



**GUIDANCE ON ENSURING
A SUFFICIENT SUPPLY OF
SAFE BLOOD AND BLOOD
COMPONENTS DURING
EMERGENCIES**



**World Health
Organization**

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PREFACE

This guidance document has been produced by the World Health Organization (WHO) to assist blood services in the development of national plans to respond to any disaster, major incident or emergency that threatens sufficiency or safety of the blood supply. Such situations can be caused by natural forces, by factors influenced by humans or directly caused by humans. This document is intended to guide the national blood service through the process of planning how to respond in a timely, controlled and appropriate way to emergencies. In the preparation of the document, WHO has tried to include the elements that blood services or providers might need to consider, providing some background on the reasons for their inclusion and guidance on different response options that may be available.

The consequences of an emergency may include interruption of blood supply due to a shortage of blood donors, or to a disrupted supply of critical materials and equipment used in blood collection, component preparation and laboratory testing, resulting in reduced availability of blood and blood components. Although the demand for transfusion may decrease in some situations, transfusions continue to be necessary for clinical emergencies and for those patients reliant on long-term transfusion support. In contrast, some emergencies, for instance those resulting in multiple casualties, could lead to a rapid surge in demand for blood over a short time. The challenge is to maintain essential transfusion services as well as responding to the emergency.

Preparedness, including business continuity planning, is essential for blood services to mitigate the impact of emergencies. Preparation should be underpinned by locally sensitive risk assessment using relevant data at the local or country level. However, it is not possible to predict the nature of every situation that could impact on the blood supply, and it is therefore expected that blood services will review the elements in this document as well as assessing their own situation, needs, capabilities and resources, along with any additional relevant country-specific factors, in the development of their own response plans. Planning should consider the concurrence and combinations of events and the response should be proportionate and coordinated with others. The aim is to maintain critical services and prepare for recovery. Staff training and support is key to resilience.

It is acknowledged that as well as affecting the sufficiency and safety of blood supply, major incidents in countries undertaking transplantation may threaten the safety and sufficiency of the supply of other products of human origin, such as cells, tissues and organs. Increasingly, blood services are taking overall national responsibility for transplantation in their capacity as the organization responsible for the collection, processing, storage and supply of cells, tissues and organs. This approach is both sensible and appropriate, as the overall donor selection and screening processes are the same or very similar. This guidance document can therefore also be used to assist those bodies responsible for the provision of cells, tissues and organs to prepare for emergencies. Resilience to disasters and emergencies requires a commitment to the blood supply and transfusion system as an integral part of the health care system.



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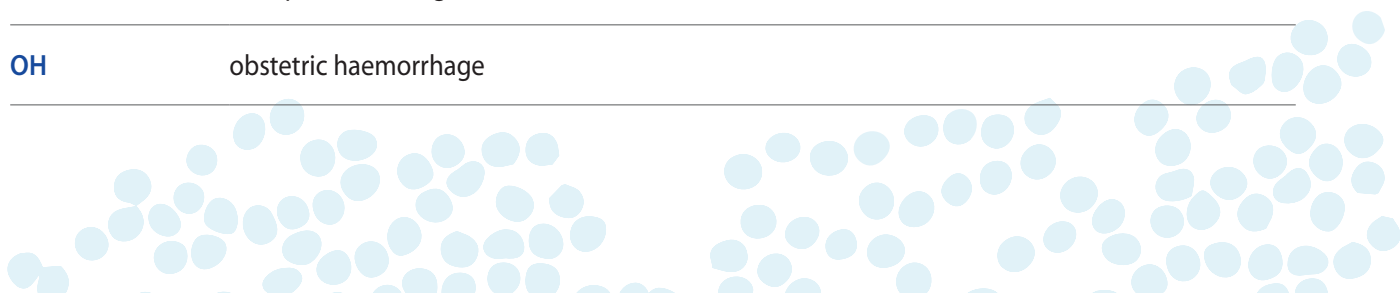
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LIST OF ABBREVIATIONS AND ACRONYMS

AABB	Association for the Advancement of Blood and Biotherapies
BCP	business continuity plan
BIA	business impact analysis
CIM	critical incident manager
COVID-19	coronavirus disease 2019 (causative agent being SARS-CoV-2)
EM	essential medicine
GBT	global benchmarking tool
GDBS	Global Database on Blood Safety
HIV	human immunodeficiency virus
ICDRA	International Conference of Drug Regulatory Authorities
ICT	information and communications technology
IFRC	International Federation of Red Cross and Red Crescent Societies
IT	information technology
LMICs	low- and middle-income countries
MCE	mass casualty event
MTPD	maximum tolerable period of disruption
NBS	national blood system
NCIM	national critical incident manager
NGO	nongovernmental organization
NPT	near patient testing
OH	obstetric haemorrhage



PBM	patient blood management
PDMP	plasma-derived medicinal product
PPE	personal protective equipment
RA	risk assessment
RBC	red blood cell
SARS	severe acute respiratory syndrome
SDG	Sustainable Development Goal
SITREP	situation report
SMS	short message service
TTIA	transfusion-transmissible infectious agent
UN	United Nations
UNDP	United Nations Development Programme
UPA	units per patient admitted
VNRD	voluntary non-remunerated blood donation
WHA	World Health Assembly
WHO	World Health Organization



EXECUTIVE SUMMARY

Globally, the number of people affected by disaster and other emergencies, including infectious disease outbreaks, natural disasters and humanitarian crises, is increasing. During some disasters or emergencies there may be an increased need for blood and components. Maintaining sufficient supplies of safe blood and blood components to treat those affected is therefore critical. However, ensuring sufficient supplies of safe blood may prove challenging, because the disaster or other emergency may have damaged the available civil and health care infrastructure, disrupting mobility, transportation and service provision. Members of the population may not be able to come forward to donate blood, for example, due to fear or illness. Furthermore, the channels of communication may no longer be reliable, and the overall health care system may become overburdened.

In response to blood service disruptions due to the increasing incidences of disasters and other emergencies, WHO has developed several tools to guide national and international efforts. The role of the national blood system during emergencies must be clearly defined and needs to be an integral part of national emergency preparedness and response planning. In this way, availability of safe blood in emergencies, such as infectious disease outbreaks (for example, the COVID-19 pandemic), natural disasters and humanitarian emergencies, can be ensured.

However, a key element in enabling a nation to sustain a sufficient supply of safe blood and components during any emergency is a properly structured, coordinated and funded blood service. Ideally this is a centralized national service within the national health care system, directly responsible to and funded by the government. Having an existing national organization makes it easier to divert resources and maintain overall organizational and management structures. It also simplifies coordination within the national response by reducing the number of individual bodies involved, as well as helping to maximize the organization's ability to respond to the situation.

This guidance on how to ensure a sufficient supply of safe blood and blood components during emergencies provides a comprehensive background followed by guidelines on risk assessment and gap analysis. It elaborates on the need for emergency preparedness planning at national and international level and explains how to respond to and enable the blood system to recover from the devastation and disruption caused by disasters and humanitarian emergencies. However, the normal functioning of an effective blood establishment is complex, encompassing various separate, but interlinked, activities, and any impact on any one of these activities may result in the blood establishment being unable to function fully.

This document provides guidance on the following key elements:

- understanding the background to emergencies and the need for blood and components during such situations;
- the need for and performance of risk assessment and gap analysis;
- understanding the critical need for emergency preparedness planning at national and international level;
- how to respond to the ongoing impact of emergencies;
- how to enable the blood system to recover after the emergency has resolved.

Development of the document

This document was developed from an initial meeting (virtual) of a selected group of experts in transfusion medicine, WHO Regional Advisers for Blood and Transplantation, WHO headquarter Blood and other Products of Human Origin staff and Health Emergency Intervention staff. The need for guidance and support for member states in maintaining a safe and adequate blood supply during emergency situations was discussed and established.

The group identified the key topic areas and individual working groups were established to produce the initial text for each of these areas. An editorial group was formed from the leaders of the individual working groups and the final document developed through a re-iterative process by the initial group before review by a number of WHO identified external experts.

Declaration of interest by external contributors

Declaration of interest for external contributors acting on their individual capacity has been collected, assessed, and managed as per WHO policy (Declarations of interest. In: About WHO Geneva: World Health Organization; 2021 (<https://www.who.int/about/ethics/declarations-of-interest>, accessed 5 November 2021). The standard WHO form for declaration of interest (DOI) was completed and signed by each expert. The WHO Blood and other Products of Human Origin Team reviewed all the DOI forms before finalizing experts' invitations to participate. No competing interests were declared, therefore no further action was taken.



1.1 Justification for the Guidance, the scope and objectives

There is an urgent need for guidelines on how to ensure that there is a sufficient and appropriately adapted supply of blood and components for blood services, especially in medical emergencies. There are multiple documents, textbooks and publications available on ensuring a sufficient supply of blood and components in all WHO Member States. However, such documents seldom deal specifically with the issue of the sufficient supply of blood and components during emergencies. As the routine blood supply is likely to be disrupted, specific guidelines covering emergencies are needed to help maximize the ability to maintain an adequate supply of safe blood and components. While preparing this type of document, numerous factors need to be kept in mind, including the types of disasters, locations, extent of human casualties, existing infrastructure in the country and likelihood of the disaster, among others.

When developing a guidance document on maintaining the blood supply during emergencies, the *Action Framework to advance universal access to safe, effective and quality-assured blood products (2020–2023)* is fundamental for defining strategic objectives (1).

The first strategic objective states that the national blood system (NBS) in a country should be well-structured, an integral part of the national health system and financially sustainable. The NBS should routinely maintain optimum quality and quantity so that it can provide adequate support during any emergency, including natural or human-made disasters, as well as during disease outbreaks.

The second strategic objective stresses the need for a well-defined regulatory system for the NBS, which requires quality assessment of blood products and medical devices, including in vitro diagnostic devices. An internal and external quality assurance system in all blood establishments is essential to maintaining quality and safety of blood and components in both routine and emergency situations.

The third objective is efficiently managed blood centres with adequate voluntary donors, minimum wastage of blood and components and where any excess plasma is made available for production of plasma-derived medicinal products (PDMPs). Meeting these three objectives will help in ensuring availability of sufficient blood and components for emergencies.

The fourth strategic objective is patient blood management (PBM) with rational use of blood and components in accordance with national or global guidelines. The hospital-based transfusion service should follow a quality system ensuring availability of quality blood components in routine practice as well as during emergencies. To achieve a sustainable continuous improvement, standardized data collection, reporting and analysis are essential.

According to the fifth objective, each NBS should develop a centralized haemovigilance system to allow continuous updating and improvements.

The sixth strategic objective is the provision of continuous training, especially at national level, and the accreditation and certification of blood establishments. Emergencies may challenge the *status quo* and self-reliant blood services should be encouraged to learn from their experience. The Action Framework and these six objectives provides a valuable tool for reflection and service improvement after the event. The aim is to ensure efficient management of the blood services in a disaster situation so that they are supplying the right quantity, right quality and right components, at the right time and to the right person.

1.2 Definitions

Disasters and emergencies may be naturally occurring, due to factors influenced by human beings, or directly caused by humans. A disaster is a sudden event causing great damage, loss or destruction. An emergency is an unforeseen occurrence or combination of circumstances that is potentially dangerous and calls for immediate action.

In the context of this document, for simplicity and clarity, reference has been made primarily to “emergencies”, but this term is used in a broad sense to describe all events or circumstances, including disasters, which could lead to an “emergency” situation.

1.2.1 Disaster

The United Nations (UN) defines a disaster as a situation or event which overwhelms local capacity necessitating a request to the national or international level for external assistance; an unforeseen and often sudden event that causes great damage, destruction, and human suffering (2). There could be multiple causes for disaster at community level, which could affect large numbers of the population. Examples include floods, fires in urban areas or wildfires, earthquakes leading to destruction of buildings, armed conflicts leading to migration or displacement of the population, large-scale spread of diseases or epidemics. In most of these disasters, the population is unable to manage the extent of the damage, and suffering is greater if outside assistance is not adequate and timely. Following a disaster at household level, immediate assistance is usually received from neighbours and local authorities. At national level, multiple agencies start providing aid in different forms according to the type of disaster and available resources. During any type of international disaster, a wide range of international agencies and bodies, including the International Federation of Red Cross and Red Crescent Societies (IFRC), the UN, national governments, nongovernmental organizations (NGOs), as well as other philanthropic agencies, take measures to mitigate human suffering in accordance with their respective mandates. The success of the disaster response will depend upon how well the population can cope with the magnitude of the disaster. It also depends on the resilience of the population in responding to the disaster to mitigate its consequences.

1.2.2 Natural disasters

Natural disasters are generated by the forces of nature with no direct involvement of human beings. Although some of these disasters are predictable, others are not, and such disasters have a sudden onset. Loss of life and property as well as human suffering could be significant depending upon the magnitude of the disaster. Natural disasters include:

- tropical storms
- floods and droughts
- extreme temperatures – heat or cold
- volcanic eruptions
- earthquakes
- landslides
- tsunamis.

1.2.3 Disasters directly or indirectly caused by humans

Disasters induced by humankind cause great harm. These disasters have an element of human intent, negligence or error involving a failure of a human-made system. Examples of disasters in which human beings are directly involved are:

- industrial events
- transportation events
- mudslides resulting from deforestation
- famine
- desertification
- economic collapse
- armed conflicts.

International humanitarian law distinguishes two types of armed conflicts, namely, international armed conflicts and non-international armed conflicts (involving terrorists, insurgents or rebels) (3).



1.3 Background

1.3.1 Principles of safety, availability and access to care including blood, blood components and PDMPs

In the mid-twentieth century, in the immediate aftermath of the Second World War, the newly established UN adopted the Universal Declaration of Human Rights, which includes the right to health (4). In 1948, the General Assembly proclaimed

this Universal Declaration of Human Rights as a common standard of achievement for all peoples and all nations, to the end that every individual and every organ of society, keeping this Declaration constantly in mind, shall strive by teaching and education to promote respect for these rights and freedoms and by progressive measures, national and international, to secure their universal and effective recognition and observance, both among the peoples of Member States themselves and among the peoples of territories under their jurisdiction.

Article 25 of the Declaration reads:

1. Everyone has the right to **a standard of living adequate for the health and well-being of himself and of his family**, including food, clothing, housing and **medical care** and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.
2. **Motherhood and childhood are entitled to special care and assistance.** All children, whether born in or out of wedlock, shall enjoy the same social protection.

Over the decades that followed, societies changed, decolonization began, and public awareness of the principle human rights started to grow. Yet there is a major difference between the industrial countries, home to around 16% of the global population, and the developing countries, home to the majority (84%) of the global population (5). The UN Development Programme (UNDP) together with the World Bank has mapped the world according to various development indices and indicators illustrating the socioeconomic gaps and the huge diversity of states of development and its consequences (6,7). With the aim of rectifying this situation, the UN launched a major human development programme at the turn of the last century – the Millennium Development Goals 2000–2015 (8). This programme included a strong element of education intended to bridge the existing knowledge and socioeconomic gaps. Because of the progress made, this work was continued in 2016 with another 15-year programme: the UN Sustainable Development Goals 2016–2030 (9) (Fig. 1.1).

Fig. 1.1 The 17 Sustainable Development Goals: Goal No 3 focuses on good health and well-being



The 2030 Agenda for Sustainable Development was adopted by the UN's 193 Member States at the historic UN General Assembly Summit in September 2015. The 17 Sustainable Development Goals (SDGs) and their 169 targets are part of this agenda. The SDGs are a bold, universal agreement to end poverty in all its dimensions and craft an equal, just and secure world – for people, planet and prosperity. The SDGs were developed through an unprecedented consultative process that brought national governments and millions of citizens from around the globe together to negotiate and adopt this ambitious agenda (10).

