses a substantial risk to the affected population and that the vaccine that protects against it has physical and biological characteristics that would be amenable to its use in a mass campaign, a challenging political context and competing priorities for limited resources, which are both common factors encountered in acute humanitarian emergency settings, influence the final decision to use a vaccine. However, if a decision to vaccinate is ultimately made additional issues may exist that require careful consideration including the desirability of add-on interventions to the vaccination campaigns; inclusion of host communities in the vaccination campaigns; and whether research should be conducted during the vaccination intervention.

1.3 Conclusion

This document provides key decision makers in the national ministries of health and international partner agencies with a systematic and comprehensive approach to decision making on use of vaccines in acute humanitarian emergencies, it also provides guidance on ethical concerns such as prioritization of interventions, targeting of high risk groups, equity, and informed consent. It is hoped that this document will make a useful contribution to optimal management of vaccine preventable diseases in acute humanitarian emergences, and ultimately to reduction in preventable morbidity and mortality commonly associated with acute humanitarian emergencies.

Figure 1: Decision making steps on vaccine use in acute humanitarian emergencies



2. Introduction

2.1 Background

Humanitarian emergencies, regardless of type or cause, have a number of common risk factors for communicable diseases including mass population movement and resettlement in temporary locations, overcrowding, economic and environmental degradation, impoverishment, scarcity of safe water, poor sanitation and waste management, absence of shelter, poor nutritional status as a result of food shortages, and poor access to health care. These risk factors are inextricably linked to excess risk of morbidity and mortality from vaccine preventable diseases, the reduction of which is the aim of public health interventions during crises.

2.2 Evidence review

In 2011, the WHO Strategic Advisory Group of Experts on Immunization (SAGE) formed the SAGE Working Group on Vaccination in Humanitarian Emergencies to review evidence on vaccination decision making processes and considerations in order to identify current gaps and make recommendations to the SAGE.

The working group carried out a comprehensive review of literature to collate existing guidelines, ethical considerations, and documented experiences of use of vaccines in humanitarian emergencies in order to analyse key factors and methods involved in the consideration of vaccination during emergencies. The review was complemented by 6 case studies with the aim of capturing the multifaceted and often complex contextual and political considerations involved in such decisions, through the recounting of experiences by organizations who participated in such decision in the affected countries; this information was not well captured in the available literature.

Key lessons learnt:

- Formal decision making tools, guidelines or processes were not detailed. Guidelines were rarely consulted; in only four experiences out of 23 experiences reviewed were actual guideline or tool cited as justification for implementation of vaccination campaign or not
- Only two decision making tools were identified among the 38 guidance documents reviewed. However, these were not sufficiently detailed to optimally support decision making process
- The phase of emergency in which vaccination was considered was vague and inconsistently defined, only measles, polio, and tetanus vaccines were reliably and consistently recommended for introduction "immediately" in humanitarian emergencies
- Epidemiological factors were considered important, but were not always reflected in the choice of antigens implemented. The most prominent considerations towards a decision to vaccinate were vaccine availability and available funding
- Political and contextual/security issues came through as strongly affecting the actual decisions or the ability to make decisions regarding use of vaccines in humanitarian

emergencies; where there was no central government such as Somalia as the lead decision maker, NGO's failed to reach a consensus regarding choice of vaccines and in some case implemented different vaccines for the same affected population

- Ethical considerations were least considered. Little guidance or experience was identified on how organizations manage decisions when needing to resolve prioritization of interventions, targeting high risk groups, equity, and informed consent

2.3 Aim

This decision making framework attempts to fill this void in the literature, by providing decision-makers with a more transparent and rigorous method for deciding on vaccination options in acute humanitarian emergencies. It provides a clear and consistent approach to assessing the local epidemiological risk of vaccine preventable diseases among a population affected by a humanitarian emergency; vaccine selection and characteristics to consider; and local contextual constraints that could further assist in effective and timely decisions regarding use of vaccines in emergencies.

This document is intended to provide a framework for thinking through the process of deciding what vaccines, if delivered pre-emptively at the outset of and emergency would constitute high priority public health interventions. Even though the principles and general approach may apply in cases when reactive vaccination should be considered during an outbreak in an acute emergency scenario, where detailed guidance already exist, these should be relied upon to guide outbreak response.

The decision making process is predicated on three essential steps: 1) an assessment of the epidemiological risk posed by each VPD within the scope of the Framework, within a given context; 2) a consideration of the properties of each vaccine to be considered for intervention; 3) prioritization of the importance of vaccination as a public health intervention in the context of the urgency of other public health interventions and intervention carried out in other sectors. Careful consideration of key ethical principles and contextual issues are key overarching considerations influencing the decision-making process.

The ultimate aim of this document is to assist the user to thoughtfully, deliberately, ethically 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 generally more favourable outcomes than might otherwise be the case.

2.4 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 vaccination and WHO guidance has been taken into account at all times
- The Framework recognizes that acute emergencies pose specific challenges to which guidelines developed for use in non-emergency settings 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 geo-distribution patterns.
- Acute emergencies also tend to cause major disruptions in the delivery of all routine health services, including routine vaccination programmes and many of these services need to be addressed on an emergency basis and re-established as quickly as possible.
- 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 to the population. This may affect the ability to deliver a recommended full series of vaccinations and forces a consideration of viable alternatives.

- In general, the objective of vaccination 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 relative short period of extreme vulnerability. In no circumstances should an acute emergency be seen as an opportunity to rapidly achieve the goals of a routine vaccination program. To the contrary, those goals should be set aside in order to use vaccines for one clear and present objective: to limit 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 Framework covers only that period of time between the onset of emergency and when routine vaccination programs can be re-established.

2.5 Intended audience

The decision framework should be used by senior level government and partner agency officials who are expected to discuss in a small group over a period of days in order to reach a decision regarding the need to use one or more vaccines in a given humanitarian emergency. It is not intended to be used by community level health workers. Even though the final decisions should lie with appropriately designated officials of the Member State in which the emergency is occurring, it has frequently been the case in the recent past that emergencies either unfold in countries with non- or poorly- functioning governments or ones that are recognized as not acting in the best interests of the populations affected by the emergency. In those cases, a designated UN agency has frequently been recognized as having policy-making authority and may lead the decision making process. In general, vaccination interventions should be decided upon by consensus and this framework is meant to guide the discussions that result in that consensus.

2.6 Obligation to apply legitimate guidelines

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 guidelines, including this framework, 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. Guidelines are of particular value in situations where: large numbers of people receive treatment or a preventive 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 of authorities and health practitioners are judged.

2.7 Core ethical considerations

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 often arise from conflict between individual good and the common good and include beneficence (duty of care and the rule of rescue), non-maleficence, as well as distributive and procedural justice.

Beneficence (doing good): 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". The obligation of beneficence is specifically determined by the urgency of the situation, severity of consequences if nothing is done, the ability to prevent such severe consequences and any sacrifice required by the responding individual or agency.

Non-maleficence (avoiding or minimizing harm): Vaccines that are likely to be considered in the acute phase of a crisis usually have established efficacy and safety track records, and thus harm is extremely unlikely. 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.

Distributive justice (fair allocation): This principle requires the fair allocation of limited resources, including vaccines if 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. 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. There should be explicit consideration of targeting distribution to high risk or high transmission groups or groups where other interventions, for example water and sanitation, cannot be rapidly deployed.

Allocation decisions require striking a balance between promotion of utility (maximizing 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.

Procedural justice (transparent and accountable decision-making): This ethical principle requires transparent decision-making and participation of communities that are affected by the decisions. Sphere, the Humanitarian Accountability Partnership and the Active Learning Network for Accountability and Performance in Humanitarian Action encourage 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.

2.8 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, including both natural disasters and man-made crises occur in so many places and have so many different characteristics, we have tried to define the situation(s) to which this Framework can be applied. All subsequent mentions of the term "acute emergency" should be understood to signify a situation meeting the criteria specified in the definition below:

This framework is designed to cover populations affected by acute emergencies. Although it may be applied at any point during the period over which acute conditions persist in a given population, its intended use is to guide decision-making on vaccination interventions immediately after the onset of an acute emergency, or during planning in anticipation of a possible or likely acute emergency.

Several definitions of what constitutes an acute (sometimes referred to as humanitarian) emergency have been proposed in the past, and different agencies employ varying classification and gravity benchmarking system. For the purposes of this framework, a single definition is used in order to maintain global equity and consistency. Furthermore, the definition aims to capture any circumstances that are known to result in an increased risk of vaccine-preventable diseases potentially warranting vaccination interventions different from or additional to those recommended for routine practice. Accordingly, an acute emergency is defined in this framework as the occurrence of one or more of the following conditions due to any reason (natural, man-made or a combination thereof):

1) **Sudden unplanned displacement** of a large proportion of the population away from the community of habitual residence and into any settlement (refugee or internally displaced persons' camps; host community; urban areas; other uninhabited areas), within the same country or across international borders;

2) Direct exposure of the civilian, non-combatant population to **new or exacerbated and sustained episodes of armed conflict** resulting in risk factors including reduced access to health care, disrupted water and sanitation, food insecurity, etc.;

3) Consistent and reliable evidence from food security and/or nutritional indicators (see note g) 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 (e.g. health care, water and sanitation, food deliveries, etc.), increased risk of injury and/or exposure to the elements for a large 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 related services (e.g. water and sanitation, housing).

The following notes accompany the above definition:

a) The conditions included in the definition merely aim to establish the need for potential application of this framework: this need is determined by the occurrence of exceptional risk due to vaccine-preventable diseases. 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 to ensure global equity and maximise the potential impact of vaccination in all emergency-affected populations. However, the framework recognises that scenarios in which a large population assembles within a given site (e.g. a large camp) usually carry a higher risk of vaccine-preventable disease epidemics, warranting more intense interventions. By contrast, it is expected that emergencies featuring very small populations (e.g. communities affected by a localised event such as a landslide) result in limited epidemiological risk and can usually be addressed by available services.

b) Many acute emergencies occur in populations that are already affected by long-duration crises due to protracted armed conflict or displacement, and/or other factors such as food insecurity, frequent natural disasters, environmental decay etc. Whether an emergency does or does not occur against a background of chronic crisis is irrelevant for the purposes of the above definitions. However, this circumstance is explicitly taken account of in the framework, as different vaccination interventions may be warranted (e.g. in long-duration crises, pre-emergency vaccination coverage is usually low).

c) Emergencies are frequently defined and their gravity benchmarked in health terms by estimates of excess population mortality. Accordingly, credible evidence may arise showing that, over a recent period (e.g. within the last 6 months), the crude death rate (CDR: deaths per person-time, e.g. per 10 000 people per day) and/or under 5 years death rate (U5DR: deaths per person-time among children aged less than 5 years) have been greatly in excess of the non-emergency baseline (at least a doubling from the baseline is typically considered evidence of acute conditions). Typically, scenarios featuring such elevations in mortality will also be classifiable as acute emergencies based on one or more of conditions 1 to 5 above. If the cause of the observed elevation is not immediately clear, urgent investigation should be carried out to decide whether the scenario does indeed meet one or more of the definition conditions. Note that plausible baseline figures should be extracted from a recent census or reputable health surveys performed either within the population itself, or, if unavailable, from neighbouring populations or countries with a similar demographic profile. In scenarios where the emergency is occurring against a backdrop of long-duration crisis, mortality may already be elevated from the counterfactual baseline level that would be expected in the absence of a crisis. In such instances, the objective gravity of an emergency should

be benchmarked by comparing observed death rates to a reference baseline that reflects a period before the crisis began, or, if the crisis has lasted many years or decades, that is based on death rates in neighbouring non-crisis affected populations with a similar demographic profile. However, comparison with the recent mortality levels observed in periods of chronic crisis is also necessary in order to decide whether a sudden deterioration consistent with acute conditions has indeed occurred.

d) If any observed elevation in death rate is mostly attributable to a confirmed infectious disease epidemic, the epidemic should be accompanied by one or more of conditions 1 to 5 specified above (displacement, armed conflict, nutritional emergency, natural disaster or breakdown of the state) in order for the scenario to be classifiable as an acute emergency. An epidemic alone is not sufficient to consider that an acute emergency is occurring.

e) Pandemics of influenza and HIV/AIDS or possible future pandemics due to other diseases are not within the scope of this framework, unless they worsen underlying socio-economic and health conditions to such an extent that the population begins to experience one or more of the above conditions 1, 2, 3 or 5.

f) Terrorist attacks, defined as per UN Security Council resolution 1566 (2004) as "criminal acts, including against civilians, committed with the intent to cause death or serious bodily injury, or taking of hostages, with the purpose to provoke a state of terror in the general public or in a group of persons or particular persons, intimidate a population or compel a government or an international organization to do or to abstain from doing any act", 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) A rapid deterioration in nutritional status (often referred to as a nutritional emergency) may be detected on the basis of food security indicators (e.g. staple prices, harvest sizes, household food consumption patterns), nutritional indicators (global [GAM] or severe [SAM] acute malnutrition prevalence) or a combination of both. Food security indicators provide early warning of deteriorations, while elevated SAM and GAM prevalences are typically seen only once a nutritional emergency is underway. Currently, prevalence estimates are typically computed among children 6-59 months old based on the 2006 WHO Child Growth Standards and weight-for-height indices, but the use of middle upper arm circumference, which may be less sensitive to regional body shape confounding, is increasingly advocated. For SAM and GAM specifically, various alert and emergency thresholds have been proposed. The WHO [*http://whqlibdoc.who.int/publications/2000/9241545208.pdf*] considers SAM and GAM prevalences of $\geq$ 5% and $\geq$ 15% respectively as indicative of a "critical" situation. In general, however, a context- specific classification of gravity that also considers underlying trends and concomitant disease risk factors is recommended. In several regions of the world (e.g. South Asia), alarming levels of malnutrition prevalence are noted on a yearly basis. These chronic situations require mostly long-term, developmental solutions, and do not fall within the scope of this framework. For the purposes of this definition, a rapid deterioration that occurs over a timeframe of weeks or a few months, above and beyond secular trends, should be considered indicative of acute conditions.

h) 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. Furthermore, the rationale for the decision should be documented carefully.

i) While it may be relatively straightforward to decide when an acute emergency has begun, it is often difficult to determine when it 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. Typically, the transition from the acute to the chronic or recovery phase is gradual and subtle. Deciding whether acute conditions have indeed ended therefore requires constant, careful reassessment of epidemiological risk as the emergency evolves. Furthermore, chronic, long-duration crises may relapse into acute emergency conditions: this eventuality should also be monitored vigilantly. In general, the framework is intended to address risk arising from acute conditions, rather than from long-duration crises: therefore, vaccine interventions arising from application of the framework should strive to reduce this risk to a level no higher than before the acute emergency began. However, it is expected that many vaccine interventions implemented during an acute emergency will have beneficial effects that result in improvements in health status even beyond pre- emergency levels

2.9 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 cold chain availability, and the contextual setting may be different for each emergency-affected population. Accordingly, many emergencies the Framework may need to be applied a number of times and the decision to proceed with a specific vaccination program may be different, and the details of any vaccination program that is implemented may vary.

In addition, the question of how to deal with populations that are not affected by an emergency but that live in close proximity to those that have been 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 neighbouring 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. The guiding principle should always be: equitable access to vaccination for equal risk.

2.10 Vaccine-preventable diseases

Diseases are considered to fall within the scope of the Framework if the following conditions are met: 1) a WHO pre-qualified vaccine exists that can provide at least some protection; and 2) their burden may be increased as a result of an acute emergency. These diseases include those with vaccines in national routine immunization programmes; those that require seasonal vaccination interventions such as avian influenza and meningococcal meningitis mainly in the meningitis belt of Africa in countries where conjugate meningococcal vaccine has not been introduced; and those with new vaccines that may not be fully integrated in national routine immunization programmes. For this reason diseases such as Anthrax, Hepatitis E and rabies have not been included in the list.

There are also other diseases for which vaccines are in various stages of development and are anticipated to become available in the next decade (malaria, dengue, etc.). These have been omitted from the Framework as there is currently insufficient information regarding their characteristics and, of course; they do not meet the pre-qualification criterion mentioned above. In any event, 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.

Relative significance of the vaccine preventable diseases in acute humanitarian emergencies is also considered, and this may vary according to pathogen specific characteristics of respective microorganism; some may cause acute severe disease characterized by high morbidity with or without high mortality, while those at the other extreme may be associated with self-limiting diseases with limited complications (Table 1).

2.11 Cost of vaccines, stockpiles and vaccine donations

Depending on the agency, government or organization funding the intervention, the price of the vaccine itself may play a role in the decision-making process. Vaccine may be purchased directly from the manufacturer (in addition to supplies need for delivery) or through UNICEF Supply Division. UNICEF Supply Division is responsible for buying all vaccines and related items for global campaigns to eradicate polio, eliminate neonatal and maternal tetanus, and control measles. In addition, the Division procures vaccines for UNICEF-supported programs, and for GAVI. Procuring vaccines is complex. In recent years, the market has changed, owing to a growing divergence between the types of vaccines used in industrialized and developing countries. The unpredictability of funding is another difficulty.

Humanitarian emergencies occur frequently enough to warrant timely access to an assured vaccine supply for VDPs with severe outcomes including increased mortality. An obligation falls on global and local communities, including governments and non-government organizations, to facilitate this access.

The international donor community has established stockpiles for meningococcal disease and yellow fever with plans to put in place a similar stockpile for oral cholera vaccine. The stockpiles make use of revolving vaccine doses managed by the four partners, UNICEF, MSF, IFRC, and WHO, through an international coordinating group (ICG). When a country requests vaccines, ICG reviews the request and comes to a decision within 48 hours to deliver the vaccine within a maximum of seven days. The decision whether or not to approve a request is based on predetermined criteria namely epidemiological evidence for an outbreak, which includes laboratory confirmation, availability of an action plan for mass vaccination as well as adequate storage conditions.

