





SUPPLY CHAIN MANAGEMENT FOR HEALTHCARE IN HUMANITARIAN RESPONSE SETTINGS

ADDENDUM TO THE SUPPLY CHAIN MANAGER'S HANDBOOK

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ADDENDUM

SUPPLY CHAIN MANAGEMENT FOR HEALTHCARE IN HUMANITARIAN RESPONSE SETTINGS

WHAT A SUPPLY CHAIN MANAGER NEEDS TO KNOW:

A supply chain manager needs to know the following about humanitarian response:

- The basic distinctions between supply chain management in a stable health service context and a humanitarian or emergency response setting
- General practices and considerations for supply chain management of health commodities within each phase of a humanitarian response
- · Considerations for transitions between humanitarian response phases
- Where to learn more or access additional resources on the topic

INTRODUCTION

Across the world, the nature of humanitarian crises is changing. Natural and man-made disasters have become more frequent, more impactful on affected populations, longer-lasting, and more complex for governments, communities, and partners to respond to effectively. The United Nations (UN) estimates that during 2019 the total population requiring assistance will reach 132 million, or more than double the amount estimated in the previous decade (UN 2018).

Strong supply chain management is needed to save lives and continue to deliver crucial health services and life-saving supplies. The Supply Chain Manager's Handbook generally refers to supply chain management in support of stable health services, but managers can benefit by learning common best practices in humanitarian and emergency response contexts. Additionally, many concepts are common between the two contexts, and a stable system for health care development represents an eventual end goal of disaster response. Many systems may fluctuate between these two contexts for extended periods. Both supply chain contexts have a similar mission orientation, namely, to improve health and enable health service delivery by making health products available to the people who need them, which is different from profit-maximizing or cost-minimizing objectives of commercial operations. This chapter provides an overview of health care supply chain management in the humanitarian response context, to help supply chain manageers understand the types of activities they may undertake throughout the logistics cycle in order to better prepare and deliver to the people who need relief during a crisis.

An international humanitarian crisis or disaster can be defined as "a catastrophe that overwhelms the local ability to respond and requires an international, multi-sectoral response to avoid significant loss of life" (Anderson and Gerber 2018). It may take the form of a natural disaster, such as an earthquake, or a

man-made event, such as an armed conflict that displaces a population. The events may occur suddenly and unexpectedly or take effect gradually. In either case, international disaster response typically includes a formal request for assistance by the government of the affected population or by the hosts of displaced persons. Similar national humanitarian response efforts may also take place without requests for international assistance if local response capacity at the national or regional level is sufficient. These crises can become complex when affected populations move across national borders and require support in new locations, or when local governments restrict access to affected areas.

DISTINCTIONS BETWEEN HEALTH CARE SUPPLY CHAIN MANAGEMENT FOR HUMANITARIAN RESPONSE AND STABLE DEVELOPMENT CONTEXTS

It is helpful to understand the major distinctions between humanitarian response operations and stable public health service provision for better supply chain management.

SUPPLY CHAIN OBJECTIVES

There are a number of key distinctions between humanitarian and development contexts: supply chain objectives, context, stakehold ers, and common challenges. The Sphere Handbook (2018) (a publication of Sphere, an organization of humanitarian response professionals that draws from numerous institutions) presents the objective of humanitarian response operations as making every possible effort to reach populations with the greatest need first, rather than aiming to give efficient services to a broad range of people. The supply chain in turn supports this rapid response by delivering required health care commodities in a timely and effective manner to these populations. Even though value for money and service quality are still important, responding organizations at the acute stage aim to avert major loss of life caused by the disaster. Health care systems in more stable

settings have a long-term vision, and they aim to provide sustainable, comprehensive, high-quality, efficient, broadly accessible health services in line with disease prevention and treatment priorities, often in support of the goal of ensuring universal health care to their population. These differences in focus and time horizons between the two contexts affect how supporting supply chains operate.

CONTEXT

Humanitarian and stable health care delivery operate in distinct contexts. By their nature, humanitarian response operations typically require very large volumes of relief items to enter into a country through potentially damaged infrastructure, often within days or weeks of the onset of the crisis. Additionally, there is often a high degree of uncertainty in demand volumes (i.e., populations affected), local commodity distribution capacity, and regulatory processes governing importation (which result in uncertain delivery lead times). This results in high costs for storage and distribution, requiring creativity and thorough coordination in order to successfully receive and deliver required items. This context can also result in significant volumes of waste if resources are not managed properly. Infrastructure and capacity can also be limited during stable development operations in developing countries, but policies, regulations, processes, capacities, and demand, at least, are relatively predictable. Further, stable systems will receive and distribute orders of goods on an ongoing basis, with routine planning, forecasting, and budgeting cycles. Over time, these systems can pursue efficiencies by improving forecast accuracy and by making better use of limited infrastructure through more frequent order cycles.

STAKEHOLDERS

For stable health care systems, public health care is typically provided by a public institution, such as a Ministry of Health (MOH), with support from a public or parastatal supply chain organization. Local NGOs and international funders may complement the system where needed. In emergency responses, these same general stakeholders may be involved, but a specific set of international stakeholders also becomes involved in a humanitarian response effort. A response effort often begins with a formal request for assistance by the host country government indicating that the disaster has overwhelmed local resources. At a global level, UN organizations, for example, the Inter-Agency Standing Committee (IASC), the Office for Coordination of Humanitarian Affairs (OCHA), UN High Commission for Refugees (UNHCR), UN International Children's Emergency Fund (UNICEF), World

In Yemen, there was previously one central government with whom organizations corre sponded. But after the onset of the civil war (2015–), approvals needed to come from two separate governments' entities (de facto and de jure), and reg istration with each government entity was required.

