Blood Supply Contingency and Emergency Plan

B-SCEP

Survey Report

EDQM
2021

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Blood Supply Contingency and Emergency Plan (B-SCEP)

Survey Report

European Directorate for the Quality of Medicines & HealthCare

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Survey Report

Background

Contingency planning and emergency preparedness are key components of a National Blood System. It is important to ensure that when faced with disruptions or emergencies, a safe and adequate supply of blood can be maintained and made available for all essential transfusions.

The Blood Supply Contingency and Emergency Plan (B-SCEP) Project aims to contribute to strengthening national and EU-level plans to ensure the continuity of the blood supply, by publishing recommendations and model preparedness plan(s), and developing strategies to support European countries in this regard.

Objectives of the B-SCEP Project:

- Map the existing interventions and tasks implemented by national-level authorities and Blood Establishments (BEs) to ensure continuity of blood supply in emergency situations.
- Identify the most common types of existing contingency plans in National Blood Systems.
- Make an assessment of the different types of contingency plans.
- Address the cross-country dimension of contingency planning.
- Identify needs for establishing guidance or a toolkit on contingency.

In order to meet these objectives, there is a need to gather information on the existing national-level frameworks in place for B-SCEP in European countries. The aim of the B-SCEP survey is to provide this information.

Abbreviations

BE	Blood Establishment
B-SCEP	Blood Supply Contingency and Emergency Plan
MoH	Ministry of Health
NCA	National Competent Authority (for blood)

Definitions of contingency planning and emergency preparedness

Contingency planning ensures that, when faced with disruptions, the capability of the National Blood System to continue the delivery of blood products and services is maintained.

Emergency preparedness is the creation of plans through which a National Blood System manages the impact of an unexpected event, enabling it to provide the required blood products and services to the healthcare community, delivering assistance to those affected by such events.

Survey scope

The survey included five areas of interest:

1. Contingency planning and emergency preparedness frameworks
2. Legislation and guidelines
3. Regulatory oversight
4. Key risk scenarios
5. National approach
   a. Planning and mitigation
   b. Preparedness
   c. Response
   d. Recovery

The responses received for each section are highlighted and discussed in the Results section of the report.

The survey did not address the individual blood supply needs of each country or approaches for monitoring the blood supply. These parameters should be further considered as part of the B-SCEP Project when developing recommendations for stakeholders and model preparedness plans.

The B-SCEP Project was initiated pre-COVID-19 pandemic; however, the survey responses were collected during the pandemic, which may have influenced the outcome.

Expected outcomes

The collected data will be assessed and used to support the development of recommendations, including a model preparedness plan, that can be expanded into concrete plans and/or guidance.

Survey timeframe

25 January 2021	Survey launch
26 February 2021	Response deadline
11 March 2021	Partially complete responses followed up; survey closed
12 August 2021	Survey report completed

Survey design

The survey was designed as a multiple-choice questionnaire consisting of 58 yes/no or multiple-choice questions, either stand-alone or follow-up to a previous yes/no question. For 13 questions, it was possible to choose more than one answer.

The survey was developed and disseminated via the LimeSurvey web app.

Selection of survey participants

Because of the possible wide variation of key stakeholders involved in contingency planning and emergency preparedness at national level, the survey was disseminated to the members of the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS) (n = 39) and representatives of the NCA for blood of the EU member states authorities via DG-SANTÉ (n = 27).

The recipients were specifically asked, if they did not consider themselves the appropriate contact to answer the survey, to forward it to the appropriate individual, organisation or body that would be able to complete the survey on behalf of their respective country.

Qualification of responses

In total, 35 complete responses from 27 European countries were received within the given timeframe (in alphabetical order): *Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Latvia, Malta, Moldova, Montenegro, the Netherlands, Norway, Poland, Portugal, Romania, Spain, Sweden, Switzerland, Turkey.*

Seven countries provided more than one response: Austria (2), Finland (2), France (2), Greece (3), Latvia (2), Portugal (2) and Turkey (2). For statistical accuracy, only one response per country could be included in the survey analysis. Where more than one response was received, the response from the national transfusion service was favoured. However, comments from all responders were kept for the survey report.