Although stockpiles for certain vaccines exist, these stockpiles are not the only recourse for vaccine and there existence does not guarantee vaccine availability for intervention planning. The application process and procedures for procurement of vaccines through existing international stockpiles should be considered as a separate process and the specific guidelines consulted.

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 statement recognizes 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 a public health perspective as determined by the senior level government and partner agency officials tasked to work together to decide on appropriate vaccine use.

Table 1: Vaccine preventable disease[1]

I.	Vaccine in routine immunization programmes
	1. Tuberculosis
	2. Mumps
	3. Rubella
	4. Pneumococcal disease
	5. Haemophilus influenzae type b
	6. Diphtheria
	7. Pertussis
	8. Rotavirus
	9. Yellow fever
	10. Tetanus
	11. Japanese encephalitis
II.	Seasonal use vaccines
	12. Avian Influenza
	13. Meningococcal disease (Polysaccharide vaccine)
III.	New or under utilized vaccines
	12. Hepatitis A
	13. Typhoid fever
	14. Hepatitis B
	15. Meningococcal disease (conjugate vaccine)
	16. Cholera
	17. HPV
	18. Varicella
IV.	Special prevention and control initiatives
	19. Poliomyelitis
	20. Measles

[1] Additional vaccine preventable diseases maybe considered as new vaccines become available

3. Epidemiological risk assessment

3.1 Chapter summary

This chapter outlines a systematic process for assessing the epidemiological risk of each VPD falling within the scope of the Framework, so as to come up with a short-list of VPDs for consideration in subsequent steps of the Framework. Epidemiological risk is defined here primarily in terms of excess mortality, but a high incidence of hospitalisations and disruptions to eradication programmes should also be considered. Risk may be due to epidemics but also to an exacerbated endemic pattern of disease, and may occur in the short as well as the long term, depending on the VPD. Furthermore, risk to host populations should also be assessed. All VPDs should be subjected to the risk assessment, but the process should require only a few days and not be delayed by missing information.

For each VPD, the risk assessment process consists of the following logical sequence of tasks:

1) **Grade the level of risk of the VPD resulting from the occurrence of one or more general risk factors** (high prevalence of acute malnutrition; young population and/or high birth rate; high HIV/AIDS burden; low access to curative health services; overcrowding; insufficient water, sanitation and hygiene) that have a cross-cutting effect on several infectious diseases:

    a) Determine which of the above general risk factors are occurring ("yes" or "no") in the given acute emergency scenario, based on available information; to aid this task, a worksheet containing key questions and suggested criteria for each risk factor is provided (Table 3). Sources of information to complete the worksheet are suggested in Annex 1. The yes-no classification obviously limits nuanced appraisal, but avoids complexity.

    b) Come up with an overall grading of risk due to general factors of "high", "medium" or "low". Risk should be graded as "high" if one or more of the general risk factors that are found to be present is highly relevant to the VPD; "medium" if none of the risk factors present is highly relevant to the VPD but at least one is moderately relevant; and "low" in all other situations. A priori knowledge about the global relevance of each factor to the VPD in question, irrespective of the specifics of the acute emergency in question, should be used here: for each VPD-general risk factor combination, a prescriptive classification of relevance into high, moderate, low and unknown is provided in Table 3.

2) **Grade the level of risk of the VPD due to additional factors that have a specific effect on the given VPD.** Though not all relevant to each VPD, these factors may include population immunity; local burden of disease; geography, climate and season; levels of sexual violence; and incidence of injuries (Table 5). VPD-specific worksheets are provided in Annex 2, containing suggested criteria and questions to consider for each relevant factor. A qualitative approach is recommended to synthesize the information in each worksheet into an overall level of specific risk, again graded as "high", "medium" or "low". A rough algorithm to help with the grading is proposed (Annex 2), and sources of information for each factor are suggested (Annex 1).

3) **Come up with an overall decision for each VPD:**

   a) Combine the "high", "medium" or "low" grading of general and specific risk (tasks 1 and 2) in a suggested matrix (Table 2) so as to classify the VPD into the mutually exclusive categories of "definitely", "possibly" or "do not consider" for vaccination: only VPDs to "definitely" or "possibly" consider are short-listed and carried over to the next step of the Framework.

   b) For each VPD short-listed, characterize the type of threat (e.g. epidemic vs. exacerbated endemic), timing (e.g. how soon excess deaths could occur) and likely age profile. This characterization should be used later in the Framework to define when and whom to vaccinate. Guidance for each disease is provided in the VPD-specific worksheets (Annex 2).

The chapter describes the above tasks in detail. However, the suggested grading procedures are not inflexible, and best judgment as well as specific information from the emergency in question should always be used as a guide. In all cases, risk assessment decisions need to be thoroughly documented.

3.2 General considerations

3.2.1 Purpose of the risk assessment

Before appraising different options for vaccination interventions, it is crucial to carry out a systematic epidemiological risk assessment of the acute emergency so as to identify VPDs for which specific vaccination interventions should indeed be considered. The step by step risk assessment process outlined in this chapter should result in a short-list of VPDs to be carried over into the subsequent step of the Framework (Chapter 3). If this risk assessment has been carried out accurately and equitably, short-listed VPDs should be those that carry the greatest epidemiological risk in the specific emergency scenario being evaluated. A final determination of whether to implement a vaccination intervention against these VPDs, however, is only made after full consideration of all three steps in the Framework process.

Risk assessment must be carried out systematically for every VPD within the scope of the Framework, lest the short-list be unduly influenced by personal bias or a priori considerations about which diseases are likely to be important and which vaccines appropriate. The suggested risk assessment process may result in short-listing VPDs for which vaccination has never or very rarely been attempted in emergencies (e.g. pneumococcal disease), or for which vaccination is unlikely to be an appropriate choice of intervention (e.g. tuberculosis). However, it is important at this stage to let the classification of risk be guided solely by need (i.e. how much excess mortality

could occur), and not by consideration of prior experiences in emergencies or of the feasibility, effectiveness, cost and opportunity of providing a specific vaccine. All of these parameters are considered systematically in further steps of the Framework.

3.2.2 The meaning of risk in the context of this document

As discussed in the Introduction, the overriding metric by which disease risk should be assessed is preventable deaths, since mortality reduction is the primary aim of emergency public health interventions. For some diseases, diminished pressure on curative health services (particularly inpatient facilities) as a result of a decreased incidence of severe disease cases is also a desirable, albeit secondary outcome of vaccination.

Furthermore, in certain emergency situations excess risk due to VPDs that are the focus of ongoing eradication programmes (e.g. polio and measles) may also be thought of in terms of potential regional or global setbacks in the eradication effort that could occur as a result of the emergency, unless vaccination interventions are implemented. This risk should be considered secondary to that of excess mortality, but where appropriate the risk assessment suggests instances in which it could warrant prioritizing a given VPD. Note that WHO regional offices routinely carry out polio importation and outbreak risk assessments: these should be consulted in the event of an emergency.

For specific VPDs (cervical cancer due to HPV, hepatitis B, tuberculosis) most excess risk will manifest well after the end of an acute emergency. For example, an armed conflict may result in a large number of female victims of sexual violence acquiring HPV, but the latency period of HPV-associated cancer means that these women will only experience excess disease and mortality later in life. For hepatitis B a similar dynamic would occur, and in addition women victims could also go on to transmit the virus during childbirth, resulting in further, future, deaths among their children. The Framework does value these lag effects of acute emergencies on health. Balancing the value of preventing a death in the immediate period after the emergency's onset (e.g. by vaccinating against cholera) against the value of preventing a death later in life or among a second generation of affected persons (e.g. by vaccinating against hepatitis B) is extremely difficult, has epidemiological, economic and ethical dimensions, and would generally require much more time and information than will be available for this risk assessment. So as to circumvent this complexity, the Framework assigns an equal value to deaths in the here and now and deaths that will occur later in time, as long as both can be attributed to excess risk due to the emergency.

Lastly, it is important to note that the above risks may arise due to explosive epidemics, but also as a result of exacerbation in the baseline endemic pattern of disease resulting from increased incidence, increased probability of developing disease once infected, and/or higher case-fatality (CFR). The Framework process only distinguishes between these mechanisms insofar as the threat of epidemics may require a particularly urgent vaccination response.

3.2.3 Timing of the risk assessment

Just as the Framework as a whole, risk assessment within the context of this document is intended to be a rapid, desk-based exercise to be completed within a few days as part of emergency preparedness or during the very first few days after the emergency begins (see Introduction).

While assessing each VPD falling within the scope of the Framework may appear time-consuming within the context of a rapid, high work-rate relief operation, it is expected that a small team of experienced assessors having access to the country's disease surveillance and vaccination programme information should be able to complete the risk assessment in a few days, thereby not appreciably slowing down emergency response planning. As suggested in Annex 1, in nearly all scenarios some information will be unavailable or questionable; this should not delay the Framework process, and, if desk-based avenues to rapidly obtain this information are exhausted, best judgment assumptions should be used to fill information gaps. Nevertheless, a balance needs to be struck between the urgency to move forward with vaccination interventions as soon as possible, and the minimal time required to complete a well-reasoned, informed and documented risk assessment which will ultimately be more beneficial than hurried, uninformed decisions.

Due to the dynamics inherent in any emergency, risk due to any VPD may intensify or lessen as the emergency evolves, or information may become available that warrants a revision of the risk assessment. Risk assessment should thus be an ongoing process: an update of the risk assessment for each disease should be performed at least every three months, or as soon as possible if important new information arises on any VPD or the general situation radically shifts, warranting immediate action (e.g. if disease surveillance systems indicate the onset of an epidemic, or if the nutritional situation suddenly deteriorates). In practice, this update will be quicker than the original risk assessment, as the answers to only a few questions are likely to change from one update to the next.

3.2.4 Risk assessment for host populations

While risk assessment will generally be carried out only for the actual emergency- affected population, in cases where a forcibly displaced population finds refuge within a host community (e.g. in a city or in a rural district), or where the two are living in proximity to each other, it is important to also assess risk for the latter, and consider vaccination interventions accordingly.

Risk assessment for host populations should be done separately from that for the displaced population, and can be somewhat streamlined so as to consider the main potential threat, namely introduction or re-introduction of a VPD that is not circulating in the host population, but that may be carried by the displaced population: this is particularly relevant for diseases that are subject to an elimination or eradication programme, such as measles and polio, or that are known to cause explosive outbreaks, such as cholera or meningococcal meningitis. A major factor to consider when assessing this threat is the immunity level of the host population (see below), and whether this is likely to be high enough to prevent an epidemic (i.e. afford herd immunity), even after considering changes in population density due to the influx of the displaced (note that crowding increases the immunization coverage requirement for herd immunity) and the degree of mixing between the host and displaced populations.

3.3 The risk assessment process

This section provides an overview of the risk assessment process for each VPD. Detail on each task in the process is provided in subsequent sections. The risk assessment process should result in a classification of each VPD within one of the following three categories:

- Definitely consider: the VPD has the potential to be one of the leading causes of mortality, and/or to cause a major epidemic (thousands of cases, hundreds of deaths); thus, a specific vaccination intervention against this VPD should definitely be appraised in the next step of the Framework.
- Possibly consider: the VPD will probably not be a leading cause of mortality, but nonetheless could cause a considerable number of excess deaths and/or a large outbreak (hundreds of cases, dozens of deaths); thus, a vaccination intervention against this VPD could be considered in specific circumstances, based on an assessment of competing priorities and other opportunities for control. In particular, vaccination against this VPD could be opportunistically coupled with that against VPDs falling in the above category, e.g. if dosage schedules and target age groups are compatible. Vaccination interventions against this VPD should thus also be appraised in the next step of the Framework.
- Do not consider: the VPD is very unlikely to cause considerable excess mortality or an outbreak consisting of more than a handful of cases; a vaccination intervention against this VPD should thus not be considered further in the Framework, unless an update to the risk assessment results in a change to this classification.

The above classification is reached by running each VPD through a two-dimensional matrix (Table 2). The two dimensions of the matrix are:

1) How high the risk of the VPD is assessed to be as a result of key general risk factors (high prevalence of acute malnutrition, young population and/or high birth rate, high HIV/AIDS burden, low access to curative health services, overcrowding, insufficient water, sanitation and hygiene) that may or may not be present, and, if present, have cross-cutting effects on various infectious diseases;
2) How high the risk of the VPD is assessed to be as a result of additional risk factors that are very specific to the VPD in question, including levels of population immunity to the disease, local burden of disease, geography, climate, season and other factors.

For both dimensions, a simple "high" / "medium" / "low" grading system is adopted. For example, in a given acute emergency scenario the presence of several general risk factors (e.g. overcrowding and insufficient water, sanitation and hygiene) could result in the risk of cholera being graded "high", the risk of Japanese encephalitis being graded "low" and the risk of diphtheria being graded "medium". Consideration of specific risk factors for each (e.g. levels of vaccination coverage and the location of the emergency) might result in a grading of "medium" for cholera, "high" for Japanese encephalitis and "low" for diphtheria. The resulting classifications would therefore be "definitely consider" for cholera, "possibly consider" for Japanese encephalitis and "do not consider" for diphtheria.

Table 2: Epidemiological risk assessment classification for any VPD.

		Level of risk due to general factors		
		High	Medium	Low
Level of risk due to factors specific to the VPD	High	Definitely consider	Definitely consider	Possibly consider
	Medium	Definitely consider	Possibly consider	Do not consider
	Low	Do not consider	Do not consider	Do not consider

Furthermore, for each VPD that is carried over into the next step of the Framework, the overall classification should be accompanied by a qualitative characterization of the VPD's expected manifestation (timing, epidemic potential, age groups most affected), so as to aid in determining the priority level of each vaccination intervention, the time window of opportunity for vaccinating pre-emptively, and which population groups to target.

Accordingly, for each VPD the risk assessment process consists of the following tasks:

1) Grade the level of risk due to general risk factors as "high", "medium" or "low", based on their occurrence and relevance to the given VPD:
   a) Determine whether one or more of the general risk factors is occurring in the given acute emergency situation, based on available information and by completing a suggested worksheet featuring key questions;
   b) Use a priori knowledge about the expected effect of these risk factors on the VPD, and a suggested decision rule, to come up with a grading.
2) Grade the level of risk due to factors specific to the given VPD as "high", "medium" or "low", based on available information: to guide this task, "worksheets" specific to each disease are provided.
3) Come up with an overall classification for each VPD:
   a) Based on the "high", "medium" or "low" grading of general and specific risk (tasks 1 and 2), use Table 2 and the suggested classification system to determine whether the VPD should be considered in the next step of the Framework;
   b) For each VPD short-listed (i.e. to "definitely" or "possibly" consider), characterise the risk in terms of type of threat, timing and age groups affected. This characterisation should be used later in the Framework to help prioritise vaccination interventions and define their key parameters.

The remainder of this chapter provides guidance on how to carry out the above tasks.

3.4 Task 1: Grade the level of risk due to general risk factors

3.4.1 Task 1.a: Determine the occurrence of general risk factors

In acute emergencies, much of the excess burden due to VPDs is attributable to a few key general risk factors that have a biological, behavioural or environmental basis; have a proximate causal relationship with disease; may already be influential before the emergency or may become exacerbated as a result of the emergency; and can affect the risk of transmission, progression to disease or CFR for a variety of VPDs. While in reality the intensity and effects of these risk factors fall along a continuum from negligible to very high, for simplicity this Framework only classifies them as present or not, based on the answer to several questions listed in a general risk factor worksheet that assessors should systematically go through (Table 3).

While a few quantitative decision rules based on relevant indicators are suggested in the worksheet (where possible, based on existing guidelines such as the Sphere Project), *these are meant for guidance only*. Robust data may not always be available within the timeframe of the risk assessment to determine whether each risk factor is occurring, and the risk assessment should not be delayed whilst data are obtained. Therefore, the classification of each should primarily be qualitative, guided by judgment, consideration of available evidence and understanding of the context. For example, in some regions (e.g. South Asia), malnutrition exhibits a predictably seasonal pattern; therefore, the period in which the emergency occurs should thus also be considered (e.g. a flood occurring at the outset of the seasonal "hunger gap"); and a high prevalence of malnutrition should be classified as occurring if there is evidence of a deterioration above and beyond expected seasonal trends.

Annex 1 suggests possible sources of pre-existing data to assess each general risk factor. Given that this Framework can apply to diverse types of emergencies, not all general factors will be immediately relevant to all situations.