Health Organization (WHO), World Food Program (WFP), and United Nations Population Fund (UNF-PA), have formalized roles in acknowledging and responding to relief requests. Many of these organizations have operational roles within the UN Cluster system (described further in this chapter), including the Logistics Cluster and the Health Cluster. Additionally, other international funders, such as USAID Office of Foreign Disaster Assistance (OFDA), UK Aid (DfID), and the European Commission's Civil Protection and Humanitarian Aid Operations (ECHO), will typically mobilize resources to help respond. Finally, the International Red Cross and Red Crescent Societies, other international and national NGOs, and militaries can also provide support. Throughout the response, however, the host government is ideally the center of coordination and provides operating approvals for organizations, but in some contexts, such as conflicts, there may not be a functioning government coordinating mechanism or it may have significantly changed.

The host government may designate various government agencies to provide coordination and government support to health care supply chain operations during emergencies, such as an emergency management agency, customs authorities, medicine quality regulatory agencies, the Ministry of Health, and/or parastatal health care supply chain operators.

For supply chain managers, this necessitates additional coordination around requirements and shipments between commodity funders, UN agencies, NGOs, and local service providers, some of whom may not have worked together or may not have worked in the affected country before.

Nigeria has established the National Emergency Management Agency with operating authority for coordination and policy support during prepared ness and response efforts. In an emer gency, these responsibilities are shared with relevant ministries (such as the Ministry of Health) and state-level emergency management agencies.

COMMON CHALLENGES

A number of distinct challenges affect humanitarian response operations, which include the following (Anderson 2018):

 Supporting a mobile population with changing demographics and disease burden. Many disasters displace populations. These populations will have varying proportions of children or women of reproductive age, for example, and may suffer from diseases not prevalent before the disaster. Responding to the needs of these populations requires updates on locations, demographics, and disease prevalence, which are not always available at the outset of an emergency.



- Working with damaged infrastructure. Depending on the type and extent of a disaster, infrastructure such as ports, warehouses, and roads may become damaged or restricted. This limits the ability to import and distribute products at the same time that a large influx of products is required. Rapid assessments must be made, and be routinely updated, to determine local capacities and identify multiple options to employ concurrently to ensure the necessary backup plans for an effective response. Given capacity limitations, deliveries must be prioritized based on their anticipated impact on the affected population.
- Importing required commodities in a timely manner. Impacted governments may not have importation procedures which reflect emergency response requirements, and may be slow to alter existing policies.
- Handling unsolicited donations. In many disasters the donation of unsolicited items can be an unfortunate outcome. These items place an additional strain on local resources and require sorting and proper disposal if they are deemed unusable.
- Navigating political challenges. Many population displacements involve civil wars, genocides, or other unrest. These can complicate or completely restrict efforts to deliver aid to affected populations, create security risks for staff involved in distribution, and generate sensitivities around data sharing. These political challenges may lead to currency problems or banking collapses, or particularly challenging importation processes. Further, there may be a lack of access to critical information for decisionmaking or misinformation about the gravity of a situation.



- Navigating a wide network of involved response organizations. Although coordination among partners has improved following dedicated efforts, supply chain management in crisis contexts inherently involves numerous diverse organizations with specialized resources. The UN Cluster System cuts across multiple disparate sectors that contribute to humanitarian response, and the Logistics Cluster provides support to all other clusters. Without strong coordination and communication, gaps or redundancies in response efforts can occur.
- Delivering required commodities within limited funding cycles and funding restrictions. Many responding organizations operate within 12-month funding cycles, which, if coupled with any delays in funding disbursement, can create a narrow span of time to source and deliver all required commodities. Funding may also include restrictions against local procurement of pharmaceuticals without prior approval, and some funding sources may not specifically cover pharmaceuticals.

GENERAL PRACTICES FOR SUPPLY CHAIN MANAGEMENT OF HEALTH COMMODITIES WITHIN HUMANITARIAN RESPONSE PHASES

Response efforts to humanitarian crises can be organized according to a common series of phases (see figure 1). In reality, the time between the onset of a humanitarian event and the full transition away from protracted interventions could last weeks to years, and at any given time a single country (or single responding organization) may experience acute crises in some geographic areas while supporting recovery in others. Additionally, areas may slip from recovery back to acute crises. The phases inform the kinds of activities undertaken by involved organizations and therefore the requirements of the supply chain. This section presents supply chain considerations and recommended practices within each of these phases, which generally can be undertaken by health system supply chain managers at the country level and also by international NGOs. This conceptualization of the phases of humanitarian response efforts draws from similar existing summarizations from OFDA, UNFPA, and OECD.



OVERVIEW OF PHASES OF HUMANITARIAN RESPONSE

FIGURE I.

PHASES OF HUMANITARIAN RESPONSE



Preparedness. This phase covers the activities that governments and partners can undertake prior to a possible humanitarian event to make their eventual responses faster, more resilient, and more aligned with the needs of the affected population. At this phase, investments can be made in the supply chain structure, policies, procedures, capacities, prepositioning of key supplies, responder training, and other operations that can support these objectives by making the supply chain more agile and responsive.