The third goal: Good Health and Well-being is intended to *Ensure healthy lives and promote well-being for all at all ages*. This includes the availability and accessibility of safe and efficacious blood and blood components as essential medicines (EMs), both the cellular components and the PDMPs.

Target 3.8 reads – *Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all*. This makes clear the importance of a high-quality blood supply as well as a professional and balanced approach to the clinical transfusion of blood, blood components and PDMPs.

At the 2010 World Health Assembly (resolution WHA63.12) concern was expressed about the unequal levels of access globally to blood products, particularly PDMPs. Such inequality of access left patients suffering without treatment, and many of those with severe congenital and acquired disorders without adequate plasma-derivative treatments (11). In this resolution, the World Health Assembly urged WHO Member States:

to take all the necessary steps to update their national regulations on donor assessment and deferral, the collection, testing, processing, storage, transportation and use of blood products, and operation of regulatory authorities to ensure that regulatory control in the area of quality and safety of blood products across the entire transfusion chain meets internationally recognized standards.

Requirements for implementing effective national blood regulation are described in the WHO *Assessment criteria for national blood regulatory systems*, which was replaced in 2019 by the WHO Global Benchmarking Tool + Blood (GBT + blood) (12).

In accordance with resolution WHA63.12, it was recognized that achieving self-sufficiency in the supply of safe and efficacious blood is an important national goal in preventing blood shortages and meeting the transfusion needs of the patient population. Blood and blood components (whole blood, red blood cells (RBCs), platelets and fresh frozen plasma) were therefore added to the eighteenth edition of the core list of the WHO Model List of Essential Medicines in 2013 (13). Self-sufficiency in this context means that the national needs of patients for safe blood and blood components, as assessed within the framework of the national health system, are met in a timely manner. It also entails equitable access for patients to safe and efficient blood for transfusion. Self-sufficiency can be accomplished by promoting voluntary non-remunerated blood donation (VNRD). Defining blood and blood components as EMs could also contribute to self-sufficiency by:

1. drawing attention to the role of national governments in providing the necessary organizational and other support required for assuring a safe and adequate blood supply in periods of peace and stability as well as in situations of disasters and humanitarian emergencies; and
2. encouraging countries to develop and ensure compliance with safety and quality standards as well as good practices in product preparation for transfusion, irrespective of the situation and environmental conditions.

Effective blood regulation is crucial for the establishment of blood components as EMs. However, in some countries, blood and blood components do not meet the legal definition of medicines, and this could require taking a different approach to assure their quality, safety and availability from the one used for conventional medicines. In 2014, the International Conference of Drug Regulatory Authorities (ICDRA) recommended that WHO should undertake a project aiming to provide guidance on the management of blood and blood components as EMs. Blood and blood components are either prepared by blood establishments and distributed to hospitals and other facilities or prepared by hospital blood banks for use in the treatment of various diseases (14,15). In some cases, the latter is perceived as part of medical practice rather than as the preparation of a biological therapeutic product. There is therefore a concern that blood and blood components could be prepared in facilities (including hospitals) that are not subject to appropriate regulatory oversight and where awareness of product liability is lacking (15). Consequently, the regulatory system should apply to all facilities whether private or public and should be focused on protection of patient and donor rights (safety, care) and product liability (quality, manufacturing or processing).

In 2018, WHO published the first edition of a *Model list of essential in vitro diagnostics*, which includes the essential diagnostics (reagents and test kits) needed for the mandatory quality testing of blood for transfusion – immunohaematology (blood grouping, alloantibody detection and compatibility testing) and for screening for transfusion-transmissible infectious agents (TTIAs) (viral, bacterial, parasitic and others) (16).

1.3.2 Ethical and legal principles in the context of natural disasters and humanitarian emergencies

Ethical questions related to health, health care including blood transfusion, and public health range from moral issues around reproduction, state obligations in the provision of health care services, and appropriate measures to control infectious disease and mitigate disaster and humanitarian emergency disparities. Scholars and health care professionals have debated ethical questions related to health and health care since the earliest days of medicine, starting with the

Hippocratic Oath. Recent formal efforts to articulate international standards of ethics applicable to health and health care can be traced to the Nuremberg military trials of 1945–1946, in the period following the Second World War (17). The principles that emerged from those trials, known as the Nuremberg Code, are applicable to many types of health-related situations involving human participants, including clinical trials. The growing breadth and complexity of contemporary health challenges has raised a range of difficult questions. Such questions cannot always be adequately addressed by relying exclusively on existing policies, guidelines or codes of conduct. There are ethical debates over access to new and expensive pharmaceuticals, specialized blood products and medical technologies in situations where infrastructure has been disrupted (18). These, together with increasing awareness of the gross health disparities that continue to exist both within and between countries, have called attention to the need for an ethics of health policy and practice. The Universal Human Rights serve as the gold standard against which to measure ethical conduct and behaviour, whatever the conditions and circumstances (4). However, despite these principles, inequality persists among and between populations as illustrated by the 2018 UNDP's human development indices and indicators (19).

Epidemics and pandemics, natural and human-made disasters, and humanitarian emergencies raise many ethical issues for the people involved, who include responders, public health and health care professionals and other workers, and internal and external policy-makers. There are three main issues that need to be continuously addressed:

1. The obligation to uphold principles and values embodied in international and national ethics guidelines, as well as human rights instruments. Economic and other sanctions and restrictions on essential supplies, for example, food, medication and medical consumables, cause a serious ethical conflict.
2. Reluctance to ground the need for ethical oversight in the classical distinction between health practice and applied health research, recognizing that such a distinction easily becomes blurred during emergencies, especially when these are protracted.
3. Adaptations of ethical principles, oversight and processes, focusing on the deliberations on the gravity of the situation and the urgency of the need.

During disasters and emergencies, one of the main objectives of medical and public health personnel is to minimize mortality and morbidity through maintaining professional standards and adequate and justified prioritization. Because of constraints on time and resources, however, their ability to do so is limited, and a way must be found to choose who should be given what treatment. Effective planning and management of resources and personnel will significantly influence the duration and severity of the situation but also raises important ethical questions about setting priorities and allocating resources fairly. The process of triage involves prioritizing the use of scarce medical resources when these are insufficient to provide immediate treatment or diagnostic interventions for everyone. Effective triage should help determine who to treat first, and with what kind of treatment. In other words, triage involves assessing the nature and severity of an individual's illness or injury to determine their health status and whether they can be saved. The information is also used to decide on the priority and type of care and blood product to give. In terms of blood procurement (collection, processing and testing), decisions will have to be made on what the acceptable minimum is to preserve fundamental safety of the supply. Triage can also be based on nonmedical factors, such as socioeconomic status, economic blockades and social utility, in deciding to whom and for what, priority should be given. Beyond decisions about care, triage can also involve decisions about priority for transport and facilities in which individuals will receive further care. Triage is used not only where the resources and/or medical personnel are insufficient to provide the necessary immediate care to everyone at the same time, but also, for example, in accident and emergency departments (20).

A second means of effective resource management is rationing, which involves delaying or withholding immediate treatment for individuals for economic or scarcity reasons. Rationing, like triage, is not only used during emergencies. For instance, most health care systems ration the number of hip replacements performed each year, because there are not enough resources to treat everyone (21).

Ethical principles can be categorized as either substantive or procedural (22). Substantive ethical principles include explanations of why a particular policy or course of action is ethically justified. Procedural ethical principles outline the way in which decisions or actions should be taken if they are to be considered ethically justified. There are ten substantive and five procedural ethical principles to be distinguished (Annex 1).

Challenges like prioritizing, economic blockades, disrupted infrastructure, displacement of people, and unpredictability of disasters and conflicts will have a major impact on the human response and on maintaining professional standards and ethics in practice. Regulatory flexibility in setting a balance and drawing a line of unacceptability together with resilience and inventiveness will provide solutions to cope with such devastating situations and continue the provision of basic care.

1.3.3 Factors affecting the demand for blood transfusion

During natural disasters and humanitarian emergencies there is an ongoing need for transfusion support for both routine and emergency care in addition to any demands or disruptions due to the emergency. Routine demand planning considers the seasonal collection and distribution of blood based on local health care requirements and organization. Emergency planning builds on this essential background data. Guidelines are available for appropriate routine use (23); however, special provision may need to be made for both emergency work and the transfusion-dependent communities during prolonged shortages. Various examples are referred to throughout this document. However, the following list is a useful prompt when planning for demand.

- **Surgical.** Limited access to safe blood can be a critical barrier to providing some elements of surgical care in resource-limited settings globally. The Lancet Commission on Global Surgery calls for global access to a safe and affordable blood supply by 2030 through a minimum collection of 15 units per 1000 people/year. Low- and middle-income countries (LMICs) collect a range of 3.9–11.7 units per 1000 people/year (24).
- **Trauma.** The foremost reason for death among under 40-year-olds is traumatic injury, which causes an estimated 5 million deaths per year globally. Of these deaths, an estimated 10–20% are preventable. Uncontrolled haemorrhage within 6 hours of injury is one of the prime causes of avoidable death and has led many trauma specialists to seek ways to reduce early mortality due to severe injuries (25).
- **Paediatric anaemia.** Severe anaemia resulting in significant morbidity and mortality is common in children in sub-Saharan Africa, South-East Asia and the Middle East and blood transfusion is a life-saving intervention. Blood shortages are common in LMICs and delays in delivery contribute significantly to in-hospital mortality of children with severe anaemia, especially when associated with malaria (26).
- **Anaemia due to malnutrition.** Globally, anaemia is a leading cause of morbidity and mortality among women and children. In 2011, 43% of children under 5 years, 38% of pregnant women and 29% of non-pregnant women between the ages of 15 and 49 years were living with anaemia (27). Chronic and untreated anaemia reduce physiological reserves.

- **Haemoglobinopathies and inherited coagulopathies.** Haemoglobinopathies and inherited coagulopathies, such as the haemophilias, may be uncommon but people with severe disease are heavily dependent on transfusion support. These patients might suffer disproportionately during blood shortages (28).
- **Haemato-oncology/cancer.** Transfusion medicine plays a vital role in the supportive care of patients receiving therapy for haematological disorders or cancer, and haemopoietic stem cell transplants (29). Mitigation strategies may be required, including choice and timing of treatment.
- **Obstetric haemorrhage (OH).** OH, which mostly occurs postpartum, is a leading cause of maternal mortality worldwide and accounts for one third of maternal deaths in Africa (23, 30). Multiple factors contribute to effective management, including timely access to emergency interventions, access to blood, availability of trained health care staff, financial and infrastructural provisions (31). All of these may be further compromised during emergencies.

1.3.4 Factors related to the blood system that are affected by disasters and emergencies

Access to and delivery of safe and sufficient supplies of blood and blood products, as well as PDMPs becomes more difficult in disasters and humanitarian emergencies. Important factors are discussed in the following sections.

1.3.4.1 Fragmented organization

Fragmented blood systems, with blood services that are often operated by different players, pose a significant challenge in many countries. This situation often leads to problems with coordination and a lack of collaboration among different stakeholders. It may also lead to unnecessary competition for blood donors, which will not only increase the cost and effort needed to motivate and retain donors but may also have a negative effect on the principle of voluntary non-remunerated donation (32) and on the health of the blood donors. On the other hand, centralized operations during emergencies, when communications and supply lines are disrupted, may not be optimal. Recent experience from conflicts in Ukraine and Bosnia suggest that decentralization allowed flexibility and the ability to operate autonomously, without reliance on supplies of blood or raw materials from other regions (33).

Coordination is essential to secure both the advantages of a larger organization and the agility of local delivery. In some countries, blood services continue to operate under the responsibility of laboratory or pathology services, which are often not nationally coordinated (34). Based on the 2015 data from the Global 4on Blood Safety (GDBS), the median number of annual donations processed per laboratory performing blood testing was 9300, with an interquartile range (IQR) of 1500–30 000 (34). An analysis by WHO found major differences between the regions, reflecting different organizational models and varying efficiencies and grades of effectiveness. An ineffective and inefficient blood supply system composed of many small-scale blood banks is a common barrier to implementation of quality screening using more sensitive assays for TTIs and diseases. Data from the GDBS 2015 indicate that 25 out of 141 (18%) responding countries use rapid tests to screen all or part of their blood supply for infectious agents (34). Although some of these rapid tests have a high sensitivity, they are handled manually, which leads to a greater potential for error, both technical and clerical. This, together with the widespread use of poor-quality and significantly less sensitive rapid tests in many LMICs, contributes to an increased risk of transmission of bloodborne infections. Many countries lack a centralized reference laboratory system for evaluation and validation of test kits and reagents. Furthermore, there are often no minimum performance requirements to guide the selection and procurement of the test kits and reagents, and procurement decisions are too often based solely on price. Also, fragmentation in procurement of consumables often results in higher costs than can be obtained through centralized “bulk” purchasing (34).

Interruptions to the regular supply of test kits, reagents and consumables were reported by 21% of countries (35). These interruptions are usually due to insufficient budgetary allocation or to ineffective and inefficient procurement systems and supply chain management (36). This may result in the procurement of poor-quality consumables tendered at the lowest price, and in the same test kits and reagents being procured for all laboratory services without any consideration of the specific needs of blood services (sensitivity for screening versus specificity for diagnostic purposes). Multiple supply contracts, for example, for the same test kits, reagents and consumables, or contracts that are of insufficient duration, are also contributing factors. In addition, trade restrictions, customs and border clearance delays, and issues with transport and cold chain logistics, may limit the range of reagents and consumables available to the blood service under normal circumstances, let alone under disaster and humanitarian emergency conditions (37).

Maternal and other health care policy interventions, concerning the national ambulance service, safe motherhood protocol, national health insurance scheme, medical supplies and health personnel are often not well coordinated at the implementation level (38). These policies are often developed and rolled out without proper planning for the implementation phase. Damage to communications networks during disasters and emergencies makes it even more difficult for women or their families to contact private transport operators, ambulance service providers and the community health officers (39).

1.3.4.2 Damage and disruption to infrastructure

Infrastructure deficits specific to health care systems during a crisis include logistic or physical collapse of health care infrastructure and institutions, insufficient supplies including of medications, exodus of local health workers, including specialists, due to long working hours, and poor payment for the remaining health workers (40). These deficits make it challenging for community health workers to provide safe and efficient care for patients, as it is difficult to maintain human resources in crisis work. Health facilities and other infrastructures can be destroyed in minutes, for example, if they lie in the path of mudflows containing volcanic debris (41). Contamination of the environment (for example, of water and food) with volcanic ash can worsen environmental health conditions; this effect is compounded when the population must be evacuated to temporary shelters.

Natural disasters can cause serious damage to health care facilities, water supplies and sewage systems and this has a direct impact on the health of the population dependent on these services. When hospitals, health and blood centres are rendered structurally unsafe by natural disasters, this jeopardizes lives and limits the capacity to provide health services and support to disaster victims. The earthquake that struck Mexico City in 1985 resulted in the collapse of 13 hospitals (42). In just three of those buildings, 866 people died, 100 of whom were health personnel. Nearly 6000 hospital beds were lost in the metropolitan facilities (43, 44). As a result of Hurricane Mitch in 1998, the water supply systems of 23 hospitals in Honduras were damaged or destroyed, and 123 health centres were affected. Peru reported that nearly 10% of the country's health facilities suffered damage because of El Niño events in 1997–1998 (45–47).

1.3.4.3 Displacement and death of health workers

Large, spontaneous or organized population movements create an urgent need to provide humanitarian assistance (48). People may move to urban areas where public services cannot cope, and the result may be an increase in morbidity and mortality. If much of the housing has been destroyed, large population movements may occur within urban areas as people seek shelter with relatives and friends. During crises, the health care workforce may be severely affected, reducing capability and capacity.