Table 3: Worksheet for determining the occurrence of key general risk factors

Risk factor	Main effects on VPDs	Key questions to ask	Possible indicators to consider
High prevalence of malnutrition	Increased risk of infection, disease progression and case-fatality.	Is there evidence of a nutritional crisis, either already established or unfolding? Is there an unusually high prevalence of acute and/or chronic malnutrition, among young children or the general population?	• Prevalence of acute malnutrition among children 6-59m old ≥ 15% (global) or ≥ 3% (severe) measured within the last 3 months, above and beyond seasonal levels • Average nutritional intake or food ration < 2100 kcal per person per day • Deteriorating food security indicators (e.g. price of staple foods or livestock; yield of last harvest)
Young population and/or high birth rate	Greater pool of susceptibles for VPDs mainly affecting children. Higher herd immunity threshold.	Is there a high number of children? Are births rapidly accumulating?	• Proportion of children aged under 5y ≥ 15% • Crude birth rate ≥ 30 per 1000 people per year
High HIV/AIDS Burden	As for acute malnutrition.	Do persons living with HIV/AIDS make up a high proportion of the population? Is there low access to highly active antiretroviral therapy (HAART), or have HAART programmes been disrupted by the emergency?	• HIV sero-prevalence ≥ 15% and • HAART coverage < 50% or probably falling due to the emergency
Low access to curative health services	Increased case-fatality for all VPDs. Increased risk of some vertically transmitted VPDs (neonatal tetanus, hepatitis B).	Has the emergency resulted in reduced access to quality outpatient and inpatient curative health services, and if so to what extent?	• <1 basic health unit per 10 000 people or <1 hospital per 250 000 people • High proportion of non- functional or inaccessible health facilities
Overcrowding	Increased transmissibility of airborne droplet and faecal-oral VPDs.	Is the population living in a large camp or a high-density urban community? How close together are residential structures?	• Size of camp > 10,000 people • < 3.5 m2 covered floor area per person
Insufficient water, sanitation and hygiene	Increased transmissibility of faecal-oral diseases (mostly) and airborne droplet diseases.	Does the population have inadequate access to water, sanitation and hygiene (e.g. soap, health promotion)?	• < 15 L water available per person per day • > 20 persons per latrine • <250g of soap per person per month

3.4.2 Task 1.b: Come up with a grading of risk due to general factors

43 summarizes very approximately what is known about the relevance of each general risk factor considered in the above worksheet to specific VPDs, irrespective of context and region of the world (i.e. all else being equal). The classification of relevance in Table 4 should be interpreted as follows:

- ***High relevance:*** globally, a large proportion of the total disease burden due to the VPD is attributable (whether proximately or distally) to this risk factor: removing the risk factor would result in a substantial decrease in the burden of this VPD. Obvious examples falling within this category are insufficient water, sanitation and hygiene and cholera; high HIV/AIDS burden and tuberculosis; overcrowding and measles.
- ***Moderate relevance:*** globally, a moderate proportion of the total disease burden is attributable to this risk factor: addressing the risk factor is not among the top priorities to control the VPD, but nonetheless its removal would probably bring about some decrease in burden (for example, insufficient water, sanitation and hygiene and influenza).
- ***Low relevance:*** there is evidence that, globally, this risk factor has a small or no effect on the burden of the VPD: removing the risk factor would make a negligible difference to attributable burden. For example, a high birth rate does not influence the burden of typhoid fever.
- ***Unknown relevance:*** there is insufficient evidence on the role that this risk factor plays in the global epidemiology of the VPD.

While Table 4 broadly reflects existing evidence, links between some risk factors and disease are tenuous or not yet investigated. In some cases, an attempt was made to grade the relevance using plausibility reasoning: for example, VPDs that are very similar in their interaction with the host and share the same route of transmission were assumed to have a similar link to certain risk factors. Low access to curative health services is almost always a risk factor for higher CFR, but its relevance was graded here according to the relative impact of treatment: for example, in most settings the absence of treatment would not greatly increase mortality from a yellow fever outbreak, given that there is no effective cure.

It is obvious that contextual factors can heavily modulate these general associations: for example, the relevance of a young population to measles would indeed be high in a setting with insufficient vaccination coverage (VC), but less so where VC is adequate. These factors are considered later when assessing specific risk for each VPD. The risk assessment is designed to ultimately output a classification decision for each VPD that balances both general and specific risk factors.

Having classified the relevance of each risk factor to the VPD being analyzed, one may come up with an overall grading of risk attributable to general factors, for that VPD. To do this, simple categories of "high", "medium" and "low" risk are proposed, as follows:

- High if one or more of the general risk factors that are found to be present according to the worksheet in Table 3 is highly relevant to the VPD in question, according to Table 4;
- Medium if none of the risk factors that are present is highly relevant to the VPD but at least one is moderately relevant;
- Low in all other situations.

In the example of measles, if the emergency features any of the general factors considered to be highly relevant to its epidemiology (high prevalence of malnutrition, high birth rate, low access to curative services, overcrowding), the general risk grade would be "high". If the features only factors considered to be moderately relevant (high HIV/ AIDS burden or insufficient water, sanitation and hygiene), the general risk grade would be "medium". If none of the general risk factors are present, the grade would be "low".

Table 4: Relevance of each general risk factor to each VPD

	High prevalence of malnutrition	Young population and/or high birth rate	High HIV/ AIDS burden	Low access to curative health services	Overcrowding	Insufficient water, sanitation and hygiene
Airborne-droplet						
Diphtheria	Moderate	Low	Unknown	Moderate	High	Low
Hib disease	Moderate	High	Moderate	High	Moderate	Moderate
Influenza	Unknown	High	Moderate	Moderate	High	Unknown
Measles	High	High	Moderate	High	High	Moderate
Meningococcal meningitis	Low	Low	Moderate	High	High	Low
Mumps	Low	High	Low	Moderate	Moderate	Low
Pertussis	Moderate	High	Low	Moderate	High	Low
Pneumococcal disease	High	High	High	High	High	Low
Rubella	Low	Moderate	Low	Moderate	Moderate	Low
Tuberculosis (meningitis and disseminated disease)	Moderate	Low	High	High	High	Moderate
Varicella	Moderate	Moderate	High	Low	High	Moderate
Faecal-oral						
Cholera	Moderate	Low	Unknown	High	High	High
Hepatitis A	Unknown	Low‡	Low	Low	Low	High
Polio	Low	Low	Low	Low	High	High
Rotavirus	Moderate	High	Low	High	Moderate	Low
Typhoid fever	High	Low	Moderate	Moderate	Moderate	High
Vector-borne						
Japanese encephalitis	Unknown	Moderate	Unknown	Moderate	Low	Moderate
Yellow fever	Moderate	Low	Unknown	Low	Low	Moderate
Other or mixed						
Hepatitis B	Unknown	High	High	Low	Moderate	Low
HPV (Cervical cancer)	Low	Low	High	Low	Low	Low
Tetanus†	Low	High	Low	High	Low	High

† A high birth rate and low access to health services are relevant because they can result in a higher incidence of perinatally transmitted cases.

‡ In fact, a young population and/or birth rate actually reduces disease burden, as infection tends to occur earlier in life, when it is mostly asymptomatic or results in mild disease.

3.5 Task 2: Grade the level of risk due to factors specific to each VPD

Next, risk factors that are specific to each VPD are considered in detail. These risk factors are listed separately as they are very contextual and only apply to the individual VPD: for example, risk assessment for Japanese encephalitis should consider whether the emergency is occurring in an area with known transmission of this virus; for typhoid fever, local evidence of previous outbreaks is an indication of higher risk.

The range of specific factors that may be assessed is shown in Table 5, along with key questions to ask. However, not all factors are relevant to each VPD (e.g. climate and season are not known to influence the risk of HPV transmission or disease progression), and the importance of each varies disease by disease. For this reason, **VPD-specific worksheets** are provided in Annex 2: these contain guidance on how to grade risk arising from each specific risk factor relevant for the VPD, based on information available.

Table 5: Specific factors to be assessed for different VPDs

Factor	Relevance	Key questions to ask	Possible data to consider
Population immunity	Major determinant of individual and community risk of transmission.	• Is a significant proportion of the population at risk currently not immune, either through vaccination or natural exposure? • Is the current VC likely to afford herd immunity or a high level of individual protection? • Is there a risk of introduction or re-introduction of the VPD in a naïve or partly naïve population?	• Latest VC data (both routine and campaigns) • Occurrence, size and mortality of past outbreaks in the population
Burden of disease	Indicates the importance of the VPD in the given setting either before or since the emergency, all else being equal.	• Is the region within the known transmission boundaries of the VPD? • What is the mortality attributable to the disease in the country? • Have epidemics previously occurred? • Has an outbreak been confirmed since the emergency began?	• Occurrence, size and mortality of past outbreaks in the region • Burden of disease estimates • Ongoing disease surveillance • Global disease risk maps
Geography, climate and Season	Certain VPDs only occur in given settlement zones (e.g. Japanese encephalitis mostly affects rural areas) or seasons (e.g. meningococcal disease); some carry a higher burden where people are exposed to cold (e.g. Hib disease).	• Does the setting where people are living favour transmission? • Is the population exposed to cold temperatures? • Is the population exposed to indoor air pollution? • Will the acute emergency unfold during the high transmission season?	• Climate data • Cooking fuel source
Levels of sexual violence	High incidence of sexual violence can result in increased transmission of HPV and hepatitis B.	• Has the emergency resulted in high incidence of sexual violence?	• Security reports • Hospital data
Incidence of injuries	A large number of untreated injuries entails a high risk of tetanus, particularly among males and if VC is low.	• Has the emergency resulted in a large number of people with injuries? • Is treatment available and prompt for these injuries?	• Field reports • Evidence from similar emergencies • Hospital data

In the example of measles (see Annex 2, measles worksheet), three factors (population immunity, burden of disease, and geography/climate/season) are considered to be relevant for consideration. Criteria are provided for each based on assumed vaccination coverage, recent outbreaks, and seasonality.

Each VPD-specific worksheet should be completed as accurately as possible given available information. An overall grading of risk arising from specific factors should then be made for the VPD on the basis of this worksheet, according to "high", "medium" and "low" categories. Unlike for general risk, no clear-cut decision rule is suggested, recognizing that the various combinations of the different specific factors constitute too many scenarios to realistically capture in simple classification rules. Instead, a **qualitative** approach informed by all available evidence and sound, objective judgment is recommended. An algorithm to aid this qualitative decision is suggested in Annex 2.

3.6 Task 3: Assess the overall risk of each VPD

3.6.1 Task 3.a: Decide whether the VPD should be considered further

Based on the result of tasks 1 (general risk grading) and 2 (specific risk grading using the disease-specific worksheets), a classification for each VPD should be reached using Table 2. The classification system is not meant to be inflexible, and careful judgment, illuminated by all available evidence, should be exercised to occasionally deviate from it, while erring on the side of caution when uncertainty precludes a clear decision. Written documentation of the rationale for each classification decision is essential to ensure transparency and buy-in from stakeholders, or learn from mistakes if the risk assessment turns out to be faulty.

3.6.2 Task 3.b: Characterize the expected risk for VPDs to be considered further

For VPDs that are carried over into the next step of the Framework, a brief, qualitative description of the expected risk should be made in terms of the following parameters:

- **Type of threat:** Would excess mortality be mainly due to the endemic pattern of the VPD or to an epidemic, or could a mixture of the two occur? For some diseases, this will be clear-cut: for example, in most parts of the world meningococcal meningitis presents mainly an as epidemic threat, while hepatitis A follows a very endemic (i.e. stable) pattern. For many diseases, however, a mix of endemic and epidemic patterns may occur depending on the setting: for example, typhoid fever cases presenting as part of the normal endemic pattern of the disease could experience excess mortality due to malnutrition or reduced access to health care, but a bona fide epidemic of typhoid fever could also occur due to water and sanitation problems.

- **Timeframe:** For each VPD, one should indicate how quickly excess mortality could manifest itself, and/or the window of opportunity for intervening through preventive vaccination. Some general guidance follows:
  - Diseases that manifest in an endemic pattern may cause excess mortality from the very start of an emergency: for example, pneumococcal pneumonia mortality, already high in many countries before an emergency, will immediately increase if the emergency severely curtails access to health care or if nutritional status suddenly deteriorates;
  - An epidemic of faecal-oral and airborne-droplet/direct-contact spread diseases can occur as soon as the first couple of weeks following the onset of an acute emergency, particularly if immune status is low from the very onset.
  - Provided the vector and pathogen are already present, an epidemic of vector-borne VPDs will usually take a few weeks longer to manifest (about one and a half months at least after the emergency), because of the time taken for vectors to breed and the latency periods of the pathogen in both vectors and humans to reach completion.
  - In protracted emergencies, epidemics of VPDs may become increasingly likely as existing vaccination programmes deteriorate and the pool of susceptible individuals increases.
- **Age-specific burden:** Which age groups would be at highest risk of infection and/or disease? Would the age range experiencing excess mortality due to the VPD be the same as the typical target age group for vaccination, or would additional age groups probably also experience excess mortality?

The disease-specific worksheets provide additional guidance on how to characterize the above parameters.

4. Considerations for Vaccines

4.1 Chapter summary

In this chapter, key terminologies are defined at the beginning of the chapter, vaccine characteristics are examined in order to determine suitability for mass vaccination in a humanitarian emergency setting, and the chapter also examines important determinants of quality mass vaccination campaigns.

4.1.1 Vaccine characteristics

Key vaccines characteristics that should be considered to reach a decision whether a vaccination intervention should be implemented or not include determination of:

- Vaccine efficacy at full schedule and efficacy at less than full schedule
- Administration course of the vaccines
- Vaccine presentation (e.g. multi-dose presentation)
- Contraindication and vaccine safety considerations
- WHO prequalification status
- Formulation of the vaccine, for examples, most freeze-dried vaccine should never be kept longer than 6hrs after reconstitution and optimal use may require more staff training
- Storage and cold chain requirements
- Cost of the vaccine, and whether sufficient quantities can be purchased

4.1.2 Mass vaccination campaigns considerations

Characteristics that would ensure successful and high quality mass vaccination campaigns include:

- Estimation of target population including age range
- Determination and prioritization of high risk groups or geographical areas
- Effective execution of the key implementation components including planning, logistics, social mobilization, monitoring and informed consent

4.2 Chapter introduction

The output of the risk assessment step is a list of VPDs that should be **definitely** or **possibly** considered in this next appraisal. Within our defined context, vaccination for the VPDs identified has the potential to save lives and limit disease but the use of these vaccines is not straightforward. An essential component of vaccination interventions in emergencies has to do with the actual implementation of the vaccination intervention: the characteristics of the vaccines themselves and how they are delivered. Before establishing a set of criteria to consider in this next step, it is important to define some common terminology.

Mass vaccination refers to the process of setting up vaccine clinic sites in traditional or non-traditional health care locations in order to administer vaccines to an unusually large number of people in a short period. There are several approaches to the implementation of mass vaccination campaigns but they can be grouped into two main categories: strategies where individuals come to sites to be vaccinated and the other where the vaccine is brought to the individual. Examples of the first type of strategy include vaccination at sites where individuals work, reside, or gather, to receive the vaccine. These may also be specifically set up sites for vaccination when an appropriate facility does not exist. Examples of this approach include vaccination sites in hospitals, health facilities, schools, markets and religious establishments. The second approach involves bringing the vaccine directly to individuals using mobile vaccination teams or door-to-door strategies where individuals may be vaccinated within their homes.

Despite the temptation to simply implement a vaccination campaign, with the assumption that any vaccine delivered does more benefit that harm, appropriate planning is needed to ensure that the campaign achieves its aims of reducing mortality. Mass vaccinations pose specific challenges, due to their objective of reaching a large number of people over a short period, and as a result necessitate extensive forethought. A key component of this decision is which antigens to include in the intervention and definition of the target population.

4.3 Classification of Vaccines

Vaccines are made using several different processes. They may contain live viruses or bacteria that have been attenuated (weakened or altered so as not to cause illness); inactivated or killed bacteria or viruses; inactivated toxins (for bacterial diseases where toxins generated by the bacteria, and not the bacteria themselves, cause illness); or merely segments of the pathogen (this includes both subunit and conjugate vaccines). Although there are differences between types of vaccines, the key difference is whether the vaccine is a live attenuated vaccine or inactivated. The characteristics of live and inactivated vaccines are different, and these characteristics determine how the vaccine is used.

Live attenuated vaccines are produced by modifying a disease-producing ("wild") virus or bacterium in a laboratory. The resulting vaccine organism retains the ability to replicate (grow) and produce immunity, but usually does not cause illness. The majority of live attenuated vaccines contain live viruses. Live attenuated vaccines produce immunity in most recipients with one dose, except those administered orally. However, a small percentage of recipients do not respond to the first dose of an injected live vaccine or rarely immunity waned (such as measles, or MMR) and a second dose is recommended to provide a high enough level of immunity in the population.

Inactivated vaccines can be composed of either whole viruses or bacteria, or fractions of either. These vaccines cannot cause disease from infection, even in an immunodeficient person. Inactivated antigens are less affected by circulating antibody than are live agents, so they may be given when antibody is present in the blood (e.g., in infancy). Fractional vaccines are either protein-based or polysaccharide-based. Protein-based vaccines include toxoids (inactivated bacterial toxin) and subunit or subvirion products. Most polysaccharide-based vaccines are composed of pure cell wall polysaccharide from bacteria. Conjugate polysaccharide vaccines contain polysaccharide that is chemically linked to a protein. This linkage makes the polysaccharide a more potent vaccine. Protection from a live, attenuated vaccine typically outlasts that provided by a killed or inactivated vaccine. However, there are overall advantages and disadvantages to live and non-live vaccines (Table 6). These factors will need to be considered in the decision-making process.

Table 6: Key advantages and disadvantages of live and inactivated vaccines

Type of Vaccine	Advantages	Disadvantages
Live attenuated	• Contain a version of the living microbe that has been weakened so that it does not cause infection • Elicit strong cellular and antibody responses and often confer long-lasting immunity with only one or two doses.	• People who have damaged or weakened immune systems—because they have undergone chemotherapy, have HIV, or are pregnant for example—cannot be given live vaccines. • Antibody from any source (e.g., trans-placental) can interfere with replication of the vaccine organism and lead to poor response or no response to the vaccine (also known as vaccine failure) • Live attenuated vaccines are fragile and can be damaged or destroyed by heat and light. They must be handled and stored carefully. • Need to be refrigerated to stay potent
Inactivated	• Can be easily stored and transported in a freeze-dried form	• Stimulate a weaker immune system response than live vaccines • Take several doses, or booster shots, to maintain a person's immunity

A major consideration is the time it takes a vaccine to provide protective immunity. This means, how many days, weeks or months after a full course of vaccine (number of doses required, which may be age specific) can the immune response be considered to be protective. In addition to host-related factors such as age, pregnancy and any immune-system related disorders, the time to protection is a function of the vaccine classification. Generally, as discussed in Table 6, live vaccines require only one or two doses and elicit a strong protective effect. For live vaccines, protection is generally considered to be acquired within a two-week window. Few inactivated vaccines induce high and sustained responses after a single dose, even in healthy young adults. Inactivated vaccines usually require at least two doses, spaced 3 to 4 weeks a part. This means, that in the case of some inactivated vaccines, there may be at least a delay of 4 weeks from first vaccine dose to a degree of protection conferred and in some instances even longer. Alternately, in individuals who previously received one or more doses of the same vaccine, protective immunity may be generated quickly (between 4-7 days).