Acute Response. An international humanitarian response begins following the onset of a crisis and the expression of need by the host government of the affected population. Other humanitarian response efforts may take place at a national level when local resources can address the needs. During this phase the mortality rate has the potential to spike as the population is exposed to the disaster event, and response efforts focus on immediately averting this potential mortality. The supply chain in turn is focused

on rapidly mobilizing life-saving commodities and supplies to the affected areas, with less emphasis on longterm efficiency and visibility. For our purposes in this chapter, this phase specifically covers the period when international response has begun.

Protracted (or Recovery, Chronic, or Post-Emergency). This phase can take slightly different forms depending on the exact type of disaster, and it can last weeks or decades. In this phase, the peak potential for mortality has passed, but the situation has not completely stabilized. The affected populations may not have returned to their original homes, and the prevailing health system may not yet be able to provide normal services. Responding organizations may begin to transition to providing routine health services to displaced populations settled in camps or in host communities, and may begin building capacity in local institutions to return to normal service. Governments and partners also work to support rebuilding of infrastructure damaged during the disaster, but generally this context is still considered too fragile for long-term development efforts. In this phase, supply chain operations for health commodities may shift to become more efficient by improving forecasting and developing more formalized supply planning operations from more sustainable sources of supply. In addition, service delivery facility, storage, distribution, and information system capacities may improve and become more consistent, while demand becomes more predictable.

Post-Crisis (or Transition). At this phase, the situation has stabilized, and the host government and its partners return to providing regular services and building long-term capacity through conventional development activities. The supply chain returns to focusing on routine delivery operations as well as risk management and preparation for any future crises. At this point, supply chain activities and approaches should follow the processes outlined elsewhere in the Supply Chain Manager's Handbook.

Supply chain strategy should adjust accordingly to the progression of the humanitarian response context, and the shift from less predictable demand to more predictable, and from less predictable supply (including lead time) to more predictable. Commercial-sector approaches indicate that in contexts of greater or lower predictability of supply and demand, supply chain strategies might shift from agile to efficient (see figure 2). Agile in this context refers to operating policies that prioritize high performance with lower regard to costs, while under more predictable environments managers should pursue greater efficiencies and lower costs. Following the trajectory of humanitarian response operations from acute response to protracted to post-crisis (figure 1), supply chain strategy and operating approaches might progress along the arrow indicated in figure 2.

FIGURE 2.



SUPPLY CHAIN STRATEGY TO CONTEXT FIT

Adapted from Chase, Richard B., Aquilano, Nicholas J., and Jacobs, F. Robert. 2000. Operations Management for Competitive Advantage. 9th ed. New York: McGraw Hill.

RECOMMENDED PRACTICES

PREPAREDNESS PHASE

Not all humanitarian crises are completely unforeseen, but an organization that aims to respond rapidly and effectively to a sudden-onset event must invest in preparedness. The practices outlined below can be considered as investments—in process design, human resources, inventory, relationships, coordination mechanisms, etc.—which yield faster, more complete responses during potential future events. This phase represents an opportunity to perform more strongly against the objectives of the acute phase following a humanitarian crisis.

PREPAREDNESS PHASE PRACTICES

- Undertake Risk Management
- Develop readiness checklists
- Engage with international coordination mechanisms
- Develop relationships with suppliers
- Create country-specific importation requirements documentation
- Develop list of "vital products"
- Become familiar with existing health kit designs

Undertake Risk Management. A host government and its partners may conduct risk management and mitigation efforts to avoid or lessen the effects of potential disasters. Supply chain managers for the health system can contribute to this process by means of the following:

- · Identifying potential sources of performance challenges during emergencies
- · Prioritizing risks to determine which one should receive active management
- And proposing solutions to avoid, mitigate, or offset potential performance challenges, which may include development of contingency plans

Some of the typical solutions in this process include developing contingency plans to potential events and making investments in receiving, storage, and distribution capacity to better handle relief operations if they are considered to be a potential bottleneck risk. For example, if a key airport is known to have limited receiving capacity, developing processes to coordinate airport freight traffic to minimize time on the runway and offloading time can reduce delivery time. Development of contingency plans can facilitate coordination during an emergency by detailing decisionmakers, points of contact, and changes to processes. The risk management process is described in detail in the risk management chapter of this manual.

Develop readiness checklists. Similar to contingency plans, readiness checklists can help supply chain managers (particularly those at the global level) with the following tasks:

- Planning for international team deployments in crises by listing all necessary documentation, approvals, and items to carry along
- Facilitating customs clearance for product shipments by listing required documentation, timelines, and points of contact
- Reducing financing delays by listing product purchase or staff hire funding requirements

Staff can develop initial readiness checklists based on experience and existing resources, and institute a policy of reviewing and updating the lists when possible.