1.3.4.4 Shortage of supplies

The supply chain (medical equipment and pharmaceutical supplies) for the health facilities is often temporarily disrupted during a disaster (49). The global spread of the SARS-CoV-2 pandemic exposed vulnerabilities in supply chains and logistics. It disrupted health supply chains, affecting the supply of active pharmaceutical ingredients and consumables, shipping, procurement, finished health care products and more. Logistic supply chains are much more than the movement of pharmaceuticals and other products between countries. Logistics faces problems at grass roots level, including the migration of labourers working in industrial units, bans on transportation activities, especially movement of trucks, lack of cooperation between different administrations and transporters, and couriers not working according to schedule (50). All these factors cause delays and hamper the supply of items such as vaccines, hand sanitizers, test kits, personal protective equipment (PPE), blood and blood components, medicines (including PDMPs), medical equipment, raw materials and much more (51).

1.3.4.5 Transport and cold chain deficits

Disasters may place a greater demand on supply chains because of increased travel times and/or a need for multi-segment journeys (for example, van to train to van). Limited road access makes it difficult for disaster victims to reach a health care centre (52). Longer supply chains are more vulnerable to weather, congestion and other external factors (53). Poor accessibility due to geographical barriers and/or unreliable transport systems may also cause difficulties (54). In geographically large countries or countries with limited transport options, longer distances and times needed for shipment of blood donations, laboratory samples and processed blood components may increase the risks of impaired cold chain management and temperature excursions (55). The speed of delivery is critical and new technologies such as drones or unmanned aerial vehicles have been used successfully for transport of both samples and blood products (56).

1.3.4.6 Economic blockades and sanctions

Recently, scholars have studied the effects of sanctions on health, focusing on finding empirical evidence. Peksen addressed this issue by studying an international sample, using child mortality as a proxy for health (57). Economic sanctions may seem to be a more humane way of resolving international disputes than wars. However, multiple studies on Burundi, Cuba, Haiti, Iraq, Nicaragua and the North Macedonia showed that due to their long-term impacts on the lives and health of a large population, the adverse humanitarian effects of economic sanctions are comparable to, if not worse than, wars (58). Through exacerbating economic difficulties and impairing the functions of the social systems of the target country, they decrease the access of people to essentials of life such as nutritious food and medical care. Several countries have been under economic sanctions for more than three decades or are currently under such sanctions. The sanctions have seriously undermined the right to health, as well as respect for international human rights obligations (4).

1.3.4.7 Disruption and interruption of power supply

Access to electricity is critical to health care delivery and to attaining the overarching 2030 goal of universal health coverage (59). Health facilities are among the largest commercial consumers of electricity, relying on power for everything from water supply, temperature control, lighting and ventilation to operation of a huge range of vital clinical equipment (61). Nevertheless, many hospitals and clinics across Africa have no access to a reliable electricity supply, if they have any supply at all (61). This leads to serious problems, including spoilage of medicines and blood, and the inability to use essential medical and diagnostic devices. Even the lack of basic lighting and communications systems can complicate treatments, especially emergency procedures. Lack of electricity limits working hours and inhibits the

deployment of medical technology. Recent reports have highlighted the importance of technology in health care and its potential to transform the way health care is delivered in Africa (62, 63).

1.3.4.8 Difficulties with maintaining cleanliness, hygiene and asepsis

Although natural disasters do not always lead to massive outbreaks of infectious disease, they do increase the risk of disease transmission (64). The disruption of sanitation services and the failure to maintain public health programmes combined with increased population density and displacement, all culminate in an increased risk for communicable disease outbreaks (66). Poor hygiene, damage to sanitation and sewage treatment plants, and lack of access to clean water and uncontaminated food further increase people's vulnerability to a variety of common communicable infectious diseases (67). A hydrological event disrupts the environment at multiple levels and can destroy pre-existing infection barriers separating hosts and agents. Water sources can become contaminated with sewage, wastewater and agricultural runoff (69). Standing water can serve as a breeding site for arthropod vectors such as mosquitoes, which can lead to outbreaks of diseases such as dengue fever (68). Displaced human populations lacking shelter are likely to encounter contaminated water, animals and arthropod vectors, while those in temporary shelters may be exposed to infections associated with crowded living conditions (69). Hydrological disasters such as hurricanes Harvey, Irma and Maria, which occurred in the second half of 2017 are poignant reminders of the power and destruction these events can unleash (70). Hydrological disasters also often raise concerns about the threat of infectious diseases associated with human remains.



CHAPTER 2

RISK ASSESSMENT AND GAP ANALYSIS

2.1 Understanding and assessing risk

Ensuring that sufficient supplies of safe blood and components are available during emergencies involves several elements, one of which is developing effective and appropriate emergency response plans. This requires a thorough understanding of:

- the possible emergencies that could arise;
- the potential outcomes of those situations;
- the potential impact of those situations on blood service activities;
- the ability of the blood service to increase availability and/or adapt blood products to meet sudden increases in demand and/or to react to constraints imposed by the circumstances.

Taken together these factors provide the information required to assess the current blood service capacity and capabilities, identify deficiencies or gaps, and to determine whether/what action needs to be taken to try to ensure that the blood service is still able to function effectively and to continue to provide the required quantities of safe blood and components during an emergency. Together these activities are commonly referred to as risk assessment (RA) and gap analysis.

An important element of preparedness is trying to prepare for the unexpected. Although there may be a finite number of emergencies that could occur, how they occur, their impact and their resolution can vary significantly, and preparedness must take this uncertainty into account. Planning needs to take into account not only the obvious potential threats and previous incidents, but also should at least consider the more extreme, albeit less likely, situations that could arise. Importantly, this may not require significant extra work, just some additional consideration and broader thinking, when developing preparedness plans.

Understanding risk is critical in the development of contingency plans at all levels, and, if they are to be performed correctly and have value, RAs must incorporate a broad range of factors. However, RA is not just about the likelihood and severity of an adverse event. It also needs to consider the vulnerability of a population to such an adverse event, what could be adversely affected and the extent of any such effect.

2.2 Definitions

See also section 1.1.

2.2.1 Risk

There is no commonly accepted single definition of risk. According to the Royal Society (71), risk is “the probability that a particular adverse event occurs during a stated period of time, or results from a particular challenge”. WHO, in the context of acute public health events, defines risk as the likelihood of the occurrence and the likely magnitude of the consequences of an adverse event during a specified period (72). There are more situation-specific definitions, but for this guidance document, the more general definitions are appropriate.

Breaking down “risk” into specific components, can, however, be useful when considering a situation where there are multiple and different risks, and where the range and potential impact of the risks may be different.

- **risk:** determined from a combination of **hazard** and **vulnerability**;
- **hazard:** a natural or human-made event that threatens to adversely affect human life, property or activity to the extent of causing a disaster;
- **vulnerability:** the predisposition to suffer damage due to external events (the **hazard**), which itself is determined by the level of susceptibility and the degree of resilience.

2.2.2 Risk assessment (RA)

RA is the process used to determine the nature and extent of any risk, by analysing hazards and evaluating existing conditions of vulnerability that together could potentially cause harm. In the context of this guidance harm could be caused by reducing or completely preventing the supply of safe blood and components. A comprehensive RA not only evaluates the magnitude and likelihood of potential losses but also allows a full understanding of the causes and impact of those losses.

An effective RA involves several steps to ensure that all aspects of the current situation, the hazards, the potential impacts and the extent of any impact are considered and assessed. These steps are described below and summarized in Box 1.



2.2.2.1 Understanding the current situation

The first step of any RA of the impact of an emergency on blood services and their activities is to determine the status of the blood service. This includes its organization, funding, effectiveness, ability to meet the current needs of recipients of blood and components, the ability to increase the availability of blood and components if needed, current issues and challenges, and future challenges and threats already identified.

2.2.2.2 Assessment of the possible hazards

The likely hazards that could result in an emergency, which could then affect blood service activities, need to be identified. These will usually be generic hazards, but they can be divided into defined categories, i.e. natural disasters, major infrastructure failures and conflict. Some emergencies could also escalate into multi-level situations or develop from a combination of “low-level” hazards. Some Member States, for several reasons, may be inherently susceptible to emergencies, nationally, regionally or locally. Also, some Member States may be impacted by emergencies developing in neighbouring Member States.

2.2.2.3 Analysis of the degree of vulnerability

The degree of vulnerability is assessed by determining the capacity, or lack of capacity, of the blood service and its supply chain to withstand and respond to any emergencies. The degree of vulnerability may vary significantly depending on the specific emergency arising and its ramifications.

2.2.2.4 Analysis of the potential impact

The potential impact of any emergency on the ability of the blood establishment to maintain a sufficient supply of safe blood and components needs to be assessed. As the range of hazards that may give rise to an emergency and their specific impact on blood establishment activities is wide and varied, the impact may vary from negligible to a total inability to supply.

2.2.2.5 Overall evaluation and development of risk reduction strategies and plans

The overall evaluation involves pulling together the information obtained and identifying the gaps and weaknesses, which may vary according to the nature of the emergency. This is used as the basis for developing the strategies and plans to ensure the maintenance of blood establishment activities and the provision of sufficient supplies of safe blood and components. These strategies and plans include setting priorities, allocating responsibilities and resources, and initiating the appropriate measures to maximize preparedness.

Box 1. Key messages – conducting a risk assessment

Risk assessment of blood services needs to:

- understand the current capabilities to deal with any emergencies;
- determine possible hazards;
- identify any areas of vulnerability;
- understand the potential impact; and
- provide the background to enable risk reduction strategies and plans to be developed.

2.3 Applying risk assessment and gap analysis to the blood system

2.3.1 Current situation

As mentioned in section 2.2.2.1, the first step of any RA of the impact of an emergency on blood services and their activities is to determine the status of the blood service (Box 2). An assessment of what already exists and what is missing helps to focus on actual needs, avoid duplication of effort, and build on existing information and capacities.

Depending on the Member State, the nature and organization of the blood establishment and the resources available, a blood establishment may already have the capacity to sustain activities and/or increase the blood supply during a range of emergencies. However, this capacity may not be sufficient to extend to all emergencies. How to ensure that the blood service maximizes its ability to respond to any such situation is the foundation of the RA. The review and assessment of current capacity and capabilities must be comprehensive and honest. At the same time, it needs to take a broad view of the blood establishment and its activities both alone and in relation to other health care activities, and consider existing weaknesses, threats and vulnerabilities that might impair its ability to maintain current activities.

Although a comprehensive review is necessary, there are certain key areas that form the core of the review, and from which the more Member State-specific elements can be identified, as discussed below.

2.3.1.1 How the blood supply is provided

Questions concerning how the blood supply is provided include the following: is there a single organization responsible for the blood supply; is the responsibility shared between more than one organization or is the blood supply hospital-based? Is there a central site with or without satellite sites or are there multiple sites of similar size and activity level?

If a single body is responsible, it is generally much easier to organize and coordinate nationally as the systems already exist. Where the blood supply system is more complex, it becomes harder to determine how responses to emergencies can be properly managed because there are likely to be problems concerning specific areas of authority and responsibility. Even in a fragmented system, the ability to organize as a single body in the case of an emergency is critical for an effective and sustained response.

2.3.1.2 Organizational structure, funding and accountability

How is (are) the organization(s) providing the blood supply structured, how is it (are they) funded and what is the accountability? Is it a national structure or is the organization all at local level; where does accountability lie? Is funding central and national, local or external, i.e. nongovernmental? Could effective overall leadership be applied nationally in an emergency, with overall national accountability? Is there a pathway for sufficient additional or emergency finances to be made available to fund the necessary response during an emergency?

2.3.1.3 Additional agencies and organizations that may assist in emergencies

The relevant external agencies and organizations need to be identified as they may be able to help in emergencies. Such assistance may be purely financial but could also extend to technical assistance and to sourcing supplies of consumable materials needed by the blood service to continue its activities. Assistance may also include creating links with neighbouring national blood establishments to provide an additional source of blood and components.

2.3.1.4 Current sufficiency of supply of blood and components

The current situation in respect of the routine supply of blood and components must be understood, including any shortages of stock, and the usual breakdown of the stocks held. If the day-to-day supplies are often limited, restricted or variable, supplies during an emergency are likely to be severely affected. The reasons for the variability of the current supply need to be understood to ensure that emergency preparedness planning takes these into account. Also, blood establishments need to be prepared to change from routine production of blood components in normal times to adapted processing during emergencies (for example, preparing blood products that are not, or are less often, requested during normal times, such as safe cryoprecipitate).

2.3.1.5 Sufficient facilities, including staffing, with capacity to continue to provide blood

Are there sufficient, suitably staffed, facilities to enable the blood establishment to continue its activities and maintain a safe blood supply? Single-site blood establishments are more vulnerable as any impact on the site would have greater repercussions than on a service with multiple sites, which could compensate for any reductions in service. Blood collection activities may be less affected, depending on the collection sites used, but the ability to transport blood from collection sites to the blood centres needs to be assessed. Current staffing levels need to be known, as does the availability to the blood service of trained and competent staff. If there are already problems with staffing, an emergency could lead to acute staff shortages, which in turn could impact on the ability of the blood establishment to maintain its activities.

2.3.1.6 Current system of stock control for consumables and disposables: ordering, supply, monitoring

How are supplies of the consumables and disposables necessary for the routine operation of the blood establishment managed? How much stock is usually held? Can extra supplies be quickly ordered and delivered? Is there the capacity to hold extra supplies, especially of temperature-controlled materials?

2.3.1.7 Current or potential issues impacting on blood service activities

There may be ongoing potential issues that could impact blood service activities. Even if these issues are not considered to be likely to affect the supply of blood and components in “normal” times, it should not be assumed that this would continue to be the case in times of emergency. In an emergency, even minor issues could become significant.

2.3.1.8 Existing emergency preparedness plans

Are any emergency preparedness plans already drawn up? What is the focus of these plans – maintaining sufficiency and/or safety, providing minimum emergency levels of blood and/or components? What range of emergencies and what elements of blood establishment activities do they cover? What level of flexibility exists in the plans?



2.3.1.9 Communications

It is important to consider how the blood service communicates with stakeholders. How does it communicate with:

- the public to motivate and recruit donors?
- hospitals to manage supplies in response to clinical needs?
- government and other appropriate bodies to engage in the emergency response, report problems in maintaining supplies, and request additional support and assistance?

Are there communications channels already in existence and in use, and how effective are they?

Box 2. Key messages – understanding the current situation

The status of the organization and its capabilities to respond to any emergencies need to be properly understood. If multiple agencies are responsible for blood supplies, they must be able to work together in times of crisis:

- Blood establishment organizational structures need to be robust.
- Blood establishment funding must be secure and sufficient.
- Other agencies may need to be approached for assistance.
- The blood supply in “normal” times needs to be sufficient.
- Blood establishment staffing needs to be sufficient and secure.
- Sufficient facilities should be available so that the services can cope if some sites are lost.
- Supplies of consumables and disposables need to be sufficient and there should be a robust resupply process.
- Any issues currently affecting the ability of the blood service to function effectively need to be considered during planning and resolved as quickly as possible.
- Any existing contingency plans should be reviewed to ensure they are sufficient and appropriate.
- Communication channels to be used during an emergency need to be identified.

2.3.2 Assessment of the possible hazards

The hazards that could result in an emergency, which could in turn affect blood establishment activities, need to be identified. In most cases these will be generic hazards, but they can be divided into defined categories (i.e. natural disasters, major infrastructure failures, conflict, disease outbreaks, mass forced population movement). Some Member States, for several reasons, may be inherently susceptible to hazards and are thus more likely to be faced with emergencies. Furthermore, some Member States may be impacted by, or end up in an emergency because of a hazard occurring and leading to an emergency in a neighbouring Member State(s). In the case of infectious disease outbreaks, depending on the infectious agent, a pandemic situation with a global impact is always possible (Box 3).