In total, **27 responses representing 27 European countries (21 EU countries)** were deemed appropriate and relevant for evaluation and analysis of results (Figure 1). Of the 27 responses, national BEs (12) and NCAs for blood (11) were equally represented. Together, they accounted for 85 % of the responses.

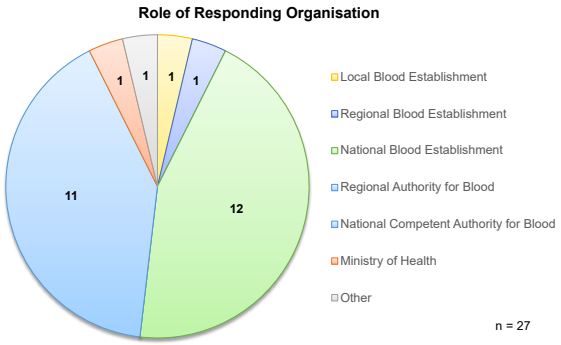


Figure 1 – *Role of responding organisation in the B-SCEP survey*

The remaining respondents included local BE, regional BE and Ministry of Health (MoH). One further response indicated that the national transfusion service and the NCA were involved in the survey response. There were no regional authorities represented among the respondents.

While the survey is used to draw general conclusions about contingency and emergency preparedness planning in European countries, it should be noted that 12 countries that received the survey did not complete it. Therefore, the survey does not necessarily represent the opinions and state of play of all individual European countries.

Results

1. Contingency Planning and Emergency Preparedness Frameworks

Objectives

The objective of this section is to obtain an overview of the country profiles: National Blood System organisational model, role of the stakeholders and the state of play of the current contingency and emergency planning frameworks present in the different European countries.

Blood system organisation

A national (i.e. centralised) blood service is the most common model (41 %) among the European countries (Figure 2a), followed by a **combination** of two of the models (30 %). Four countries each have **regional (i.e. decentralised)** or **local (i.e. independent)** blood services.

In 20 of the 27 represented countries (74 %), the main blood operators belong to the **public sector** (Figure 2b).

The **military** has a blood operator function in 8 countries (30 %); however, in all these countries, there is also at least one civil function.

Almost half of the countries (48 %) have **more than one category** of blood operators.

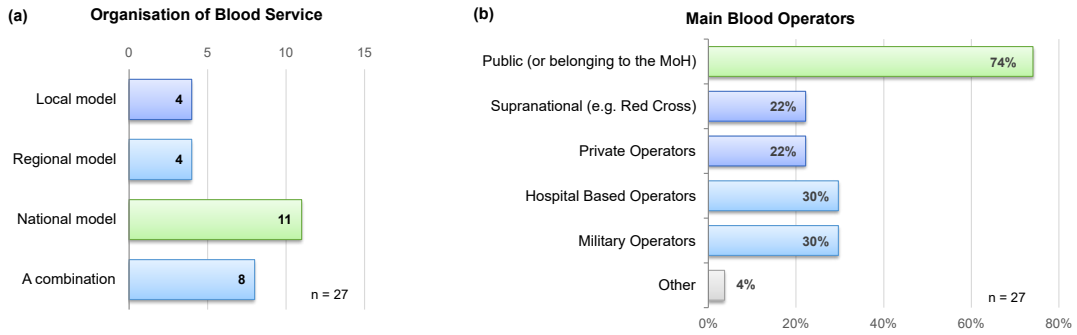


Figure 2 – *(a) Organisational model of the Blood Transfusion System in the European countries (b) Main blood operators in the European countries*

Examples of private operators (22 %) are **plasma donation centres** and the **fractionation industry**, but also **privately owned** BEs/donation centres.

Current status of emergency preparedness and contingency plans

In 78 % of the countries, emergency preparedness and contingency plans are in place to ensure the continuity of the blood supply. The **majority** (76 %) of these are **co-ordinated on a national level** (Figure 3).

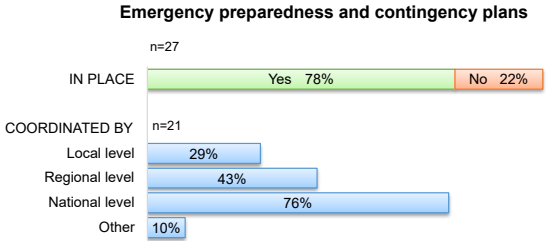


Figure 3 – *Emergency preparedness and contingency plans currently in place in the European countries, and their co-ordination*

In total, 26 % of the countries have plans co-ordinated on **more than one level**.

