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Vaccination in acute humanitarian emergencies: a framework for decision making

Immunization, Vaccines and Biologicals

World Health Organization

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Abbreviations and acronyms

AIDS	acquired immunodeficiency syndrome
BCG	bacille Calmette-Guérin (vaccine)
CMR	crude mortality rate
CE-DAT	complex emergency database
CFR	case-fatality ratio
CRS	congenital rubella syndrome
DHS	Demographic and Health Survey
Dt	diphtheria toxoid
DTaP	diphtheria, tetanus, acellular pertussis (vaccine)
DTP	diphtheria-tetanus-pertussis vaccine
DTwP	diphtheria, tetanus, whole cell pertussis (vaccine)
EPI	Expanded Programme on Immunization
EWARN	Early Warning Alert and Response Network
FEWS	famine early warning systems
GAM	global acute malnutrition
HAART	highly active antiretroviral therapy
HAV	Hepatitis A virus
HbsAG	Hepatitis B surface antigen
HCW	health-care worker
HepB	Hepatitis B
HeRAMS	Health Resources Availability Mapping System
Hib	Haemophilus influenzae type b
HIV	human immunodeficiency virus
HPV	human papillomavirus

ICG	International Coordinating Group
IFRC	International Federation of Red Cross
JE	Japanese encephalitis
MICS	Multiple Indicator Cluster Survey
MMR	measles, mumps & rubella (vaccine)
MSF	Médecins Sans Frontières
NGO	non-governmental organization
NRA	national regulatory authority
OMP	outer membrane protein
OPV	oral polio vaccine
PCV	pneumococcal conjugate vaccine
ProMED	Program for Monitoring Emerging Diseases
PRP	polyribosylribitol phosphate
RCT	randomized controlled trial
SAGE	Strategic Advisory Group of Experts on Immunization
SAM	severe acute malnutrition
SIA	supplemental immunization activity
TB	tuberculosis
TT	tetanus toxoid
U5DR	under 5 death rate
UN NICS	UN National Influenza Centres
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
VC	vaccination coverage
VPD	vaccine-preventable disease
VVM	vaccine vial monitor
WHO	World Health Organization
YF	yellow fever

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 (VPD), and often decision-makers must decide on use or non-use of one or more vaccines. The WHO SAGE reviewed current literature and practice experiences relating to decision-making on vaccine use at the onset of 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 which vaccines, if pre-emptively and properly delivered at the outset of an emergency, would constitute high priority public-health interventions and would reduce avoidable death and disease. It will assist the user to determine thoughtfully, deliberately, ethically and rationally 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 VPD 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, including careful consideration of key ethical principles and prevailing contextual factors.

1.2.1 Epidemiological risk assessment

In this section, a systematic desk-based process for assessing the epidemiological risk of each VPD following an acute emergency, is described. 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 on 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 4 and 5) 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, impact in terms of severity/caseload, age groups affected).

1.2.2 Vaccine characteristics

Key vaccines characteristics that should be considered in reaching a decision whether a vaccination intervention should be implemented include: vaccine efficacy using the recommended full schedule and efficacy obtained using less than the full schedule; method of vaccine administration; contraindication and vaccine safety considerations; WHO prequalification status (Chapter 2); formulation of the vaccine (e.g. most freeze-dried vaccine should never be kept longer than six hours 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 other supplies required for vaccine delivery, 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 an accurate estimation of the target population, including age range, and prioritization of high-risk groups or geographical areas. Other key considerations for optimal implementation include operational planning, logistics, adequate staffing, social mobilization, and informed consent and monitoring.

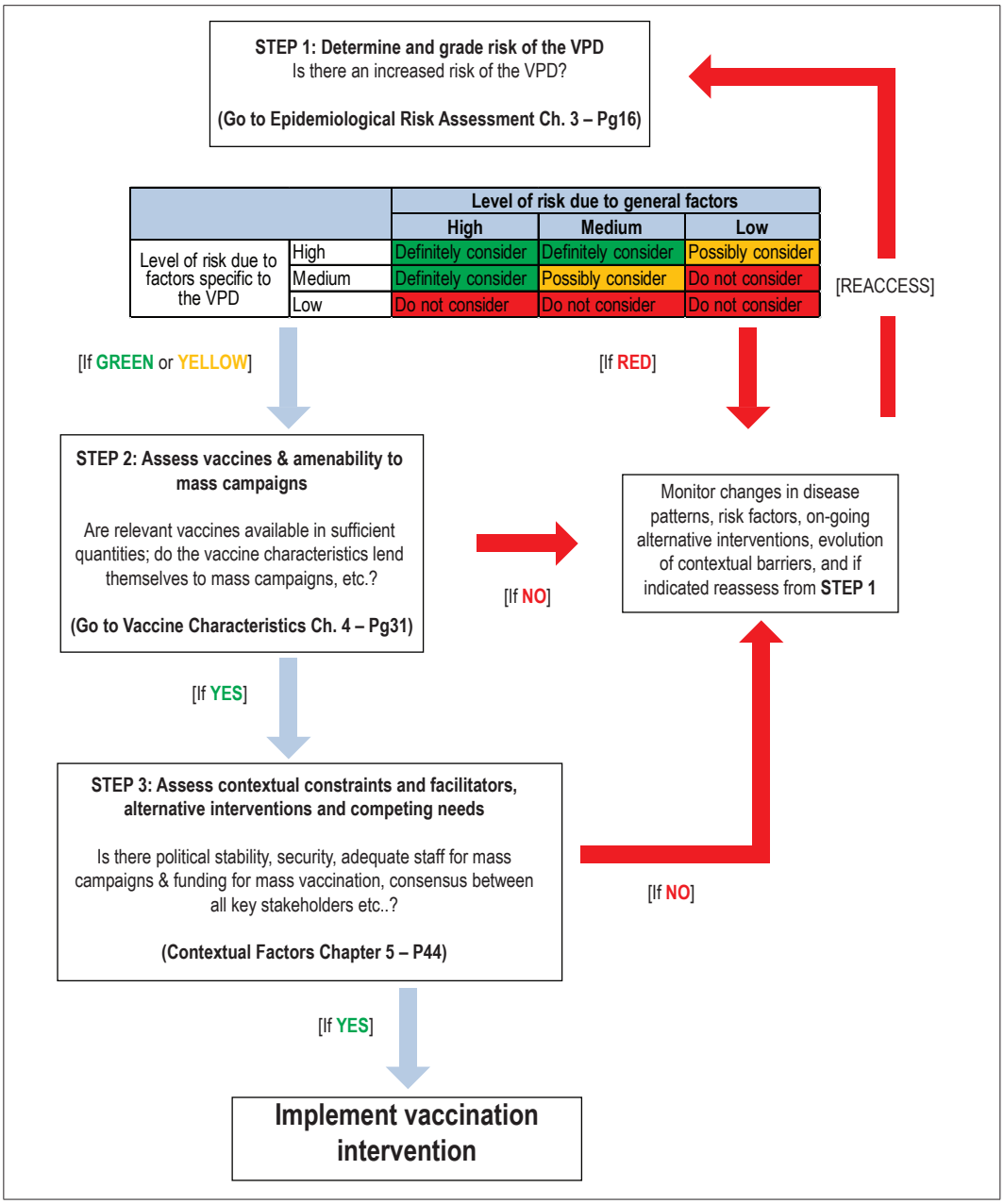
1.2.3 Contextual factors

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 campaign, ethical considerations, such as inclusion of host communities in the vaccination campaign 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 the use of vaccines in acute humanitarian emergencies, and 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 VPDs, 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 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 six case studies that were actively conducted by the Working Group, 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 which participated in such decisions 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 of the 23 documented experiences were actual guidelines or tools cited as justification for decision-making on a vaccination.
- Only two decision-making tools were identified among the 38 guidance documents reviewed. However, these were not sufficiently detailed to optimally support decision-making.

- 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 "immediately" in humanitarian emergencies.
- Epidemiological factors (i.e. the potential risk and impact of the disease) were considered important, but were not always reflected in the choice of vaccines implemented. Vaccine availability and funding were the most influential factors in decision-making to vaccinate.
- 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 as the lead decision-maker (e.g. Somalia in 2010), non-governmental organizations (NGOs) failed to reach a consensus regarding choice of vaccines and, in some cases, different vaccines were implemented for the same affected population.
- Ethical considerations were least considered. Little guidance or experience was identified on how to prioritize interventions, select high-risk groups, ensure equity and obtain informed consent.

2.3 Aim

This decision-making framework attempts to fill the 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 VPDs 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 which vaccines, if delivered pre-emptively at the outset of an emergency, would constitute high priority public-health interventions. Even though the principles and general approach may apply in cases where reactive vaccination should be considered during an outbreak in an acute emergency scenario, where detailed outbreak response guidance already exists for a VPD, these should be relied upon to guide outbreak response once an outbreak starts.[1]

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 carried out in other sectors. Careful consideration of key ethical principles and contextual issues are key overarching considerations influencing the decision-making process.

[1] *http://www.sphereproject.org/handbook/*

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 VPDs, 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 so 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 also for health providers to the population. This may affect the ability to deliver a recommended full series of vaccinations and force 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 programme. On the contrary, those goals should be set aside in order to use vaccines for one clear and present objective, that is, 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 programmes 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 deliberate 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 in ones that are recognized as not acting in the best interests of the populations affected by the emergency. In these cases, a designated United Nations agency has frequently been recognized as having policy-making authority and may lead the decision-making process. In general, however, 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 and 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), or in emergency situations where delays or sub-optimal approaches could result in severe detrimental outcomes and where 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 actions of authorities and health practitioners are judged.

2.7 Core ethical considerations

Ethical considerations are central to this decision-making framework, as numerous factors that need to be considered, e.g. vaccine quantities available, selecting target groups, delivery strategies and surveillance and research, pose a conflict between individual good and the common good. Therefore, a careful consideration of beneficence (duty of care and the rule of rescue) and non-maleficence, as well as distributive and procedural justice, needs to occur.