2.3.2.1 Natural hazards

There are many potential natural hazards – “natural disasters” – but not all natural hazards are likely to affect all Member States. Susceptibility to a natural disaster depends on the geography and geology of the Member State, and on the population distribution and type and level of infrastructure. However infectious disease outbreaks, which may be

“natural” or “human-made” may impact any susceptible population. The natural hazards that could lead to an emergency need to be identified, together with other possible hazards. Whether the hazards could extend to directly affect the whole of the Member State or would affect only specific regions or areas needs to be considered. The range of natural hazards that could affect the Member State must be identified and the likelihood of these hazards giving rise to an emergency and impacting on the ability of the blood service to maintain its activities or to provide sufficient blood and components must be determined. Unfortunately, natural hazards are rarely controllable: they cannot be prevented, they usually occur randomly, their impact is hard to control and they do not respect national borders (see section 2.3.2.3).

2.3.2.2 Human-made hazards

Human-made hazards that are likely to give rise to emergencies, whether short-lived or long-term, can vary widely. They range from localized but short-term major incidents, to extended conflict affecting an entire Member State and the whole of its population, and even to the emergence of an infectious agent that results in a global pandemic. Although the causes of human-made incidents are varied, the nature of the likely incidents can generally be predicted. The range, duration and severity of human-made hazards that could affect a Member State and lead to an emergency must be identified and the likelihood of an impact on the ability of the Member State’s blood establishment to maintain its activities or to provide sufficient blood and components assessed.

2.3.2.3 Indirect hazards

Indirect hazards may be natural and/or human-made. These hazards often begin outside the Member State but the hazard or its impact extends into the Member State to give rise to an emergency. Depending on the nature of the hazard, the impact may vary significantly, and may result in an increased demand for blood rather than disrupting blood establishment activities. Indirect hazards are harder to predict, but a significant hazard of any type occurring in a neighbouring Member State should trigger an alert and a review of the emergency in the affected Member State.

2.3.2.4 Consequences of hazards

In addition to identifying the types of hazards, their consequences must also be considered in light of the seriousness of the emergency that could arise. In a similar way to the hazards themselves, the consequences of a hazard occurring can vary significantly, from no impact on the blood service to major disruption of its activities and/or a significantly increased demand for blood and components. The consequences of each type of hazard need to be considered and included in the RA (see section 2.3.4). This would include assessing the severity of the impact at all levels, from organization-wide to individual site level, as well as how long the impact would last, and how long recovery would take.

Box 3. Key messages – characteristics of hazards

Determine and assess the likely hazards that could result in an emergency, which could then impact on blood establishment activities. Such hazards may be external and arise from emergencies in neighbouring and other Member States. They include:

- natural hazards;
- human-made hazards; and
- indirect hazards.

Determine all the possible consequences of each of the hazards identified, considering all elements of blood establishment activities.

2.3.3 Analysis of the degree of vulnerability

The degree of vulnerability is analysed by determining the capacity, or lack of capacity, of the blood establishment and its supply chain to withstand and respond to an emergency. An important outcome of any RA process is to identify issues that need to be addressed, which would include vulnerabilities identified during the process. This may lead to developing plans to mitigate those issues when threats arise (Box 4). Identifying clear areas of vulnerability to any of the potential threats that could arise from an emergency provides the opportunity to mitigate in advance of any such situation arising and helps to improve the overall resilience of the blood service in an emergency. If vulnerabilities can be identified but little or no action can be taken to reduce or alleviate the vulnerability, preparedness at least enables a range of response actions to be planned and then put in place as required.

Box 4. Key messages – identifying and addressing vulnerabilities

Determine the actual capacity of the blood service to respond to any emergencies.

- Identify key gaps.
- Determine possible solutions to fill gaps.

2.3.4 Analysis of the potential impact

The potential impact of any emergency on the ability of the blood service to provide and maintain a sufficient supply of safe blood and components should be analysed. As the range of hazards that may give rise to an emergency and their specific impact on blood establishment activities is wide and varied, their impact may vary from negligible to a total inability to supply the blood and components required. Importantly, however, even if the impact of an emergency on blood service activities is likely to be negligible, there should be an awareness that the situation could change and its impact increase. The potential impact of an emergency on the blood service can be broadly split into two quite different areas:

- 1) the impact on its ability to provide adequate supplies or to avoid discarding of safe blood and components; and
- 2) significant changes in the demands for its services because of a sudden increase or decrease in the need for blood and components.

The normal functioning of an effective blood establishment is complex, encompassing various separate, but interlinked, activities, and any impact on any one of these activities may result in the blood service being unable to function fully. Core areas of activity of a functioning blood service are:

- donors and donation
- screening and processing
- storage and distribution.

These activities have a range of common needs as well as some specific ones, and the potential for an impact of an emergency on all these needs must be considered. The specific nature of the emergency and the extent of its impact determines just how much effect it will have on these core areas.

2.3.4.1 Direct impact on blood service activities

An emergency resulting in a direct impact on blood service activities would have the most significant effects, although the level of impact would depend on the nature of the emergency and the specific activities affected. Questions to be asked regarding the core areas of activity include the following:

- **Donors and donation** – will donors be available and willing to donate; will the appropriate collection staff be available to work; will there be suitable donation venues available with the required power supplies; will both donors and staff be able to get to the donation venues; will there be sufficient supplies of the items required to safely collect donations; will the required levels of safety, quality and security be maintained; will appropriate transport be available to return the collected donations to the blood service premises under the required temperature-controlled conditions; will any information technology (IT) systems or other technology required still be functioning or will a manual system be able to temporarily replace any electronic system?
- **Screening and processing** – will the appropriate staff be available to work; will the staff be able to travel to the blood centre; will the laboratory and processing areas be accessible and able to function normally, including the necessary power and water supplies; will there be sufficient supplies of the items required to test and process donations; will the required levels of safety, quality and security be maintained; will any IT systems or other technology required still be functioning or will a manual system be able to temporarily replace any electronic system?
- **Storage and distribution** – will the required temperature-controlled storage be available for the components produced; will the storage and distribution areas be accessible and able to function normally, including the necessary power and water supplies; will the required levels of safety, quality and security be maintained; will transport be available to distribute the blood and components ordered; will the transport be able to reach the hospitals requiring the blood; will other means of transport be required if the normal routes are not available?

2.3.4.2 Increased demand on the blood service

An emergency may not have an impact that threatens to reduce or stop blood service activities. Rather, its impact may be to require a rapid increase in the amount of blood and components available. Such an impact might be perceived as less serious because blood establishment buildings and facilities are not put out of action. Nonetheless, the blood service would still face the challenge of increasing the availability of safe blood and components, and this may be beyond its normal capacity. Questions to be asked regarding the direct impact on blood service activity include the following:

- **Donors and donation** – will sufficient extra donors be available and willing to donate; will there be sufficient collection staff available; will there be suitable additional or emergency donation venues available; will there be sufficient supplies of the items required to safely collect the extra donations; will the required levels of safety, quality and security be maintained?
- **Screening and processing** – will the laboratory and processing areas be able to handle the extra work; will there be sufficient laboratory and processing staff available; will there be sufficient supplies of the items required to test and process the extra donations; will the required levels of safety, quality and security be maintained; will testing and processing be completed within acceptable time frames to ensure product quality is maintained and that the blood is available when required?

- **Storage and distribution** – will sufficient space under the required temperature-controlled storage conditions be available for the extra blood and components being collected; will the required levels of safety, quality and security be maintained; will sufficient transport be available to distribute the blood and components ordered; will the transport be able to reach the hospitals requiring the blood; will other means of transport be required if the normal routes are not available?

2.3.4.3 Recovery

Irrespective of the impact of the emergency on the blood establishment, the duration of the impact and the possible routes for recovery need to be considered (Box 5). If buildings and infrastructure are likely to be damaged or destroyed, rebuilding and re-equipping will be necessary. This will be associated not only with financial costs, but also the need to restore blood establishment activities as quickly as possible, even if using temporary facilities. Loss of donors and of staff should also be considered. If the situation is likely to result in loss of life, it is very likely that donors and staff will be lost. Also, the emergencies may result in displacement of the population with donors no longer being able or even willing to donate. Considering the route to recovery after an emergency may inform the RA process, enabling mitigating actions and activities to be considered as part of any risk reduction strategies.

An additional potential consequence to be considered during the recovery period is the temporary unavailability of specific blood components or products. This may be due to the impact of the emergency on production facilities, a lack of source materials or an inability to transport finished products to blood establishments. To help buffer such a situation, part of the recovery plan could include the temporary provision of clinically appropriate alternative components, which could be prepared locally and used temporarily to provide immediate support to patients until normal supplies are restored.

Box 5. Key messages – analysis of the potential impact

Determine the potential impact of any emergencies on the ability of the blood establishment to provide and maintain a sufficient supply of safe blood and components.

- The range of hazards and their impact on blood establishment activities is wide and varied. The impact may:
 - range from negligible to a total inability to function;
 - reduce ability to provide safe blood and components;
 - be a significant increase in demand for blood and components;
 - necessitate changes in processing to ensure continuity in the supply of plasma-derived medicinal products.
- Determine the impact on each core area of activity of a functioning blood service, donors and donations, testing and processing, and storage and distribution.
- Develop recovery plans.

2.3.5 Overall evaluation and development of risk reduction strategies and plans

All blood services face threats to their activities, but many have strategies and plans in place that enable them to respond appropriately when the threats arise. Ideally these strategies and plans should be embedded in the national strategies and plans which set out the national responses to emergencies.

Pulling together the information obtained from the RA process and properly analysing it enables all the gaps, weaknesses and vulnerabilities to be identified. These can then either be addressed as part of the risk reduction strategies developed and put in place to improve resilience prior to any emergencies arising or be specifically addressed in the preparedness plans developed. However, it is critical that the RA process leads to the development of appropriate and effective risk reduction and preparedness plans (Box 6).

As there are many different types of threats from the many different types of emergencies that may arise, the strategies and plans produced need to be very broad in their coverage, but also quite specific in the responses and actions to be undertaken. The sole purpose of these strategies and plans is to ensure the maintenance of blood service activities and the provision of sufficient supplies of safe blood and components. Consequently, they need to include acknowledgement of the potential threats and their possible impact, setting priorities, allocating responsibilities and resources, and initiating the appropriate measures to maximize preparedness. The needs in different types of emergencies must be properly understood and planning for a range of emergencies is essential. The core issues may be similar, but the degree of impact will vary.

Importantly, the plans need to include an acknowledgement that the normal organizational structure with its levels of authority, accountabilities and responsibilities may not be either appropriate or even possible to maintain in an emergency. To enable important and urgent decisions to be made to ensure that the most appropriate actions are taken in a potentially rapidly changing situation, the plans need to include a clear process for the provision of the authority needed to act independently in an emergency, to be able to make the decisions necessary at operational level. No matter how good the plans are, if the authority to act is not included, there is a significant risk of failure because the right decisions are not made and/or cannot be made quickly enough. Additionally, the plans need to provide the general framework necessary to support whatever measures are needed to respond to an emergency. This framework should ideally include the need for sufficient emergency funding, allow for the procurement of sufficient stocks of all items necessary to maintain activities, allow for staff to be reallocated as required to maintain services, and include the possibility of seeking assistance from other neighbouring blood establishments.

To ensure strategies and plans remain up to date and appropriate, they need to be reviewed regularly. To support this, the RA also needs to be reviewed regularly: risks do change and any changes, externally or within the blood establishment, which may have a significant impact on the blood service's ability to respond to any emergencies need to be reviewed and the plans updated accordingly.

Box 6. Key messages – development of risk reduction strategies and plans

Develop appropriate strategies and plans to enable an effective response to any emergency.

- Embed the blood service plans in the national strategies and plans that set out the national responses to emergencies.
- Use the risk assessment and planning activities to identify existing gaps, weaknesses and vulnerabilities.
- Address these gaps, weaknesses and vulnerabilities.

CHAPTER 3

EMERGENCY PREPAREDNESS

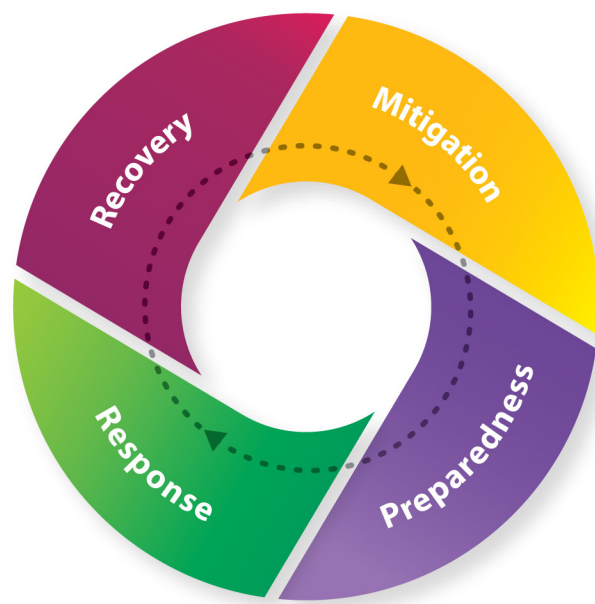
Given the frequency, scope and diversity of disasters and emergencies in different parts of the world, it is important to be well prepared for diverse crises and their potential impact on the availability and safety of the blood supply. Disaster and emergency planning for events that could affect the blood supply should be carefully considered at the local and national levels. The need for blood during disasters is not limited to injured people as transfusion-dependent patients are also likely to be affected due to disruption of the blood supply. Planning for disaster should involve a coordinated, multidisciplinary approach to define and document the various tasks and responsibilities. The plan should be documented, validated, well communicated and tested to ensure that it can address critical needs depending on the available resources. Emergencies and disasters may affect blood collection, screening, processing, storage, distribution, issuing and transfusion in different ways.

Emergency managers and planners think of disaster management as a cycle of recurring events with four interwoven phases: mitigation, preparedness, response and recovery (Fig. 3.1 and Box 7) (73).

Fig. 3.1. The significance of the emergency management cycle is that all communities are in at least one phase of emergency (73)

3.1 Mitigation

The mitigation phase occurs before a disaster and includes a group of actions to prevent or reduce the cause, impact and consequences of disasters with a view to minimizing their adverse effects. Mitigation begins by conducting a vulnerability assessment (see chapter 2) to identify the critical points in the system that may be susceptible to risk (74). Modelling and simulation methodology has been used by WHO and many countries in deciding on the best strategies to



mitigate the impact of emergencies. Modelling can be performed using forecasts or data on previous emergencies and offers solutions and help to mitigate existing risks. Different modelling methodologies would produce different decisions that need to be tested and approved by decision-makers. Regarding blood establishments, mitigation includes but is not limited to the following:

3.1.1 Inspection of the main building structure

The main building structure should be periodically inspected to determine its condition (including, for example, ceilings, windows, walls, columns, partitions and related buildings).

3.1.2 Inspection of the infrastructure and essential systems

The inspection of the infrastructure and essential systems includes the water and electricity supplies, telephones and other communications systems, Internet, fuel, generators, air conditioning system, medical store and hazardous material store.

3.1.3 Assessment of the emergency and evacuation elements

Emergency elements that need to be assessed include building layout, evacuation routes, extinguisher locations, access to exit doors, assembly point and signage.