Stakeholders in the emergency preparedness and contingency plans

BEs are involved in the emergency preparedness and contingency plans in **all but one of the countries**.

Hospitals/hospital blood banks, NCAs for blood and the **MoH** are involved in the plans in about 60 % of the countries. Regional authorities are involved in 37 % of the countries, more specifically in 57 % of the countries with a regional blood service.

At least two of the stakeholders are involved in the plans in all countries, except one where the MoH is the exclusive stakeholder.

Armed forces are involved in the plans in 41 % of the countries, whereas the **Government** is involved in only two countries (7 %) (Figure 4).

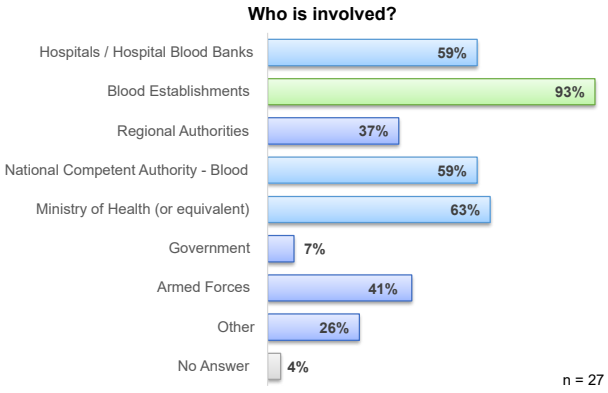


Figure 4 – *Different stakeholders involved in the emergency preparedness and contingency plans*

2. Legislation and guidelines

Objectives

The objectives of this section are to define what legislation, guidelines and additional standards related to contingency and emergency planning to ensure blood supply continuity are in place at national level in the European countries. The level of specificity of the legislation/guidelines in place for the blood sector, and the perceived need for defined legislation and/or guidelines are also assessed.

Current status of legislation and guidelines

The emergency preparedness and contingency plans may be related to legislation, guidelines and/or other recommendations/standards.

A slightly higher percentage of European countries have guidelines in place related to emergency preparedness and contingency plans (70 %) than corresponding legislation (63 %) (Figure 5a). In addition, 48 % of the countries have other recommendations or standards. At least two of the three categories are implemented in 63 % of the countries.

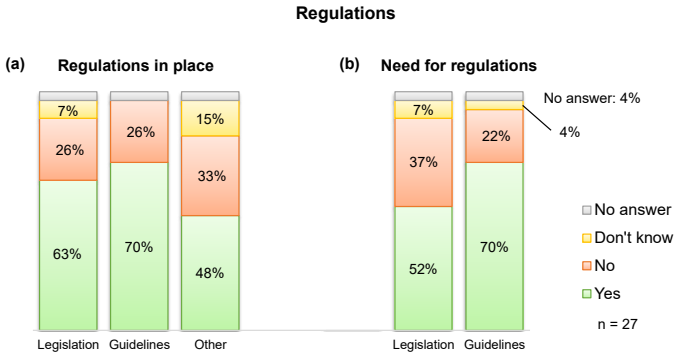


Figure 5 – *(a) Percentage of countries with legislation, guidelines or other recommendations/standards in place (b) Self-assessment on the need for legislation, guidelines or other recommendations/standards*

Other recommendations or standards include, for example, BE business continuity plans, national BE standards, local BE SOPs, national overall disaster protection plans or incident-specific recommendations. For instance, one country describes a BE business continuity plan that contains a pandemic plan, an emergency plan for blood collection and risk analyses based on the FMEA* method.

Two countries (7 %) do not know whether legislation on blood supply emergency preparedness and contingency plans exists or not.

Scope of current legislation

Of the countries that have **legislation** related to emergency preparedness and contingency plans (n = 17), 53 % (n = 9, 33 % of all countries) have **specific** legislative provisions for ensuring the continuity of blood supply, whereas a larger proportion, 71 %, have **general legislation** ensuring the provision of critical services (Figure 6).