Beneficence (doing good). As the risk of communicable diseases during humanitarian emergencies is often increased, 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, the 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; 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 of distributing resources is often not perfect, as humanitarians can only do the "best they can" in the context of imperfect information and 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 that everyone should have a fair chance of receiving vaccination.

Procedural justice (transparent and accountable decision-making). This ethical principle requires transparent decision-making and also participation of communities that are affected by the decisions. The Sphere Project, 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 VPDs. Because so many different kinds of emergencies, 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. We will use the term "acute emergencies" henceforth, and 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 emergency have been proposed in the past, and different agencies employ varying classification and gravity benchmarking systems. 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 (VPDs) 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 adverse weather conditions 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 VPDs. 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 to maximise the potential impact of vaccination in all emergency-affected populations. However, the framework recognises that scenarios in which large populations assemble within a given site (e.g. a large camp) usually carry a higher risk of VPD epidemics, warranting more intense interventions. By contrast, it is expected that emergencies featuring very small populations (e.g. communities affected by a localized 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 purpose of the above definition. However, this circumstance is explicitly taken into consideration in the framework, as different vaccination interventions may be warranted (e.g. in crises of long-duration, 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 six months), the crude mortality rate (CMR) deaths per person-time, e.g. per 10 000 people per day, and/or under five years death rate (U5DR) deaths per person-time among children aged less than five 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 1–5 above. If the cause of the observed elevation is not immediately clear, urgent investigation should be carried out to ascertain 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 1–5 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 denote 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 above conditions 1, 2, 3 or 5.

f) Terrorist attacks, defined as in 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 based on 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 ≥ 5% and ≥ 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 VPDs 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 and 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, in many emergencies, the framework may need to be applied a number of times, the decision to proceed with a specific vaccination may be different and the details of any vaccination 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 are, has often raised issues. Whether it refers to populations that are hosting displaced people or to people exposed to a higher risk of VPD 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 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 (VPD)

Diseases are considered to fall within the scope of the framework if the following conditions are met.

1) Burden of the disease may increase because of an acute emergency.
2) A WHO prequalified vaccine exists that can provide at least some protection against the disease in an emergency setting.
3) In exceptional cases, where a prequalified vaccine for the specific disease does not exist, the following additional criteria may be applied:
    a) the manufacturer should be WHO prequalified for supply of at least one other vaccine;
    b) the vaccine should be licensed by the national regulatory authority in the country of origin, and in the country of intended use;
    c) the vaccine should be licensed and marketed in at least two additional countries with functional national regulatory authorities as assessed by WHO.[2]

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 into national routine immunization programmes.

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 prequalification criteria mentioned above. 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.

The relative significance of VPDs in acute humanitarian emergencies is also considered, and this may vary according to pathogen-specific characteristics of respective microorganisms — 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] The criteria for the exceptional case where a prequalified vaccine does not exist, are currently under revision by WHO. These criteria are intended as guidance. It is recommended that any modifications made on the basis of national benefit-risk considerations should ensure that if a non-prequalified vaccine is used, it is at least as safe and efficacious as one which would comply with these criteria.

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 needed 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 Supply Division procures vaccines for UNICEF-supported programmes, 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 VPDs with severe outcomes, especially increased mortality. An obligation falls on global and local communities, including governments and NGOs, 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 and availability of an action plan for mass vaccination, as well as adequate storage conditions.

These stockpiles are not the only recourse for vaccine, and their 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 diseases*

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
12.	Avian influenza
13.	Meningococcal disease (polysaccharide vaccine)
14.	Hepatitis A
15.	Typhoid fever
16.	Hepatitis B
17.	Meningococcal disease (conjugate vaccine)
18.	Cholera
19.	HPV
20.	Varicella
21.	Poliomyelitis
22.	Measles
23.	Hepatitis E
24.	Rabies

* Additional vaccine-preventable diseases may be 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 produce a short list of VPDs for consideration in subsequent steps of the decision-making process outlined in the framework. Epidemiological risk is defined here primarily in terms of excess mortality, but a high incidence of hospitalizations 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 no more than a few days and should not be delayed by absent 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 due to the presence 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. General risk factors are those that have a cross-cutting effect on several infectious diseases.

    a) Based on available information, determine which of the above general risk factors are present ("yes" or "no") in the given acute emergency scenario. 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) Establish 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, 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 4.

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 are 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). A qualitative approach is recommended, to synthesize the information for each VPD under consideration, into an overall level of specific risk, again graded as "high", "medium" or "low". A rough algorithm to help with the grading is proposed (Figure 3, Annex 3) and sources of information for each factor are suggested (Annex 1).

3) **Provide 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 shortlisted and carried over to the next step of the framework.

   b) For each VPD shortlisted, characterize the type of threat (e.g. epidemic versus 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 3).

This 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 certainly be considered. The step-by-step risk-assessment process outlined in this chapter should result in a shortlist 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, shortlisted 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 shortlist 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 shortlisting 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 in the framework.

3.2.2 The meaning of risk in the context of this document

As discussed in the introduction to the framework, 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 and elimination programmes (e.g. polio and measles) may also be thought of in terms of potential regional or global setbacks in the eradication/elimination 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 risk assessments for polio importation and outbreaks, and 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 human papillomavirus (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 ratio (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 the emergency response planning. As suggested in Annex 1, in nearly all scenarios some information will be unavailable or questionable; however 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 if 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 relatively 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 assess risk also for the latter population, and to 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, high burden of chronic diseases, 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, an algorithm (Figure 3, Annex 3) and worksheets specific to each disease (Annex 3) 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 shortlisted (i.e. to "definitely" or "possibly" consider), characterize the risk in terms of type of threat, timing and age groups affected. This characterization should be used later in the framework to help prioritize 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 1a: 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 go through systematically (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 to determine within the timeframe of the risk assessment whether each risk factor is present, and the risk assessment should not be delayed while 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 presence 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 three 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)
High burden of chronic diseases	Increased risk of infection, disease progression and case fatality	Is there an unusually high burden of chronic diseases in the general population?	• Prevalence of chronic diseases including diabetes, cardiovascular and renal diseases in the general population • Medium- to high-income population
Young population and/or high birth rate	Greater pool of susceptibles for VPDs mainly affecting children Higher herd immunity threshold	Are there a high number of children? Is there an increase in deliveries? Is there low access to highly active antiretroviral therapy (HAART), or have HAART programmes been disrupted by the emergency?	• Proportion of children aged under 5y ≥15% • Crude birth rate ≥30 per 1000 people per year • 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 Insufficient water, sanitation and hygiene	Increased transmissibility of airborne droplet and faecal-oral VPDs Increased transmissibility of faecal-oral diseases (mostly) and airborne droplet diseases	Is the population living in a large camp or a high-density urban community? How close together are residential structures? Does the population have inadequate access to water, sanitation and hygiene (e.g. soap, health promotion)?	• Size of camp >10,000 people • <3.5 m2 covered floor area per person • <15l water available per person per day • >20 persons per latrine • <250g of soap per person per month

3.4.2 Task 1b: Produce a grading of risk due to general factors

Table 3 summarizes very approximately what is known about the relevance of each general risk factor to specific VPDs considered in the above worksheet, 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 little or no effect on the burden of the VPD; thus, 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 outbreaks 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 analysed, it may be possible to 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 are 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 emergency 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 risk 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	High prevalence of chronic diseases	Over-crowding	Insufficient water, sanitation and hygiene
Airborne-droplet							
Diphtheria	Moderate	Low	Unknown	Moderate	Low	High	Low
Hib disease	Moderate	High	Moderate	High	Low	Moderate	Moderate
Influenza	Unknown	High	Moderate	Moderate	Moderate	High	Unknown
Measles	High	High	Moderate	High	Low	High	Moderate
Meningococcal meningitis	Low	Low	Moderate	High	Low	High	Low
Mumps	Low	High	Low	Moderate	Low	Moderate	Low
Pertussis	Moderate	High	Low	Moderate	Low	High	Low
Pneumococcal disease	High	High	High	High	High	High	Low
Rubella	Low	Moderate	Low	Moderate	Low	Moderate	Low
Tuberculosis (meningitis and disseminated disease)	Moderate	Low	High	High	Low	High	Moderate
Varicella	Moderate	Moderate	High	Low	Low	High	Moderate
Faecal-oral							
Cholera	Moderate	Low	Unknown	High	Low	High	High
Hepatitis A	Unknown	Low‡	Low	Low	Low	Low	High
Hepatitis E	Unknown	Low‡	Low	Low	Low	Low	High
Polio	Low	Low	Low	Low	Low	High	High
Rotavirus	Moderate	High	Low	High	Low	Moderate	Low
Typhoid fever	High	Low	Moderate	Moderate	Low	Moderate	High
Vector-borne							
Japanese encephalitis	Unknown	Moderate	Unknown	Moderate	Low	Low	Moderate
Yellow fever	Moderate	Low	Unknown	Low	Low	Low	Moderate
Other or mixed							
Hepatitis B	Unknown	High	High	Low	Low	Moderate	Low
HPV (cervical cancer)	Low	Low	High	Low	Low	Low	Low
Tetanus†	Low	High	Low	High	Low	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 3; these contain guidance on how to grade risk arising from each specific risk factor relevant for the VPD, based on the 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 naive or partly naive 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 a 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 3, 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 in the light of 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 is recommended informed by all available evidence and sound, objective judgment. An algorithm to aid this qualitative decision is suggested in Figure 3, Annex 3.

3.6 Task 3: Assess the overall risk of each VPD

3.6.1 Task 3a: 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 algorithm in Annex 3, Figure 3 and disease-specific worksheets in Annex 3, 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 to learn from mistakes if the risk assessment turns out to be faulty.

3.6.2 Task 3b: 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 as an 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, it should be indicated how quickly excess mortality could manifest itself, and/or the window of opportunity for intervening through preventive vaccination. Some general guidance is as 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 two weeks following the onset of an acute emergency, particularly if immune status is low from the very outset.