As multiple vaccines may be delivered as a part of the same intervention, it is important to consider that provided separate syringes and different injection sites are used, all inactivated vaccines can be administered concurrently. Live vaccines may also be delivered concurrently. If not delivered concurrently, an interval of at least 4 weeks should be used. This means that if two live vaccines are to be delivered during the intervention, they should be delivered at the same time, or one delivered and then a second 4 weeks later. This is to ensure a sufficient immune response is mounted without interference. The exception to this rule is oral polio vaccine (OPV) (see Annex 3) which may be given without consideration of other live vaccines.

When several doses of vaccine are required, similar vaccines (same antigen), but produced by different manufacturers may be used interchangeably while following the any changes in specified number of doses or contra-indications.

4.4 Vaccine characteristics

Understanding vaccine characteristics and mode of vaccine delivery plays an essential part in determining whether a specific antigen is appropriate to include in the intervention. Each situation is unique, and it is impossible to determine one strategy valid for all situations, but there are certain common elements to be examined concerning the vaccines themselves. Consideration of these factors helps provide important information for whether vaccines for VPDs identified in the risk assessment can then be delivered. Tables 7 and 8 provide an overview of the criteria, their definitions and additional considerations.

Table 7: Definitions and considerations of vaccine characteristics concerning conferred protection

Criteria	Definition	Considerations
Efficacy[1] at full schedule	Protection and duration of immunity assuming entire course is given (e.g., 68% two-dose efficacy in adults lasting for 2 years).	It goes without saying that higher efficacy vaccines are preferable to lower efficacy vaccines.
Efficacy at less than full schedule	Efficacy of vaccine at less than full course (e.g., 50% one-dose efficacy in adults)	Although a full course of vaccine should be delivered, this is not always possible due to many different factors. Particularly in emergencies, populations may not be accessible due to security constraints or population movement making delivery of multiple dose vaccines difficult.
Exclusion criteria	Groups or ages to which the vaccine is contra-indicated (e.g., children under age 1 year or pregnant women or women of child-bearing age)	This criterion is important in the implementation of mass vaccination campaigns where the exact age of an individual may not be known or when only certain segments of a population may benefit from vaccination.
Administration Course	Schedule of administration and age (e.g., dose 1 at age 9 months and 2nd dose at 12 months or above)	The administration course of a vaccine (schedule) should be considered in the decision-making process. With population movements, or erratic access to populations it may not be possible or realistic to deliver the full-course of recommended vaccine. There may only be means or access for one mass vaccination campaign and therefore only one dose of supervised delivery. The possibility of non-delivery of subsequent doses (less than the full schedule) or doses delivered by another means (oral doses delivered at home) should be weighed in terms of their risks and benefits. It is also important to investigate whether there are different possible schedules for each specific antigen (e.g., one dose under the age of 1 year and a booster dose later in life)
Safety[2]	WHO prequalification	Vaccines which are prequalified have an assurance of safety. There may be specific age ranges or underlying conditions for which the vaccine is not considered safe.

[1] Efficacy in preventing disease in the immunized populations is obtained from controlled studies, where immunization is delivered under ideal conditions. In those trials, vaccines tend to be given to healthier people who may present a better immune response. Efficacy may also vary depending on age, nutritional status, co-infections, and other factors. As a result, the efficacy of some vaccines is lower in "real world" settings. Vaccine effectiveness is a different concept that describes protection under programmatic implementation and reflects the performance of the vaccine in the actual target population. Programmatic factors like errors in vaccine storage, preparation or administration, which can impair the vaccine, are more likely to occur in the field. Therefore, vaccine effectiveness is usually lower than vaccine efficacy. It is also important to note that although there may be instances of overdose (e.g., 3 doses instead of 2 in an individual with prior vaccination but undocumented vaccination status) the risks of overdose are minimal or absent.

[2] Vaccines being considered should meet international standards of quality and safety and have obtained WHO prequalification. However, under certain circumstances vaccines may be approved for use in a specific country, while not having WHO prequalification status. The decision to use vaccines not meeting WHO prequalification is a difficult and delicate decision which necessitates expert advice. Although the safety of a vaccine is assessed by clinical trials before it is considered for use, trials may not capture rare adverse events. Information on safety needs to be assessed carefully, weighing the risks against the benefit of the vaccine. The risk: benefit ratio may vary between situations, but in emergencies, where morbidity and mortality is high, the expected benefits may far outweigh the risk of adverse events.

In addition to the criteria listed above concerning protection conferred by the vaccines themselves, there are important factors to consider concerning the formulation, presentation, storage and cost of vaccine that play a role in deciding whether to include a vaccine in the intervention.

Table 8: Definitions and considerations of vaccine characteristics concerning formulation and delivery

Formulation	Combination, lyophilized, liquid	The formulation of the vaccine is important in terms of the need for trained staff to deliver the vaccine. Most freeze-dried (lyophilized vaccines) do not contain preservatives and consequently must not be kept more than the manufacturer's recommended limit and never longer than six hours after they are reconstituted. Death due to toxic shock syndrome has resulted when reconstituted live virus vaccines kept longer than the recommended period have been injected. Liquid injectable vaccines contain preservatives that prevent growth of bacterial contamination. Should contamination take place within the vial, the action of these preservatives prevents any increase in bacterial growth over time and actually decreases the level of contamination.[1]
Presentation	Individual or multi-dose presentation (vial/ampoule, prefilled injection device, vial size) and volume (e.g., glass multi-dose vial at 11 cm3)	Like formulation, the vaccine presentation plays a role in determining the type and number of staff required for delivery and the storage necessary for the vaccines.
Storage	Temperature and conditions of storage (e.g., 2-8°C in a dark room)	Cold-chain capacity for storage should be considered and if not present, whether there is the capacity to mount a cold-chain in the affected area.
Stability	Duration vaccine can be exposed to ambient temperatures (e.g., one month at 37°C). The Vaccine Vial Monitor (VVM) should be used as a guide.	The vaccine vial monitor (VVM) is a small sticker that adheres to the vaccine vial and changes colour as the vaccine is exposed to heat. The colour of the sticker tells health workers whether the vaccine is bad—or can be safely used for immunization.[2]
Current Price	GAVI listed price	

1 See *http://www.path.org/vaccineresources/files/Getting_started_with_VVMs.pdf* for additional information on VVMs.

2 See *http://extranet.who.int/ivb_policies/reports/open_vials.pdf* for additional information on open vial guidance for specific antigens.

In addition to those listed in Table 8, there are a few additional important considerations.

First, vaccines currently introduced or used in a country's routine program afford important benefits. There may be additional supply of the vaccine present in the country and more importantly less quantifiable factors, such as healthcare workers' and the populations' familiarity with the antigen can have important benefits. The same is also true for vaccines for seasonal diseases, such as meningitis where countries may have prior experience in conducting campaigns. Inversely, introducing vaccines into an intervention when they are not currently a part of EPI (for example, oral cholera vaccine) is important to consider. Vaccines that have not yet been introduced into EPI, or are not destined for inclusion in EPI, may necessitate a different approach in terms of procurement and community acceptance.

Second, supply (availability) is an important factor and ideally should be investigated prior to crises. Manufacturers have different capacities for supply of vaccine. The delay expected for the vaccine supply to be delivered may play a role in the decision-making process. Whether a vaccine is currently incorporated into a country's routine program and the supply of vaccine available are context dependent. Third, the shelf life of the vaccine is also important to consider. This is the time before the vaccine expires, or can no longer be considered protective under ideal conditions. Vaccine shelf-life may play an important role in insecure contexts, where plans for a mass vaccination campaign may need to be delayed or may occur in a "stop-start" manner with the target population receiving vaccination at irregular intervals over a long period of time. If the vaccine is to be incorporated into the intervention, it is important to note the time the shelf-life of the vaccine (this may vary by lots) to ensure that there is enough time for delivery.

4.5 Vaccine specific information

The previous tables present an overview of the different vaccine and delivery factors, which are interlinked and should then be used to consider which vaccines are feasible to implement through mass vaccination. The characteristics listed previously vary by vaccine and are presented in Annex 3. In some cases, evidenced-based information is not yet known or scanty for specific antigens. This is especially the case concerning protection afforded by delivery of less than the full-course of vaccine. As a result, in situations where there may not be sufficient access to the target population due to logistic and/or security constraints, the decision to include a vaccine in the intervention where a priori there is a realistic possibility of not delivering a full course of vaccine, the decision is not straightforward. The decision needs to balance known information about vaccine efficacy at full-course and best available information at less than full-course balanced with the potential benefits of vaccination. Further, if less than a full-course is delivered, this information should be documented during the intervention.

4.6 Deciding Which Vaccines to Consider

For each of the VPDs you have listed as definitely or possibly consider, this next step in the process aims to help determine whether the vaccine for each of these VPDs could be included in the intervention. In order to do this, what vaccines, for who to use them, where to use them and how to use them need to be considered. In order to do this, the first step is to answer the question: Does a vaccine exist for the VPDs listed as definitely or possibly to consider? Appendix X provides a list of available vaccines and their characteristics. If the answer to this question is yes, then the first step is to determine the target population for vaccination.

4.6.1 Age group targeted for vaccination and estimated doses needed

Estimating the target population is required to determine the number of vaccine doses needed. This information should have been obtained during the risk assessment step where the denominator (at-risk population) has been determined. Target populations vary by antigen, with some vaccines necessitating the vaccination of wide age ranges, and others a smaller subset. The target age range for vaccination should be based on the expected age distribution of cases or if the outbreak as started on the age profile of early cases. This information is then used to provide an estimate of the expected number of vaccines that are needed to afford protection to those at risk of death.

For example, it is recommended that all individuals 6 months to 15 years of age be vaccinated for measles (see WHO/UNICEF guidelines). However, for other antigens, such as an intervention where meningococcal disease has been identified as a high-risk, then the target group for vaccination includes those aged 2 to 30 years (see Annex 3). In both cases however, the target age range needs to be adapted based on both the epidemiologic risk and pragmatic issues. The target population at risk for all candidate vaccines should be listed in the following way:

Table 9: Worksheet for each vaccine corresponding to VPDs definitely and possibly to be considered for the intervention

Vaccine for VPD priority	Expected age distribution of cases (at-risk population)	Denominator estimate for at-risk population (include host population here if relevant)	Doses per person	Number of doses of vaccine needed (population	Estimated number of vaccines +10% wastage + 10% buffer
Ex. Measles	Ex. 6m to 15 years	Ex. 100,000	Ex. 1	Ex. 100,000	Ex. 100,000+10,000 + 10,000 = 120,000 doses

When different population figures are available, or the expected age distribution of cases is not known, it is better to over-estimate, rather than to under-estimate, the target population for vaccination. This means that the highest number available should be used as a precautionary measure.

4.6.2 Determining when and where to vaccinate

It is important to remember that all vaccination interventions identified from the risk assessment should be implemented as soon as possible. Failure to deliver these interventions is a sub-optimal intervention. However, this said there may be logistical, political or ethical barriers to delivering all interventions simultaneously. In these cases, interventions should be prioritized in terms of urgency (which interventions are most important to do first).

Prioritizing vaccine interventions in terms of urgency should be based on the epidemiologic risk. Vaccines for VPDs indicating a high risk should be prioritized in terms of the timing of their delivery. Following the same example of measles and meningococcal disease, measles vaccine should be delivered immediately due to the high risk of an epidemic. Meningitis vaccine, if the emergency occurs outside of the meningitis season, could be postponed until operational concerns are addressed. Although in most cases, vaccination will be considered an urgent need.

An additional criterion for prioritization includes geographic area. Certain high-risk populations may be located in a particular area. These include very crowded sites or areas with no access to safe water or sanitation or population sub-groups, such as children under the age of 5 years. Selecting specific geographic areas for vaccination needs to be balanced with ethical issues. Vaccination of only specific geographic areas may create tension among the population and leads to the need to justify why only certain groups are eligible for vaccination while others are not.

When looking at Table 10, when risk groups overlap, and they will do most of the time, it may be better and more efficient to deliver all vaccine interventions at the same time, rather than organizing individual campaigns for each antigen. Delivering multiple antigens at the same time may require better organization in terms of setting up the logistics of the campaign, but have the important advantage of maximizing the opportunities of delivering vaccine to individuals in one planned intervention.

4.6.3 Considerations for VPD priorities and inclusion of vaccines in the intervention

At this point in the process, after consulting the appendix listing available vaccines and filling in the worksheet in Table 10, there may already be some vaccines addressing the VPD priorities established in step one of this guide that may not be feasible. Considering responses in the worksheet, for each vaccine, the following questions are to be considered:

- Does a vaccine exist for the VPD?
- Is the vaccine available in sufficient quantities for those who need it including buffer stock for wastage and errors in the denominator?
- What are the cold chain requirements for the vaccine and is the cold chain adequate?
- Does the mode of delivery require skilled staff and can such staff be mobilized in adequate numbers for the campaigns?
  - Injectable vaccines require trained staff to deliver the vaccines. The number of vaccines an individual vaccinator can deliver varies by context and by the number of antigens to deliver. Different agencies and actors have different experience in delivering mass vaccination interventions and the experience of the staff plays a role in human resource needs. There are several guidelines available on planning of vaccination campaigns including estimation of needed human resources.
- Can injection safety and waste disposal be assured throughout the duration of the intervention?
  - If not considered from the start, poor injection safety can result in transmission of infection, eroding of donor and community confidence and most importantly, a lack of impact in terms of reduction of morbidity and mortality. For specific information on injection safety and waste disposal, refer to WHO/V&B/02.10 for specific information.

If the answer to any of the above questions is "no" for any of the antigens under consideration, then they should not be considered further.

The output for this section should be a list of the priority VPDs and their associate vaccines with the following information:

1) Timing of the intervention (are all antigens to be delivered simultaneously? Phased?)
2) Age range for each antigen
3) Size of target population for each antigen
4) Dosage and quantity of vaccine for each antigen

4.7 Implementation considerations

Although mass vaccination campaigns in acute emergencies are an intervention rather than a program, they still require the same components as other mass campaigns such as supplementary immunization activities. Mass campaigns have four key components that ensure campaigns are successful in reaching the target population:

1) **Planning:** A clear and comprehensive plan on how to reach populations and budgeting accordingly. Who will do what, at both the macro level and micro level, is clearly laid out and everyone is aware of their responsibilities. This stage also entails the decision of which antigens to include.

2) **Logistics:** The logistics of having the vaccine reach individuals is perhaps the most important component. Ensuring the safe transportation route of the vaccine from procurement through to injection must be ensured and clearly identified. Human resources must also be available for the campaign.

3) **Social mobilization:** Getting word of impending vaccination to a population is essential to ensure vaccines are delivered. Social mobilization may be limited only to word of mouth, but when circumstances permit, includes other formal and informal channels. Social mobilization also serves to provide the population with important information about the risks and benefits of vaccination.

4) **Monitoring and evaluation:** During a campaign, monitoring provides an essential component to trouble-shoot potential problems and provide information on the implementation of the campaign. After mass campaigns have been implemented and the target population has received vaccine, documentation of successes and failures is a critical step. The follow-up phase capitalizes on the experience to provide lessons learned and identify additional needs of the target population. The follow-up phase also serves as an important step in terms of documenting the rationale of the emergency intervention.

4.7.1 Planning mode of delivery

As discussed previously, mass vaccination can be divided into two main strategies: vaccine delivery from fixed sites and from mobile posts (mobile teams), or both.

1) **Fixed sites:** These sites are located at permanent health facilities or health posts. Vaccination can be provided at the facilities for at least the whole day (sometimes at night) throughout the duration of the campaign. These sites may also be storage areas and sites for vaccine distribution to mobile teams. Additional fixed sites, which may be specifically constructed as semi-permanent structures if necessary, may be located at schools, churches, mosques, bus depots, roadblocks, markets, village squares, etc. Villages and settlements with small populations may also be served through such temporary sites.

2) **Mobile posts:** Mobile posts, of mobile vaccination teams, move from community to community reaching populations that are living in hard–to–reach areas, which may not have access to a fixed site. Mobile teams may set up a vaccination posts at a fixed site for a few hours or a day, and then move the post to a new site after completing their task. A mobile vaccination team may also vaccinate from door-to-door or shelter-to-shelter.

Fixed sites have the advantage that they can be identified in advance (schools, health facilities) or constructed in the form of temporary structures. Fixed sites also provide additional advantages in terms of providing a secure shelter for vaccination teams and an identifiable location for the population to participate in the intervention. Further, due to their fixed nature, many people can be vaccinated in a short period. However, as fixed sites necessitate the population displacing to receive the vaccine, not all individuals may be able to reach the site to be vaccinated, due to restricted movement, lack of awareness about the intervention or simply not wanting to travel.

Mobile vaccination teams, which may either bring the vaccine to groups of people, or deliver the vaccine from door-to-door, have the advantage of bringing the vaccine directly to the target population. Vaccination teams bring the vaccine in vaccine carriers and vaccinate individuals where they are located. The advantages with mobile teams are clear in that difficult to reach populations may be accessed. However, the use of mobile teams requires additional resources as less of the population can be reached per day.

In most situations, a combination of fixed and mobile vaccination sites is necessary. Both strategies, fixed and mobile, should be identified in the planning stage and may require creative solutions to provide sufficient opportunities for the target population to be reached. In areas spanning a large geographic area, urban and densely populated areas may best be served by fixed sites, ensuring that a large portion of the target population can be vaccinated quickly. In a rural area, mobile teams may be more appropriate to reach the population.

In emergencies it is essential to consider different non-traditional places for vaccination and opportunities. This may mean that sites are opened during non-traditional hours and dispersed across the geographic area so that individuals across the area are able to access a site. A classical program based strategy may not be the most appropriate, but considering opportunities such as vaccination at registration if the emergency entails refugees, or vaccination within other interventions, such as food distributions, should also be considered. It is essential to remember that mass vaccination campaigns in emergencies need to be accomplished quickly and are not a replacement for routine programs.