* FMEA: Failure Modes and Effects Analysis.

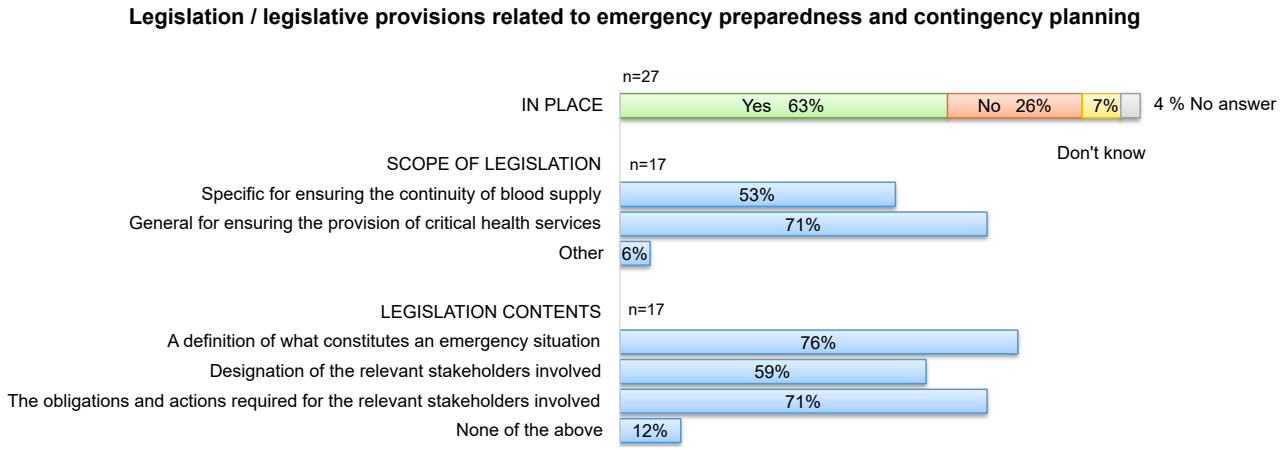


Figure 6 – *Countries that currently have legislation/legislative provisions related to emergency preparedness and contingency plans, and the scope and contents of the legislation*

The legislation most commonly contains a **definition of what constitutes an emergency situation** (76 %), followed by obligations and actions required for the relevant stakeholders (71 %) and designation of relevant stakeholders (59 %).

Scope of current guidelines

Of the countries that have **guidelines** related to emergency preparedness and contingency plans (n = 19), 63 % (n = 12, 44 % of all countries) have **specific guidelines** for ensuring the continuity of blood supply. Fewer, 58 %, have **general guidelines** for ensuring the provision of critical services (Figure 7).

The guidelines most commonly contain **obligations and actions required for the relevant stakeholders** (79 %), followed by a definition of what constitutes an emergency situation (74 %) and identification of relevant stakeholders (68 %).

In summary, more countries have guidelines than legislation related to emergency preparedness and contingency plans. The guidelines are more likely to involve specific obligations and actions for stakeholders, whereas the weight of the legislation is placed on the definition of an emergency situation.