Engage with regional and international coordination mechanisms. Supply chain managers should become familiar with, engage, and undertake preparatory activities with relevant humanitarian response coordination mechanisms, which include the following:

- UNOCHA has responsibility for convening partners at the global and country levels in order to coordinate response efforts. This occurs through its role as the secretariat of the Inter-Agency Standing Committee and the implementation of the UN Disaster Assessment and Coordination (UNDAC) system, facilitating agreement on response priorities and mobilizing funding. OCHA also hosts an annual Humanitarian Networks and Partnerships Week.
- Logistics Cluster is a group of stakeholder organizations led by the World Food Program (WFP) that
 provides coordination and access to shared capacities for physical commodity flows during emergency
 response efforts. These roles include coordination of common logistics assets and services, shipment
 prioritization based on input from other technical clusters, and information management to strengthen
 operational decisionmaking. Biannual Cluster Global Meetings serve as opportunities for cluster organizations to discuss performance and initiatives. Country-specific pages on the Logistics Cluster website
 host relevant updates on response operations.
- Health Cluster contains stakeholder organizations led by WHO to share relevant information and build member capacity in health service areas, via a strategic framework, workplan, and dedicated task teams that address workplan initiatives. The organization supports country-level Health Clusters by providing guidance to ensure health response efforts follow global standards. The Health Cluster also promotes the importance of humanitarian health action among other global stakeholders.
- USAID Office of Foreign Disaster Assistance (OFDA) provides resources for partner organizations in the form of grants and cooperative agreements.

At a minimum, supply chain managers should bookmark points of contact and relevant policy documents. For example, the Logistics Cluster establishes clarified roles for involved institutions and facilitates cluster meetings which are vital for collaborative logistics solutions. Managers should also become familiar with the other involved organizations, and pursue facilitated training or e-learning opportunities, which they advertise on their websites (see table I at the end of this chapter for list of relevant resources). These organizations also develop and disseminate relevant guidance documents.

Many of these resources may provide general guidance for emergency response and may not include guidance specific to pharmaceutical management.

Supply chain coordination during the preparedness phase may also include sharing of country-specific information via coordination mechanisms: population data, information on roads, ports, and warehouses, and any other relevant resources or capacities.

Develop relationships with suppliers. Particularly if your organization will be sourcing commodities during a crisis, having existing relationships in place with potential suppliers can facilitate rapid response. Prior to an emergency response event, supply chain managers can screen suppliers for basic suitability, establish points of contact, and map basic capacities and lead times. Recurring contact, contracting, and information may lead to lower and more stable unit prices over time. Framework contracts, minimum volume guarantees, or bulk purchase agreements require global forecasting that projects requirements for at least one year at a time, but these approaches help manufacturers plan better, thereby reducing their costs, which can be shared with the purchasing organization.

Managers should also be aware of product prepositioning undertaken by WFP, UNFPA, and other partners in the United Nations Humanitarian Resource Depots (UNHRD) network, and consider the potential for prepositioning through their own organization if they are expected to respond to multiple emergencies over time. OFDA currently manages prepositioned stocks in four warehouses across the world, but these do not include pharmaceuticals.

Create country-specific documentation on importation requirements for medicines. Medicines procured and imported for the public sector or for emergency response may qualify for customs exception. However, processing shipments through customs without all necessary approvals can potentially delay shipments. Building documentation of these requirements for individual countries, or accessing this documentation from other local partners, can avoid costly delays. Another approach includes using an alternative consignee with proper import permits for the shipments, Managers should also prepare to work with freight forwarders familiar with particular country requirements or restrictions for importation. If possible, also look for opportunities to work with national authorities on preauthorization of kit import and other supplies, if it is anticipated that partners will import those commodities in the near future.

Country governments themselves can also create alternative emergency guidance or exemptions that will expedite the importation process for emergency items. Donor agencies and NGOs can help advocate for these processes during the preparedness phase. Additionally, ensuring that required medicines, including those packaged into kits, are included in the national drug list can help avoid future delays.

Develop lists of "vital" products for sourcing and importation during acute and protracted emergencies. In consultation with existing essential medicine lists from the governments, WHO, OFDA, and health service practitioners, develop consolidated product lists of the most critical items for health service provision in emergency contexts. These lists can be refined and adjusted after the onset of actual emergencies, but during the preparedness phase a generic list can be drafted. Organizations should formulate these lists for their contexts independently from the existing health kits (see below), and should make the decision about how best to procure these items (within existing kits or as separate items) separately following the onset of an emergency. Humanitarian organizations can work with governments on this effort during the preparedness phase to establish a vital list of medicines, which replaces the longer national essential medicines list during emergencies.

From this stage onward these items should be tracked and managed at the dispensing-unit level of each commodity to the extent possible. For example, even if health kits are eventually used to source desired antibiotics, quantities of dispensing units for each individual drug should be monitored to the extent possible, rather than the number of kits.

The guidance documents available from WHO and OFDA can also support development of guidelines for ensuring pharmaceutical product quality during sourcing efforts. UNFPA and UNICEF maintain supply catalogs of quality-assured health care commodities, while WHO also maintains a list of prequalified medicines, including specific manufacturers and the specific regulatory authority that approved the item.

Development of these lists should also include efforts to identify tentative sources of supply in terms of the number of suppliers for each desired commodity and their geographic locations. This exercise will highlight potential sourcing risks, either from suppliers becoming affected by disasters themselves (such as the example of IV fluid bag manufacturers in Puerto Rico, which were disabled by Hurricane Irma in 2017, causing shortages in the United States) or when supply is clearly constrained compared to global demand for the item. As with risk management (described above), these realizations should prompt associated action, either to exclude the commodity from the list of vital products or to take preemptive action to secure supply.