4.7.2 Logistics

Campaign logistics entail the development of a specific and concrete plan to ensure that vaccines are delivered to individuals. There are numerous guidelines on how to plan campaigns, which include information on how to design an operational strategy. These include information on the size of vaccination teams, how to set up a fixed and mobile vaccination site and include information on how to calculate needs. This logistic exercise should try to come up with valid and realistic estimates of the resource needs based on the target population and the reality on the ground concerning existing and locally available resources – human as well as material. The goal of this guide is not to provide specific information on how to set up an operational strategy, but rather to ensure that logistic considerations are an integral part of the planning process.

4.7.3 Social Mobilization

Social mobilization activities, even in an emergency, are needed to ensure that the community is aware of impending vaccination activities. They need to be planned to enlist support from the population and include mobilization of support of religious and community or group leaders, groups that may be functioning in the area and other informal support networks. Contact with individuals and groups should be made prior to vaccination, asking for their views and support that they can provide so that they participate in the process. Leaders may be given specific tasks, which may include providing human resources, passing the word within their communities or even announcing the event formally. Clear messages therefore need to be designed and disseminated through methods suitable to reaching populations by those that can motivate or influence them. Specific activities will depend on each situation and may range from walking though the community, radio messages, religious gatherings and publicity by village or group leaders or town criers. Some countries have utilized mobile phone companies successfully to mobilize communities through the mass dissemination of text messages. Efforts should be tailored to reach underserved populations or special populations. These may include minority groups or marginalized populations, religious communities that may resist public health interventions, nomadic/migratory groups, refugees, elite groups and their staff.

4.7.4 Monitoring

Formal documentation of emergency response is often not a part of the standard operating procedure of many emergency organizations. Although documentation of interventions is often difficult, monitoring of interventions and documentation of specific decisions made is a critical component of ensuring that lessons are learned from interventions and ensuring that populations are reached. Monitoring provides an important tool to keep track of intervention progress and provides an opportunity to adjust plans if needed. This includes both quantitative and qualitative aspects of campaigns. The quantitative component of monitoring includes careful tallying and recording of doses administered, vials utilized, and doses wasted; and reviewing of the number of doses administered against the expected to be delivered on a daily basis. The qualitative component addresses observation of vaccination teams in action, with specific emphasis on the cold chain and handling of vaccines and injection practices. Empowering supervisors or teams with the necessary means of communication, where immediate and effective action to address issues related to vaccine stocks, injection safety, rumours and resistance, etc., will be crucial to the success of the campaigns.

4.7.5 Informed consent

Obtaining valid consent from individuals prior to offering medical intervention is an obligation created by the ethical 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. 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 recognizing that health literacy levels, including a basic understanding of germ theory and immunology, will be limited in some affected communities.

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 immunizing 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". 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. The Siracusa Principles 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."

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 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.

As children are at particularly high risk in humanitarian crises, 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.

5. Contextual considerations and competing needs

5.1 Chapter summary

This chapter adds to the preceding ones by factoring in to the Framework considerations that go beyond the diseases and the vaccines. It takes into account some of the political and social properties of the environment in which an emergency is unfolding. It suggests that proceeding with a vaccination intervention should be considered in relation to the many other interventions that need to be implemented in order to save the most lives in a disaster setting. Like the preceding chapters, it does not provide answers, but it does suggest that decision-makers need to consider broad array of evidence from non-vaccine areas of the health sector and from other sectors as well in order arrive at a decision that will result in the best possible outcomes of the emergency-affected population.

Specific factors examined include;

- Political considerations
- Security concerns
- Human resources
- Financial considerations
- Alternative interventions
- Target population
- Add-on interventions
- Research

5.2 Introduction

The preceding chapters of this Framework deal with issues pertaining to the risks posed by vaccine-preventable disease and to the vaccines that prevent them. However, even though an assessment of these characteristics may justify a mass vaccination intervention, the final decision will be influenced both by the context in which the emergency is unfolding and by ethical considerations. Every emergency setting is unique and what applies in one will not necessarily be appropriate to another. This chapter highlights some of the principal issues posed by context and discusses them briefly.

5.3 Political considerations

Many emergencies are associated with highly charged, unstable political conditions. Tensions may exist between a ruling government and parts of its population, or between local authorities and the international relief community, or between any other combination of actors, making both the delivery and the acceptance of humanitarian assistance of any kind problematic due to suspicion and mistrust. In these circumstances, vaccination interventions have been politicized and have become the subject of contention.

Authorities in charge of emergency relief must decide whether to advocate for with recalcitrant or slow moving civilian and/or military authorities for proceeding with mass vaccination of target populations when indicated, or to postpone this intervention, at least temporarily, in order to be able to deliver other forms of assistance more rapidly and effectively. Bypassing local authorities or proceeding without their approval can lead to significant problems.

5.4 Security concerns

The most serious potential political impediment to vaccination is the insecure environment that often characterizes humanitarian emergencies. Violence, or even the threat of violence, can have important adverse consequences for health interventions of any kind, but mass vaccination campaigns are especially vulnerable – experience has taught that large gatherings are desirable targets for those intent on social disruption, especially if the population consists largely of unarmed women and children. In addition, access of the population to organized services can be severely affected if insecurity affects travel and communications. Even where access is possible, the real fear of violence takes a toll on the rate of utilization of available services – people who are concerned for their physical safety may not risk travelling by themselves or with their children to places where vaccination is offered. Even if vaccination is offered in as many individual communities as possible, the risk of violence directed towards health workers is real. The probability of conducting a successful mass campaign is clearly higher if security concerns have been adequately addressed. A choice must be made, therefore, between pushing ahead with a vaccination campaign that is entirely justified on public health grounds and foregoing vaccination until the security situation becomes more stable, whether it be on the basis of a negotiated, temporary truce between warring parties or a longer-term settlement.

This consideration has led some to argue that addressing the security situation in an emergency setting is a higher priority than initiating public health interventions. Even some epidemiological studies have shown that reductions in mortality are associated with more secure environments as much as they are by the availability of primary health care services[2], including vaccinations. Of course, what should specifically be done in any particular setting in regard to the relative priorities of action in different sectors such as protection and health is entirely dependent on the context and only a careful analysis of the local situation by those working closest to it will result in the adoption of the best course of action.

[2] Coghlan B, Brennan RJ, Ngoy P et al. Mortality in the Democratic Republic of Congo: A Nationwide Survey. Lancet 2006 Jan 7;367:44-51.

5.5 Human resources availability

While political instability and physical insecurity are not prominent features of all emergencies, resource limitations are. The needs of emergency-affected populations always exceed the ability of national, regional, or international relief efforts to deliver appropriate and effective relief in a timely manner. Qualified public health personnel are consistently in short supply, especially at the onset of emergency. Program managers, logisticians, public health workers, drivers, and translators, among others, are all needed for the successful implementation of vaccination programs. However, these same people, with the same skills, are also needed for other health and non-health sector interventions that could be of great benefit to the same population. Deploying them for days or weeks to a vaccination campaign could adversely affect the relief effort and slow down scaling up of life saving health delivery capacity. The competition between priority programs for individuals with these qualifications can be fierce; strong and respected leadership is critical to ensuring that any intervention program undertaken in an emergency is adequately staffed in order to maximize its chances to succeed. It requires close collaboration with national and subnational health authorities, as in most cases qualified health workers and supervisors required for campaigns are recruited from the existing national health system.

Utilitarian considerations require that allocation decisions achieve maximal benefits in terms of aggregate wellbeing, i.e. achieving "the greatest good for the greatest number".

5.6 Financial considerations

As with other interventions, financing of any vaccination program must be assured prior to the decision to implement it. Nevertheless, the distribution of funds between the many priorities that need to be met during an emergency is a serious concern. Different mechanisms exist for procuring necessary funding – through the Central Emergency Response Fund or in response to the Consolidated Appeals Process of the UN's Office for the Coordination of Humanitarian Affairs or through the grants of regional or bilateral donors. All of these are competitive mechanisms and the case for vaccination must be made (this is true even though vaccination against at least some VPDs is widely recognized as among the highest of priorities) . In some cases emergency campaigns overlap with planned or delayed development/elimination or preventive/control campaigns. In such cases it is necessary to be clear about the urgency of vaccinating areas which are either at high risk or are experiencing confirmed outbreaks, in order to avoid delays due to confusion over whether or not a particular campaign should be funding from emergency or development budgets as to who the appropriate implementing partners might be.

5.7 Alternative interventions

In regard to competition between interventions, unfortunately there is no algorithm that can determine the relative value of one intervention versus another, no mathematical formula that can be applied. The balance between the potential benefits and adverse consequences of implementing a mass vaccination campaign during the emergency phase of a crisis, compared to those of other interventions,, is specific to each setting. Good judgment, based on a careful and systematic consideration of a variety of contextual and ethical factors, is the key to arriving at an appropriate solution to what may seem to be an intractable problem.

Ultimately, the decision as to whether or not to proceed with a vaccination campaign should take into account the degree to which vaccination, weighed against other interventions, and assuming that not all interventions can be implemented, will result in reduced morbidity and mortality in the population. In any event, even if a vaccination campaign is delayed while other interventions, in the health sector or in other sectors such as food distribution, water and sanitation, and shelter are being implemented, planning and preparing for a vaccination campaign should proceed.

Within the health sector, the prioritization of specific services should be carefully considered. The distribution of human and financial resources between activities that provide immediate clinical care to the sick or wounded who are in grave danger of dying or of suffering severe disability needs to be weighed against the value of preventive interventions such as vaccination that may not have an immediate visible impact but that, if implemented in a timely manner, may save more lives in the longer term. Health authorities should never have to choose between offering clinical and preventive services – it is obvious that both are necessary to maintain the health of any population. However, emergencies such as those being considered in this Framework impact heavily on the health status of a population and the sad reality is that this choice often has to be made.

5.8 Target population

The extent of the target population for vaccination interventions must also be taken into account. In many emergencies, especially those in which displacement of large populations is a prominent feature, the risk of vaccine-preventable disease affecting the "host" population may be increased. Furthermore, especially where international emergency relief is provided, the level of services, including vaccination, available to the emergency-affected population may, in fact, surpass that which is available on a routine basis to the surrounding communities. This can result in heightened tensions in the area and can, at times, complicate the relief effort. For these reasons, it has become standard practice to try to include these communities in health interventions. Doing so means those resources must be devoted to those not directly impacted by the emergency, perhaps at the expense of providing more services to the affected population. The epidemiological, ethical, and political consequences of this decision are addition context-specific factors that must be taken into consideration.

5.9 Add-on interventions

In a somewhat similar vein, not only the population that benefits from vaccination may expand, but the vaccination intervention itself may be asked to expand into other areas. Once a decision is made that a mass vaccination campaign is warranted, there will always be a temptation to add additional antigens to those that have been selected. Even more than that, the argument is frequently heard that as long a people are going into communities to vaccinate, why do they not also distribute soap, jerry cans, shovels, mosquito nets, blankets, and so on as well? Indeed, in some cases, such as with the addition of vitamin A capsules to measles vaccine campaigns, "add-ons" have become routine. Yet, depending on the context, the addition of commodity distribution to a vaccination campaign should be approached warily as the risk of overwhelming limited human and logistical resources is real and fraught with risk.

5.10 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. However, it is imperative that medical care and service delivery take precedence over research in resource limited settings during an acute humanitarian emergency.

Ideally a local research ethics committee should establish that care needs have been met before such personnel are permitted to conduct research Consideration should be given to developing regional or international ethical review boards to assist where there is no appropriate local expertise. In countries where research governance structures are not functioning researchers must use credible international ethics review boards.

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.

5.11 Conclusion

The decision to implement vaccination against one or more high-risk diseases during the acute phase of an emergency must be made on the basis of epidemiological, vaccine, political, and ethical considerations that are specific to the context in which the emergency is unfolding. The question of who makes that decision is an important one. In accordance with increasingly accepted standards of accountability such as those enunciated in the IFRC Code of Conduct and by the Inter-agency Steering Committee's "transformative agenda", emergency –affected communities should be as involved in the prioritization and decision-making process to the maximum extent possible. In emergencies, perhaps especially in emergencies, where lives are almost always at stake, winning and maintaining the trust of the population being served is crucial.

A decision to proceed with vaccination in emergencies should take into consideration all of the areas discussed in this chapter, from highly charged political situations to ones of overt conflict and general insecurity; from weighing the benefits and consequences of different interventions to dealing with how to distribute limited resources; and from selecting from among health interventions to considering the relative priority of interventions from other sectors. The ability to arrive at the decision that best serves the interest of the emergency-affected population will depend not only on epidemiological risk assessment, vaccine characteristics, or a consideration of context. In addition, that ability will be dependent on authoritative but respected leadership, on rapid but effective consensus building, and on a cautious and real respect from the entire relief community for decisions that have been made on the basis of the best available evidence, the lessons learned from prior experience, and considered judgment of the broadest consensus of all those involved.

6. Annex 1: Sources of information for the risk assessment

6.1 General guidance

In many emergency scenarios, reliable field data quantifying the parameters that need to go into the risk assessment (e.g. the burden of a given disease; the prevalence of acute malnutrition; the number of litres of water per person per day) will mostly be missing during the timeframe of the initial risk assessment, and some assumptions will need to be made about what is happening on the ground, supplemented by knowledge of the typical profile of given typologies of emergency. One must not wait to carry out the risk assessment until sufficient field data become available to accurately answer each question, as this could take weeks or months. One should however be prepared to update the risk assessment later on if new data warrant a revision.

Risk assessment should nonetheless be carried out in close contact with field agencies, and any available information, including personal impressions of experienced field staff, situation reports and rapid assessments should be sought and reviewed so as to "ground-truth" any assumptions made.

In many situations, only national data may be available while only a specific region or population group may be affected by the emergency. If specific information on the emergency-affected population is not easily obtained, plausible assumptions may need to be made based on available information on the extent to which the emergency- affected population is likely to differ from the national average in terms of all the factors considered (for example, if the affected population clearly has lower socio-economic status than the national average, an appropriate adjustment should be made to the expected occurrence of risk factors).

6.2 Sources of information to assess general risk factors

In addition to direct contact with agencies present on the ground, which may be facilitated by the Health Cluster or other coordinating bodies, useful published information and assessments will typically be found on one of the main humanitarian information portals, such as Reliefweb (*http://reliefweb.int/*) and AlertNet (*http://www.trust.org/alertnet/*).

In addition, suggested sources that can be consulted when assessing the presence of general risk factors are listed in Error! Reference source not found..

Table 10: Suggested sources of information on the occurrence of key general risk factors

Risk factor	Suggested sources
High prevalence of malnutrition	• For baseline levels of malnutrition prevalence, see latest DHS and/or MICS survey results; more recent, site-specific data may also be found in the CE-DAT (http://www.cedat.be/) and UN NICS (http://www.unscn.org/en/publications/nics/) databases. • Food security information may be available from surveillance systems that cover the region, e.g. FEWS (http://www.fews.net/Pages/default.aspx). • Information on food access and nutritional intake since the emergency may be found in assessments published since the emergency, e.g. by the UN World Food Programme.
Young population and/or high birth rate	• UN World Population Prospects: http://esa.un.org/unpd/wpp/index.htm
High HIV/AIDS burden	• Prevalence estimates may be found on the UNAIDS website: http://www.unaids.org/en/regionscountries/countries/ • HAART coverage figures may be found on the WHO website: http://www.who.int/hiv/data/en/ • Information on disruption to curative health services (see below) may be taken as a proxy of disruption to HAART access
Low access to curative health services	• Health Resources Availability Mapping System (HeRAMS) assessment reports, if available • Initial rapid assessments, Health Cluster situation reports, damage reports and anecdotal information from the ground, if available
Overcrowding	• Initial rapid assessments, if available • Satellite imagery of the camp or the city, if available (see for example http://www.unitar.org/unosat/maps)
Insufficient water, sanitation and hygiene	• For baseline information, see latest census, DHS and/or MICS results; • Initial rapid assessments and anecdotal information from the ground, if available

6.3 Sources of information to assess VPD-specific risk factors

As suggested in Table 10, most of the information on specific risk factors will be found in any available rapid assessments or ground reports from agencies.

Information on **vaccination coverage** may be found in the most recent DHS or MICS survey reports, as well as in site-specific surveys reported on in the CE-DAT (http://www.cedat.be/) database. Some countries' Ministry of Health also maintains online information on administrative VC (i.e. derived from health facility reports or the Health Management Information System). Obtaining the very latest information for each vaccine used in the country, however, is paramount before undertaking the risk assessment: this will usually be readily available from the Ministry of Health and the country WHO and UNICEF offices and from the WHO online database http://apps.who.int/immunization_monitoring/en/globalsummary/countryprofileselect.cfm. In general, survey-based estimates of coverage are known to be far more reliable than administrative figures, and should be given greater consideration. Unfortunately, for many countries survey-based estimates are not up to date, and may not reflect recent developments (e.g. deteriorations or improvements in routine vaccination, mass campaigns such as Child Health Days or Supplementary Immunization Activities).

When survey estimates are out of date (e.g. not reflecting the situation in the last 2 years or obtained before a mass campaign), they should be adjusted approximately by considering the following:

- Any information on the coverage of the latest mass campaign;
- Evidence of recent changes in the performance of the routine vaccination programme, e.g. reduced funding levels, disruption due to insecurity, cold chain problems, etc.

Information on burden of disease requires a somewhat more sophisticated and VPD-specific analysis. In high-resource settings (e.g. western Europe) disease surveillance is nearly exhaustive and fairly reliable data on the incidence and mortality due to each VPD are usually publicly available on the internet, for example from the country's national public health agency website. However, in most of the world this is currently not the case. For some diseases, information is likely to be so sparse that proxy variables need to be considered instead, including VC itself.