  - Provided the vector and pathogen are already present, an epidemic of a vector-borne VPD 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, VPDs identified by the risk-assessment step for further assessment in the preceding chapter, are analysed based on vaccine characteristics and operational considerations, in order to determine suitability of the vaccines for mass vaccination campaigns in a humanitarian emergency.

4.1.1 Vaccine characteristics

Key vaccine characteristics that should be considered include determination of:

- vaccine availability in sufficient quantities;
- vaccine efficacy at full schedule and efficacy at less than full schedule;
- administration course of the vaccines;
- vaccine presentation (e.g. multi-dose presentation);
- vaccine safety and waste-disposal considerations;
- WHO prequalification status;
- formulation of the vaccine; for example, most freeze-dried vaccine should never be kept longer than six hours 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 Implementation considerations

Operational factors that would ensure successful and high-quality mass vaccination include:

- good estimation of target population including age range;
- good timing of the campaigns;
- determination and prioritization of high-risk groups/geographical areas;
- implementation strategy;
- adequate logistics;
- sensitization of target population and informed consent for vaccination;
- effective monitoring and evaluation of the campaigns;
- adequate human resources.

4.2 Chapter introduction

The output of the risk-assessment step is a list of VPDs which should be **definitely** or **possibly** considered in this second appraisal step. While vaccination against VPDs identified may have the potential to save lives and limit disease, successful implementation of mass vaccination with these vaccines may not be straightforward. Mass vaccination campaigns pose specific challenges (due to their objective of reaching a large number of people over a short period) and, as a result, necessitate extensive planning. Key factors to consider are, which vaccines to include in the intervention, how they are delivered, whether their characteristics favour mass vaccination and the target population.

Mass vaccination refers to the process of setting up vaccination sites in traditional or non-traditional health-care locations in order to administer vaccines to a large number of people in a short period. The approaches to the implementation of mass vaccination campaigns can be grouped into two main categories; one 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, live or gather to receive the vaccine. These may also be sites specifically set up 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.

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 different characteristics of live and inactivated vaccines 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 wanes (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 individual. 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 (carbohydrate) 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	• Careful assessment is required before giving administration of attenuated vaccines to individuals with impared immunity e.g. those on chemotherapy, have HIV, or are pregnant • 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

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 establishing whether vaccines for VPDs identified in the risk assessment can then be delivered. Tables 6, 7 and 8 present an overview of the different vaccine and delivery factors which are interlinked and should be used to assess feasibility of the vaccine for use in mass vaccination. The characteristics vary by vaccine and are presented in Annex 2, Table 12. Note that, in some cases, evidence-based information on certain parameters is not yet known or is scanty for specific antigens.

4.4.1 Availability

Vaccine supply should ideally be investigated prior to any crises. Manufacturers have different capacities for supply of vaccine and the delay expected for the vaccine to be delivered should be taken into account in the decision-making process. 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 shelf-life of the vaccine (this may vary by lots) to ensure that there is enough time for delivery. There are advantages to the use of vaccines already in a country's routine immunization programme as there may be an additional supply of the vaccine present in the country and, more importantly, less quantifiable factors, such as health-care workers' and the populations' familiarity with the antigen, which can facilitate acceptance and implementation. The same is also true for vaccines for seasonal diseases, such as meningitis, where countries may have prior experience in conducting campaigns. Vaccines which have not yet been introduced into the Expanded Programme on Immunization (EPI), such as oral cholera vaccines, or perhaps are not destined for inclusion in EPI, may necessitate a different approach in terms of procurement and community acceptance.

4.4.2 Efficacy

Vaccine efficacy is a major consideration in choice of vaccine. Efficacy in preventing disease in the immunized populations is obtained from controlled studies, where immunization is delivered under ideal conditions. In these trials, vaccines tend to be given to healthier people who may have a better immune response. Efficacy may also vary depending on age, nutritional status, co-infections and other factors. Programmatic factors such as errors in vaccine storage, preparation or administration, which can impair the vaccine, are more likely to occur in the field. As a result, the efficacy of some vaccines is lower in "real world" settings. Vaccine effectiveness is a different concept which describes protection of the vaccine in the actual target population under programmatic conditions. Therefore, vaccine effectiveness is usually lower than vaccine efficacy.

Vaccine efficacy will also be determined by the number of doses of a recommended schedule or course of a vaccine that are given (see section 4.4.3) below.

4.4.3 Administration

The administration course of a vaccine (schedule) should be considered in the decision-making process. With population movements, or erratic access to populations due to security or logistic constraints, it may not be possible or realistic to deliver the full course of a 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 one year and a booster dose later in life).

As multiple vaccines may be delivered as 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 but, if not delivered concurrently, an interval of at least four 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 four weeks later — this is to ensure that a sufficient immune response is mounted without interference. The exception to this rule is oral polio vaccine (OPV) (see Annex 2) which may be given without consideration of other live vaccines. When several doses of vaccine are required, similar vaccines produced by different manufacturers may be used interchangeably while following any changes in specified number of doses or contraindications.

The decision to use a vaccine then needs to consider known information about vaccine efficacy at full course and best available information about vaccine efficacy at less than the full dose or delivery through alternate means, balanced with the potential benefits of vaccination. If less than a full-recommended course is delivered, this information should be documented during the intervention. It is also important to note that, although there may be instances of overdosing (e.g. three doses instead of two in an individual with prior vaccination but undocumented vaccination status), the consequences of overdosing are minimal or absent.

4.4.4 Time until protection

The time it takes a vaccine to provide protective immunity (Table 7) is an important factor. This means, how many days, weeks or months after a full course of vaccine (number of doses required, which may be age-specific) the immune response can 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 shown 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 three to four weeks apart. This means that, in the case of some inactivated vaccines, there may be at least a delay of four weeks from first vaccine dose to a degree of protection conferred, and in some instances even longer. Alternatively, in individuals who previously received one or more doses of the same vaccine, protective immunity may be generated quickly (between 4–7 days).

4.4.5 Safety (see section 2.10)

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 one 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.

4.4.6 Formulation

The formulation of the vaccine, in addition to logistics of transportation and storage, is important in terms of the need for trained staff to deliver the vaccine. Most freeze-dried (lyophilized) vaccines do not contain preservatives and should not be kept longer than the recommended period. Liquid-injectable vaccines contain preservatives that prevent growth if there is 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.

4.4.7 Presentation (Table 8)

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.

4.4.8 Storage (Table 8)

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.

4.4.9 Cost (see section 2.11)

Adequate funding should be secured to ensure procurement of the right amount of vaccines. Sometimes this may be difficult to achieve in a timely manner.

Table 7: Vaccine protection characteristics and key questions

Characteristic	Definition	Key questions
Efficacy at full schedule	Protection and duration of immunity assuming entire course is given (e.g. 68% two-dose efficacy in adults lasting for two years)	• Full schedule consists of how many doses? • What is the administration interval and suitability for use in humanitarian emergency settings?
Efficacy at less than full schedule	Efficacy of vaccine at less than full course (e.g. 50% one-dose efficacy in adults)	• What is the efficacy at less than full course? • Is the level of protection optimal for mass vaccination campaigns?
Exclusion criteria	Groups or ages for which the vaccine is contraindicated (e.g. children under age one year or pregnant women or women of child-bearing age)	• Out of safety concerns who should not be vaccinated?
Administration course	Schedule of administration and age (e.g. dose 1 at age nine months and second dose at 12 months or above)	• How many doses does the full course require? • What is the time interval between the doses? • Is the schedule feasible for a humanitarian emergency-affected population?
Safety	WHO prequalification. Vaccines that are prequalified have an assurance of safety	• Is the vaccine WHO prequalified? and if NO • Is the manufacture prequalified for supply of at least one other vaccine? • Is the vaccine licensed by the NRA in the country of origin? • Is the vaccine licensed and marketed in at least two additional countries with functional NRAs as assessed by WHO?

Table 8: Vaccine formulation and delivery characteristics and key questions

Characteristic	Definition	Key questions
Formulation	Combination, lyophilized, liquid	• Is it a combination vaccine? • Is it a lyophilized vaccine? • Is it a liquid vaccine? †
Presentation	Individual or multi-dose presentation (vial/ampoule, prefilled injection device, vial size) and volume (e.g. glass multi dose vial at 11 cm3)	• Is it an individual or multi-dose presentation?
Storage	Temperature and conditions of storage (e.g. 2°C–8°C in a dark room)	• Is cold chain capacity for storage adequate? If not present, is there 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	• Can the vaccine withstand ambient temperature for a prolonged period of time?
Current price	GAVI listed prices in GAVI eligible countries	• Is there adequate funding for procurement of vaccines and for implementation?

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

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

4.5 Implementation considerations

Although mass vaccination campaigns in acute emergencies are an intervention rather than a programme, they still require the same components as other mass campaigns, such as supplementary immunization activities. In this section these components are outlined, and key questions that should be asked in deciding whether to implement a vaccination intervention in a humanitarian emergency are summarized (Table 9).

4.5.1 Target population

Estimating the target population is required to determine the number of vaccine doses needed. This information should be obtained during the epidemiological risk-assessment step where the denominator (at-risk population) should be 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 has 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 six 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 high risk, then the target group for vaccination includes those aged two to 30 years (see Annex 2). In both cases, however, the target age range needs to be adapted based on both the epidemiologic risk and also pragmatic issues. When different population figures are available, or the expected age distribution of cases is not known, it is better to overestimate, rather than underestimate the target population for vaccination. This means that the highest number available should be used as a precautionary measure.

4.5.2 Timing

It is important to remember that all vaccination interventions should be implemented as soon as possible. Failure to deliver these interventions on time is a sub-optimal intervention. However, this said, there might be logistical, political or ethical barriers to delivering all interventions simultaneously (see contextual considerations, chapter 5). In such cases, interventions should be prioritized in terms of urgency (i.e. which interventions are most important to do first).

Prioritizing vaccine interventions in terms of urgency should be based on the epidemiological risk assessment. 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. However, in most cases, vaccination will be considered an urgent need.

When risk groups overlap (Table 10), 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 has the important advantage of maximizing the opportunities of delivering vaccine to individuals in one planned intervention.