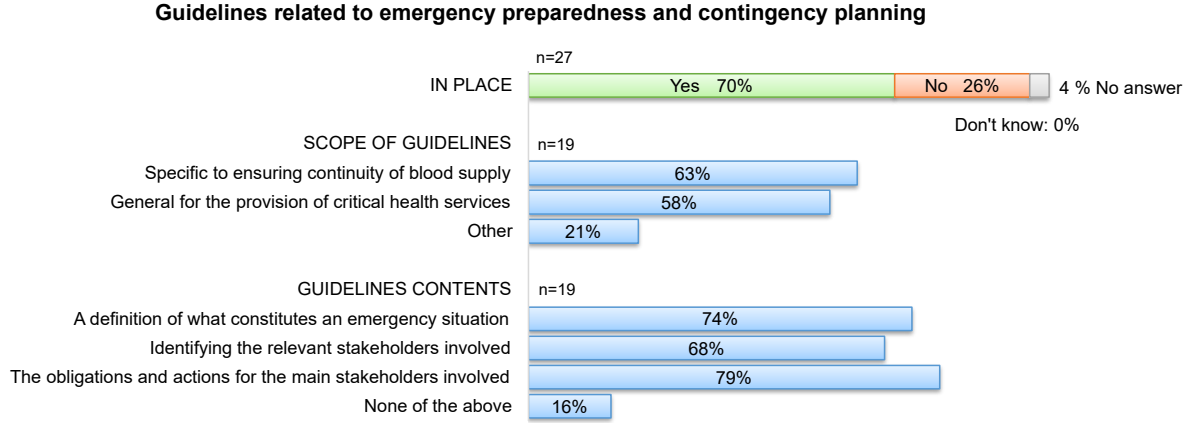


Figure 7 – *Countries that currently have guidelines related to emergency preparedness and contingency plans, and the scope and content of the guidelines*

Self-assessment on the need for legislation and guidelines

The countries' self-assessment on the need for **legislation** related to emergency preparedness and contingency plans shows a decline in interest compared to the current situation: 63 % of the countries currently have legislation, but only 52 % think legislation is needed (Figure 5b). Five of the countries which currently have legislation are uncertain or think legislation/additional legislation is not needed. Only one country that does not currently have legislation believes that it is needed.

The percentage of countries experiencing a need for guidelines related to emergency preparedness and contingency plans is similar to current countries with guidelines, 70 %. However, only 12 of the 19 countries that currently have guidelines think they are a necessity.

Among the suggestions for the contents of **guidelines** are surveillance tools for monitoring the blood stock, situation risk analysis instruments and model preparedness plans including geographically sensitive areas. One NCA respondent emphasised that guidelines should be issued subsequent to any new regulations.

3. Regulatory oversight

Objectives

The objective of this section is to gain information on the regulatory oversight and the role of the NCA in emergency preparedness and contingency planning by assessing the requirements for authorisation and inspection.

NCA inspection requirements and involvement

In 59 % of the European countries (71 % of the countries in which such plans are already in place), emergency preparedness and contingency plans are **subject to inspection** by the relevant blood regulatory authority or inspectorate (Figure 8a).

Emergency preparedness and contingency plans are a **requirement for obtaining a BE authorisation** in half of the countries (Figure 8b). Where this is required, the plans need to be **reviewed and approved** by relevant regulatory authorities in an additional 54 % (26 % in total), often close to or during an inspection.

However, even though the plans may be subject to inspection, they are not always inspected. As stated by one country: "In theory the inspectorate can/should also inspect preparedness plans, but in practice it does not happen."

The NCA is involved in the development of emergency preparedness and contingency plans in 14 of the 21 countries (67 %) that have them. However, the level of involvement (general or specific plans) varies.

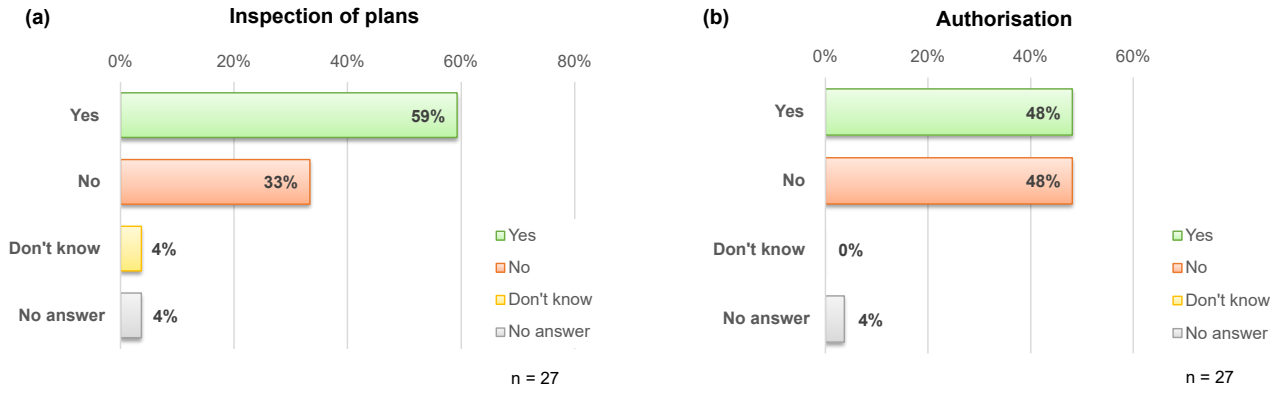


Figure 8 – *(a) Countries whose emergency preparedness and contingency plans are subject to inspection (b) Countries in which plans are a requirement for BE authorisation*

Derogations to BE authorisations

More than half of the countries (52 %) lack a system to **allow specific derogations** to BE authorisations to ensure the continuity of blood supply in emergency situations, and an additional 11 % of the countries are unsure whether such a system is in place (Figure 9).