Furthermore, the list of vital products should not include any item that could potentially impede the importation of other products in the same shipment. For example, controlled substances have the potential to delay an entire shipment's customs clearance process, and in an acute crisis it may be preferable to exclude these items if they pose a risk to the timely delivery of other life-saving commodities or supplies.

This list should ultimately include the following:

- Generic name of product
- Type of diseases treated
- Potential amount needed for a large target population
- · Potential sources of supply and their location
- Whether the product is in shortage at a global or regional level
- Whether the product requires additional approvals for importation

Become familiar with existing health kit designs. Some suppliers offer standardized, prepackaged sets of health commodities that are likely to be required in tandem. These kits offer the benefit of faster procurement (particularly if the kits are held ready in inventory by the supplier or prepositioned), faster importation, and simplified distribution to service delivery points. Their primary drawback is that some items will go unused and may expire because the ratios between the items are fixed and some items may not be equally suitable for all response settings. Additionally, kits do not support establishment of longer-term, sustainable supply systems. However, given the emphasis on rapid deployment in the acute phase, and the lack of detailed demand data, kits can serve as a helpful initial approach.

To combat the drawbacks of globally designed kits, some kit providers now offer optional modules or supplements in order to provide some tailoring towards the specific target population. For example, malaria is a significant burden of disease in some regions of the world but not in others. Antimalarial drugs then can be supplemented onto a standard emergency health kit to support service delivery in endemic locations, or left out for nonmalarial geographies.

The specific medications and consumables contained in the kits and their ratios are typically selected and endorsed by technical committees (such as those organized by the WHO) to fulfill specific health care service requirements based on assumed average incidence or prevalence rates. Each kit will support service provision to a specified quantity of target population over a given period of time. Some examples:

- The Interagency Emergency Health Kit (IEHK), WHO
- Cholera Kits, WHO
- Inter-Agency Reproductive Health Kits for Crisis Situations, UNFPA/WHO
- Non-communicable Diseases Kit (NCDK), WHO

If your organization already operates within specific countries, it may be beneficial to pursue inclusion of specific health kits and their contents in national logistics management information systems (LMIS), so that partners can easily report stock balances, transactions, and amounts dispensed to users. This requires that humanitarian organizations, NGOs, and government agencies work together to define processes, provide approvals, and determine the circumstances under which the government can activate the option to use the LMIS by partners during the emergency.

ACUTE PHASE

After the onset of an emergency and a formal request by the host country government for international support, funding agencies (such as CERF, USAID/OFDA, and others) approve access for funding to respond. At this point all involved partners work towards the objective of minimizing any potential loss of life. This cooperation will differ by disaster type, but the response will typically include a health care component and the supply chain for health commodities, which is often managed by multiple actors, including the lead organizations working in the health arena that will be tasked with getting commodities to the service delivery locations. At the acute phase, strong supply chain management for health care commodities becomes particularly critical for ensuring the delivery of life-saving health services.

Organizations may have specific guidance regarding which contexts qualify as emergencies, thereby allowing for certain operational practices to change. During these emergencies, managers will face numerous challenges, but over time solutions have emerged to improve supply chain performance in these contexts.

ACUTE PHASE PRACTICES

- Conduct needs assessment
- Select pharmaceutical suppliers
- Coordinate response efforts
- Manage safety risks to staff

- Utilize private sector capacity
- Plan for difficult delivery conditions
- Conduct responsible waste management
- Establish basic visibility into inventory and transactions

Conduct needs assessment. An initial step for the overall response effort is to determine the likely needs of the affected population. Unlike most commercial or health system supply chains, the initial humanitarian response is based on a rapid, on-the-ground, targeted estimate and relevant secondary information rather than specific orders or more detailed forecasting. This needs assessment contributes to a Humanitarian Needs Overview (HNO), which combines survey results, existing secondary data, and expert input and analysis to generate a shared consensus on the current scope and priorities of the required response and the likely evolution of the requirements during the planning cycle. The initial needs assessment may be conducted by UNDAC, OFDA-DART, and other rapid response organizations.

The initial needs assessment will capture information that supports decision making for all sectors, but critical aspects of the health care response should include total population affected, demographic breakdown, sources of morbidity, locations of population, locations and capacities of health care service provision (e.g., whether affected populations have access to a functioning secondary hospital or whether service provision will occur at temporary sites), current inventory quantities of medical commodities, and relevant pharmaceutical regulation (particularly regarding importation). Over subsequent weeks during the response, partners will update and refine this estimate, but the first deliveries rely on the initial needs assessment. Subsequent needs assessments can capture current system capacities and government requests, and any data from service delivery or logistics information systems. The HNO specifically is usually produced twice per year to support Humanitarian Country Teams in developing a shared understanding of the evolution of a crisis and to inform continued response planning.

One approach for tracking population movements and other developments over time is to conduct crisis mapping via web-based mapping applications. NGOs, other organizations, or communities may establish mapping systems that capture locations and live data reported by individuals on mobile devices (Cavelty and Giroux 2011). Currently, organizations such as UNHCR, IOM, and the CDC include these technologies in their operations.

Select pharmaceutical suppliers for quality adherence. Regulatory systems worldwide have not kept pace with the rapid globalization of pharmaceutical production and distribution over the last 30 years. For this reason, supply systems in low- and middle-income countries (LMICs) remain exposed to the risk of poor-quality medicines, and, as a consequence, humanitarian partners have a responsibility to select the appropriate suppliers and deliver quality health products to their patients (Van Assche et al. 2018).