4.5.3 Geographical 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 five years. Selecting specific geographic areas for vaccination also needs to be balanced with ethical issues. Vaccination of only specific geographic areas may create tension among the population and lead to the need to justify why certain groups are eligible for vaccination while others are not.

Table 9: Vaccination implementation considerations and key questions

Factor	Key questions
Target population	• What is the target age group? • What is the estimated number of people targeted? • Are host communities included? • Are the people stable and well defined in a camp setting, or is highly unstable with new arrivals and departures?
Timing	• Can the mass vaccination be implemented soon, before the population begins to disperse/move back to their homes?
Geographical areas	• Are there hard-to-reach areas? • Are there special high-risk population groups in some areas?
Strategy	• Whether fixed sites, mobile posts, or a mix of both constitutes the most appropriate strategy?
Logistics	• Is cold-chain capacity for storage adequate? • If not present, is there capacity to mount a cold chain in the affected area? • Are there adequate human resources for implementation?
Social mobilization	• Can the population be adequately sensitized and informed about the mass vaccination within a reasonable period of time?
Monitoring and evaluation	• Is there capacity to monitor implementation of the mass campaign?
Informed consent	• Can the population be well-informed and their consent, or refusal, received?

4.5.4 Strategy

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 outreach posts, 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 post 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. Furthermore, due to their fixed nature, many people can be vaccinated within 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 hard-to-reach populations may be accessed. However, the use of mobile teams requires additional resources as less of the population can be reached every 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 other opportunities for vaccination. 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 programme-based strategy may not be the most appropriate. 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 programmes.

4.5.5 Logistics

The logistics of having the vaccine reach individuals is perhaps the most important component. This includes: adequate transport; cold-chain facilities; storage and safe transportation of the vaccine from procurement through to administration to the target population; 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 provide 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, both human and material.

4.5.6 Social mobilization

Getting word of upcoming vaccination to a humanitarian emergency-affected 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.

Social-mobilization activities should 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 any 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 using 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.

4.5.7 Monitoring and evaluation

During a campaign, monitoring provides an essential component to troubleshoot 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.

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 also 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, plus 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 campaign.

4.5.8 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 either implied (by the mother bringing the child to a vaccination session with the expectation that the child will be immunized) or needs to be 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 who vaccinate individuals 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 (and other children's) best interests.

5. Contextual considerations and competing needs

5.1 Chapter summary

This chapter adds to the preceding ones by factoring into 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 an acute emergency. Like the preceding chapters, it does not provide answers, but it does suggest that decision-makers need to consider a broad array of evidence from non-vaccine areas of the health sector, and from other sectors as well, in order to arrive at a decision that will result in the best possible outcomes of the emergency-affected population.

Specific factors examined include:

- ethical considerations
- political considerations
- security concerns
- human resources
- financial considerations
- alternative interventions
- target population
- add-on interventions
- research.

5.2 Introduction

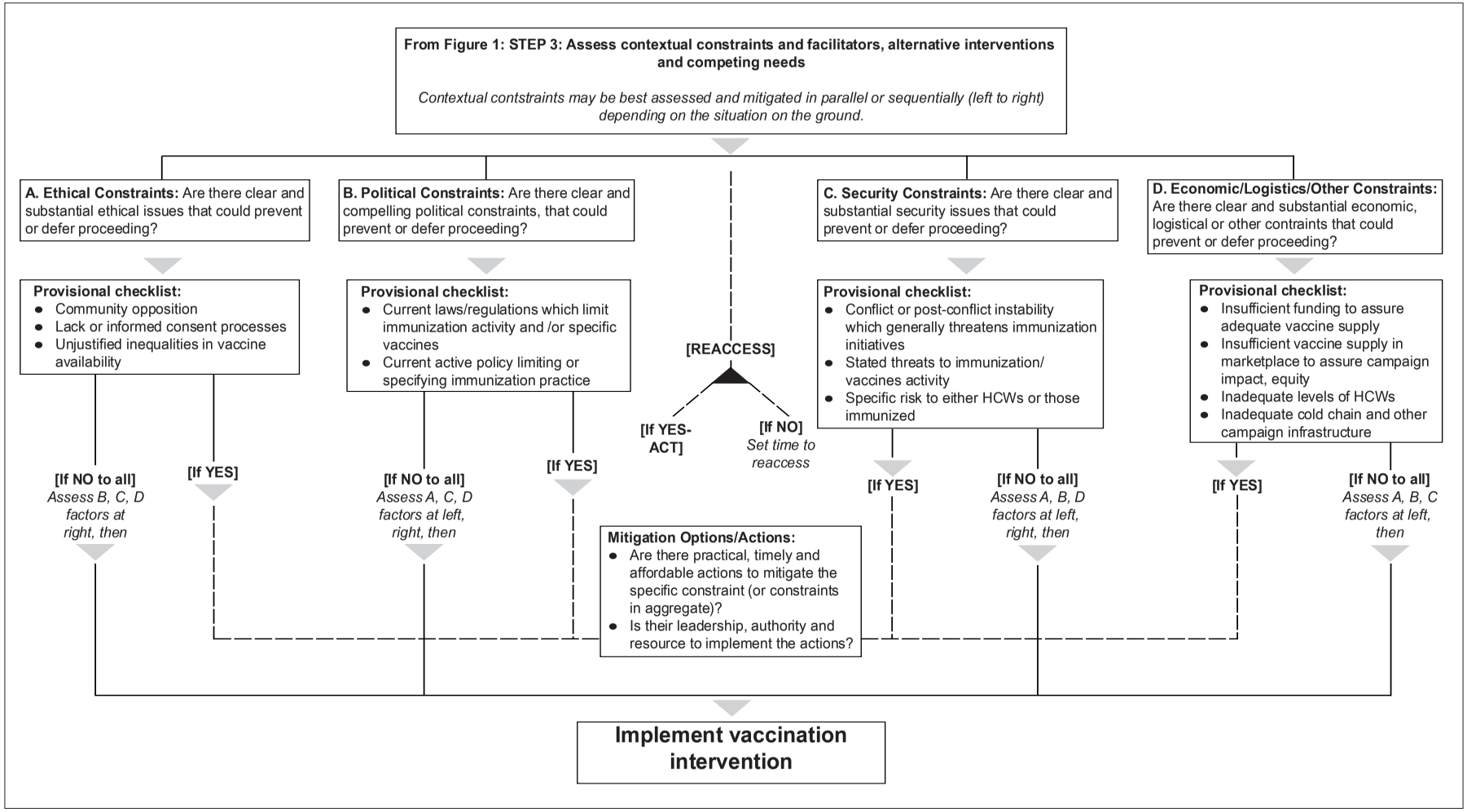
The preceding chapters of this framework deal with issues pertaining to the risks posed by VPD and to the vaccines that prevent them. However, even though an assessment of these characteristics may justify a mass vaccination intervention, the final decision will be influenced, both by the context in 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, discusses them briefly, and includes anassessment algorithm (Figure 2) to provide an orderly means to consider them.

The framework does not provide a specific methodology or process for appraising contextual factors comparable to those outlined earlier for Tasks 1 and 2. As a result, this framework stresses the importance of careful documentation of field decision-making overall, stressing especially how evidence, ethical principles and contextual factors contribute to these decisions.

Indeed, the framework acknowledges that any one of the contextual factors and competing needs discussed in this chapter might be argued by decision-makers on the ground as being sufficient to defer on immediate action, or decline immunization altogether, in a given emergency situation. Such deferral or declination could relate to a specific vaccine or function as a blanket decision about immunization in general. It is therefore particularly important to document decisions where immunization is clearly indicated, as a result of Tasks 1 and 2 but deferred or declined at Task 3, in the light of any of the factors discussed in this chapter, or additional factors not captured here.

Equally, there may be situations where such contextual factors may result in a suspension or cessation of immunization already underway, whether this framework is utilized or not in making such a decision. Documentation of these instances and the supporting evidence driving decision-making is also critical. Overall, such documentation will be critical to further refinement of the framework, and should, therefore, be shared transparently with the humanitarian and public-health community.

Figure 2: Contextual factors assessment algorithm in acute humanitarian emergencies



5.3 Ethical considerations

In 2.7 *Core ethical considerations* above, and at other points earlier in this framework, a number of ethical principles are referenced. These include beneficence, non-maleficence and distributive and procedural justice, as well as informed consent. Ethical considerations also underpin much of the discussion below around political, security, financial and other contextual factors, although they may not be overtly identified as "ethical" per se.

For example, the discussion below in 5.6 *Human resources availability argues* "utilitarian considerations require that allocation decisions achieve maximal benefits in terms of aggregate wellbeing, i.e. achieving 'the greatest good for the greatest number'". This ethical principle is certainly broadly accepted in many cultural contexts, but may not be the most relevant or compelling factor in final decision-making.

Immunization decisions which may be supported after completing Tasks 1 and 2 of the framework may still be burdened by significant ethical challenges. When that occurs, strategies to resolve or mitigate those challenges should be identified and undertaken by decision-makers before proceeding with, or in orderly parallel to, immunization campaigns. Without specific action to successfully resolve ethical challenges, the immunization decision process can be considered to have "failed" Task 3 contextual consideration. If mitigating actions to address such ethical challenges, in parallel with a campaign, are unsuccessful, then a specific decision to suspend immunization activity at a predefined milestone should be engaged.

Furthermore, this framework anticipates that, in some emergency situations, decision-makers on the ground will encounter vigorous assertions that the duty of care and rule of rescue (beneficence) should outweigh all other "contextual considerations and competing needs" and that immunization campaigns should proceed. While such advocacy is understandable and, indeed, informs humanitarian response at its most fundamental level, this framework recognizes that other contextual factors must and will play a crucial role in decision-making, as elaborated below.

Overall, the framework encourages documentation of decision-making and the evidence employed when considering how ethical principles or specific ethical challenges impact immunization decisions — whether the given decision faced is to proceed with, defer on, decline, or suspend an immunization action.