In general, one or more of the following types of sources should be consulted for each VPD:

1) Surveillance and epidemic reports:

i) Nearly all countries have a surveillance system designed to detect and respond to outbreaks, although the coverage and effectiveness of such systems may be limited. It is always useful to review information generated by such systems (which may not always be accessible on the internet, but can be obtained by contacting Ministries of Health or the WHO country office) to gain an overview of which epidemic-prone VPDs have been observed most frequently in the past, and how large outbreaks associated with these diseases have been. Any surveillance or Early Warning Alert and Response Network (EWARN) system established since the emergency may also have detected an ongoing outbreak.

ii) Reports of past or ongoing epidemics in the country should also be identified, e.g. by consulting the archives of ProMED-mail (*http://www.promedmail.org/*) and WHO (*http://www.who.int/csr/don/en/*), searching the internet through a standard search engine, and consulting scientific abstracts (*http://www.ncbi.nlm.nih.gov/pubmed/*).

Information from disease surveillance and previous outbreak reports should be interpreted with caution. Evidence of high burden due a given VPD (e.g. repeated outbreaks of measles during the past few years) is useful, but absence of evidence does not necessarily mean low burden, mainly for the following two reasons: (i) these sources tend to focus on epidemic-prone threats and may not be designed to quantify the risk of VPDs that usually manifest in a more endemic pattern (e.g. pneumococcal and Hib disease, other childhood cluster diseases); (ii) some diseases (rotavirus, pertussis and seasonal influenza in particular) are hard to detect even if they occur in an epidemic fashion due to their non-specific presentation and challenges in laboratory confirmation in many low-resource settings, and thus may be subject to severe under-reporting.

2) **Burden of disease estimates.** These are particularly useful for diseases that exhibit a fairly stable, endemic incidence pattern. However, current estimates are somewhat outdated (*http://www.who.int/healthinfo/global_burden_disease/estimates_country/en/index.html*). An update centred in the year 2010 is due to be published in 2012 (*http://www.globalburden.org/*).

3) **Proxy variables:**

For certain childhood cluster diseases that have an endemic as well as epidemic pattern, burden is often severely under-estimated by surveillance (see above), but is reasonably well predicted by the child mortality ratio (probability of dying before reaching age 5 years per 1000 live births): as the above VPDs account for a majority of post-neonatal deaths under 5 years worldwide, a high child mortality ratio (e.g. > 100 deaths per 1000 live births) indicates that their burden should be assumed to be high, unless there is strong evidence to the contrary (e.g. a very high routine VC or very reliable surveillance data).

Table 11 suggests which among the above sources of information, and which other sources if applicable, should be consulted to review the burden of each VPD where national surveillance cannot be relied upon fully.

Table 11: Suggested sources of information to assess local burden of disease attributable to given VPDs

Disease	Surveillance and epidemic reports	Burden of disease estimates	Proxy variables	Other specific sources	Additional factors to consider
Cholera	X				
Diphtheria	X	X			
Hepatitis A		X			Regions with highest transmission have the lowest burden, as infection is acquired early in life when disease is mostly mild
Hepatitis B		X			
Hib disease		X	X		
HPV disease		X			
Influenza (seasonal)	X				Seasonality may be less pronounced in the tropics
Japanese encephalitis	X				Regional, mostly rural disease: see recent risk maps
Measles	X		X		Assume low burden at baseline; check local data for high season
Meningococcal meningitis	X				Epidemic risk highest in the African meningitis belt
Mumps	X		X		Assume low burden at baseline
Pertussis	X	X	X		Pertussis epidemics generally indicate the tip of the iceberg
Pneumococcal disease		X	X		
Polio	X			Global Polio Eradication programme (*http://www.polioeradication.org/*)	Assume low burden at baseline
Rotavirus		X	X		
Rubella			X		Risk of congenital rubella probably higher if the country is not using the vaccine
Tetanus		X (neonatal)	X (neonatal)	Assume low burden of non-neonatal tetanus at baseline.	
Tuberculosis		X		WHO country profiles (*http://www.who.int/tb/country/data/profiles/en/index.html*)	
Typhoid fever	X				
Varicella				Assume low burden at baseline.	
Yellow fever	X			See WHO page: *http://www.who.int/topics/yellow_fever/en/*	Not found in Asia

7. Annex 2: Characteristics of potential vaccines to be considered as a part of the intervention

Table 12: Characteristics of potential vaccines to be considered as a part of the intervention

Vaccine	Reported Efficacy at full schedule[1]	Reported Efficacy at one dose (or less than full schedule)	Target age group in emergencies	Exclusions	Number of doses required/ administration course	Presentation	Stability	Cold chain volume (cm3/dose)
Measles[2]	~90-100%	~85%	6m -15 yrs; also consider local epidemiology	Previous anaphylaxis; severe immunodeficiency	2	multi-dose (10)	Can be frozen	2,6
MR	~90-100%	~85%	Infants & young children; also consider local epidemiology	Previous anaphylaxis; severe immunodeficiency	2	multi-dose (10)	Can be frozen	2,6
MMR	~90-100%	~85%	Infants & young children; also consider local epidemiology	Previous anaphylaxis; severe immunodeficiency	2	multi-dose (10)	Can be frozen	2,6
DTP-HepB-Hib (pentavalent liquid)	>90%	varies with antigen, more than one dose required	6 weeks - 2 years; also consider local epidemiology	Previous anaphylaxis	3	single-dose, two dose or multi-dose (10)	Do not freeze	Range 10.3 -26.1, 13.1 and 2.6
DTP-HepB-Hib (penta-valent lyophilized)	>90%	varies with antigen, more than one dose required	6 weeks - 2 years; also consider local epidemiology	Previous anaphylaxis	3	single-dose, two dose or multi-dose (10)	Do not freeze	58.7, 19.2, and Range 5.1-7.5
DTP-Hib (liquid)	>90%	varies with antigen, more than one dose required	6 weeks - 2 years; also consider local epidemiology	Previous anaphylaxis	3	multi-dose (10)	Do not freeze	2,5
Hib (lyophized)	≥95%	70-80% for PRP-OMP; others<50%	6 weeks - 2 years; also consider local epidemiology	Previous anaphylaxis	3	multi-dose (10)	Do not freeze	12
HepB	≥95%	~56% in adults; for children no information	1st dose preferably at birth, but may need to consider wider age range	Previous anaphylaxis	3 or 4	single-dose, two dose or multi-dose (10, 20) and unijject	Do not freeze, VVM30	16.8, 7.2, 5.3, 4.4, 2.6, 12

Vaccine	Reported Efficacy at full schedule[1]	Reported Efficacy at one dose (or less than full schedule)	Target age group in emergencies	Exclusions	Number of doses required/ administration course	Presentation	Stability	Cold chain volume (cm3/dose)
PCV 10	~90% depending upon serotype	not known	6 weeks to 5 years or wider range depending on epidemiology	Previous anaphylaxis	3	single and two dose	Do not freeze, VVM30	11.5, 4.8
PCV 13	~90% depending upon serotype	not known	6 weeks to 5 years or wider depending on epidemiology	Previous anaphylaxis	3 to 4	single dose	Do not freeze, VVM30	15,7
BCG	50% all TB. Fulm TB in infancy >70%	50% all TB. Fulm TB in infancy >70%	neonates and infants	HIV+ and other immuno-deficiencies.	1	multi-dose (20)	VVM30	1,3
Rotavirus (RotaTeq Liquid)	~50% varies with Setting	not known	6-32 weeks	Previous anaphylaxis; vaccination outside time-limits	3	single dose	Do not freeze. No VVM.	46,3
Rotavirus (Rotarix Liquid)	~50% varies with Setting	not known	6-24 weeks	Previous anaphylaxis; vaccination outside time-limits	2	single dose	Do not freeze, VVM14	17,1
Rotavirus (Rotarix Lyophized)	~50%, varies with Setting	not known	6-24 weeks	Previous anaphylaxis; vaccination outside time-limits	2	single dose		110,6
OPV	~70-95%	~10-50%	Depends on Epidemiology	Previous anaphylaxis	3	multi-dose (10, 20)	Store frozen,VVM2	1.0, 2.0
JE (SE Asia) (liquid)	~95%	~95%	individuals aged ≥ 1 year	Previous anaphylaxis; immunodeficiency; pregnancy	1	multi-dose (10)	Do not freeze	3,4

Vaccine	Reported Efficacy at full schedule[1]	Reported Efficacy at one dose (or less than full schedule)	Target age group in emergencies	Exclusions	Number of doses required/ administration course	Presentation	Stability	Cold chain volume (cm3/dose)
TT	~90-99%	1 dose not protective	particularly in infants and women of childbearing age	Previous anaphylaxis	3+2	multi-dose (10, 20)	Do not freeze	3.0, 2.5
DT	~90-99%	1 dose not protective	infancy and children <7 yrs	Previous anaphylaxis	3 +2	multi-dose (10)		3
dT	~90-99%	1 dose without primary DT not protective	children ≥7 yrs and adults	Previous anaphylaxis	2 doses: booster DT; 3 doses: primary vacc ≥7 yrs olds	multi-dose (10)		3
MenA/C (lyophilized)	85% –99%	85% –99%	individuals aged 1-30 yrs	Previous anaphylaxis	1	multi-dose (10, 50)	Do not freeze	2.5, 1.5
MenAfriVac (A)	~75-95%	~75-95%	individuals aged 1-30 yrs	Previous anaphylaxis	1	multi-dose (10)	Do not freeze, VVM30	2,6
Influenza, seasonal	70-90%	70-90%	individuals ≥ 6 months	Previous anaphylaxis	1			
Varicella	~95%	~95%	>9 months	Previous anaphylaxis; immunodeficiency; pregnancy	1 (in some countries 2)			
Cholera (Dukorol)	~70%	No information	Above 1 year	Previous anaphylaxis, pregnancy depending on risk benefit analysis	3 doses (2-5 yrs), 2 doses (≥ 6 yrs)	single dose		136
Cholera (Shanchol)	≥ 65%	no information	Above 1 year	Previous anaphylaxis, pregnancy depending on risk benefit analysis	2	single dose		16,8

Vaccine	Reported Efficacy at full schedule[1]	Reported Efficacy at one dose (or less than full schedule)	Target age group in emergencies	Exclusions	Number of doses required/ administration course	Presentation	Stability	Cold chain volume (cm3/dose)
Typhoid	Vi -polysacch. ~70% ; Ty21a: 33-78%	no information		Previous anaphylaxis	Vi polys: 1 dose; Ty21a: 3-4 doses	multi-dose (20)		1,6
Hep A	94-100%	>90%	depends on epidemiology; risk groups	Previous anaphylaxis	2	two-dose		
YF	~99%	~99%	≥9 months	<6 months of age; pregnancy; previous anaphylaxis	1	multi-dose (5,10,20, 50)		6.3, 3.6, 1.5, 0.70
HPV (Cervarix)	~90-100%	no information	10-14 yrs	Previous anaphylaxis	3	singe and two dose		9.7 and 4.8
HPV (Gardasil)	~90-100%	no information	10-14 yrs	Previous anaphylaxis	3	single dose		15

[1] Information contained in the column on efficacy is derived from what is known at present concerning the vaccine. This information derived from published data. It is important to keep in mind that this information does not necessarily reflect the effectiveness of the vaccine in field conditions and is best conceptualized of as an upper bound.

[2] Extensive guidance on measles vaccination in emergencies exists. As reminder, this document does not supersede existing recommendations for humanitarian emergencies. See WHO/UNICEF Joint Statement on measles vaccination in emergencies.

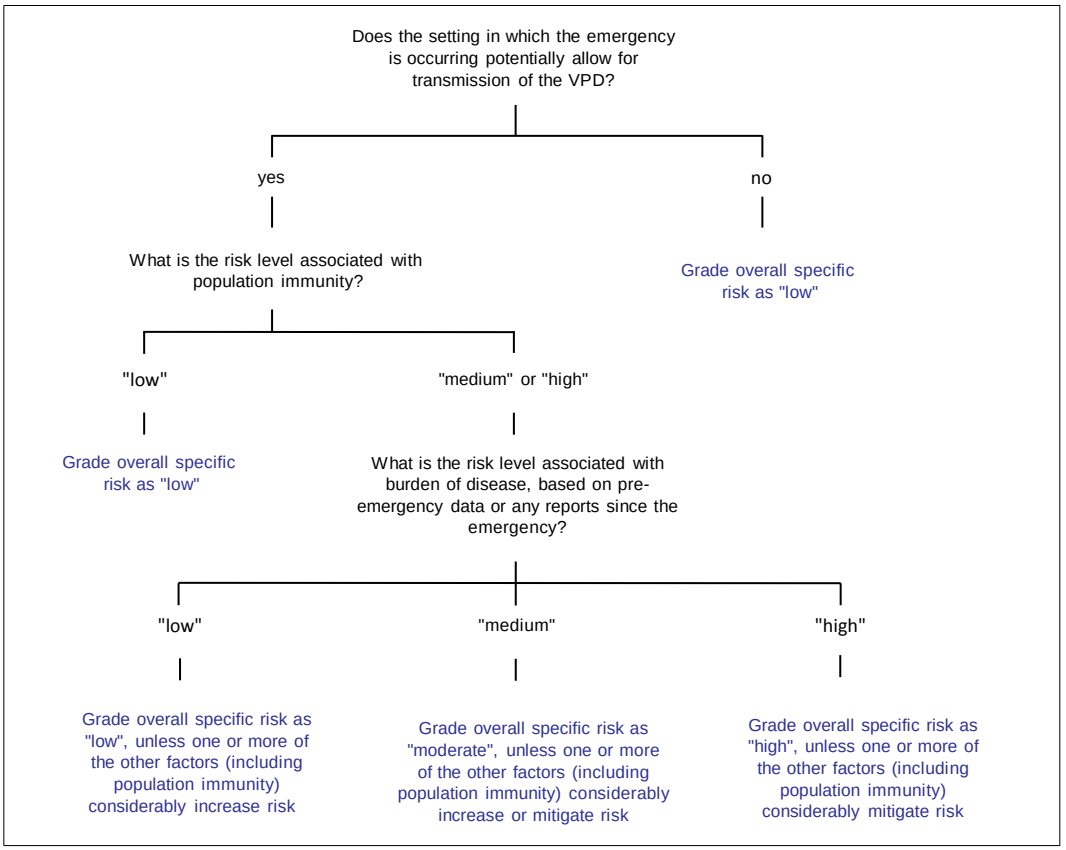
8. Annex 3: Disease-specific risk assessment worksheets

8.1 Guidance for going through each worksheet

While each worksheet differs, the overall procedure for going through each is similar:

- For each factor, the user should first consider whether the criteria suggested for the classification of "High" is met; if not, whether the criteria for the "Medium" classification are met; and if not, adopt a classification of "Low". Thus, the column for "Low" risk indicates absence of "High" or "Medium" level risk factors and is therefore the default for all situations not meeting "High" or "Medium" risk level criteria.
- Unless otherwise specified, the user is asked to assess whether any of the criteria listed under the High, Medium or Low categories, for any factor, are fulfilled (i.e. based on "and/or" logic). Note that for some criteria, and statements are instead made (these are explicitly stated whenever used).
- Having completed the worksheet, the user can refer to below as the basis for coming up with a summary classification of specific risk. Note that this flowchart is to be interpreted qualitatively, and that some recursive logic will be needed: for example, having established that the level of population immunity is insufficient in the second node of the flowchart, it may be necessary to reconsider its contribution to overall risk when coming up with the overall grading after the third node.

Figure 2: Algorithm for qualitatively synthesising VPD-specific worksheets into an overall grading of specific risk, for any VPD



Note also the following specific points:

- The criteria suggested to classify the level of risk due to population immunity are, as all other criteria in these worksheets, arbitrary and, as such, may occasionally be superseded by best judgment and special considerations specific to the emergency in question; however, thresholds suggested for the classification of "low" risk broadly reflect existing evidence on what is required to ensure a level of immunity sufficient to probably confer either herd (community) protection or a high level of individual protection.
- The occurrence of a 'large' outbreak, either in the past or in the present, is listed in some of the worksheets as a criterion for determining risk level, and a case definition of what constitutes a large outbreak (based on number of cases or deaths) is suggested where appropriate as a rough guide. Judgment should however be used to decide whether in a given setting an outbreak should be considered large or not (e.g. in a country where surveillance is known to be very incomplete, one should expect that the reported number of cases is a considerable underestimate of the true number, and adjust the case definition accordingly).
- 'n/a' in any risk column indicates 'not applicable', i.e. the for the VPD and specific factor in question risk should never be classified at that level.
- Sources for all data reported are the latest relevant WHO position papers unless otherwise indicated.

8.2 Risk assessment worksheets

8.2.1 Cholera

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• The population does not experience year-round cholera transmission; and – No vaccination has taken place before; or – A primary series campaign was conducted ≤3 y ago with a VC <50%; or – A primary series campaign was conducted >3 y ago, and ♦ No booster campaign was conducted ≤3 y ago; or ♦ A booster dose campaign was conducted ≤3 y ago with a VC <50%	• A primary series campaign was conducted ≤3 y ago with a VC of 50-74%; or • A primary series campaign was conducted >3 y ago with a VC ≥50%, and a booster dose campaign was conducted ≤3 y ago with a VC of 50-74%	• All other situations, i.e. absence of criteria warranting "high" or "medium" classification	The primary series consists of 2 doses, with a 1 dose booster. Current vaccines afford relatively short-lived immunity (about 2-3 years), but seem to confer strong transmission reduction effects, even at low VC. VC should be assessed among people ≥ 2y old.
Burden of disease	• The area has experienced one or more large outbreaks in the past 5y; • An outbreak is currently ongoing	• The area has experienced one or more outbreaks in the past 5y, but none of them large	• All other situations	The area refers to where emergency-affected people are currently living, and could be a city or a district/ region.
Geography, climate and season	• Widespread flooding resulting in potential large-scale contamination of water supply with excreta; dry weather	• The population lives alongside a large body of water (river, estuary, lake); • Warm surface water temperatures; • El Niño year; • Limited flooding	• All other situations	

Risk characterization:

Type of threat: Epidemic, either in a setting with no prior transmission or superimposed on an endemic pattern of transmission.