The prequalification of medical supplies (i.e., appearing on the WHO's list of prequalified products, or when it has been approved by an entity described in Article 4(2)(d)) and the certification of a supplier (i.e., distributors or manufacturers which are compliant with WHO quality assurance standards and certified by an internationally recognized accreditation body) are key concepts to ensure the quality of medical supplies. However, because of limited technical capacity and resources, the majority of humanitarian partners may delegate prequalification to their suppliers.

To select their suppliers, humanitarian partners may request acceptable proofs of quality. Acceptable proofs of quality are those issued either by the WHO, a Stringent Regulatory Authority, or a donor, such as the OFDA-approved suppliers. A Stringent Regulatory Authority can be a National Drug Regulatory Authority of a country participating either in the PIC/S (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme) and/or in the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) initiatives. If none of these proofs of quality are available in the country of operation, then the proof of quality may be issued by an independent, internationally recognized accreditation body.

If the latter is not available at all, then the humanitarian partner will be responsible for assessing and ensuring the quality of their suppliers and of their health products by itself.

In all cases, a humanitarian partner should launch a procurement procedure only among its short-listed certified candidates. The invitation to negotiate should indicate the following selection criteria:

- Respect of the WHO's principles of Good Manufacturing Practice (GMP¹) or Good Distribution Practices (GDP²) and Good Storage Practices (GSP³) or Good Laboratory Practice (GLP), Good Clinical Practice (GCP⁴) or the WHO's Model Quality Assurance Standards MQAS.⁵
- Ongoing monitoring of the production and quality-control activities of both their supplies and suppliers, compliant with the WHO guidelines (see above bullet) and an adequate quality-control testing program, including protocols and standard operating procedures, and based on a demonstrated risk analysis policy.
- Monitoring of customers' complaints and remedial follow-up, including recall procedures.
- Any other certification that ensures compliance with at least one of the following standards or an equivalent: United States QS (21 CFR part 820⁶) on quality system regulation; ISO9001/2008 on quality management system; ISO9002/1994⁷ on quality assurance in production, installation, and servicing.

To assess the offer(s), the procurement notice sent with the invitation to negotiate should include the following award criteria, at a minimum:

- Respect of the minimum quality standards, such as the WHO's principles of GMP, GSP, GDP, or GLP
- Respect of the national drug regulations in the country of destination
- Respect of any intellectual property rights and patent regulation applicable in the country of operation

Coordinate response efforts. As under the preparedness phase, managers should continue to coordinate operations through relevant channels under OFDA and/or the UN Logistics or Health Clusters. Coordination through these mechanisms in the acute phase allows for sharing of needs assessment information, coordinated shipments, shared capacity (warehouses and deliveries), and improved predictability and accountability as compared to the more independent, uncoordinated approaches used by organizations prior to the adoption of the cluster approach (Altay and Labonte 2011). Under these systems, individual organizations assume clarified roles, which together can help share logistics and health data maps, inventory, and staff lists, and coordinate use of constrained infrastructure to avoid congestion. Attending weekly Health and Logistics Cluster meetings can be an opportunity to share and receive shipment updates and collaborate to address challenges. Ideally, partners should have both health managers and supply chain managers attend both of these meetings to ensure full coordination. Historically, health or pharmaceutical supply chain needs, constraints, and special considerations have not systematically been included in these coordination meetings, but it is recommended that organizations already involved in these activities increasingly bring these specific challenges to those and other key coordinating bodies.

Manage safety risks to staff. Logistics operations inherently require individuals to fill deliveries in warehouses and drive and offload shipments near service delivery locations. During humanitarian crises, these same locations may present physical threats to delivery staff, particularly during civil unrest or conflict. Managers can reduce the risks to staff by taking the following measures:

• Establishing and using situation monitoring. Use field staff or reporting from other organizations based in the field to obtain daily updates on hotspots. This information will guide decisionmaking about where deliveries should take place, or whether inventories should be moved to a safer area.

¹ http://apps.who.int/medicinedocs/documents/s18619en/s18619en.pdf

² https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf

³ http://apps.who.int/medicinedocs/documents/s18675en/s18675en.pdf

⁴ https://extranet.who.int/prequal/sites/default/files/documents/GCP_handbook_1.pdf

⁵ http://apps.who.int/medicinedocs/documents/s21492en/s21492en.pdf

⁶ https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm

⁷ ISO 9001/2008 supersedes ISO9001/2000.



- Providing relevant training to staff. Training for drivers and delivery teams exists that imparts practices for avoiding and responding to active threats that they might encounter. These staff should also be included on security updates.
- Identifying relevant local authorities, whose influence can be leveraged to protect staff and shipments.
- Utilizing Red Cross/Red Crescent logos when applicable. Article 44 of the first Geneva Convention dictates proper use of these logos to help identify materials as humanitarian and nonmilitary in nature (Turner et al. 2018).

Utilize private sector capacity. Where available, private industry may have storage and distribution capacity and valuable supply chain information. In some countries, companies have created organizations to coordinate use of private sector capacity in emergency response operations. For example, ALANAID, an NGO in the United States, uses its membership to connect commercial supply chain capacity and expertise with organizations responding to emergencies. Private sector courier companies will likely have strong information systems that can support tracking of supplies shipments.