3.1.4 Management of medical resources

Blood establishments should have a control policy for continuous assessment of supplies and their accessibility, safety and sufficiency. Required medical supplies and consumables should be available as strategic stock items for emergency use only. Certain countries should keep enough of the required strategic stock for 3–6 months, taking into account the expiry dates of the items and the necessity for a suitable storage environment. Proper management of medical resources is essential to ensure business continuity. Sharing medical resources locally, nationally or within the region should be considered as part of mitigation strategies for emergencies.

3.1.5 Connection of critical equipment to the electricity supply

Critical equipment that needs to be connected to an electrical power supply needs to be identified. Such equipment includes storage devices for blood and components, and for storing critical reagents; and equipment for blood collection, processing, testing, storage and transportation.

3.1.6 Risk assessment

Risk reduction requires continuous assessment and proper corrective actions, see also chapter 2.

3.1.7 Health and safety regulations

The existence of health and safety regulations to cover people such as patients, donors, visitors and employees when exposed to different hazards needs to be assessed.

3.1.8 Assessing and activating the collaboration between blood transfusion services and other health sectors

Different levels of collaboration are required – between the blood establishment and local hospitals, governmental and private health care providers.

3.1.9 Availability and efficiency of human resources

Human resources management should be considered as part of the mitigation strategies. Staff rotation and sharing between different sectors is good practice. For example, during the SARS-CoV-2 pandemic in 2020, some countries shared their medical staff with other countries to support their health care services.

3.1.10 Engagement with higher management, policy-makers and experts in the field

Blood establishments should be well represented on medical committees and in working groups to highlight their needs, share their plans and ensure availability of the budget required to continuously be prepared for emergencies and disasters. This would underpin good communication strategies between the blood establishment and other related health services and decision-makers.

3.1.11 Financial planning

Financial planning is an essential part of mitigation strategies. Countries should estimate the risks of disasters and plan for required funds and sources of funding to help reduce such risks. They should also keep in mind that funding of interventions to reduce disaster risk is very effective in reducing the amount of funding needed after the occurrence of loss and damage that a disaster could cause, especially when the identified risks can be mitigated.

Both governments and the private sector can invest in reducing risk and loss, and international organizations can be part of this planning. In certain countries, where private health care providers are well established, partnership in risk reduction and response during emergencies and disasters should be considered.

3.1.12 Developing research and tools to support the mitigation phase

It is crucial to conduct research and studies during the mitigation phase to help the blood establishment to find the most effective tools to reduce risks and help in planning the response to emergencies.

3.1.13 Planning for community support and engagement

During emergencies and disasters, community involvement and support may play an important role in determining the outcome. Giving members of the public the opportunity to serve as volunteers and support health services helps in sharing responsibilities. Volunteers need training and direction, and blood establishments should include these in their mitigation strategies.



3.1.14 Procedures and methodologies for cybersecurity in digital health care services

Cybersecurity includes all actions required to protect and defend computers, servers, networks, electronic systems, mobile applications and personal data. It is a part of disaster recovery and business continuity planning. Cybersecurity requires a well-structured policy and procedure for continuous data backup, off-site storage for critical data, and end-user training and education.

3.2 Preparedness

The preparedness phase covers actions that are taken prior to an emergency or disaster, including planning, training and educational activities to ensure mitigation or containment of incidents when they do occur.

3.2.1 Preparation, approval and communication of the emergency and disaster plan

Emergency plans must be regularly reviewed and updated whenever there has been a change in circumstances that would affect their execution. This includes changes in blood donation centre layout or changes in related processes. An emergency operation plan should define the management structure, stakeholders, responsibilities, communications procedures, training and guiding policies to assist the facility when responding to an emergency. Proper emergency planning can efficiently protect and save lives, stabilize the incident, minimize damage to the environment and to property, and continue the provision of critical services during emergencies.

Disaster plans can apply to different levels (global, regional and national). Countries need to establish mutual agreements with other countries, involving their respective authorities, before emergencies happen. The level of coordination is dependent on the level of the emergency. National planning is usually done at governmental level, coordinating with relevant local authorities in which the health service providers and related organizations, as well as blood establishments concerned with blood collection, and transfusion organizations may play a major role. The national plan should set the standards for coordinated communications and responses. The local and blood establishment plans should be linked and coordinated with the national plan. Before the local health service or blood establishment prepares the emergency and disaster plan, it is advisable for the team creating the plan to search for published guidelines, previous data and related national and international standards. The planning team should include members with experience and knowledge of different aspects of transfusion as well as other members from related departments and sectors. The emergency plan must work around the clock, appropriate staff must be trained to communicate, and the response to the emergency should be process- or task-dependent and not person-dependent. The emergency plan should be documented, approved and properly communicated to all those concerned: staff, departments, sectors and stakeholders. It should be tested periodically to ensure its effectiveness and readiness. Many international organizations, for example, the Association for the Advancement of Blood and Biotherapies (AABB), have included emergency and disaster planning, communications and testing among their accreditation standards, reflecting the importance of these plans (75).

3.2.1.1 Internal emergency and disaster committee formulation

Facilities involved in emergencies and disasters should have an internal disaster committee or team to ensure proper management of any emergency. The committee's formulation should be documented and communicated to the staff concerned and related higher management depending on the structure of the organization. It should include different teams to cover the different tasks during an emergency. The working groups or teams can include, for example, disaster management, communications, media and public relations, evacuation, first aid, statistical, risk reduction, technical and training teams. Member responsibilities, communications cascade, personnel lists, contact numbers and tools of communication should be clearly identified and communicated. The staff involved should be assessed periodically assessment to ensure their competencies are maintained.

3.2.1.2 Blood disaster plan

A blood disaster:

- refers to any natural or human-made disaster that suddenly requires a much larger amount of blood than usual; or
- temporarily restricts or removes a blood collector's ability to collect, test, process and distribute blood; or
- temporarily restricts or prevents the local population from donating blood; or
- restricts or prevents the use of the available inventory of blood products and thus requires immediate replacement or resupply of the region's blood inventory from another region; or
- creates a sudden influx of donors, requiring accelerated drawing of blood to meet an emergent need elsewhere (76).

Blood collection facilities and hospitals that supply blood and components to patients should collaborate in formulating a blood disaster preparedness plan. Previous disasters have shown the need to ensure that collecting and supplying facilities maintain inventories to meet disasters in different locations. To plan for that, inventory management procedures are required, to avoid over-collection, having expired units, insufficient inventory, and improper distribution of available units, and to ensure optimization and prioritization of blood usage during disasters, for example using O positive and negative blood units only for patients who need them (77).

An important part of a blood disaster plan is for the blood collection facility to have a predictable and required inventory of different blood groups and components. Depending on the structure of the blood facility and the areas covered by it, stock levels needed can be estimated using either previous data or reports of previous emergencies. It is good practice to have, for example, three levels or zones for inventory (green, amber and red). These levels indicate the available blood units and components, the number of days such an inventory can cover demand for the different blood groups during an emergency, and whether the coverage includes daily routine use. Predefining the different inventory levels will allow the facility to receive an alert when the inventory level reaches the threshold and certain actions need to be taken to avoid reaching a critical inventory level that leads to a shortage of blood. The blood facility should aim to keep the blood inventory at the minimum level that is able to cover the expected immediate transfusion requirements during an emergency (while more blood is being collected following the emergency, provided this is feasible). Using the modelling and simulation methodology mentioned in section 3.1 "Mitigation" will help in predicting the amounts of blood and components stock required for different scenarios.

The blood collectors, suppliers and higher authorities responsible during emergencies and disasters should be regularly informed about the inventory levels. The method of communication will differ according to the tools available. It can be done intermittently via a paper-based system or electronically, allowing for real-time inventory management, so that concerned authorities can support and take the required actions before the inventory reaches a critical level. During the first 24 hours of an emergency, Group O RBCs are mainly requested, followed by RBCs of all blood groups and platelets if the emergency continues.

Depending on the severity of an emergency and the available blood stock, changes to routine policies and procedures may need to be considered. Such changes would be aimed to support availability while maintaining safety and quality of blood services. Aspects to consider include:

- Flexibility of the donor eligibility criteria: eligibility criteria should be reviewed and assessed according to the situation without compromising donors' or patients' safety.
- Routine screening assays for infectious agents, such as molecular screening or screening assays for malaria
- Rationalization of the use of whole blood versus blood components
- Frequency or threshold of transfusion for regularly transfused patients
- Adaptation of treatment regimens (products used, dosages, timing)
- Transportation of blood and blood components: transport of blood and blood components between certain countries may be restricted in normal circumstances, but there should be proper logistics plans for transportation during disasters or when needed.

Disaster preparedness includes the need for policies regarding triage for donors and patients. Donor triage is usually done by the collection facility when collection priority is given to donors with blood group O and RhD negative groups, or collection from regular donors is considered first. Patients' transfusion triage is done by the treating physician who assesses the clinical urgency for transfusion of blood or components when collection of blood or components is limited for any reason. The preparedness plan should include prioritization of blood supply during the first hours or days of the disaster. Plans should also take into consideration an extended disaster that would affect not only the RBC inventory, but also the availability of platelets, due to their short shelf life, and then frozen plasma and PDMPs and their substitute blood products (for example, pathogen-reduced cryoprecipitate and virus-safe cryopoor plasma). A good communications system should be in place so that prescribing physicians and hospital-based blood banks are notified of the situation and able to play their part in prioritizing the utilization of blood components. PBM should be promoted during routine clinical use, as this can further enhance the effective utilization of blood products during an emergency. During disasters, frequent needs assessment (depending on the severity of the disaster) is required, and the results should be communicated with the blood service to ensure sustainability of blood supply. Therefore, during preparation of the emergency and disaster plan, experienced members of the above-mentioned teams need to take part in the planning and advocate for and participate in training sessions as part of the preparation phase.

3.2.1.3 Communications strategies

Blood services should highlight to higher management and the relevant authorities the importance of considering and incorporating blood services within the local and national emergency and disaster plans. As part of the communication

strategies, the internal and external communications with stakeholders, government and disaster authorities should be considered. Each organization should identify the stakeholders and their responsibilities and means of communication at different levels of a disaster response. During the preparedness phase, governments, organizations and individuals develop plans to save lives, minimize disaster damage and enhance disaster response operations.

A clear and well-structured communications strategy provides guidelines and procedures for how information should be shared during all phases of an unexpected occurrence that requires immediate action – this can improve the response to any emergency and optimize outcomes. While preparing communications strategies and related plans, the following aspects need to be borne in mind:

- Hierarchy of communications or sequence of communications;
- List of key contacts (facilities, authorities and individuals);
- Mode of communication (landlines, mobile phones, emails, short message service (SMS) or other communications system);
- The trigger to activate the plan, stipulated time of response, how and when to end it, and by whom the actions will be taken;
- Requirement for periodic testing of the communications plan; and
- Key contacts in the media and for public communication (recommended to be included within the plan).

The emergency and disaster plan should be clearly and effectively communicated at the different levels of each blood establishment. These include the:

- Leadership team and employees of the facility;
- The relevant authorities (e.g., higher management, disaster office, department of public health);
- Stakeholders (e.g., police, civil defence, utility companies such as water and electricity suppliers);
- Other blood facilities (e.g., other blood suppliers and alternative facilities); and
- Blood collection facilities together with their donor base and the public (to increase donations).

During a disaster, backup lines of communication (such as wireless radio communication devices) need to be in place in case of damage to landlines, computers, cell phones, the Internet and other means of contact.

3.2.1.4 Blood donor data and communication tools

The blood establishment needs to stay connected with its registered blood donors by finding the best tools for communication, which may differ from one donor to another and according to the availability of the tool during the emergency. Communication can be by phone, email, SMS, smart applications, etc. The blood facility needs to find a method of regularly updating donors' contact information (for example, asking donors to check their contact

information at each visit). It is also necessary to ensure the confidentiality of such information and that it is accessible to authorized personnel when needed during emergencies.

The blood establishment also needs to communicate with the public during disasters to reach people who are not registered with their database. Such communications can be made through television or radio broadcasts. Social media have also become a very effective tool to announce the need for certain blood donors or certain components, or to announce the location and opening times for public donations and to encourage people to support their communities by donating blood. One example of best practices is the development of a mobile application in certain countries to encourage members of the public to register their availability to donate during emergencies and disasters. This application widens and strengthens the donors' database and supports blood services to reach more donors when needed.

Target groups for communications also include volunteers, schools, college and high school students, VNRD, family and first-time donors. The communication strategies for action need support from the following partners: employers, education and health care sectors, religious communities, NGOs, civil sectors, media and governments. A communications plan targeting existing or potential new donors to encourage blood donation during emergencies is essential. However, it is equally important to have communications plans using the channels already mentioned to prevent a sudden huge surge in blood donations. This helps to space out the blood donations, ensuring the consistent availability of eligible donors, since to protect donor health, there must be a suitable interval between donations. In this way a constant supply of blood components (especially platelets, which have a short shelf life) can be made available throughout the whole period of the disaster or emergency. It also helps to minimize wastage of the blood components, overcrowding of the blood collection centres and long waiting times.

3.2.1.5 Education, training and drills.

Education and training for members and staff of the emergency and disaster committees or related services is essential to ensure proper implementation of the emergency and disaster plan and an efficient response. Different teams at different levels should be trained to familiarize them with their role and responsibilities as defined within the plans.

Drills and exercises should be conducted regularly to validate all components of the emergency response and to assess the ability of personnel to carry out their assigned roles and responsibilities. Staff should be aware of the disaster codes, which are coded messages often announced over a public system in the facility, for different types of emergencies. Support services staff (security, maintenance staff, cleaners, etc.) should be considered in the education and training plans. For visitors and donors, personnel should be available to assist and direct them during an emergency.

The training plan should be supported by drills which can be conducted at different scales. Smaller ones focus on specific critical parts of the emergency response, whereas large-scale ones cover all parts of the emergency response and involve multiple stakeholders at the local or national levels. Drills should be properly evaluated, and corrective actions taken and improvements made when needed.

3.2.1.6 Information system and record management procedures

The information system is an essential part of health care services and therefore it should be included within the RA procedure to identify areas that need improvement (78). The blood establishment should have a list of all critical IT systems including the software and hardware in use. The vendor for the systems and the IT department should be aware of the importance of blood services and consider the need to create a daily backup of the data and to have facilities for data storage off-site to ensure data security and safety. Regulatory policies and procedures are essential to ensure that

authorization, authentication and system access are controlled to avoid any damage to data or unauthorized access to the system (see section 3.1.14). Information system and electronic data availability and integrity should be included in business continuity planning. The electronic data in blood collection centres will include personal details of donors who may be reached through calls or emails asking for donations during disasters. This is in addition to patient data, which are essential and confidential data.

Medical, personal or manual financial records should be listed and stored in a safe area with limited access to ensure safety. Countries should consider having digital records to avoid them being damaged by floods or other natural disasters. Also, digital records will make storage and access to required records easier.

3.2.1.7 Media and social marketing plans

The blood establishment should coordinate with the media and social marketing department concerning the communication needs during an emergency and this should be part of the planning process.

During emergencies and disasters, controlled messages should be transmitted to the public through the media about the situation. Informing the public about the need for donors, donation sites and about the working hours and eligibility criteria is essential to support blood collection facilities in attracting the required number of donors. During the COVID-19 pandemic in 2020, the eligibility criteria for donors were updated many times, needs for blood and plasma donation were announced, service locations and timings were changed in certain places and all such information needs to reach the public correctly through the media. Media can include television, radio, newspapers and social media. The media and social marketing team should be provided with contact information for the key person authorized to update the public about the progress of the emergency (75).