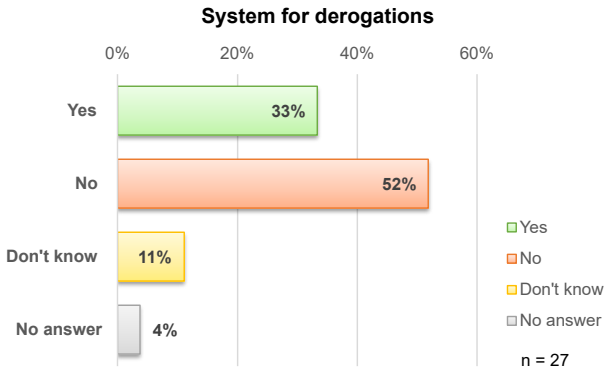


Figure 9 – *The existence of an organised system to allow specific emergency derogations*

However, even without a system, several countries report a **case-by-case collaboration** between BEs and the NCAs when needed.

Retaining a reserve stock of blood components is a common pro-active approach to avoid the need for derogations.

4. Key risk scenarios

Objectives

The objectives of this section are to assess which key risk scenarios are covered in the national contingency plans, and determine whether there is equal preparedness for blood supply decrease and blood demand increase.

Blood supply decrease and blood demand increase

In a majority of the European countries (70 %), emergency preparedness and contingency plans are in place for **both a blood supply decrease and a blood demand increase**; 11 % of the countries have no plans in place for either scenario.

Several countries have **emergency donation plans** in place. In countries with local or regional organisation models, it is common to have established arrangements for BEs to **supply each other** with blood components in cases of emergency.

Key risk scenarios

Five key risk scenarios are covered in the emergency preparedness and contingency plans in more than 60 % of the countries: interruptions in the supply and critical service (70 %), epidemics/pandemics (70 %), disruption or damage to premises or facilities, adverse weather conditions and terrorist attacks (all 63 %) (Figure 10).

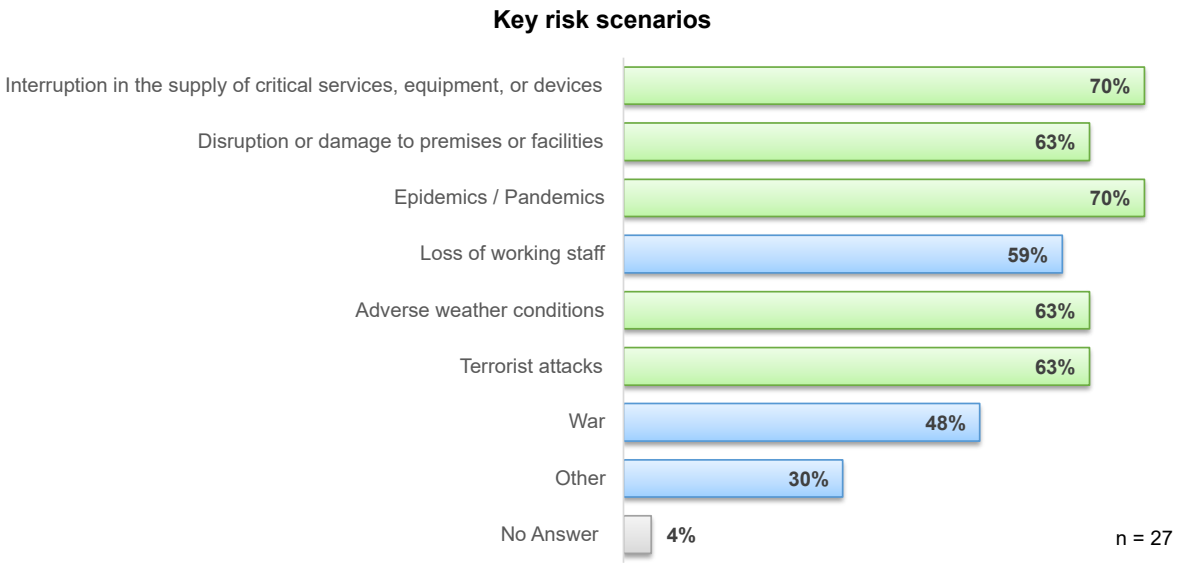


Figure 10 – *Key risk scenarios covered in the emergency preparedness and contingency plans*