Plan for difficult delivery conditions. Many settings may have infrastructure, security, or weather challenges beyond the emergency itself. Consider sourcing and storing fuel for vehicles and generators to keep commodities cool where cold chain may be unavailable, including insulation equipment to extend the reach of cold chain. Also consider forward deployment or prepositioning of inventory closer to service delivery points in areas that may become cut off by rainy seasons.

Conduct responsible waste management. Improperly disposed medical waste creates a risk for local populations, who can become exposed to expired medicines, sharps, or infectious material. In ideal settings, a waste management system comprehensively addresses all waste throughout the system with a

combination of collection and approved on-site disposal. However, emergency situations can disrupt those processes even in places where they exist, and, combined with an influx of commodities that may be dispensed outside of conventional health facilities, they can create additional exposure.

The following are some approaches to properly manage the volume of waste:

- Improving forecast accuracy and/or transitioning away from the use of kits-only procurement to reduce potential expiries and wastage
- Managing warehouses under a policy of first-to-expire, first-out (FEFO) and tracking expiration dates of products in order to encourage use of soon-to-expire items
- Establishing a process of transferring soon-to-expire items between service delivery points to move items to a location where they will be more likely to be used
- Establishing a process of recollecting expired items from service delivery points for proper disposal at a more central location

Establish basic visibility into inventory and transactions. Partners must track inventory and transactions in order to better establish demand, determine requirements, fill orders faster, and discourage pilferage. However, at the acute phase, it may be difficult for partners to establish a comprehensive, collaborative means of visibility across distribution partners, even if individual partners are able to quickly set up proprietary information systems that track inventory in their direct control. In contexts where a logistics management information system (LMIS) does not exist, it typically requires significant time and effort to design and implement a properly functioning system. In the early stages of a response effort, funding partners and lead organizations should, at a minimum, require that central warehouses track stock levels and quantities issued out to other partners. Additionally, this approach should ideally capture distinct commodities in terms of the medication, formulation, and dosage, counted in numbers of dispensing units. Preferably, this system also should extend down to the service delivery level, capturing quantities of stock on hand, any losses or adjustments including receipts, and quantities dispensed to recipients over time. Organizations supporting the service delivery level may already capture much of this data, and may simply need to regularly complete a standardized form for upstream partners to consolidate.

Mobile applications and technologies offer a relatively rapid means to establishing basic visibility of inventories and transactions. These technologies exist on a variety of hardwares (simple phones, smart phones, tablets, etc.), and support a range of products and particular means to establishing visibility and ensuring accuracy and real-time data sharing. Some solutions, such as C-stock, allow health workers to send a structured SMS that communicates quantities dispensed for a small number of items. Other OpenLMIS-based solutions allow for a broader set of features on more sophisticated hardware.

PROTRACTED PHASE

Following the acute response phase, the initial major threat of mortality has passed, but local systems may not yet be stabilized to return to normal supply chain operations and strengthening efforts, and lingering population displacement may present a risk of further outbreak or crises. Displaced persons may have settled into refugee camps or host communities, which require ongoing health services while their future status is determined. During this time, the health care supply chain responds to ongoing requirements that no longer present the urgency of the acute phase but have not yet fully stabilized to allow for normal service delivery and long-term continuous improvement. At this stage, supply chain managers may find opportunities to improve supply chain visibility, forecasting, and inventory management to aid the transition away from kits and towards more efficient procurement of individual items and ownership through country systems.

PROTRACTED PHASE PRACTICES

- Transition from use of standardized kits to individual items
- Transition procurement to local sources
- Manage sources of supply over long term

Some valuable practices at this stage:

Transition away from use of kits to procurement of individual items. Standardized emergency response kits are designed to support health services for a standard population for a given period of time (often three months). The organizations that stock and preposition the kits also assume that they will primarily be used for acute emergencies. In reality, partners in many settings procure and distribute kits beyond the acute crisis because of their relative ease and rapid delivery, even in some cases importing the kits but opening them up at a warehouse in order to deliver the individual items specifically required by the service delivery points. However, the continued use of kits is inefficient at a local level because underutilized commodities will accumulate, and at a global Transitioning to management of individual items:

- I. Assess current inventory management practices
- 2. Establish inventory control systems
- 3. Incorporate logistics data into forecasting

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- 4. Conduct supply planning
- 5. Build staff capacity

level it may cause shortages of the kits, waste, and delays in fulfillment for actual acute emergencies. For

UNFPA's Emergency Reproduc tive Health Kit Forecasting Tool creates forecasts based on the structure of the existing kits by building up forecasted require ments of the individual items contained in the kits. Using such a tool, local partners can identify the individual items and quantities that should continue to be sourced when transitioning away from kits. these reasons, responding organizations should transition towards sourcing of individual commodities as health service delivery begins to stabilize. The vital lists prepared during the preparedness phase, adapted from standard national or WHO essential medicines lists, can be further tailored at this stage to the services needed, standard treatment guidelines, and disease burden of the changing population served and can be useful tools to use at this stage for forecasting, quantification, and changing policies and procedures for sourcing and delivering those supplies outside of the kit modality. In some instances at this point the scope of health services may change or broaden to cover longer-term population requirements. A change in services supported would necessitate a growth in the number of products to be sourced, which may include but also go beyond the items available in standard kits.