5.4 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 become the subject of contention.

Where relevant, authorities in charge of emergency relief must decide whether to advocate with recalcitrant or slow-moving civilian and/or military authorities for proceeding with vaccination 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.

Such political problems must be weighed against the benefits lost to those in need of an indicated vaccination intervention. If a decision to vaccinate has moved through Tasks 1 and 2, any rejection, postponement, or suspension of indicated immunization action for "political considerations" should be based on clear evidence that there is sufficient counter-balancing benefit for those in need, and should be well documented.

5.5 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 shown 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 or foregoing vaccination until the security situation becomes more stable, whether it is based on 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,[3] including vaccinations. Of course, what should specifically be done in any particular setting concerning the relative priorities of action in different sectors, such as protection and health, is entirely dependent on the local 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.

5.6 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 an emergency. Programme managers, logisticians, public-health workers, drivers and translators, among others, are all needed for the successful implementation of vaccination programmes. 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 populations. Deploying them for days or weeks to a vaccination campaign could adversely affect the relief effort and hamper other life-saving interventions, such as health service delivery. The competition between priority programmes for individuals with these qualifications can be fierce; strong and respected leadership is critical to ensuring that any intervention programme undertaken in an emergency is adequately staffed, in order to maximize its chances of succeeding. It requires close collaboration with national and sub-national 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"; although, in some situations, this principle may not have primacy for various reasons.

[3] Coghlan B et al. Mortality in the Democratic Republic of Congo: a nationwide survey. Lancet, 2006, 367:44–51.

5.7 Financial considerations

As with other interventions, financing of any vaccination 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 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 funded from emergency or development budgets, and who the appropriate implementing partners might be.

5.8 Alternative interventions

Concerning competition between interventions, unfortunately, there is no algorithm that can determine the relative value of one intervention versus another and no mathematical formula that can be applied. The balance between the potential benefits and adverse consequences of implementing a mass vaccination campaign during the acute phase of an emergency, 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 might 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, the planning and preparation for a vaccination campaign should still 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 which, 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, influence heavily on the health status of a population, and the sad reality is that this choice often has to be made.

5.9 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 a VPD 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 resources must also be devoted to those not directly affected 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 additional context-specific factors that must also be taken into consideration.

5.10 Add-on interventions

In many cases, the vaccination intervention may also be used as a vehicle to add on other distributions, be it another vaccine, or other drugs and commodities such as deworming tablets, vitamin A, soap, jerry cans, shovels, mosquito nets, blankets, etc. Depending on the context, the addition of each additional item to a vaccination campaign should be approached warily, as the risk of overwhelming limited human and logistical resources is real. Of course, specific situations may argue that such "add-on interventions" may be both justified and the most practical means to ensure that indicated interventions actually reach the targeted populations in a timely manner.

5.11 Research

The acute emergency setting presents a unique opportunity to conduct research that can be extremely beneficial in providing a better understanding of the health and humanitarian consequences of emergencies, in establishing the safest and most effective health interventions and in 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 which carry the burdens of research must stand to benefit. Research protocols should be relevant and methodologically sound, and should make explicit the benefits or potential harms for participants. They should also contain clear plans for returning results to participants, recognising that they may relocate in the months following the humanitarian crisis.

5.12 Conclusion

The decision to implement vaccination against one or more high-risk diseases during the acute phase of an emergency must be made based on epidemiological, vaccine, political and ethical considerations that are specific to the context in which the emergency is unfolding. 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, must be considered.

In addition, the decision-making process requires authoritative but respected leadership, rapid but effective consensus-building and 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. In accordance with increasingly accepted standards of accountability, such as those enunciated in the International Federation of the Red Cross (IFRC) Code of Conduct and by the Inter-agency Standing Committee's Transformative Agenda, emergency-affected communities should be involved in the prioritization and decision-making process to the maximum extent possible. In emergencies, where populations are highly vulnerable and lives are almost always at stake, earning and maintaining the trust of the population being served, is crucial.

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 time frame 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. The risk assessment should not be delayed until sufficient field data become available to accurately answer each question, as this could take weeks or months. You 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 socioeconomic 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, there are other suggested sources that can be consulted when assessing the presence of general risk factors (Table 10).

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. In some countries the 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. Unfortunately, in 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 two years, or obtained before a mass campaign), they should be adjusted 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 a 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 regional office) to gain an overview of which epidemic-prone VPDs have been observed most frequently in the past, and how large any 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 to 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. They may, thus, 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 was 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 underestimated by surveillance (see above), but is reasonably well predicted by the child mortality ratio (probability of dying before reaching age five years per 1000 live births); as the above VPDs account for a majority of post-neonatal deaths under five 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 fully relied upon.

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			
Hepatitis E		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	Measles & Rubella Initiative	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 Initiative http://www.polioeradication.org/	Assume low burden at baseline
Rabies	X				
Rotavirus		X	X		
Rubella			X	Measles & Rubella Initiative	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

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

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

Antigen[1]	Presentation[2]	Full course	Efficacy at full course[3]	Target age[4]	Efficacy at 1 dose	Efficacy at 2 doses	Packaging	Stability	Cold-chain volume (cm3/dose)
Measles, mumps, and rubella	Measles	2	~90%–100%	All susceptible children ≥9 months and adults	~85%	_	Multi-dose (10)	Can be frozen	2,6
	MR	2	~90%–100%	≥9 months	~85%	_	Multi-dose (10)	Can be frozen	2,6
	MMR	2	~90%–100%	≥9 months	~85%	_	Multi-dose (10)	Can be frozen	2,6
Diphtheria, Tetanus, Pertussis, Hib, and HepB	DTP (liquid)	3	>90%	≥6 wks to <7 years,	Varies with antigen; more than one dose required	_	Single-dose, two dose or multi-dose (10)	Do not freeze	Range 10.3–26.1, 13.1 and 2.6
	DTP-HepB-Hib (pentavalent liquid)	3	>90%	≥6 wks to <7 years,	Varies with antigen; more than one dose required	_	Single-dose, two dose or multi-dose (10)	Do not freeze	Range 10.3–26.1, 13.1 and 2.6
	DTP-HepB-Hib (pentavalent lyophilized)	3	>90%	≥6 wks to <7 years,	Varies with antigen; more than one dose required	_	Single-dose, two dose or multi-dose (10)	Do not freeze	58.7, 19.2, and range 5.1–7.5
	DTP-Hib (liquid)	3	>90%	≥6 wks to <7 years,	Varies with antigen; more than one dose required	_	Multi-dose (10)	Do not freeze	2,5
	Hib[5] (lyophilized)	3	≥95%	6 wks to 2 years	PRP-OMP >90%; others <70%	PRP-OMP >90%; others 80%–90%	Multi-dose (10)	Do not freeze	12

1 Precautions and contraindications should be considered for all vaccines. These include previous anaphylaxis for all vaccines; immune-deficiency states for live vaccines; age group (i.e. rotavirus and yellow fever) and pregnancy.
2 Not all combination vaccines are covered, but only the most frequently used in developing countries.
3 Information contained in the column on efficacy is derived from what is known at present concerning the vaccine. The information is 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 viewed as an upper boundary.
4 Target age group in emergency settings should be based on epidemiological considerations.
5 Relevant vaccine effectiveness studies: Vadheim, 1994 (USA); Jafari, 1999 (USA); Adegbola, 2005 (the Gambia); and Harison, 1994 (USA).

Antigen[1]	Presentation[2]	Full course	Efficacy at full course[3]	Target age[4]	Efficacy at 1 dose	Efficacy at 2 doses	Packaging	Stability	Cold-chain volume (cm3/dose)
Diphtheria Tetanus, Pertussis, Hib and HepB	HepB	3	≥95%	Birth dose within 24 hours	~56% in adults; for children no information	~56% in adults; for children no information	Single-dose, two dose or multi-dose (10, 20) and Uniject	Do not freeze, VVM30	16.8, 7.2, 5.3, 4.4, 2.6, 12
	TT	3+2	~90%–99%	Not recommended	1 dose not protective	-	Multi-dose (10, 20)	Do not freeze	3.0, 2.5
	DT	3+2	~90%–99%	Infancy and children <7 years	1 dose not protective	-	Multi-dose (10)	-	3
	dT	2 +1; 3	~90%–99%	≥7 years & adults	1 dose without primary DT not protective	-	Multi-dose (10)	-	3
HepE	Hecolin[6]	3	≥95%	>16 years	n/a	100% according to Lancet paper 2010 (Phase III)	Single dose	Do not freeze, 4□, 24months; 25□, 30days; 37□, 14days	132.6 (706.7 with the capability to maintain the cold chain for 48 hours)
PCV[7]	PCV 10 & 13	3	>90% depending upon serotype	6 wks to 5 years	73% reported by one case-control study4	96% reported by one case-control study4	Single and two dose	Do not freeze, VVM30	11.5, 4.8
BCG	BCG	1	50% all TB. Fulminant TB in infancy □70%	Neonates	50% all TB. Fulminant TB in infancy □70%	n/a	Multi-dose (20)	VVM14–30[8]	1,3

1 Precautions and contraindications should be considered for all vaccines. These include previous anaphylaxis for all vaccines; immune-deficiency states for live vaccines; age group (i.e. rotavirus and yellow fever) and pregnancy.

2 Not all combination vaccines are covered, but only the most frequently used in developing countries.

3 Information contained in the column on efficacy is derived from what is known at present concerning the vaccine. The information is 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 viewed as an upper boundary.

4 Target age group in emergency settings should be based on epidemiological considerations.

5 Relevant vaccine effectiveness studies: Vadheim, 1994 (USA); Jafari, 1999 (USA); Adegbola, 2005 (the Gambia); and Harison, 1994 (USA).

6 Contraindications in any one who is allergic to any ingredient of the product or any other vaccine allergy, or has blood coagulation disorders, aminoglycoside drug allergy, uncontrolled convulsive disorder, or any acute or severe chronic illness; precaution should be taken with pregnant and lactating women.