3.2.1.8 Safety and security preparation

During emergencies and disasters, service providers should ensure the safety and security of donors, patients, visitors and other service providers on the premises, such as maintenance engineers and cleaning staff. The blood establishment should make appropriate preparations during the planning phase. All employees and service providers should be properly identified and wear their photo identification. The staff should be aware of the emergency plan, which includes an evacuation plan, emergency codes, exits and shelter, in addition to important contact information for notifications when needed. Visitors should be properly assisted and guided during emergencies. Important emergency supplies should be provided in each facility, such as torches, water, first aid kits and wheelchairs, among others. Facilities differ in their security and safety preparation levels depending on the available resources and local and national policies. Conducting at least an annual drill and training is essential to ensure proper implementation of the plan.

3.2.1.9 Supply chain strategies: ensuring the availability of critical material, reagents and consumables

Emergency and disaster plans require blood facilities to have strategic stock of the critical supplies that are essential to ensure continuity of services for a specified period (to be determined by each facility) when an emergency causes difficulties in obtaining new supplies. Emergency critical supplies of reagents, consumables, kits, etc. should be listed and clearly described with the quantities required and contact information for local suppliers. Such supplies should be stored properly in accordance with the manufacturer's instructions. The facility should have a procedure to avoid expiry of supplies by rotating the stock, and the storage location should be accessible to the facility during different

types of emergencies. In its BCP, the blood establishment should consider the need to obtain required supplies from other facilities when possible. The geographical distribution of storage locations should be considered to avoid the problem of destroyed infrastructure (roads, warehouses) that may occur during an emergency.

3.2.1.10 Staffing strategies

During the mitigation and preparedness phases, it is important to consider the availability of trained staff during disasters. Disasters may lead to staff shortages due to illness, quarantine rules and difficulty in reaching the workplace, as well as possible mental health problems. Therefore, the blood establishment should consider training staff from other sections or hospitals to serve in the blood establishment when needed by enabling rotation and mixing of the workforce.

Box 7. Key messages – emergency preparedness

- It is imperative to be well prepared for different crises and their potential impact on the availability and safety of the blood supply.
- Disaster and emergency planning for events that could influence the blood supply should be conducted at the local and national levels with the engagement of government and policy-makers.
- Planning for disasters should involve a coordinated, multidisciplinary approach to define and document different tasks and responsibilities.
- The emergency and disaster plan should be documented, well communicated, and periodically evaluated and tested.
- The disaster management cycle includes four interwoven phases: mitigation, preparedness, response and recovery.
- Education and training for members and staff of the emergency and disaster committees and related services is essential to ensure proper implementation of the emergency and disaster plan and an efficient response.
- Blood facilities need to stay in contact with their registered blood donors by finding the best tools of communication.
- Blood collection facilities and hospitals that supply blood and blood components to patients should collaborate during emergencies for proper evaluation and response to the event.

3.2.2 Preparation, approval and communication of the business continuity plan

A business continuity plan (BCP) is primarily concerned with maintaining an organization's business functions and critical operations after a disaster or major emergency (76). Blood services should have a well-developed BCP to restore routine operations as soon as possible after a disruption, with minimal loss. The plan should be contained in a document that is easily accessible, has been properly communicated internally and externally to stakeholders, and has been continuously reviewed, updated and tested (77).

Before preparing a BCP, a business impact analysis (BIA) needs to be conducted. This involves analysing the effects that a business disruption might have upon business activities. The BIA should include a list of critical business activities (processes/services) and identify the minimal required personnel, resources and recovery time during emergencies. The purpose of the BIA is to determine the maximum tolerable period of disruption (MTPD) for each business activity. The MTPD is used as a prioritization indicator that determines the length of time a business activity can be discontinued or affected before the consequences of not performing that activity become unacceptable to the organization (78). The business continuity procedures should be tested to ensure that they are consistent with the plan objectives (Box 8). A business continuity checklist can help the blood facility to ensure preparedness to continue its services during an emergency (Annex 2).

Box 8. Key messages – business continuity planning

- Blood services should have a well-developed business continuity plan (BCP) setting out how to restore routine operations as soon as possible after a disruption, with minimal loss.
- The business continuity procedures should be tested to ensure that they are consistent with the plan's objectives.
- Business impact analysis (BIA) involves analysing the activities and the effects that a business disruption might have upon them.
- The BIA should include a list of critical business activities (processes/services) and identify the minimal required personnel, resources and recovery time during emergencies.



4

CHAPTER

RESPONSE AND RECOVERY

4.1 Overview

This chapter covers the response to critical incidents, planning for recovery and future resilience (Box 9). Its scope includes disease outbreaks, natural disasters and humanitarian emergencies, but it also refers to the recent lessons learned from mass casualty events (MCEs). This chapter builds on the earlier chapters on risk analysis and preparedness, which cover the most likely scenarios. However, each event is different and requires a well-rehearsed rapid assessment and options appraisal to confirm both the significance of the event and the required response for both acute and protracted emergencies. The initial assessment and situation analysis are key to ensuring a proportionate response. Any transfusion system response should be embedded within the wider health care and emergency response, including support from WHO (79).

4.1.1 Triggers for activation

Scenarios that could trigger activation of emergency transfusion plans include:

- Internal or external incidents involving a loss of people, premises, resources, or information and communication technology (ICT). Such events may be natural or human-made or both and affect not only supply but also distribution.
- External Major Incidents declared by wider health care or emergency service partners, which could lead to a spike in demand for key products or services. Such events include MCEs.
- Concern that a “rising tide” event could affect the future ability to deliver key products and services. Examples include pandemics and worsening blood shortages.

4.1.2 Notification and verification

The initial response following notification is to verify the event. Event verification is undertaken when the occurrence, nature, or cause and extent of a potential public health event are not known, or when the sources of the report require substantiation. Activating the emergency response diverts activity and resources from business as usual to critical tasks only. The challenge is to balance the benefits of a high readiness mindset, which supports the early reporting of potentially disruptive incidents, with a managed and proportionate response.

4.1.3 Purpose of the response

The purpose of the transfusion emergency response is to:

- enable continued safe supply of key products and services to meet routine demand as well as meeting the demands arising from the incident;
- coordinate incident management to ensure the safety of individuals and to minimize adverse impacts on the products and services; and
- minimize the impact of the incident on the organization and prepare for recovery.

4.2 Incident assessment

4.2.1 Assessment

An initial rapid assessment is required to confirm the nature and impact of the incident. The situation will evolve over time, especially if it is protracted and the situation and impact of the response will need regular reassessment. The framework for RA should be as outlined in section 2.3.

Some of the key initial questions and decisions related to transfusion include:

- What is the nature, severity and location of the incident and how could it affect transfusion services including demand?
- What are the current local and regional levels of stocks, staff and essential consumables?
- Can this incident be managed locally or provincially, or does it require a national emergency response with or without mutual support from other countries?
- Is the incident likely to be protracted? If so, its duration should be estimated.
- What needs to be done now and what can be done later?



4.2.2 Grading of severity

Grading triggers emergency procedures and activities for the management of the response. The grade assigned to an acute emergency for the transfusion community indicates the level of operational response required. The challenge is to deliver a timely response which is also proportionate. An external event may be graded significant but only minor if the incident does not have an impact on blood supply or demand. In contrast, a business continuity incident affecting transfusion ICT, such as a cyber-attack, may be a major event due the potential impact on blood sufficiency and safety. An example of severity levels for local or national events is as follows:

- **Level 1** – minor (usually local) disruption to product or service delivery
- **Level 2** – significant (usually provincial) disruption to product or service delivery
- **Level 3** – major (national) disruption to product or service delivery
- **Level 4** – if required, a significant national event requiring external or international assistance.

4.2.3 Emergency response framework

Transfusion emergency preparedness should not exist in isolation. It should be embedded within a wider emergency preparedness and response framework. Transfusion-specific plans may add value to both and should be considered in disaster planning and in the emergency plans of action. Planners should be familiar with the resources available for external support.

The overarching framework for emergency planning is well established by humanitarian aid organizations. WHO's immediate operational response to acute events and emergencies is described in the Emergency Response Framework (80). If the RA or situation analysis indicates the need for a WHO operational response, WHO immediately initiates response activities and then proceeds to grade the event within a maximum of 24 hours of its onset. Protracted emergencies that persist for longer than 6 months are assigned protracted grades (1–3) to indicate the level of operational response to be sustained by WHO over a prolonged period.

4.3 Plan activation and stand down

4.3.1 Activation

Existing plans should be activated by authorized staff after rapid assessment. The initial priority is safety and to secure essential assets. Staff should be familiar with their own drills as well as with the wider response. The initial assessment of the situation should be shared with higher management as soon as possible to determine the appropriate severity level, likely duration and initial response. An example of an incident response algorithm is shown in Fig. 4.1. Whereas a significant incident may be dealt with locally, major incidents or disasters would be expected to be managed at the regional or national level.



4.3.2 Organizational response

An internal emergency committee should be convened. The lead should invite representatives according to the expertise and membership required. Escalation to government officers should take place as per the plan. In addition, regional or local representatives should be available for national meetings. “Meetings” may often be hybrid with both face-to-face and remote options as available, using phones or other means. Further coordination can be based on pre-prepared aide mémoires to structure the meeting and support documentation. Key decisions should be documented.

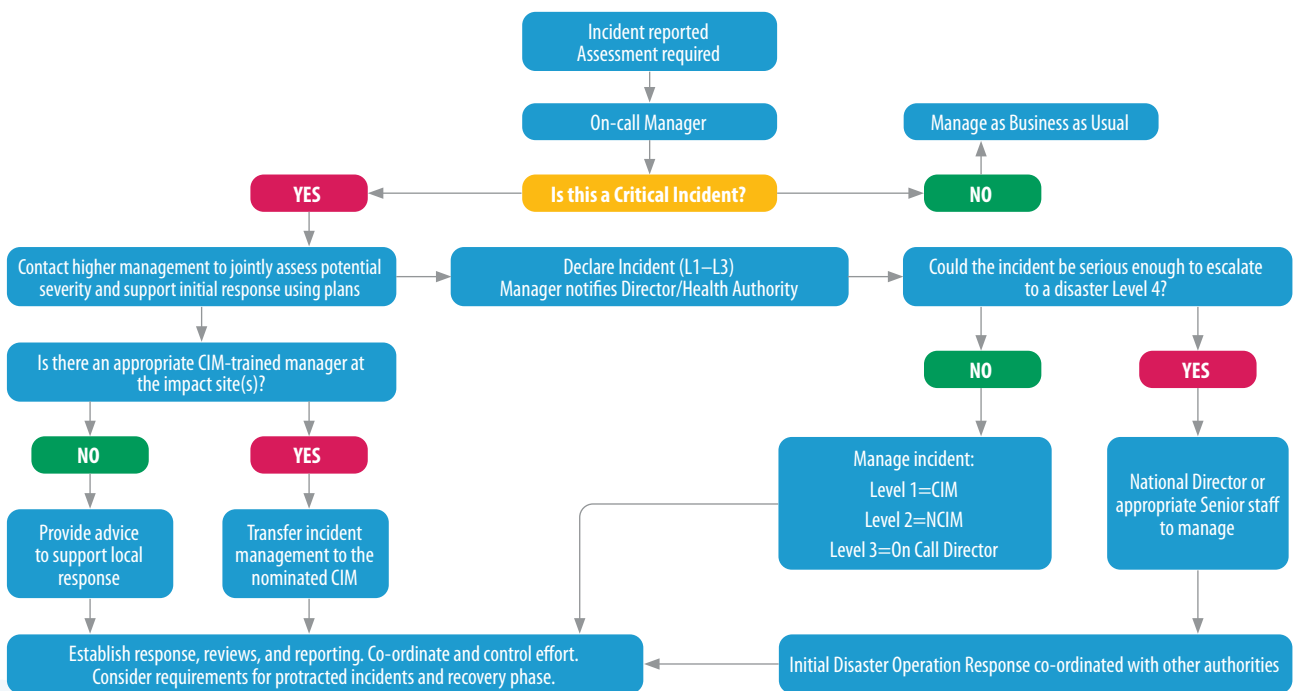
4.3.3 Coordination with government authorities

Emergency plans should include a list of the key local and state government authorities and organizations to contact in an emergency. Coordination with the wider community is essential, especially if external support is requested for the blood service. Requirements for external support or access to finance or emergency modules via WHO or other agencies need to be considered. Mutual agreements should be activated if such agreements have been previously established with other countries. Preparations should be made for multi-agency discussions and progress meetings.

4.3.4 Progress management

The purpose of progress meetings is to ensure regular review of response objectives, the route to de-escalation, and delegation of response and recovery activity. Decision-making requires prompt and accurate data, ideally digitized. Critical information includes the actual impact of the event on the blood centres and their essential infrastructure and utilities together with levels of stocks of blood, consumables and staff. The information should be available in the form of a situation report (SITREP). Arrangements should be made at every level for collating and sharing this essential information, and for taking decisions on resource use.

Fig. 4.1. An example of an incident response algorithm^a



^a The terminology used here includes a Critical Incident Manager (CIM) and National Critical Incident Manager (NCIM). These should be replaced by appropriate local terms. Source: Adapted from a figure produced by NHS Blood and Transplant.

4.4 The immediate response

4.4.1 Continuity of operations

The immediate emergency response is primarily determined by the type and severity of the incident and the expected period of disruption. The aim of the response phase is to ensure continuity of essential operations by protecting supply, assessing demand and then balancing the two. Protecting supply requires plans not only for donation but also for distribution, taking into consideration the regulatory framework for transfusion. Options for balancing demand and supply are described in section 4.4.2. An example of how various response options may be linked to the severity is given in Table 4.1.

4.4.2 Options for balancing demand and supply

4.4.2.1 Clinical demand.

The estimate needs to include clinical demand for both the emergency and the essential ongoing requirements for meeting local health needs. Requirements beyond the immediate emergency should be considered. Such assessments should be underpinned by the previous assessments of baseline blood demand. Staff should have access to clinical guidance designed for use during shortages and be aware of the priorities for the use of universal components, tolerance of substitutions and less than optimal replacement.

4.4.2.2 Blood stock management.

An inventory check within wider networks and hospitals with central reporting is required. Options to improve stock in the affected area might include:

- Use of preplanned emergency stocks;
- Moving stock as required between centres or major hubs;
- Redistribution from hubs to hospitals and health care facilities in need; and
- Use of alternative distribution routes and methods.

4.4.2.3 Options to increase blood stocks.

Consideration should be given to blood group, component type and special requirements. The challenge is to meet the immediate demand without compromising the longer-term requirements, for example by overuse of universal donors. Options might include:

- Use of preregistered emergency or readily available donors (see section 4.7);
- A temporary increase in collection targets; and
- Mutual support from other agencies or countries. This may be quicker if local services are severely disrupted.

4.4.2.4 Adjustments to processing and testing

Adjustments need to be pre-approved as part of planning. Temporary changes in processing may be considered, to produce haemostatic components as an alternative to PDMPs. However, where component production is under strain, providers may consider the use of whole blood to simplify the manufacturing process. Whereas this may help in responding to the emergency, it reduces the supply of components and the supply of plasma for future manufacturing of PDMPs.

Table 4.1. Examples of preplanned responses related to incident management level

INCIDENT MANAGEMENT LEVELS	EXAMPLES OF RESPONSE OPTIONS					
	Redistribution from centres to hospitals in need	Stock movements between hubs	Increase in collection targets	Mutual support from other organizations	Adjustments to testing, processing and shelf life	Use of emergency or high-readiness donors
Level 1 – Minor (usually local) disruption to product/service delivery	X	X				
Level 2 – Significant (usually provincial or national) disruption to product/service delivery		X	X	X		
Level 3 – Major (national) disruption to product/service delivery		X	X	X	X	X

4.5 Transfusion laboratories and the emergency response

Safe laboratory practice lies at the heart of the emergency response for transfusion and the interface between laboratory and transfusion medicine should be covered at the planning stage (81). Central laboratories may hold nationally strategic stocks of sera, cells or research material and robust protective measures should be in place.