This transition may require significant effort on several fronts, including the following:

- Conduct an assessment to understand the relative gaps in inventory management and supply planning processes, current procurement mechanisms, and the available options for transition.
- Establish robust, sustainable inventory control systems and LMIS for stocking locations: these processes for monitoring inventory levels and determining resupply amounts will rationalize inventory and improve availability. This may require implementation of an existing national system at locations established for emergency response—incorporating local MOH staff can facilitate this transition, particularly if the emergency response locations will begin to order their items from an MOH system.
- Incorporate logistics data into forecasting, which include current stock levels, quantities issued over time down to partners or service delivery points, or consumption (quantities dispensed to users) over time. Using logistics data will greatly improve the accuracy of forecasts and supply plans. In the absence of

logistics data, service statistics can also be considered (see Chapter 5 on quantification in the Supply Chain Manager's Handbook), which may be superior to broad demographic estimates used during the acute crisis.

• Conduct supply planning to manage shipment quantities and timings. Supply planning includes comparison of forecasted requirements to existing stocks and lead times in order to rationalize required shipment quantities and timings. Monitoring of the national product pipeline and shipments should be conducted and shared routinely with involved partners.

At refugee support operations in Cox Bazar, Bangladesh, staff use the national LMIS system for managing commodities. Although this system does not yet report into the existing national health care system's supply chain, use of the same procedures and policies today can expedite any eventual transition.

• Conduct relevant trainings in these areas for involved staff, which may include both NGO staff and national health care supply chain staff.

Where possible, transition procurement to local sources of supply. Many countries will have wholesalers and government parastatals or agencies that import health commodities or consolidate products from manufacturers for sale to the local market, but in many developing countries not all of these sources will fulfill drug-quality standards. Some of the product needed by humanitarian partners or health managers in the affected regions may be available at the central government level via traditional development donors or normal government funding. As the humanitarian crisis stabilizes, partners should consider the opportunities for credible local sources to supply the commodities needed for health service delivery while still following agency procurement policies regarding GDP distributors or GMP products. However, commodity funders often have strict pharmaceutical quality guidelines, meaning that procurements within the local market under these funding streams would need approval prior to purchase.

Manage sources of supply over long term. Potential suppliers of medical supplies who meet funder requirements may be limited. Orders may have to be spread across multiple suppliers to cover all commodity needs, and delays in delivery may extend beyond funding timelines. Some potential approaches to address this challenge include starting procurement as early as possible in a project, getting extensions on funding as needed, and transferring goods custody to a follow-on project or a separate partner.



POST-CRISIS (OR TRANSITION) PHASE

At this phase the threat of increased mortality has largely passed for the population, and systems have stabilized enough for partners to focus on long-term development. For the health care supply chain, international organizations that have focused on the humanitarian response may depart from the country and focus resources elsewhere, while the government and other partners will return to supporting the health system and continuously improving performance. Infrastructure rebuilding projects may continue, and supply chain practices should mirror those recommended in other chapters of this handbook.

It is important at this stage that supply chain managers return to activities that support emergency response preparedness, such as going through trainings or establishing supplier relationships, or updating vital and essential medicines lists, or incorporating risk monitoring and management into their routine health supply chain management activities. Within the affected country, building capacity of local staff should continue with an expectation of long term supply chain performance improvement.

This phase is also an opportunity for partners to obtain input from the community on the initial response to identify gaps, successes, and opportunities for future improvement for the supply chain.





WHERE TO LEARN MORE

A number of online resources and portals exist that can provide up-to-date guidance, recommendations, and updates for current ongoing response efforts. Table I summarizes these resources.

TABLE I.

USEFUL RESOURCES FOR HUMANITARIAN RESPONSE LOGISTICS

RESOURCE NAME	WEBSITE	DESCRIPTION
International Association of Public Health Logisticians (IAPHL)	https://community.iaphl. org/hcl/	Online community of practitioners hosting technical discussions and peer-to-peer knowledge sharing. Currently adding a subgroup to focus specifically on supply chain management for humanitarian response (requires account set up).
ReliefWeb	https://reliefweb.int	An online resource of OCHA, providing reliable and timely information on global crises and disasters, as well as job listings and training programs.
Humanitarian Response	https:// humanitarianresponse. info	An online resource portal supported by OCHA that includes current information on ongoing response efforts and also global guidance documents and resources for coordination.
International Council of Volunteer Agencies (ICVA) Network	www.icvanetwork.org	A global network of NGOs focused on improving humanitarian response. The website includes a repository of policy descriptions, e-learning links, and coordination for working groups.
UN Office for the Coordination of Humanitarian Affairs	https://www.unocha.org/	Office overseeing coordination for humanitarian response efforts.
UN Logistics Cluster	https://logcluster.org	Updated logistical service support and information for ongoing response operations hosted by the Logistics Cluster. Individual country pages with up-to-date capacity information, maps, documents, and contact information.
Georgia Tech Health and Humanitarian Systems	https://chhs.gatech.edu/ home	Website containing links to academic articles, teaching materials, and case studies.
Sphere Handbook 2018	https://www. spherestandards.org/ handbook/	Globally developed handbook for humanitarian response that includes guidance on delivery of health services.
Inter-Agency Working Group 2018 Field Manual	http://iawg. net/2018-inter- agency-field-manual- reproductive-health- humanitarian-settings/	Inter-Agency working group focused on reproductive health in crises, including links to resources on logistics and the Inter-Agency Field Manual, a comprehensive field manual on Reproductive Health in humanitarian settings.

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