7 Pneumococcal conjugate vaccines: a systematic review of data from RCTs and observational studies of childhood schedules using 7-, 9-, 10- and 13-valent vaccines. WHO (2011); PCV7 is being phased out and cannot be supplied in future through the UN; PCV9 is only used in clinical trials.

8 VVM heat stability for BCG varies with manufacture from 14 to 30.

Antigen[1]	Presentation[2]	Full course	Efficacy at full course[3]	Target age[4]	Efficacy at 1 dose	Efficacy at 2 doses	Packaging	Stability	Cold-chain volume (cm3/dose)
Rota	Rotavirus (RotaTeq® liquid)	3	40%–90% varies with setting	6 wks to 2 years	-	-	Single dose	Do not freeze No VVM	46,3
	Rotavirus (Rotarix® liquid)	2	40%–90% varies with setting	6 wks to 2 years	-	~50%, varies with setting	Single dose	Do not freeze VVM14	17,1
	Rotavirus (Rotarix® lyophilized)	2	40%–90%, varies with setting	6 wks to 2 years	-	~50%, varies with setting	Single dose	-	110,6
Polio[9]	tOPV	Birth dose + 3 primary	~70%–95%	Neonates and children	~10%	-	Multi-dose (10, 20)	Store frozen,VVM2	1.0, 2.0
	bOPV	-	-	-	~50%	-	Multi-dose (10, 20)	Store frozen,VVM2	1.0, 2.0
	mOPV	-	-	-	~50%	-	Multi-dose (10, 20)	Store frozen,VVM2	1.0, 2.0
JE	JE (SE Asia) (liquid)	2 + booster doses	~95%	≥ 1 year	n/a	n/a	Multi-dose (10)	Do not freeze	3,4
Rabies	Rabies (lyophilized)	Pre-exposure: 3-dose regimen Post-exposure: 4 or 5-dose regimen	-	-	2 vials for complete course		-	-	-
Meningitis	MenA/C® (lyophilized)	1	85%–99%	1–29 years	85%–99%	n/a	Multi-dose (10, 50)	Do not freeze	2.5, 1.5
	MenAfriVac® A	1	~75%–95%	1–29 years	~75–95%	n/a	Multi-dose (10)	Do not freeze VVM30	2,6

1 Precautions and contraindications should be considered for all vaccines. These include previous anaphylaxis for all vaccines; immune-deficiency states for live vaccines; age group (i.e. rotavirus and yellow fever) and pregnancy.

2 Not all combination vaccines are covered, but only the most frequently used in developing countries.

3 Information contained in the column on efficacy is derived from what is known at present concerning the vaccine. The information is 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 viewed as an upper boundary.

4 Target age group in emergency settings should be based on epidemiological considerations.

5 Relevant vaccine effectiveness studies: Vadheim, 1994 (USA); Jafari, 1999 (USA); Adegbola, 2005 (the Gambia); and Harison, 1994 (USA).

8 Mono- and bivalent OPV are commonly used for stockpiles and mass vaccination campaigns while trivalent OPV is predominantly used in routine vaccination. A switch from tOPV to bOPV is expected in the near future.

Antigen[1]	Presentation[2]	Full course	Efficacy at full course[3]	Target age[4]	Efficacy at 1 dose	Efficacy at 2 doses	Packaging	Stability	Cold-chain volume (cm3/dose)
Influenza	Influenza, seasonal	1–2	Varies	≥ 6 months	70%–90%	n/a	-	-	-
Varicella	Varicella (MMRV)	1 or 2	~95%	>9 months	~95%	~95%	-	-	-
Cholera[10]	Dukorol®	n/a	n/a	≥2 years	-	~70%	Single dose	-	136
	Shanchol®	n/a	n/a	≥1 year	-	≥ 65%	Single dose	-	16,8
Typhoid	Typhoid (Ty21a: 3–4 doses; efficacy 33%–78%)	n/a	n/a	School-age and/or preschool-age children ≥2 years-of-age	Vi polys: 1 dose; ~70%	-	Multi-dose (20)	-	1,6
Hepatitis	HepA	1	94%–100%	≥1 year	>90%	n/a	Two-dose	-	
Yellow fever	YF	1	~99%	≥9 months	~99%	n/a	Multi-dose (5,10,20, 50)	-	6.3, 3.6, 1.5, 0.70
HPV	HPV (Cervarix®)	3	~90%–100%	10–14 years	-	-	Single and 2-dose	-	9.7 and 4.8
	HPV (Gardasil®)	3	~90%–100%	10–14 years	-	-	Single dose	-	15

1 Precautions and contraindications should be considered for all vaccines. These include previous anaphylaxis for all vaccines; immune-deficiency states for live vaccines; age group (i.e. rotavirus and yellow fever) and pregnancy.

2 Not all combination vaccines are covered, but only the most frequently used in developing countries.

3 Information contained in the column on efficacy is derived from what is known at present concerning the vaccine. The information is 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 viewed as an upper boundary.

4 Target age group in emergency settings should be based on epidemiological considerations.

5 Relevant vaccine effectiveness studies: Vadheim, 1994 (USA); Jafari, 1999 (USA); Adegbola, 2005 (the Gambia); and Harison, 1994 (USA).

10 The full doses for the Dukoral® and Shanchol® is 2-dose, and children 2–5 years old should be given a third dose of Dukorol®.

Annex 3: Disease-specific risk-assessment worksheets

8.1 Guidance for going through each worksheet

Although each worksheet differs, the overall procedure for going through each is similar.

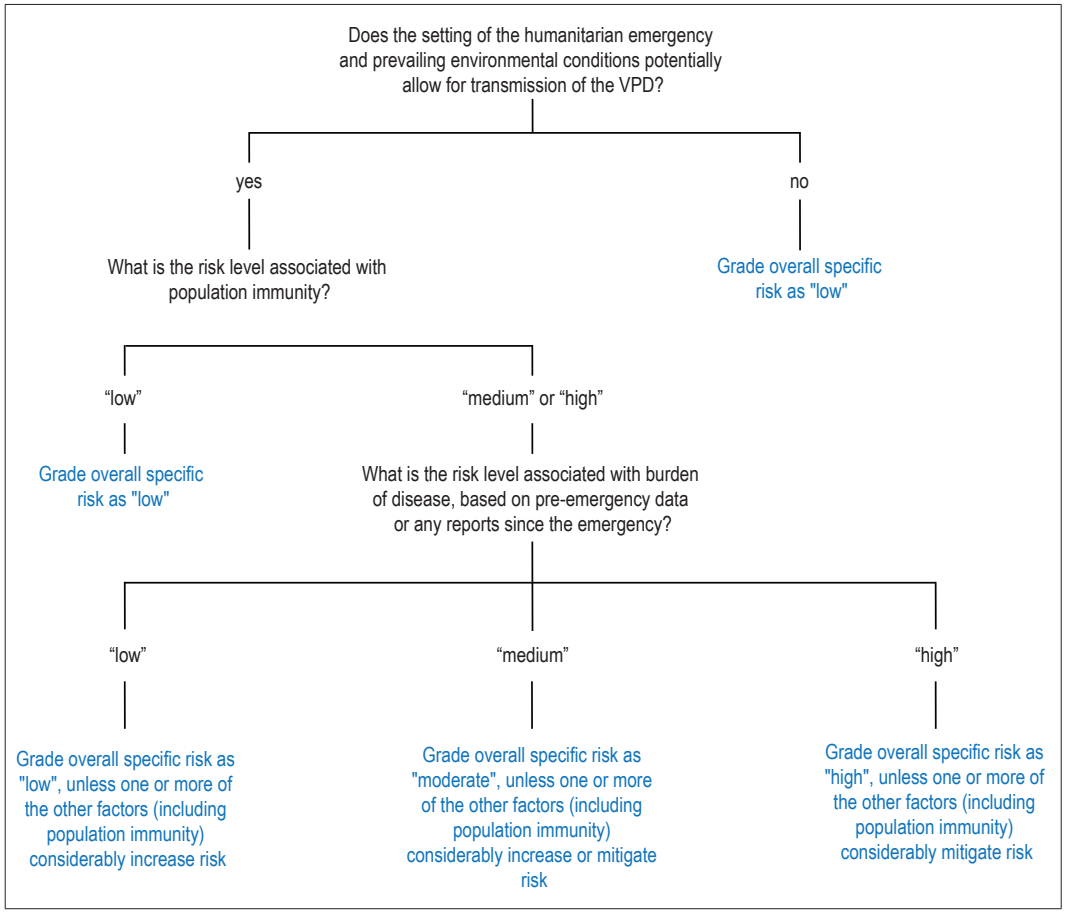
- For each factor, the user should first consider whether the criteria suggested for the classification of *High* are met; if not, whether the criteria for the *Medium* classification are met; if not, adopt a classification of *Low*. Thus, the column for *Low* risk indicates absence of *High* or *Medium* risk level 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, statements are made instead (these are explicitly stated whenever used).
- Having completed the worksheet, the user can refer to the points below as the basis for advancing 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.

Note also the following specific points.

- The criteria suggested to classify the level of risk due to population immunity are, as per 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 likely confer either herd (community) protection or a high level of individual protection.
- The occurrence of a 'large' outbreak, either current or in the past, 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, it would be expected that the reported number of cases would be a considerable underestimate of the true number and the case definition should be adjusted accordingly).

- 'N/a' in any risk column indicates 'not applicable', i.e. 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.