Timeframe: An outbreak could start within days of the onset of an acute emergency, particularly if sudden environmental change occurs (e.g. due to flooding) or there is mass displacement into a camp. Risk would remain high as long as risk factors, particularly overcrowding and insufficient water, sanitation and hygiene, persist. Any outbreak would propagate very quickly in a camp or urban setting, with local peaks within a few days; and diffuse more slowly (peaking within weeks) in a rural setting.

Age-specific burden: All age groups are at risk.

8.2.2 Diphtheria

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Primary series coverage* for children <1 yr old is <70%	• Primary series coverage* for children <1 yr old is 70-89% and there is no booster dose or natural boosting is low	• All other situations	*Primary series = 3 doses of DTwP- or DTaP-containing vaccine (DPT) provided through EPI • Achieving herd immunity requires >85% VC • Infection is thought to provide long-lasting, possibly lifelong immunity
Burden of disease	• The area has experienced one or more large outbreaks in the past 5y; and/or • An outbreak is currently ongoing	• The area has experienced one or more outbreaks in the past 5y, but none of them large	• All other situations	Global burden estimated at 140,000 deaths/year. • CFR can range from <1% to 5-6% (especially in Africa, SE Asia); CFR >10% have occurred in refugee camps
Geography, climate and season	• The disease is endemic in the area • Cold seasons	• High transmission season within the next 3-6 months	• All other situations	Perennial transmission in tropical countries Transmission increased during cold seasons in temperate countries

Risk characterization:

Type of threat: Diphtheria mainly occurs as sporadic cases or small outbreaks in endemic settings. Most cases are asymptomatic or have a mild clinical course (some fever, and diminished activity and irritability in some children). However, in severe cases pseudo-membranes form in the throat may cause airway obstruction. CFR from respiratory diphtheria is 5-10%.

Timeframe. The incubation period for diphtheria is typically 1-5 days. Onset is relatively slow and characterized by moderate fever and mild exudative pharyngitis. Communicability is generally <2 weeks, and rarely >4 weeks for respiratory diphtheria. Rare chronic cases of diphtheria may transmit for 6 or more months.

Age-specific burden. Pre-school and school-age children are the most commonly affected by respiratory diphtheria in endemic settings. Diphtheria is generally rare among both infants, presumably due to the presence of maternal antibody, and adults as a result of acquired immunity.

8.2.3 Hepatitis A

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Low transmission areas (see below) • Travel to (humanitarian relief workers) or displacement to high transmission areas (see below)	• Intermediate transmission areas (see below)	• High transmission areas (see below)	• Vaccine is not routinely used in EPI. Recommended as a 2 dose series. • Infection is thought to induce lifelong immunity. In high transmission areas, lifetime risk of infection is >90% and occurs mainly in childhood and is asymptomatic. Therefore, individual susceptibility, disease severity and thus burden of disease actually increase as transmission decreases.
Burden of disease	• Low transmission areas such as America, Canada, Europe, Japan, Australia and New Zealand with <30% seroprevalence	• Intermediate transmission areas such as North Africa, Middle East, Central Asia and South America with 30-70% seroprevalence	• High transmission areas such as Sub-Saharan Africa; Indian sub-continent; and Central America with >70% seroprevalence	• Global burden 1.5 million cases per year
Geography, climate and season	• Widespread flooding and destruction of sanitary infrastructure	• Limited flooding and damage to sanitary Infrastructure	• All other situations	Even within regions of high transmission, seroprevalence may be low due to variable economic development and status of sanitary infrastructure within a country or sub-region.

Risk characterization:

Type of threat: Not epidemic prone, although time-space clusters of cases could occur following poor hygienic and sanitary conditions in acute humanitarian emergencies. CFR is 0.1-0.3%, but can reach 1.8% for adults over 50. No chronic infection is known to occur. Disease severity generally increases with age, but complete recovery without recurrence is the rule.

Timeframe. The average incubation period is around 28 days (range: 15-50 days). Increase in incidence would mirror access to inadequate water and sanitation facilities in acute humanitarian emergencies.

Age-specific burden. Age-specific profiles of anti-HAV prevalence and disease incidence are endemicity-dependent. In highly endemic areas, most infections occur in early childhood (<5 years) and are asymptomatic. In intermediate endemicity countries, most cases occur in late childhood and early adulthood. In areas of low endemicity, hepatitis A occurs mainly in adolescents and adults in high risk groups.

8.2.4 Hepatitis B

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Primary series VC for children <1y old is <80%	• Primary series VC for children <1y old is 80-90%	• All other situations	Primary series = birth dose + 2 or 3 doses of HBV containing vaccine. 3-dose series induces protective antibody levels in >95% of recipients.
Burden of disease	• China, Southeast Asia, most of Africa, most Pacific Islands, the Amazon Basin • Sero-prevalence (HBsAg) > 8%	• Middle East, other parts of Asia • Sero-prevalence (HBsAg) 2-7%	• All other situations	Global burden estimated as 360m chronic infections and 600,000 deaths per year.
Geography, climate and season	• High incidence of consultations or hospitalisations for sexual violence-related conditions • Consistent reports of sexual violence being used as a weapon of war or systematically occurring during/after battles and attacks in civilian areas	• Moderate incidence of consultations or hospitalisations for sexual violence-related conditions • Some reports of sexual violence occurring during/ after battles and attacks in civilian areas	• All other situations	Sexual transmission possible; Risk of transmission related to sero-prevalence in the adult population.

Risk characterization:

Type of threat: Not epidemic prone, although time-space clusters of infections could occur following mass sexual violence events. World-wide distribution but prevalence of infection and patterns of transmission vary greatly by region and country. The outcome of HBV infection is age-dependent and includes asymptomatic infection, acute hepatitis B, chronic HBV infection, cirrhosis, and hepatocellular carcinoma. Most infections in high prevalence zones are asymptomatic with very little acute disease but long-term sequelae. In these areas, most transmission is perinatal or person-to-person in early childhood. Fulminant hepatitis with CFR of 70% develops in 0.1-0.6% of acute hepatitis cases. 5% of acute infections progress to chronic HBV infection with risk decreasing with age.

Timeframe: Incubation period of 30-180 days. Increases in transmission would mirror patterns in the incidence of sexual violence, but most disease manifestations would occur many years later.

Age-specific burden: Acute hepatitis B occurs in 1% of perinatal infections, 10% of early childhood (1-5 y), and 30% of late infections (people aged >5y). Chronic hepatitis B infection develops in 80-90% of perinatal infections, 30% of children infected before age 6, and <5% of adults. Maybe tie more with target age range for vaccination in an emergency.

8.2.5 Hemophilus influenzae *type B (Hib) disease*

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Primary series routine VC among children 12-59m old is <50%	• Primary series routine VC among children 12-59m old is 50-74%	• All other situations	The primary series consists of 3 doses of Hib-DPT-HepB conjugate vaccine, during the EPI schedule. Hib transmission has been shown to rapidly decrease to near-zero even at low vaccination coverage.
Burden of disease	• Child mortality ratio pre-emergency ≥100 per 1000 live births • Hib-attributable mortality rate among children 1-59m old estimated at ≥100 per 100 000	• Child mortality ratio pre-emergency 25-99 per 1000 live births • Hib-attributable mortality rate among children 1-59m old estimated at 10-99 per 100 000	• All other situations	Generally, Hib is the second most important cause of pneumonia, but local exceptions are common. Studies of Hib carriage or pneumonia aetiology may be available from the emergency-affected region.
Geography, climate and season	• Most households are exposed to outside temperatures due to poor shelter, lack of blankets, lack of heating etc.; and – Cold climate; or – High altitude with cold nights; or – Cold/wet season within the next 3 months; or – Most households use fossil fuels to cook or heat	• A substantial proportion of households are exposed to outside temperatures due to poor shelter, lack of blankets, lack of heating etc.; and – Cold climate; or – High altitude with cold nights; or – Cold/wet season within the next 3 months; or – Most households use fossil fuels to cook or heat	• All other situations	

Risk characterization:

Type of threat: Exacerbation of the endemic pattern of Hib disease (which includes pneumonia, meningitis and invasive bacterial disease), due to higher transmission, greater risk of progression to disease and higher CFR.

Timeframe: As soon as the emergency starts, and for as long as emergency conditions persists.

Age-specific burden: Children under 2y bear the highest burden.

8.2.6 Human papilloma virus (HPV) disease

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• No vaccination programme; or • Primary series VC for girls 9-13yr <50%	• Primary series VC for girls 9-13yr 50-74%	• All other situations	Primary series = base line dose followed by 2 doses of HPV containing vaccine. 3-dose series induces protective antibody levels in >95% of recipients.
Burden of disease	• Highest burden in the developing world (Latin America, Caribbean, sub-Saharan Africa, Melanesia and south-central and south-East Asia)	• Intermediate burden in transition economies including Eastern Europe	• All other situations	• Global burden 1-50 per 100,000 females • 500,000 cervical cancer cases and 260,000 related deaths per year, 80% in the developing world
Geography, climate and season	• High incidence of consultations or hospitalisations for sexual violence-related conditions • Consistent reports of sexual violence being used as a weapon of war or systematically occurring during/after battles and attacks in civilian areas	• Moderate incidence of consultations or hospitalisations for sexual violence-related conditions • Some reports of sexual violence occurring during/ after battles and attacks in civilian areas	• All other situations	• Overcrowding conditions in acute humanitarian emergencies can increase the risk of sexual violence

Risk characterization:

Type of threat: Not epidemic prone, may manifest up to 20 years later in form of cervical cancer among infected women. Time-space distribution of cervical cancer cases may follow patterns of sexual abuse in humanitarian emergencies.

Timeframe: In most cases, HPV infections are asymptomatic and clear spontaneously within 1-2 years. The average interval between initial HPV infection and cervical cancer development is 20 years.

Age-specific burden: HPV prevalence in populations peaks at or around the age sexual debut and gradually decreases with age, although a second peak at older ages is observed in some populations. Up to 70% of sexually active young women will acquire infection within the first 5 years after sexual debut, about half of which are of high-risk genotype. In many developed countries, there is a steady rise in cervical cancer incidence from mid-20s to mid-40s, after which rates become relatively constant. Most cervical cancer cases are diagnosed in women >40 years.

8.2.7 Influenza (seasonal)

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Geography, climate and season	• Within 2 months of high transmission season	• Within 3-4 months of high transmission season	• All other situations	High in winter months of temperate countries All year round transmission in some tropical countries with two peaks each year

Risk characterization:

Type of threat: Influenza A virus can cause large epidemics with moderate to high mortality. Malnutrition and poor access to health care in acute humanitarian emergencies contribute to higher rates of complications and death. Clinical attack rates during annual epidemics range from 5%-20% and may exceed 20% in crowded camp settings in humanitarian emergencies. The highest CFRs are observed among infants <6 months.

Timeframe: The average incubation period for influenza is 2 days (range: 1-4 days). Epidemics or outbreaks typically last 6-8 weeks or longer.

Age-specific burden: Rates of serious disease and complications are highest among children <2 years, adults >64 years, and persons of all ages with certain chronic medical conditions. Pregnant women may also experience increased severity of disease, especially after the first trimester. Over 90% of influenza deaths occur among those aged 65 and older.

8.2.8 Japanese encephalitis

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Primary series routine VC among at risk population is <80%; and • SIA done >5y ago; and • No large epidemic (1000s of cases) within last 5y • Naïve population moving into endemic area	• Primary series routine VC among at risk population is 80-90%; and • SIA done 2-5y ago; and • No large epidemic (1000s of cases) within last 5y	• Primary series VC among at risk population is >90% • Large epidemic within last 5y affecting same population • SIA within last 2y with coverage >80%	The primary series consists of 1 (Chimeric live attenuated vaccine) or 2 doses (other vaccines).
Burden of disease	• Southeast Asia, Indonesia • Endemic area with known large epidemics w/n past 10y • Incidence >100/100,000/ y • Evidence of ongoing outbreak	• East Asia (Japan, Korea, China), northern Australia • Endemic area with known outbreaks (100s of cases) • Incidence of 10-100 100,000/ y	• All other situations	Global burden of disease is estimated at 50,000 cases, 10,000 deaths, and 15,000 cases of long-term sequelae per year.
Geography, climate and season	• High season currently or within the next 3 months; and • rural area; and • widespread flooding	• High season within the next 3-6 months; and • rural or peri-urban area; and • small scale flooding	• All other situations	Primarily in rural agricultural areas, but can occur in peri-urban centres—rare in urban areas. High transmission season is usually Apr-Oct in temperate climates; less seasonality in tropical climates but increases with rainy season. Flooding can result in vector proliferation.

Risk characterization:

Type of threat: Hyper-endemic outbreaks in endemic areas (e.g. Southeast Asia, Indonesia). Seasonal epidemics can be explosive with thousands of cases over a period of several months. About 1 in 250-500 infected individuals manifest clinical disease; of those with clinical disease, the CFR is 20-30% and another 30-50% experience severe sequelae. Outbreaks have occurred in several previously non-endemic regions.

Timeframe: The incubation period is 4-14 days. Outbreaks can occur 1-2 months after a trigger event (e.g. flooding).

Age-specific burden: The vast majority of cases are <15y old in endemic areas, and <10y in hyper-endemic areas. In areas with high routine JE VC, incidence declines and cases shift to older children and adults. Children <5y old experience the highest morbidity and CFR, but in naïve populations all age groups may be at risk.

8.2.9 Measles

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• First dose coverage for children <18mo is <70%	• First dose coverage for children <18mo is 70-89%	• All other situations	*Primary series = 2 doses of Measles containing vaccine (MCV) either through EPI or SIA. • VC complicated in areas giving the 2nd dose through SIAs. • Infection is thought to provide long-lasting/lifelong immunity
Burden of disease	• The area has experienced one or more large outbreaks in the past 5y; and/or • An outbreak is currently ongoing	• The area has experienced one or more outbreaks in the past 5y, but none of them large	• All other situations	A large outbreak could consist of >100 cases or >10 deaths. Global burden estimated at 20 million cases/year; 140,000 deaths/year. • CFR can range from <1% to 5-6% (higher in Africa, SE Asia); CFR >10% have occurred in refugee camps
Geography, climate and season	• Sub-Saharan Africa • South and South-east Asia • High transmission season occurring currently or within the next 3 months	• High transmission season within the next 3-6 months	• All other situations	Likely that seasonal climate patterns influence population density that in turn increases the transmission of measles. Strongest seasonal affect is in the Sahel, where cases peak in the dry season as people congregate in villages and towns. In other parts of Africa cases peak in the cool rainy season. Local experts should be consulted on local seasonal changes

Risk characterization:

Type of threat: Epidemics occur in population groups where the number of susceptibles builds up to > the number of the birth cohort. Measles outbreaks can result in many deaths in unvaccinated individuals, especially among young, malnourished children. The risk of death is greatly reduced in people who are vaccinated; therefore in areas with high vaccination coverage the risk of death is also lower as most cases are in vaccinated individuals.

Timeframe: Incubation period of 10-14 days. Measles is highly infectious. Outbreaks can occur rapidly (<1 month) in crowded settings w/ high proportion of non-immune population.

Age-specific burden: Children <5yrs are especially vulnerable; children 5-14 generally have lower rates of complications or death but should also be vaccinated. The risk of complications and death increases with age beginning around 15y, and recent epidemics have featured considerable transmission in young adults, warranting consideration of these age groups for vaccination.

8.2.10 Meningococcal meningitis

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Conjugate vaccine not in EPI programme or EPI VC <80%; and • SIA conjugate vaccine VC within the past 3 years <80%; and • No large outbreaks in the last 3 years	• VC of conjugate vaccine 80-89% through EPI or SIA in last 3 years	• All other situations	MenA conjugate vaccine usually provided through SIA for age 9 months to 18 years (up to 29yr) followed by inclusion in EPI
Burden of disease	• The area has experienced one or more large outbreaks in the past 5y; • An outbreak is currently ongoing • Incidence >10 cases/100,000 population	• The area has experienced one or more outbreaks in the past 5y, but none of them large • Incidence 2-10 cases/100,000 population	• All other situations	High burden in meningitis belt of Africa (21 countries) - rates of sporadic infection 1-20 case /100 000 and up to 1000 cases/100 000 during epidemics
Geography, climate and season	• High transmission season occurring currently or within the next 2 months	• High transmission season within the next 3-4 months	• All other situations	Incidence is highest in dry season in the tropics especially in the meningitis belt; spring and winter seasons in temperate countries

Risk characterization:

Type of threat: . Group A meningococcus is associated with large-scale epidemics, particularly in the 'meningitis belt' in sub-Saharan Africa with regular epidemics every 8-12 years, observed incidence rates exceeding 1,000 cases per 100,000, and CFRs of 10-15%. Group B disease is more commonly observed in developed countries.

Timeframe: Incubation period is typically 3-4 days (range: 2-10 days). Outbreaks of Group A can develop within 2 weeks among susceptible populations.

Age-specific burden: Infants (3-12 months) have the highest risk of meningococcal disease. Incidence rates decrease after infancy and then increase in adolescence and young adulthood. During epidemics, however, rates may rise in older children and young adults.

8.2.11 Mumps

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• VC with 2 doses in children <18m old is <50%; and • No large outbreaks in the last 3 years	• VC with 2 doses in children <18m old is 50-79%; and • No large outbreaks in the last 3 years	• All other situations	2 doses of mumps containing vaccine (MMR) should be provided during EPI schedule. Infection is thought to provide long-lasting, possibly lifelong immunity. A large outbreak could feature > 100 cases.
Burden of disease	• n/a	• High child mortality ratio (≥100 deaths per 1000 live births); • The area has experienced one or more large outbreaks in the past 5y; • An outbreak is currently ongoing	• All other situations	Annual incidence of mumps in the absence of vaccination is in the range of 100–1000 cases/100 000 population, with epidemic peaks every 2–5 years in most parts of the world. CFR is low (0.01%), but permanent sequelae including paralysis, seizures, cranial nerve palsies and hydrocephalus can occur.
Geography, climate and season	• n/a	• High transmission season occurring currently or within the next 3 months in temperate countries	• All other situations	Perennial transmission in tropical climates; in temperate zones, cases peak in late winter to early spring.