4.5.1 Critical activity

Planning should have identified the critical activities provided and the MTPD (see chapter 2). Early activity includes an assessment of blood stocks, consumables and staff and of the ability to deliver blood and services including testing. The capacity and capability of the laboratory and any significant hazards should be communicated to higher management. Laboratory personnel should be familiar with the likely risks and emergency procedures required to mitigate release of hazardous materials and loss of vital utilities. The most vital assets are the staff themselves and all should be trained in both general and laboratory-specific safety measures including access to shelter and a safe place.

4.5.2 Emergency evacuation

Upon notification of an emergency, the broad options include whether the laboratory is to be shut down, to continue working or be moved. If the laboratory is to be shut down, laboratory personnel should be aware of the procedures for securing materials and work in progress. Care for refrigerated or frozen materials is a priority in transfusion. Staff should activate the procedures for consolidating and maintaining materials that require refrigeration or freezing in case of a power outage. If the laboratory is to be moved or re-established, staff should activate existing plans to establish a functional area.

4.5.3 Laboratory workload

Laboratory support for transfusion includes both sample screening and provision of blood. Timely ABO and rhesus D antigen blood grouping are essential if group-specific blood is to be used. Staff may also manage local blood donation, testing, processing and distribution as well as issue of blood products and medicines. Work must be prioritized. Laboratory-based testing for patient monitoring may be at a premium during incidents and near patient testing (NPT) should be used for non-transfusion testing, where appropriate and available.

4.5.4 Stock management

Blood stock management aims to maximize availability of blood for the incident and to support other patients requiring urgent transfusion. However, stocks of essential consumables and equipment may already be compromised. A rapid assessment of existing stock and potential demand should be undertaken, and risks communicated. Re-ordering and movement of essential supplies should be as prompt as possible; however, contingency measures should be put in place and demand managed.

4.6 Blood demand management

Blood demand management requires active planning and close collaboration between blood providers and the clinical community. The initial estimate of blood stocks and blood required, should guide stock management and replacement. Demand planning should consider blood components by blood group over time, including provision for replenishing stocks. In emergencies where the patient's blood group is unknown, "universal components" such as group O red cells and group AB plasma, are often used. The AABB provides valuable planning guidance in which they assume that group O red cells are the most likely blood product to be needed in the first 24 hours of an emergency (79).

4.6.1 Universal versus group-specific transfusion

Best practice may suggest that group-specific blood should be used once the blood group is known. However, the biggest risk in transfusion is an ABO-incompatible blood transfusion due to human error where the wrong blood is accidentally given to the patient. The error may occur anywhere in the transfusion process from donation to bedside administration. Some authors suggest that in less controlled environments, only group O red cells or whole blood should be used, to reduce the risk of incompatible transfusion. However, the wider use of group O may in turn compromise essential group O stocks for which there are no substitutes. The decision to use universal versus group-specific blood components should be made locally based on the relative risks to both safety and sufficiency.

4.6.2 Calculating demand

Demand planning is based not only on clinical use but may also be affected by operational issues, especially logistics. In brief, demand planning is a product of the estimated number of hospitalized patients, the units per patient admitted (UPA) and a locally determined variable demand factor. During past events a hospital demand that may be two to three times greater than the blood immediately required has been noted. The remaining blood is subsequently used for later surgery without the need for further deliveries (82). Whereas this approach may provide local reassurance at hospital level it reduces the quantity of centrally available blood for others.

4.6.3 Stock movement

Stock movement should be determined following the initial assessment not only of clinical demand from different hospitals but also the availability of logistic support and future donations as well as feasibility. Clinicians should take part in the decision-making and be included in communications to enable the best care to be provided for their patients within the constraints of the situation. Published guidance for planning has traditionally been based on units of RBC; however, plans should accommodate local transfusion practice, including resuscitation based on minimal transfusion, “plasma first” or whole blood (83).

4.6.4 Blood shortage plans

The need to balance demand and supply necessitates transfusion triage and shortage plans. Shortage plans build on the principles of PBM but may raise ethical challenges. These principles have been set out in the earlier chapters (sections 1.1 and 1.2.2). Emergency planning for transfusion should include not only the clinical groups but also the first responders providing haemorrhage control and the wider community as blood donors.

Emergency plans to manage demand for transfusion are best developed in close partnership with clinical stakeholders, as part of preparedness efforts (84). Examples of joint agreements include shortage plans for components with limited shelf life, such as RBCs and platelets. Such plans may use a traffic light system, where **green** indicates normal supply; **amber** when the blood inventory suggests insufficient stock to continue usual transfusion practice; and **red** when the shortage is either severe or prolonged.

4.6.5 Patient blood management

Shortage plans should be underpinned by routinely practising good PBM together with principles for prioritization (i.e., triage). The most pertinent principles of PBM relevant to the emergency response for massive bleeding are haemorrhage control and toleration of lower haemoglobin. Cell salvage and other methods of auto-transfusion may offer some resilience; however, timely access to treatment and prevention of shock requires a coordinated approach across the continuum of care. Therefore, it is essential that the public are familiar with first aid, especially early and effective haemorrhage control (85). Community first aiders should also be taught to triage when dealing with multiple patients.

4.6.6 Transfusion triage staff

Triage can be applied throughout the vein-to-vein process of transfusion. For example, the most severely injured patients should be treated first, and their blood samples prioritized for testing. Recent events have demonstrated the value of proactively using “transfusion coordinators” in clinical areas (86, 87). These staff, from a variety of backgrounds, can assist

in a range of activities, including clinical transfusion triage, emergency issue of blood, rapid handling of blood samples and communication. Triage can also be applied to donor selection and the conduct of emergency donor sessions.

4.7 Emergency donor sessions

Blood providers should aim to hold sufficient reserve stock to meet an initial demand during emergencies and then to replace the stock after the event. However, in many communities, stocks are marginal and therefore rely on movement of stock and support from other blood providers. Some communities may need or choose to be self-reliant and use local emergency donor panels (88, 89). The standards for these should be as close to national standards as possible and subject to proportionate quality management systems.

4.7.1 Alternative donation sites

Emergency donor sessions may be considered in areas where the risks of disruption are high and health care communities may be isolated. Policy and plans should include access to emergency equipment modules and potential donation sites. When setting up an emergency response capability, it is important to confirm that there is local capacity to handle the event.

4.7.2 Donor selection

Considerations for donor selection should include donor status, accessibility and the blood groups required. Group O may be prioritized for red cells and whole blood, whereas group A or B may be more appropriate for component donation. The mix is dependent on local blood group distribution, processing capacity, clinical transfusion practice and duration of the current event. Known or regular donors who have already been tested offer the advantage of known blood group and probable safe TTIA status. As already mentioned, there is a risk of ABO incompatibility due to human error within the transfusion system. Some isolated communities may choose to reduce this risk and simplify their transfusion system by prioritizing collection of tested low-titre group O whole blood (group O whole blood tested for low isoagglutinin) from known emergency donors for whole blood. Whole blood is emerging as a valuable option for massive haemorrhage, especially in the context of trauma (90).

4.7.3 Transfusion-transmitted infection

The risk of exposure to TTIA is dependent on disease prevalence, donor status and blood safety measures, including testing. Further risks related to bacterial infection may be introduced by staff undertaking unfamiliar procedures in emergency areas. A recent meta-analysis was unable to demonstrate an increase in TTIA rates in donations following disasters. However, the authors emphasized the importance of following national blood policy and legislative frameworks (91). Appropriate training, equipment, consumables and preparation should further mitigate risks.

4.7.4 Communications with donors

There is often a strong urge to donate after a disaster although this is short-lived, which may temporarily lead to more blood than required (92). The surge may be made worse by well-meaning encouragement via the media and other areas of influence. The challenge is to collect enough blood safely without compromising later supply. A surge in donation may overwhelm local transfusion services. Emergency donor education during the community preparation phase and proactive communication during the response should reduce these risks, especially following MCEs.

4.8 Mass casualty events

4.8.1 Multi-agency response

The causes of MCEs are varied and include transport incidents, infrastructure collapse or warlike activities. An MCE should trigger a multi-agency response. Many countries have formulated principles for joint working of emergency services (Joint Emergency Services Interoperability Programme) (93). The same principles apply to working with other agencies including the armed forces.

4.8.2 Surge in demand

An MCE implies a surge in demand for blood and transfusion services following a traumatic event with many survivors. Transfusion services should be notified as early as possible but may have to wait for the details of casualty numbers and severity. Security and safety must come before health care, and emergency health care responders may initially be denied access to a scene until the dynamic RA is complete. Therefore, it is essential that the public are familiar with first aid, especially early and effective haemorrhage control.

4.8.3 Prehospital triage

Once prehospital staff have access to the site, casualties should be rapidly triaged to prioritize treatment and evacuation from the scene(s) (Fig. 4.2). P3 patients (minor injuries or unharmed) rarely require blood. These patients are often managed outside the hospital system. Only patients admitted to hospital with bleeding would be expected to require blood.

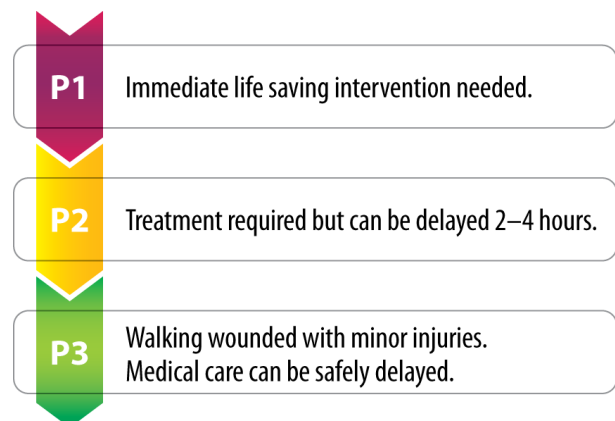
4.8.4 Demand planning for MCEs

Demand planning for MCEs is best locally defined based on analysis of past events. Regular and systematic review of transfusion requirements during incidents informs the current and future response. Global reviews of available data suggest that the percentage of patients transfused following an incident varied from 7–67% (mean 25%) but only 5% (range 3–33%) received massive transfusion (94).

4.8.5 Triage and transfusion

Triage systems have traditionally been used to inform demand planning. Whereas P1 patients are those expected to require the most blood, the confirmation of P1 and P2 status is often applied with the benefit of hindsight. Some authors have therefore suggested that the P1 and P2 categories could be combined and treated as a single group for the purposes of planning (95). However, a recent analysis of triage systems has shown that well-conducted prehospital triage can be a reliable indicator of health resource requirements including requirements for blood (96).

Fig. 4.2. A simple prehospital triage system based on priorities 1 to 3



4.8.6 Blood use per patient

The amount of blood used per patient is often less than anticipated. MCE reviews in well-resourced environments recommend a UPA of two to four units for adult casualties admitted to hospital with bleeding. Children require proportionally less. However, the use of haemostatic components in trauma patients is increasing, including the use of whole blood (94). Blood allocation should consider patient distribution and the requirements of different hospitals. Most components are initially ordered as “universal” components and used within the first 6 hours. Blood group substitutions, such as group A plasma with low anti-B (typically <1:200), have been used successfully after local RA to reduce the use of rare group AB (97).

4.8.7 Continuity of demand

Some trauma patients may have a continuing demand for blood over days and weeks, especially where repeat surgery is necessary (98). In addition, the hospital demand for blood may increase once normal and catch-up surgical activity resumes. It is essential that the donor planning ensures a continuous supply of blood stock across all groups to support emergency work and “business as usual”, especially where incidents are protracted.

4.9 Protracted incident management

Some critical incidents will require incident management structures at all levels to remain in place for many weeks if not months. For many, the challenge of unpredictable supply and demand becomes a part of the normal situation. However, some organizations may choose to make additional provisions for a protracted incident when a new significant incident is not resolved within a defined period, for example, 2 weeks. Two types of emergencies in this category are pandemics and humanitarian disasters.

4.9.1 Pandemics

WHO has provided comprehensive guidance for protecting the blood supply during infectious disease outbreaks (99). Actions in response to a threat include:

- No action;
- Identification and deferral of at-risk donors;
- Cessation of collections in the affected area(s);
- Implementation of specific screening of at-risk donors;
- Implementation of universal screening of all donations;
- Utilization of pathogen reduction procedures (including virus-removal technologies) or other processing approaches to reduce the risk;
- Importing blood and components from unaffected areas of countries.

The COVID-19 pandemic emphasized the need for global preparedness, although it was not a bloodborne problem. During the first wave, blood services experienced staffing pressures and an impact from collecting convalescent plasma, leading to an overall reduction in blood collection (100). However, this was often mitigated by decreased demand, which in turn led to unplanned build-ups of blood stocks in some countries. Other pandemic preparations included stockpiling PPE, making locations COVID-19 secure, securing new donation venues and eventually vaccination. The wider planning during the recent pandemic benefited from shared situational awareness, organizational agility and access to computer modelling systems. An early review of the effects of the COVID-19 pandemic on the supply and use of blood identified a range of strategies used to maintain equitable access (99). Pandemics may have a disproportionate impact on donation. Vital measures included negotiation to secure donation sites and enable donors to attend public sessions. Other measures included relaxation of donor-selection criteria. Strategies to modify production, specification and storage of blood included extension of shelf life, reduction of platelet doses for prophylactic transfusion (101) and use of novel components such as cold stored platelets (102).

Management of staff is more complicated during a pandemic as staff absences increase. Technologists may need training for potential cross-coverage of disciplines and an enhanced scope of practice. The pandemic raised the profile of laboratory staff in the guardianship of rare resources such as blood. Staff should be empowered to refer clinicians to pre-agreed guidelines. In more extreme shortages, the use of blood may be referred to independent clinicians (103) or committees to share the burden (104).

The pandemic disrupted far more than just clinical care. Travel and transport restrictions disrupted the continuity of essential supplies such as blood bags and reagents as well as vendors' technical support for equipment repair and maintenance. The post-recovery review emphasized the need for ongoing refinements of disaster and BCPs and the importance of the government's role in transfusion emergency preparedness.

4.9.2 Humanitarian disasters

Humanitarian disasters may require emergency management structures at all levels to remain in place for months or years. Recent studies in war surgery and transfusion have been conducted in the context of a well-resourced health care system. In contrast, humanitarian disasters are characterized by a fragmented, poorly resourced environment where there are war-wounded but transfusion support is scarce. Trained staff are equally scarce in populations that have endured regular targeting of hospitals and health workers.

A 2018 review of the availability and safety of blood during humanitarian emergencies highlighted common strategies that include donor mobilization, use of emergency or strategic blood stocks, and support from other blood centres in neighbouring cities. Familiar challenges include intermittent power supplies and a shortage of essential consumables. Some mitigation is provided through central coordination and collaboration together with support from NGOs (105). Clinical demand management is essential to address the balance between demand and supply.

Transfusion practice for trauma patients needs to be aligned to basic war surgery using the principles of surgical triage and early surgical haemorrhage control. It should be assumed that there will be no postoperative ventilatory support. Excellent results have been achieved through shortening the prehospital transfer times, decisive judgement, minimization of all infusions (including blood) and tolerance of low postoperative haemoglobin (106). Naumann et al. describe a recent small series from Syria in which the median haemoglobin concentration at 72 hours was 62 g/L (range 45–98 g/L). Blood transfusion was given as fresh whole blood once bleeding was controlled, with most patients receiving one unit (106).