Figure 3: Algorithm for qualitatively synthesizing VPD-specific worksheets into an overall grading of specific risk, for any VPD



8.2.1 *Cholera disease-specific risk 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 vaccination campaign was conducted ≤3 years ago with coverage <50%; or >3 years ago and no booster dose ≤3 years ago/booster dose ≤3 years ago with coverage <50%	• A vaccination campaign was conducted ≤3 years ago with a coverage of 50%–79%; or >3 years ago with coverage of ≥50% and a booster dose campaign ≤3 years ago with coverage of 50%–79%	• All other situations, i.e. absence of criteria warranting "high" or "medium" classification	Current vaccines afford relatively short-lived immunity (about 2–3 years), but seem to confer strong transmission reduction effects, even at low coverage
Burden of disease	• The area has experienced one or more large outbreaks in the past 5 years • An outbreak is currently ongoing	• The area has experienced one or more outbreaks in the past 5 years, but none of them large	• Non-endemic area	The area refers to where emergency-affected people are currently living, and could be a city or a district/region A large outbreak could consist of >100 cases or >10 deaths
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 • Limited flooding	• Minimal contamination of water supply; good water and sanitation infrastructure	

Risk characterization

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

Time frame: 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 disease-specific risk factors*

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine DPT3 coverage* for children <1 year old is <50%	Routine DPT3 coverage* for children <1 year old is 50%–79%	Routine DPT3 coverage* for children <1 year old is >79%	Herd immunity requires >85% coverage 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 5 years, and/or • An outbreak is currently ongoing	The area has experienced one or more outbreaks in the past 5 years, but none of them large	Low endemicity area	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	• High transmission in cold seasons	High transmission season within the next 3–6 months	Low transmission season	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 and may cause airway obstruction. CFR from respiratory diphtheria is 5%–10%.

Time frame: 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 six or more months.

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

8.2.3 *Hepatitis A disease-specific risk 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%, 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 Australia and New Zealand, Canada, Europe, Japan and the USA with <30% seroprevalence	• Intermediate transmission areas, such as North Africa, South America, Central Asia and the Middle East with 30%–70% seroprevalence	• High transmission areas, such as Sub-Saharan Africa, Central America and the Indian sub-continent 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 a 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 years-of-age. No chronic infection is known to occur. Disease severity generally increases with age, but complete recovery without recurrence is the rule.

Time frame: 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-hepatitis A virus (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 disease-specific factors*

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children <1 year old is <80%	• Routine vaccination coverage for children <1 year old is 80%–90%	• Routine vaccination coverage for children <1 year old is >90%	Full schedule = birth dose + 2 or 3 doses of HBV-containing vaccine
Burden of disease	• Most of Africa, the Amazon Basin, South-east Asia, China, most Pacific Islands • Seroprevalence (HBsAg) > 8%	• Middle East, other parts of Asia • Seroprevalence (HBsAg) 2%–7%	• The Americas and Europe	Global burden estimated as 360 million chronic infections and 600 000 deaths per year
Levels of sexual violence	• High incidence of consultations or hospitalizations 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 hospitalizations for sexual violence-related conditions • Some reports of sexual violence occurring during/after battles and attacks in civilian areas	• Minimal incidence of sexual violence in humanitarian emergency settings	Sexual transmission possible; risk of transmission related to seroprevalence 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. Worldwide distribution, but prevalence of infection and patterns of transmission vary greatly by region and by 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. Five percent of acute infections progress to chronic HBV infection with risk decreasing with age.

Time frame: 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 years), and 30% of late infections (people aged >5 years). Chronic hepatitis B infection develops in 80%–90% of perinatal infections, 30% of children infected before age six, and <5% of adults.

8.2.5 *Hepatitis E disease-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)	China has produced and licensed the first vaccine to prevent hepatitis E virus infection, although it is not yet available globally
Burden of disease	• Low transmission areas, such as Australia and New Zealand, Canada, Europe, Japan and the USA with low seroprevalence	• Intermediate transmission areas, such as North Africa, South America, Central Asia and the Middle East with 30-moderate seroprevalence	• High transmission areas such as Sub-Saharan Africa, Central America and the Indian sub-continent with high seroprevalence	Every year there are 20 million hepatitis E infections, over three million acute cases of hepatitis E and 70 000 hepatitis E-related deaths
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 a sub-region

Risk characterization

Type of threat: Sporadic and epidemic viral hepatitis. Increased risk of outbreaks in poor hygienic and sanitary conditions in acute humanitarian emergencies. In rare cases, acute hepatitis E can result in fulminant hepatitis (acute liver failure) and death. Overall population mortality rates from hepatitis E range from 0.5% to 4.0%. Fulminant hepatitis occurs more frequently during pregnancy. Pregnant women are at greater risk of obstetrical complications and mortality from hepatitis E, which can induce a mortality rate of 20% among pregnant women in their third trimester. It is an acute disease that never progresses to chronicity.

Time frame: The incubation period following exposure to the hepatitis E virus ranges from three to eight weeks, with a mean of 40 days. Increase in incidence would mirror access to inadequate water and sanitation facilities in acute humanitarian emergencies.

Age-specific burden: The hepatitis E virus causes acute sporadic and epidemic viral hepatitis. Symptomatic infection is most common in young adults aged 15–40 years. Although infection is frequent in children, the disease is mostly asymptomatic or causes a very mild illness without jaundice (anicteric) that goes undiagnosed.

8.2.6 *Haemophilus influenzae type B (Hib) disease-specific factors*

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children 12–59 months old is <50%	• Routine vaccination coverage for children 12–59 months old is 50%–79%	• Routine vaccination coverage for children 12–59 months old is >79%	Hib transmission has been shown to 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 1–59 months old estimated at ≥100 per 100 000	• Child mortality ratio pre-emergency 25–99 per 1000 live births • Hib-attributable mortality rate among children 1–59 months old estimated at 10–99 per 100 000	• Child mortality ratio pre-emergency <25 per 1000 live births • Hib-attributable mortality rate among children 1–59 months old estimated at <10 per 100 000	Hib is the second most important cause of pneumonia in children, but local exceptions are common
Geography, climate and season	• Most households have 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 three months, **or** - Most households use fossil fuels to cook or heat	• A substantial proportion of households have 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 three months, **or** - Most households use fossil fuels to cook or heat	• A substantial proportion of households have good shelter and heating • Warm weather	

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.

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

Age-specific burden: Children under two years-of-age bear the highest burden.

8.2.7 *Human papilloma virus (HPV) disease-specific factors*

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• No vaccination programme, or • routine vaccination coverage for girls 9–13 years <50%	• Routine vaccination coverage for girls 9–13 years 50%–79%	• Routine vaccination coverage for girls 9–13 years >79%	3-dose schedule induces protective antibody levels in >95% of recipients
Burden of disease	• Highest burden in the developing world (sub-Saharan Africa, Latin America, south-central and south-East Asia, the Caribbean and Melanesia)	• Intermediate burden in transition economies, including eastern Europe	• Developed countries	500 000 cervical cancer cases and 260 000 related deaths per year, of which 80% in the developing world
Levels of sexual violence	• High incidence of consultations or hospitalizations 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 hospitalizations for sexual violence-related conditions • Some reports of sexual violence occurring during/after battles and attacks in civilian areas	• Minimal incidence of sexual violence	Overcrowded 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.

Time frame: 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 of 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 five 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.

8.2.8 *Influenza (seasonal) disease-specific factors*

Factor	Risk level			Comments
	High	Medium	Low	
Geography, climate and season	• Within two months of high transmission season	• Within 3–4 months of high transmission season	Low transmission season	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 during humanitarian emergencies. The highest CFRs are observed among infants <6 months.

Time frame: The average incubation period for influenza is two 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.

8.2.9 *Japanese encephalitis disease-specific factors*

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for at-risk population is <80%, **and** • SIA done >5 years ago, **and** • No large epidemic (1000s of cases) within last 5 years	• Routine vaccination coverage among at-risk population is 80%–90%, **and** • SIA done 2–5 years ago, **and** • No large epidemic (1000s of cases) within last 5 years	• Routine vaccination coverage among at-risk population is >90% • Large epidemic within last 5 years affecting same population • SIA within last 2 years with coverage >80%	
Burden of disease	• South-East Asia, Indonesia • Endemic area with known large epidemics within past 10 years • Incidence >100/100 000/year • Evidence of ongoing outbreak	• East Asia (China, Japan, Korea), northern Australia • Endemic area with known outbreaks (100s of cases) • Incidence of 10-100/100 000/year	• Africa, the Americas, South Asia, Europe and the Middle East	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	• Low transmission season	Primarily in rural agricultural areas, but can occur in peri-urban centres—rare in urban areas. High transmission season is usually April to October 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. South-East 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.

Time frame: 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 <15 years old in endemic areas and <10 years in hyper-endemic areas. In areas with high routine JE VC, incidence declines and cases shift to older children and adults. Children <5 years old experience the highest morbidity and CFR, but in naive populations all age groups may be at risk.

8.2.10 Measles disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children <18 months is <70%	• Routine vaccination coverage for children <18 months is 70%–89%	• Routine vaccination coverage for children <18 months is >89%	Vaccination coverage is 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 5 years, **and/or** • An outbreak is currently ongoing	• The area has experienced one or more outbreaks in the past 5 years, but none of them large	• The country has achieved elimination status	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	• Low transmission season • The Americas, Europe and the Middle East	Likely that seasonal climate patterns influence population density that, in turn, increases the transmission of measles Strongest seasonal effect 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.

Time frame: Incubation period of 10–14 days. Measles is highly infectious. Outbreaks can occur rapidly (<1 month) in crowded settings with a high proportion of non-immune population.

Age-specific burden: Children <5 years 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 15 years, and recent epidemics have featured considerable transmission in young adults, warranting consideration of these age groups for vaccination.

8.2.11 Meningococcal meningitis disease-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	• VC of conjugate vaccine >89% through EPI	MenA® conjugate vaccine usually provided through SIA for age 9 months to 18 years (up to 29 years) followed by inclusion in EPI
Burden of disease	• The area has experienced one or more large outbreaks in the past 5 years • An outbreak is currently ongoing • Incidence >10 cases/100 000 population	• The area has experienced one or more outbreaks in the past 5 years, but none of them large • Incidence 2–10 cases/100 000 population	• Non-endemic area	High burden in meningitis belt of Africa (21 countries) — rates of sporadic infection 1–20 cases/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	• Low transmission season	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 1000 cases per 100 000 and CFRs of 10%–15%. Group B disease is more commonly observed in developed countries.

Time frame: Incubation period is typically 3–4 days (range: 2–10 days). Outbreaks of Group A can develop within two 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.