Risk characterization:

Type of threat. Mostly an endemic disease; epidemics can occur but with low CFR. –

Timeframe. An outbreak could start within days or weeks after the onset of an acute emergency in a situation of overcrowding. The incubation time averages 16-18 days (range: 12-25 days).

Age-specific burden. Mumps is predominantly a childhood disease with peak incidence varying globally but typically at 5-9 years. Mumps can also affect adolescents and adults, in whom complications, including meningitis and orchitis, are more common.

8.2.12 Pertussis

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Primary series VC in children <1y old is <50%	• Primary series VC in children <1y old is 50-79%	• All other situations	Primary series = 3 doses of DTwP- or DTaP-containing vaccine (DPT) provided through the EPI schedule. Natural infection does not confer long term immunity.
Burden of disease	• High child mortality ratio (≥100 deaths per 1000 live births); • The area has experienced one or more large outbreaks in the past 5y; • An outbreak is currently ongoing	• Moderate child mortality ratio (25-100 per 1000 live births); • The area has experienced one or more outbreaks in the past 5y, but none of them large	• All other situations	Ongoing transmission in all countries. In 2008 approximately 16 million cases of pertussis occurred globally, 95% of which were in developing nations, and which resulted in 195,000 child deaths. Outbreaks typically occur every 3-4 years. There is no consistent seasonal pattern of incidence. A large outbreak could feature > 100 cases.

Risk characterization:

Type of threat. Epidemic super-imposed onto existing pattern of transmission. An exacerbation of the existing burden could occur even without an epidemic due to factors that increase the CFR, such as malnutrition and low access to curative health services.

Timeframe. An exacerbation of the typical burden of pertussis could occur immediately after the emergency's onset. An outbreak could also start as soon as days or weeks after the emergency's onset if there is overcrowding, or a few months into the emergency if cohorts of unvaccinated infants accumulate due to disrupted routine vaccination. The typical incubation period for pertussis is 9-10 days (range: 6-20 days).

Age-specific burden. The highest incidence of pertussis is in children aged <5 years, particularly among infants <6 months. CFR in unimmunised children is 3-4% for children <1y old and 1% for children 1-4 y old. Incidence, morbidity and mortality are higher in females than males. Mortality in populations with high VC is low, usually occurring in infants too young to have received the primary series.

8.2.13 Pneumococcal disease

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Primary series routine VC among children 12-59m old is <50%	• Primary series routine VC among children 12-59m old is 50-79%	• All other situations	The primary series consists of at least 2 doses of pneumococcal conjugate vaccine by 12m of age, at least 10-valent, administered during the EPI schedule. Some countries also offer a booster in the second year of life.
Burden of disease	• Child mortality ratio pre-emergency ≥100 per 1000 live births; • Pneumococcus-attributable mortality rate among children 1-59m old estimated at ≥100 per 100 000 • Local pneumonia aetiology studies showing that vaccine-type pneumococcal serotypes, taken together, are the main causative agent	• Child mortality ratio pre-emergency 25-99 per 1000 live births; • Pneumococcus-attributable mortality rate among children 1-59m old estimated at 10-99 per 100 000 • Local pneumonia aetiology studies showing that vaccine-type pneumococcal serotypes, taken together, are among the top three causative agents	• All other situations	Most pneumococcal mortality is due to pneumonia, with the remainder attributable to meningitis or other invasive manifestations. Generally, pneumococcus is the main cause of pneumonia, but local exceptions are common. Studies of pneumonia aetiology may be available from the emergency-affected region, and should be consulted.
Geography, climate and season	• n/a	• Most households are exposed to outside temperatures due to poor shelter, lack of blankets, lack of heating etc.; and – Cold climate; or – High altitude with cold nights; or – Cold/wet season within the next 3 months; or – Most households use fossil fuels to cook or heat	• All other situations	Exposure to cold temperatures or indoor fuel smoke is known to increase the risk of disease progression to pneumonia.

Risk characterization:

Type of threat. Exacerbation of the endemic pattern of pneumococcal disease (which includes pneumonia, meningitis and invasive bacterial disease), due to higher transmission, greater risk of progression to disease and higher CFR. Overcrowding, malnutrition, insufficient health services and other factors listed above may cause this.

Timeframe. As soon as the emergency starts, and for as long as the above risk factors remain highly prevalent.

Age-specific burden. Children under 5y bear the highest burden. Old people are also at high risk and may partially be protected by pneumococcal polysaccharide vaccine, but this vaccine is only offered in very few, high-income countries. Old people can be protected indirectly by vaccinating children.

8.2.14 Poliomyelitis

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Primary series VC in children <18m old is <80%, regardless of whether transmission is occurring; • In an area that has recorded >1 polio case in the last 6m, the last Supplementary Immunization Activity (SIA) was – done >6m ago; or – done within the last 6m but with VC <80%	• Primary series VC in children <18m old is 80-89%, regardless of whether transmission is occurring; • In an area that has recorded >1 polio case in the last 6m, or in a bordering area with high border traffic, the last SIA was done within the last 6m but with VC <90%	• All other situations	Primary series = 3 doses of Inactivated Polio Vaccine (IPV) or Oral Polio Vaccine (OPV) in all areas + OPV birth dose in areas with high risk of transmission. Countries at risk also carry out regular SIAs. Infection with one type of poliovirus does not convey immunity against other types.
Burden of disease	• The area has recorded >1 polio case in the last 6m; • The country in which the emergency is occurring (or from which refugees have fled) is endemic for polio (Nigeria, Pakistan, Afghanistan, Chad, the DRC or Angola as of 2012);	• The area has recorded >1 polio case in the last 12m;	• All other situations	An 'area' could be a region, province or large urban agglomeration. About 1 in 200 infections results in paralysis. The CFR of paralytic polio is 2-5% among children and up to 15-30% among adults. Elimination has been achieved in the Americas, Europe and the Western Pacific but all areas remain at risk.
Geography, climate and season	• High transmission season occurring currently or within the next 3 months • The area has a history of importation from and/or high border traffic with an endemic country	• High transmission season occurring within the next 3-6 months; • The area experiences high border traffic with an area that has recorded >1 polio case in the last 12m;	• All other situations	Transmission typically peaks in the summer months in temperate climates, but occurs year-round in tropical climates with peaks in some areas.

Risk characterization:

Type of threat. In endemic areas, clusters of cases commonly occur. Elsewhere, the main threat is reintroduction of the virus, with snowball effects for global eradication efforts. Reintroduction could manifest as small clusters or even single cases. In an endemic country or where transmission has been reintroduced, large outbreaks (>200 cases) can occur if population immunity is low and other factors such as poor water, sanitation and hygiene and overcrowding are present.

Timeframe. Re-introduction and/or a large outbreak could occur within weeks of the emergency's onset. The incubation period is 7-10d; infectiousness lasts 3-6 weeks.

Age-specific burden. Cases usually occur in children <5years, with highest burden among those <36 months; however, epidemics affecting adults have recently occurred where the virus has been reintroduced after decades of absence.

8.2.15 Rotavirus

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Primary series VC for children <1y old is <50%	• Primary series VC for children <1y old is 50-79%	• All other situations	Primary series: 3 doses of RotaTeq or 2 doses of Rotarix. Prior infection does not lead to immunity, but reduces chances of severe disease in subsequent episodes.
Burden of disease	• Child mortality ratio pre-emergency ≥100 per 1000 live births; • Sub-Saharan Africa and South Asia; • Annual rotavirus-attributable mortality rate ≥100 deaths per 100,000 children <5y; • ≥15% of <5y mortality is due to diarrhoea; • Ongoing cluster of diarrhoea cases	• Child mortality ratio pre-emergency 25-99 per 1000 live births; • Central Asia, South-east Asia, Central and South America; • Annual rotavirus-attributable mortality rate 50-99 deaths per 100,000 children <5y; • 10-14% of <5y mortality is due to diarrhoea	• All other situations	Global burden of disease is estimated at >500,000 deaths, 2.3 million hospitalizations and 114 million episodes. There is a wide clinical spectrum from mild to severe diarrhoea, but the first exposure usually most severe. Global CFR is <1% but varies widely by country's development status. >80% of deaths occur in developing countries.
Geography, climate and season	• High season currently or within the next 3 months in temperate climate	• High season within the next 3-6 months in temperate climate	• All other situations	In temperate climates, incidence peaks in the winter; in tropical settings, transmission is perennial.

Risk characterization:

Type of threat. Exacerbation of endemic disease pattern due to more intense transmission and/or increase in the CFR as a result of malnutrition and low access to health services. Not epidemic prone, but clusters of cases can occur.

Timeframe. Excess burden could occur from the very start of the emergency or as soon as the season starts. The incubation period is <48 hours.

Age-specific burden. Severe rotavirus gastroenteritis (and mortality) is primarily limited to children 6-24 months; the initial episode in low-burden, industrialised countries is usually between 2-5 years, but within the first year of life in high-burden countries.

8.2.16 Rubella

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• One dose VC for children <1y old is <50%	• One dose VC for children <1y old is 50-79%	• All other situations	One dose of rubella containing vaccine should be given with measles.
Burden of disease	• n/a	• The area has experienced one or more large outbreaks in the past 5y	• All other situations	In the absence of vaccination, rubella occurred worldwide with epidemics every 5-9yrs, but has now been eliminated from the Region of the Americas. A large outbreak could consist of >100 cases or >10 deaths.
Geography, climate and season	• High season currently or within the next 3 months in temperate climate	• High season within the next 3-6 months in temperate climate	• All other situations	In temperate climates cases peak in late winter/early spring.

Risk characterization:

Type of threat. Rubella is primarily a mild, self-limiting disease with low CFR (1/10,000 cases). Its public health importance is related to effects on the foetus associated with Congenital Rubella Syndrome or CRS (approximately 90% of infections in the first trimester of pregnancy result in congenital defects). Increased transmission would result in higher incidence of CRS. Large epidemics with hundreds or thousands of cases can occur, but their extent and periodicity is highly variable.

Timeframe. An outbreak or increased transmission could occur within days or weeks of the emergency's onset. The incubation period is 12-23 days (average 14 days).

Age-specific burden. Primarily a childhood disease affecting those <5 years. In settings with high VC, age of susceptibility can increase.

8.2.17 Tetanus

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	Neonatal tetanus: • <50% VC of the primary series among pregnant women Non-neonatal tetanus: • <50% VC of the primary series among infants • <50% VC of age-appropriate booster doses among older children and adults	Neonatal tetanus: • 50-79% VC of the primary series among pregnant women Non-neonatal tetanus: • 50-79% VC of the primary series among infants • 50-79% VC of age-appropriate booster doses among older children and adults	• All other situations	Primary series: 2 doses of TT or Td for women; and 3 doses of DPT for children administered during in fancy as part of EPI schedule.
Burden of disease	Neonatal tetanus: • Child mortality ratio pre-emergency ≥100 per 1000 live births Non-neonatal tetanus: • n/a	Neonatal tetanus: • Child mortality ratio pre-emergency 25-99 per 1000 live births Non-neonatal tetanus: • n/a	• All other situations	In 2008, neonatal tetanus was estimated to represent approximately 65-75% of the estimated 90,500 total tetanus deaths worldwide. CFR varies between 10-70% depending on treatment availability.
Geography, climate and season	Non-neonatal tetanus: • Reports of a very large number (>10,000) of people with untreated, recently sustained injuries.	Non-neonatal tetanus: • Reports of a considerable number (1000-10,000) of people with untreated, recently sustained injuries.	• All other situations	

Risk characterization:

Type of threat. For neonatal tetanus, an exacerbation of the endemic pattern of disease, with more cases and higher CFR, may occur. Any increase in non-neonatal tetanus cases due to mass injuries will resemble an epidemic, even though there will be negligible person to person transmission.

Timeframe. An increase in neonatal tetanus cases and deaths could occur immediately if there is a sudden disruption in obstetric care and safe births. However, a more progressive increase could also occur if the emergency is protracted and routine vaccination/antenatal care deteriorates with time. The vast majority of non-neonatal cases will present within the first 2-3 weeks after a mass injury event.

Age-specific burden. Neonatal tetanus affects neonates, usually 3-14 days after birth. The largest proportion of non-neonatal cases in developing countries is among male older children and young adults, but the age and gender distribution may vary depending on who is at greatest risk of injuries in an emergency.

8.2.18 Tuberculosis (meningitis, disseminated disease)

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Single-dose Bacillus Calmette Guerin (BCG) VC <50% among children <5y old	• BCG VC 50-74% among children <5y old	• All other situations	The vaccine should be administered as soon as possible after birth. Vaccination only protects against meningitis and disseminated disease.
Burden of disease	• n/a (refers only to tuberculosis meningitis and disseminated disease)	• TB period prevalence (all forms) ≥ 200 per 100 000 people (all ages)	• All other situations	Period prevalence of any TB may be considered a proxy of the burden of TB meningitis and disseminated disease in children (the latter condition is difficult to monitor through routine surveillance). TB meningitis and disseminated disease are fairly rare, though severe, manifestations and, as such, their burden should never be considered high.

Risk characterization:

Type of threat: An exacerbation of the endemic pattern of TB meningitis and disseminated disease cases.

Timeframe: Excess cases could start occurring a few weeks/months after the emergency's onset if the risk of TB transmission increases straight away due to overcrowding, HIV/AIDS burden and other general risk factors. Generally, most cases of TB meningitis occur within a year of primary infection, but, because infection may occur at various times during early life, most excess cases due to high transmission and insufficient VC would likely occur after the acute emergency, as the cohort of neonates that missed their BCG vaccination goes through the childhood years.

Age-specific burden: Mainly children <5y old in settings with high TB transmission, and mainly adults in settings with low TB transmission. Globally, children account for most of the burden.

8.2.19 Typhoid fever

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Asia; • The area has experienced one or more large outbreaks in the past 5y; • An outbreak is currently ongoing	• The area has experienced one or more outbreaks in the past 5y, but none of them large	• All other situations	Annual global incidence is 21 million cases. CFR is 1-4%. 90% of deaths occur in Asia. A large outbreak could consist of >100 cases or >10 deaths.
Geography, climate and season	• Widespread flooding or other event resulting in potential large-scale contamination of water supply with excreta	• Limited flooding or other event resulting in potential large-scale contamination of water supply with excreta	• All other situations	

Risk characterization:

Type of threat. Epidemic.

Timeframe. An outbreak could occur days or weeks after major disruption to water supplies, and would remain a threat for as long as people are exposed to contaminated water. The incubation period is normally 8-14 days (range: 3-60 days). Around 10% of untreated patients remain infectious for 3 months after symptom onset.

Age-specific burden. A characteristic age-specific incidence is often observed, with very low incidence in infants <1 year, low incidence in children 2-4 years (although this may be greater in some countries in Asia), peak incidence in school-aged children (5-19 years), and low incidence in adults >35 years. CFR is 4% in children aged <5y, versus 0.4% in older children. Although infants may manifest severe clinical forms of typhoid fever, infection in children <2y old is typically mild and non-descript.

8.2.20 Varicella

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Varicella single-dose VC among children <10y old is <50%; and • <50% of children are infected before age 10y (if known)	• Varicella single-dose VC among children <10y old is 50-74%; and • <50% of children are infected before age 10y (if known)	• All other situations	Vaccination (single dose to older children) is offered in very few industrialised countries. Infection induces lifelong immunity.
Burden of disease	• n/a	• n/a	• All other situations	Transmission seems more intense intemperate climates, where at least 90% of the population has been infected and is thus immune by age 15y. In tropical settings sero-prevalence is lower. Usually a benign childhood disease, very occasionally complicated by varicella zoster virus-induced pneumonia or encephalitis. CFR is 0.001% for children aged 5-9 years but 0.02% for adults.

Risk characterization:

Type of threat. Periodic large outbreaks may occur with an inter-epidemic cycle of 2-5 years, and could manifest in an acute emergency if other factors such as overcrowding are present.

Timeframe. An outbreak could occur weeks after the onset of an emergency in an overcrowded setting. The incubation period is usually 14-16 days (range: 10-21 days) and infectiousness lasts for 10-21 days following infection.

Age-specific burden. In temperate climates, varicella affects at least 90% of the population by age 15y. In tropical areas, a greater proportion of cases and deaths would be among adults.

8.2.21 Yellow fever

Table to assess risk from VPD-specific factors:

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• No previous vaccination campaigns or routine vaccination; • Naïve or unvaccinated population moving into endemic area	• Single dose VC <50% among children <5y old; and • Vaccination campaign done within the last 10y but with VC <50%	• All other situations	Vaccination with a single dose should be administered with measles as part of routine schedules, or in campaigns. Vaccination provides protection for at least 10 years, while infection provides lifelong immunity.
Burden of disease		• Tropical regions of Africa and South America; • Outbreak in the area within the past 5 years	• All other situations	CFR among unvaccinated people is about 0.1% per infection. 90% of reported cases occur in Africa. 30,000 deaths are believed to occur annually.
Geography, climate and season		• Middle or end of the rainy season • Emergency is occurring in a jungle/forest setting	• All other situations	

Risk characterization:

Type of threat. Epidemic.

Timeframe. Difficult to predict, but likely to be concomitant with the rainy season. Incubation period is approximately 3-6 days.

Age-specific burden. Children are at greatest risk given that the prevalence of natural immunity accumulates rapidly with age. High attack rates in children (>70%) typically may reflect areas where older individuals are protected by prior vaccination campaigns. CFR is greatest among young children and the elderly.