The findings are in line with those of earlier work from the ICRC (107). The general guideline is not to transfuse patients with a haemoglobin level above 70 g/dL. Before transfusion, each unit of blood should be cross-matched and have been screened for at least the infectious agents considered by WHO to be the minimum requirement: syphilis, hepatitis B and C, and HIV. Additional screening, for example, for malaria should be performed as indicated and if the appropriate screening assays are available. Past ICRC guidance for the quantity of blood needed for war surgery was 45 units per 100 patients admitted. This rose to 60 units if the patients were admitted within 6 hours of being wounded and to 100 if anti-personnel mines were widely used in the conflict concerned (107). Despite the recent trends towards greater blood use, these figures continue to provide useful guidance.

Many of the people affected in war and humanitarian disasters are women and children. Staff should be familiar with the processing and dosing of blood and blood components based on weight as well as haemoglobin. Women continue to require support for obstetric care, especially haemorrhage. In addition, there is often widespread chronic anaemia in the general and refugee populations. Appropriate guidance and resources are advised for humanitarian workers including on the collection of smaller donation volumes and preparation of paediatric units (108). Preventing anaemia and re-establishing some supply together with judicious use of the available blood is therefore essential to maintain a safe, sufficient supply of blood.

4.10 Operational support

Transport, logistics and communications preparation is essential so that plans can be activated promptly. Transportation is needed for a range of transfusion operations during emergencies which in turn need communication to coordinate. Vehicles and radios should be maintained and available at short notice.

Transport may be required for moving staff and donor teams as well as for delivering blood and moving supplies. Other activities may include administrative tasks, trucking water, moving clinical and other waste. An organization should estimate what and how much it will need to move and arrange for its existing resources to be made available during an emergency.

Efforts should be made early on to determine road conditions and operating constraints. Information should be coordinated and shared among all the groups involved in the emergency transfusion response. Depending on local geography, the state of the infrastructure and other factors, alternatives may be used to supplement air and road transportation. These include novel air delivery systems using drones (109) and airdrops (110, 111).

Whatever the mode of transportation chosen, a system is required for tracking and receiving temperature-sensitive items. Plans and procedures should be in place to receive such goods.

4.11 Maintaining and monitoring the response

The immediate post-emergency phase is a key period in which to assess compliance with the existing emergency plan and take corrective action. In addition, consideration should be given to recovery (see section 4.13). The recovery team should begin to plan recovery activities as soon as the initial response phase is over, with a focus on returning to “business as usual”, or normality, as quickly as possible.

4.11.1 Activities during the planning of the recovery activities

- Evaluate the extent to which the emergency demand has been met and the requirements to address any shortfalls and meet the ongoing demand.
- Review the need to modify or make changes to the original plan and communicate changes.
- Ensure that staff and stakeholders have access to key resources such as shortage plan guidance and standard operating procedures. Shortage plans are underpinned by practising good PBM with guidance for prioritization of blood use.
- Review blood stock holdings and the status of shortage plans and amend them as required. For example, should certain components or blood groups remain at amber or be increased to red until more donations are processed? Guidance may need to be based on clinical conditions or on an operational consideration such as a geographical area. An estimated date or time for future updates is necessary to enable staff to plan.
- Monitor the effectiveness of the response using the agreed performance indicators.
- Manage newly identified risks that have arisen during the response.
- Continue communication of guidance on future actions and reviews to external and internal stakeholders. Schedule coordination meetings as required and gain the confidence of the community.
- Ensure that critical information requirements have been met and recorded and that emergency documentation has been secured and can be retrieved.
- Review adverse events and regulatory issues and report the results to external stakeholders including haemovigilance systems.

4.12 Recovery and resilience

4.12.1 The recovery phase

The recovery phase following an incident covers the full restoration of services to “business as usual” and should begin at the earliest opportunity following the onset of a Critical Incident, running in tandem with the response. A focus on immediate challenges can sometimes be a distraction from the overall objectives of restoring normal service as quickly as possible. Incident managers and emergency teams should anticipate the structures, planning activity and resources required to support the eventual restoration of services to normal capacity, thus shortening the overall period of disruption.

4.12.2 Coordinated recovery

Coordinated recovery should be overseen by senior leadership. Responsibility should be assigned to an individual or group not directly involved with immediate response activity. For complicated or protracted incidents, the early formation of a dedicated “recovery group” is recommended so that consistent targets for restoration of normal business can be

agreed, monitored and promptly acted upon. The aim of this phase is to manage the return to normal service delivery and to restore resilience. Considerations include the examples given in the business continuity checklist (section 3.3.2).

4.12.3 Resilience

Psychologists define resilience as the process of adapting well in the face of adversity. Health system resilience is the ability to prepare for, manage (absorb, adapt and transform) and learn from shocks – where the shock is a sudden and extreme change that impacts on a health system. The key health service functions that are best associated with a resilience strategy are governance, finance, resource and service delivery associated with alternative and flexible approaches to deliver care. The key resource is a motivated and well-supported workforce who deserve support and encouragement to anticipate, cope and adapt.

4.12.4 Supporting staff

Resilience should be embedded through staff preparation and leadership. Staff training and rehearsal are essential. In addition, a flexible approach is needed to allow staff to use their full range of skills, even if that means improvisation and changes to accepted roles and responsibilities. Where possible, staff should be trained together with key partners. Practical support should be in place including pay, food, rest facilities and safe accommodation for staff unable to travel home (77, 112). Transfusion staff should be treated as essential health care workers and have access to protective measures such as security, PPE and vaccination.

4.12.5 Lessons identified

Lessons identified should be captured as soon as is practical after major incidents. Formal debriefing may take place later using additional material. Methodology varies between organizations but may include informal one-to-one interviews, questionnaires and staff suggestion schemes. Debriefing should be used to thank staff and recognize their achievements. The principles of joint organizational learning should then be used across the global transfusion community to enable us all to “be prepared”.

4.13 Building blood establishments in disaster areas

Disaster may offer an opportunity to build better for the future. Lessons learned from past problems should be used to inform the location and design of blood establishments to mitigate the impact of common scenarios. For example, after earthquakes, efforts should be made to promote improvement in seismic resilience of buildings (113). Adopting building standards in blood establishments that take into account local conditions and require conformity with national standards should be considered for safety improvement.

Options when starting the reconstruction of blood establishments include:

- *Reconstructing the infrastructure destroyed by a disaster.* There should be political will and availability of resources because the risk awareness is high.
- *Planning new infrastructure.* This option is most cost-effective and politically acceptable when it is part of the earliest planning and negotiation step.

- *Strengthening of existing facilities (retrofitting)*. This is the most expensive step that could be taken. Several developing countries (Chile, Colombia, Costa Rica, Mexico, Peru, and others) have adopted retrofitting to protect their most critical health facilities.

WHO's *Design guidelines for blood centres (115)* could be used to guide the design of new buildings, to direct the renovation of existing facilities or for strengthening the existing facilities to enable safe and efficient functioning. The blood establishment is the hub for the collection, screening, processing, storage and distribution of blood and blood products. If the new facilities are likely to be built in new locations, these must be accessible to the staff, donors, the deliverers of supplies and equipment, and for the dispatch of blood. It is also preferable for the premises to be near the central hospital in the area. Adequate services including water and power should be available to the site. The blood establishment should be designed to ensure the health and safety of staff, visitors and donors. The implementation and enforcement of current Good Manufacturing Practices (cGMP) in blood establishments is considered a priority tool to minimize the risk of currently known and emerging bloodborne TTIs as well as inconsistent quality and characteristics of blood products, especially after a disaster. Also, the adherence to cGMP guidelines in the design of blood establishment facilities is essential to ensure that the collection and manufacturing environment will be suitable to produce safe and quality assured blood and blood products (115).


In the emergency phase, temporary measures for blood provision may be required. Practical guidance for the emergency phase is available from the WHO Regional Office for the Eastern Mediterranean's publication on *Health laboratory facilities in emergency and disaster situations*, which includes sections on blood transfusion (116). There are four types of emergency blood centre that could be established:

- **Portable blood establishment.** This is designed for locations that are inaccessible by vehicle and perform only critical tests, such as walking blood banks.
- **Mobile blood transfusion service.** This type of service is transported by a vehicle so it can be moved from place to place.
- **Temporary stationary blood transfusion service.** This service could be set up in tents or in local premises, such as in a local house, school or community building in a place which previously had no blood transfusion service facility.
- **Existing (or constructed) fixed blood transfusion service facilities.**

However, there must be a commitment to the restructuring of the blood supply and transfusion system as an integral part of the health care system, including good governance, legislative and regulatory framework and oversight, human resources, finance, and quality system/quality system management.



Box 9. Key messages – response and recovery phases

1. The aim of the response phase is to ensure a sufficient supply of safe blood and blood components during the emergency.
 2. Coordinated incident management should ensure the safety of individuals, minimize adverse impacts on products, services and the organization while preparing for recovery.
 - The transfusion system response should be embedded within the wider health care and emergency response, including support from WHO.
 - The initial assessment and situation analysis are key to ensuring a proportionate response. The nature, estimated severity and duration of the emergency should determine activities.
 - The transfusion workload should be triaged to prioritize efforts, focus on critical activities and aim to restore acceptable services as soon as feasible.
 - Security and safety must come before health care, and emergency responders may be delayed. It is essential that the staff and the public are familiar with disaster response and first aid including haemorrhage control.
 - Transfusion providers should periodically review the nature of relevant incidents and their own health care response to help them make decisions on stock holding and other aspects of their business continuity response.
 - The immediate post-emergency phase is a key period in which to assess compliance with the existing emergency plan and take further corrective action, especially where incidents may be protracted.
 - The recovery phase following an incident refers to the full restoration of services to business as usual and should begin at the earliest opportunity.
 - Resilience to disaster requires a commitment to the blood supply and transfusion system as an integral part of the health care system.
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ANNEX 1

Substantive ethical and procedural values¹

Substantive ethical values

Individual liberty: In an emergency, restrictions to individual liberty may be necessary to protect the public from serious harm. Restrictions to individual liberty should be proportional, necessary, relevant, be the least restrictive possible and be applied equitably.

Protection of the public from harm: To protect the public from harm, health care organizations and public health authorities may be required to take actions that impinge on individual liberty. Decision-makers should weigh the imperative for compliance, provide reasons for public health measures to encourage compliance and establish mechanisms to review decisions.

Proportionality: Proportionality requires that restrictions to individual liberty and measures taken to protect the public from harm should not exceed those necessary to address the actual level of risk to or critical needs of the community.

Privacy: Individuals have a right to privacy in health care. In an emergency, it may be necessary to override this right to protect the public from serious harm.

Duty to provide care: Inherent to all codes of ethics for health care professionals is the duty to provide care and to respond to suffering. Health care providers will have to weigh the demands of their professional roles against other competing obligations to their own health and to their families and friends. Moreover, health care workers will face significant challenges in resource allocation, scope of practice, professional liability and workplace conditions.

Reciprocity: Reciprocity requires that society supports those who face a disproportionate burden in protecting the public good and take steps to minimize the burden as much as possible. Measures to protect the public good are likely to impose a disproportionate burden on health care workers, patients and their families. This is particularly the case in a situation of massive displacement or evacuation of people which may cause an increase in demand.

Equity: All patients have an equal claim to receive the health care they need under normal conditions. During a pandemic or a humanitarian emergency, difficult decisions will need to be made about which health services to maintain and which to defer. Depending on the severity of the event, this could curtail not only elective surgeries but could also limit the provision of emergency or other essential services.

Trust: Trust is an essential component of the relationships between clinicians and patients, staff and their organizations, the public and health care providers, or organizations and among organizations within a health system. Decision-makers will be confronted with the challenge of maintaining stakeholder trust while simultaneously implementing various control measures during an evolving emergency. Trust is enhanced by maintaining such process values transparently in a situation of protracted humanitarian emergency.

¹ This annex is based on Ethics in epidemics, emergencies and disasters: surveillance and patient care. Training manual. Geneva: World Health Organization; 2015.

Solidarity: As the world learned during the severe acute respiratory syndrome (SARS) and COVID-19 outbreak, a pandemic outbreak of influenza will require a new vision of solidarity among nations. A pandemic can challenge conventional ideas of national sovereignty, security or territoriality. It also requires solidarity within and among health care institutions. It calls for collaborative approaches that set aside traditional values of self-interest or territoriality among health care professionals, services or institutions.

Stewardship: People entrusted with governance roles should be guided by the notion of stewardship. Inherent in stewardship are the notions of trust, ethical behaviour and good decision-making, politically as well as professionally. This implies that decisions regarding resources are intended to achieve the best patient health and public health outcomes in the unique circumstances of, for example, a pandemic or an armed conflict or violent aggression.

Procedural values

Reasonable: Decisions should be based on reasons (i.e. evidence, principles, and values) that stakeholders can agree are relevant to meeting health needs in a disaster or emergency. The decisions should be made by people who are credible and accountable (competent leadership).

Open and transparent: The process by which decisions are made must be open to scrutiny, and the basis on which decisions are made should be publicly accessible.

Inclusive: Decisions should be made explicitly with stakeholders' views in mind, and stakeholders should have opportunities to engage in the decision-making process.

Responsive: There should be opportunities to revisit decisions as new information emerges throughout the event. There should be mechanisms to address disputes and complaints as important elements of sustained quality management.

Accountable: There should be mechanisms in place to ensure that decision-makers are answerable for their actions and inactions. Defence of actions and inactions should be grounded in the fundamental ethical values discussed.



ANNEX 2

Example of a business continuity checklist and relevant content

Building and facilities

- Do you have evacuation procedures for your buildings?
- Are the fire exits clearly marked and fire procedures in place?
- Do your staff participate in regular fire drills?
- Do you have a site plan of your building(s)?
- Do you have generator backup systems in place?
- Do you have an alternative building to use in an emergency? It is important for a blood facility to have alternative collection, processing, testing and storage sites and an alternative transportation system.
- Do you carry out end of day inspections, i.e. to check everybody has left?
- Do you have procedures for periodic facility inspections?

Personnel

- Do you have a list of all employees' contact telephone numbers and home addresses?
- Do your staff know who is in charge in times of crisis?
- Have your staff been given specific roles in the event of a crisis?
- If the blood establishment cannot operate from its present location could your staff work from an alternative location, or could some of them work from home?
- Do you have members of staff with first aid or medical training?
- Have your staff been trained and assessed for competency to deal with emergencies and disasters?

Equipment

- Do you have a critical equipment list?
- Do you have backups for critical equipment?
- Do you have comprehensive maintenance schedules to ensure the proper and continued functioning of critical equipment?
- Is your critical equipment connected to an emergency power supply?
- Do you have a method to continuously monitor the temperature of blood and components equipment (cold chain)?

Suppliers

- Do you have alternative suppliers for critical equipment, consumables and reagents?
- Do you have an arrangement with your critical suppliers so that they will inform you if they cannot make a delivery?
- Do you have enough stocks of critical reagents to perform the activities for a reasonable period of time if delivery of supplies is affected?
- Do your suppliers have a business continuity plan?
- Do you have your suppliers' correct contact details?

Blood donors

- Do you have the correct contact details of your blood donors?
- Can you reach your blood donors by different methods: phone, emails or SMS?
- Do you encourage the public to register to donate during emergencies?
- Do you have smart applications to notify your donors with updates during a disaster or emergencies?

Information system

- Do you have a system in place for continuous data backup; is that off-site?
- If your IT systems fail, do you have manual processes that could maintain critical documentation and administrative functions?
- Do you know how long it would take to recover IT functions if your system breaks down?
- Do you have a tested and validated IT disaster recovery plan?
- Have your staff been trained in down-time procedures?

Media and marketing services

- Is the public receiving correct and updated information?
- Have you assigned a person to communicate with media to make announcements?
- Are the new working hours, location and other required information made available to the public?





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