8.2.12 Mumps disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children <18 months old is <50%, **and** • No large outbreaks in the last 3 years	• Routine vaccination coverage for children <18 months old is 50%–79%, **and** • No large outbreaks in the last 3 years	• Routine vaccination coverage for children <18 months old is >%	Two 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 5 years • An outbreak is currently ongoing	• Very low incidence of the disease in the area	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	• Low transmission season in temperate zones	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.

Time frame: 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.

8.2.13 Pertussis disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children <1 year old is <50%	• Routine vaccination coverage for children <1 year old is 50%–79%	• Routine vaccination coverage for children <1 year old is >79%	Full schedule = 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 5 years • 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 5 years, but none of them large	• Low endemicity area	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 superimposed 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.

Time frame: An exacerbation of the typical burden of pertussis could occur immediately after the onset of the emergency. 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 unimmunized children is 3%–4% for children <1 year old and 1% for children 1–4 years 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.

8.2.14 Pneumococcal disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children 12–59 months old is <50%	• Routine vaccination coverage for children 12–59 months old is 50%–79%	• Routine vaccination coverage for children 12–59 months old >79%	Full schedule consists of at least 2 doses of pneumococcal conjugate vaccine by 12 months of age
Burden of disease	• Child mortality ratio pre-emergency ≥100 per 1000 live births • Pneumococcus-attributable mortality rate among children 1–59 months 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 1–59 months 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	• Child mortality ratio pre-emergency <25 per 1000 live births; • Pneumococcus-attributable mortality rate among children 1–59m old estimated at <10 per 100 000	Most pneumococcal mortality is due to pneumonia, with the remainder attributable to meningitis or other invasive manifestations
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	• Optimal shelter • Warm weather	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.

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

Age-specific burden: Children under 5 years 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.

8.2.15 Poliomyelitis disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children <23 months old is <80% • In endemic or countries at high risk of outbreak from importation - The last SIA was done >6 months ago; or in the last 6 months but with VC <80%	• Routine vaccination coverage in children <23m is 80%–89% • In endemic or countries at high risk of outbreak from importation - The last SIA was done within the last 6months but with VC <90%	• Routine vaccination coverage in children <23 months is >89%	Polio-free countries at high risk of outbreaks following virus importation also carry out regular SIAs
Burden of disease	• The country experiencing the emergency (or from which refugees have fled) has ongoing virus transmission, i.e. is either endemic for polio or is currently affected by transmission	• The country experiencing the emergency, or affected by cross-border movement, was recently endemic or affected by an outbreak, but has not reported a polio case for at least 12 months	• No polio case for at least 3 years, with good surveillance	About 1 in 200 infections of non-immune persons results in paralysis. The CFR in outbreaks can vary from 2%–5% in children and up to 15%–30% in adults Wild poliovirus eradication certified regions are the Americas, Europe and the western Pacific; all polio-free areas remain at risk as long as any country remains endemic

Risk characterization

Type of threat: Main threats are: renewed outbreaks in polio-free countries; in areas affected by emergencies, and in areas with low performing immunization systems subsequent to reintroduction of virus from endemic areas. New outbreaks in polio-free countries represent a major setback for the Global Polio Eradication Initiative.

Time frame: Reintroduction and/or a large outbreak could occur within weeks of the emergency's onset. The incubation period is 7–10 days; infectiousness lasts 3–6 weeks.

Age-specific burden: Cases usually occur in children <5 years, with highest burden among those <36 months; however, epidemics affecting adults have recently occurred where virus was imported into populations with past immunity gaps.

8.2.16 Rabies disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Burden of disease	• Endemic regions (Sub-Saharan Africa, Latin America, South- East Asia and the Indian sub-continent) **and** - Large numbers of stray dogs with poor vaccination programme for canines - Increase number of stray dogs and contact with humans in a humanitarian emergency setting	• Endemic regions **and** - Good vaccination and control programme for stray dogs - Minimal contact between humans and canines in a humanitarian emergency setting	• Non-endemic regions • Rabies-free country or region	Global burden of disease is estimated at 55 000 deaths Highest case-fatality rate of any illness known, at 99.99% Vaccination programme available for canines. Pre-exposure prophylaxis is available for individuals at increased risk of infection e.g. laboratory workers, Humans receive post-exposure vaccination. No known immunity to rabies even though not all infected become symptomatic Rabies can spread to rabies-free countries in regions where the disease is endemic

Risk characterization

Type of threat: Not epidemic prone. 40%–60% of those bitten by canines/bats develop the disease. Potential for high mortality in endemic humanitarian emergency settings if access to proper care is compromised.

Time frame: Excess burden could occur from the very start of the emergency. The incubation period ranges from 7 days to several years, but is less than 60 days in 70% of the cases.

Age-specific burden: Shorter incubation periods and severe disease are commonly seen in children because they are likely to receive multiple, severe wounds of the head, which is richly innervated).

8.2.17 Rotavirus disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children <1 year old is <50%	• Routine vaccination coverage for children <1 year old is 50%–79%	• Routine vaccination coverage for children <1 year old is >79%	Full schedule: 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 <5 years • ≥15% of <5 year mortality is due to diarrhoea • Ongoing cluster of diarrhoea cases	• Child mortality ratio pre-emergency 25–99 per 1000 live births • Central and South America, central Asia, South-East Asia • Annual rotavirus-attributable mortality rate 50–99 deaths per 100 000 children <5 years • 10%–14% of <5 year mortality is due to diarrhoea	• Child mortality ratio pre-emergency <25 per 1000 live births • Developed countries • Annual rotavirus-attributable mortality rate <50 deaths per 100 000 children <5 years • <10% of <5 year mortality is due to diarrhoeal disease	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 is usually the 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	• Low transmission season	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.

Time frame: 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, industrialized countries is usually between 2–5 years, but within the first year of life in high-burden countries.

8.2.18 Rubella disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children <1 year old is <50%	• Routine vaccination coverage for children <1 year old is 50%–79%	• Routine vaccination coverage for children <1 year old is >79%	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 5 years	• Low transmission area	In the absence of vaccination, rubella occurred worldwide with epidemics every 5–9 years, but has now been eliminated from the WHO 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	• Low season	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 fetus associated with Congenital Rubella Syndrome (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.

Time frame: 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.

8.2.19 Tetanus disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	Neonatal tetanus: • Routine vaccination coverage <50% among pregnant women • Non-neonatal tetanus: • Routine vaccination coverage <50% VC among infants • Routine vaccination coverage <50% of age-appropriate booster doses among older children and adults	Neonatal tetanus: • Routine vaccination coverage 50%–79% among pregnant women • Non-neonatal tetanus: • Routine vaccination coverage 50%–79% among infants • Routine vaccination coverage 50%–79% of age-appropriate booster doses among older children and adults	Neonatal tetanus: • Routine vaccination coverage >79% among pregnant women • Non-neonatal tetanus: • Routine vaccination coverage >79% among infants • Vaccination coverage >79% of age-appropriate booster doses among older children and adults	Full schedule: 2 doses of TT or Td for women, and 3 doses of DPT for children administered during infancy
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	Neonatal tetanus: • Child-mortality ratio pre-emergency <25 per 1000 live births • Non-neonatal tetanus: • n/a	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
Incidence of injuries	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	Non-neonatal tetanus: • Reports of a limited number (<1000) of people with untreated, recently sustained injuries	

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.

Time frame: 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 over 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.

8.2.20 Tuberculosis (meningitis, disseminated disease) disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children <5 years old <50%	• Routine vaccination coverage for children <5 years old 50%–79%	• Routine vaccination coverage for children <5 years old >79%	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)	• TB period prevalence (all forms) < 200 per 100 000 people (all ages)	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.

Time frame: 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 are likely to 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 <5 years old in settings with high TB transmission, and mainly adults in settings with low TB transmission. Globally, children account for most of the disease burden.

8.2.21 Typhoid fever disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Burden of disease	• Asia • The area has experienced one or more large outbreaks in the past 5 years • An outbreak is currently ongoing	• The area has experienced one or more outbreaks in the past 5 years, but none of them large	• High endemicity area	Annual global incidence is 21 million cases. CFR is 1%–4%. Ninety percent 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 and poor sanitary conditions	• Limited flooding or other event resulting in potential large-scale contamination of water supply and poor sanitary conditions	• Access to optimal water and sanitation • No flooding	

Risk characterization

Type of threat: Epidemic.

Time frame: 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 <5 years versus 0.4% in older children. Although infants may manifest severe clinical forms of typhoid fever, infection in children <2 years old is typically mild and nondescript.

8.2.22 Varicella disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children <10 years old is <50% and • <50% of children are infected before age 10 years (if known)	• Routine vaccination coverage for children <10 years old is 50%–79% and • <50% of children are infected before age 10 years (if known)	• Routine vaccination coverage for children <10 years old is >79%	Vaccination (single dose to older children) is offered in very few industrialized countries Infection induces lifelong immunity
Burden of disease	• n/a	• n/a	• n/a	Transmission seems more intense in temperate climates where at least 90% of the population has been infected and is thus immune by age 15 years In tropical settings, seroprevalence 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.

Time frame: 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 15 years. In tropical areas, a greater proportion of cases and deaths would be among adults.

8.2.23 Yellow fever disease-specific factors

Factor	Risk level			Comments
	High	Medium	Low	
Population immunity	• Routine vaccination coverage for children <5 years old <60% • No previous vaccination campaigns or routine vaccination • Naive or unvaccinated population moving into endemic area	• Routine vaccination coverage for children <5 years old	• Routine vaccination coverage for children <5 years old >80%	Vaccination with a single dose should be administered with measles as part of routine schedules, or in campaigns Vaccination confers lifelong immunity
Burden of disease	• n/a	• Outbreak in the area within the past 5 years	• Non-endemic areas	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	• n/a	• Tropical regions of Africa and South America • Middle or end of the rainy season • Emergency is occurring in a jungle/forest setting	• Temperate countries	

Risk characterization

Type of threat: Epidemic.

Time frame: 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.

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