However, several countries state that the key risk scenario assessment is only **provided on a local BE or hospital level**, and is not mentioned in a national plan.

5. National approach

Objectives

The objective of this section is to determine the national approach to four different stages of emergency preparedness and contingency planning: planning and mitigation, preparedness, response and recovery.

Planning and mitigation

Planning and mitigation: key factors in plan establishment

When establishing emergency preparedness and contingency plans to ensure continuity of blood supply in the European countries, the factors most frequently considered are:

- Type of blood products or services provided (81 %)
- Legal and regulatory requirements (78 %)
- Human, equipment and material resources (78 %)

These are taken into account in approximately 4 out of 5 countries (Figure 11).

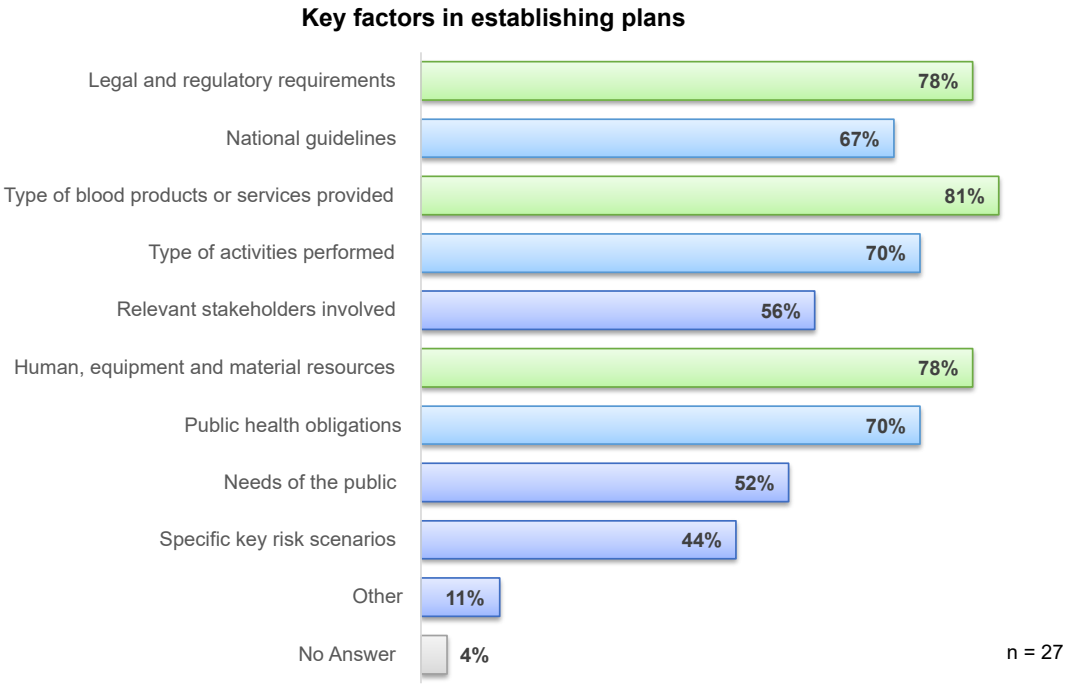


Figure 11 – *Key factors taken into account when establishing emergency preparedness and contingency plans*

Risk assessment of the likelihood of specific disruptions or emergency situations is carried out during the development of the plans in 63 % of the countries (Figure 12a). There is **no common risk assessment tool**, although in 48 % of cases, the **potential impact of key risk scenarios on the blood supply** is assessed (Figure 12b), such as total inability to produce blood (destruction of BE), sudden massive increase in blood requirement and failure of the NAT platform.

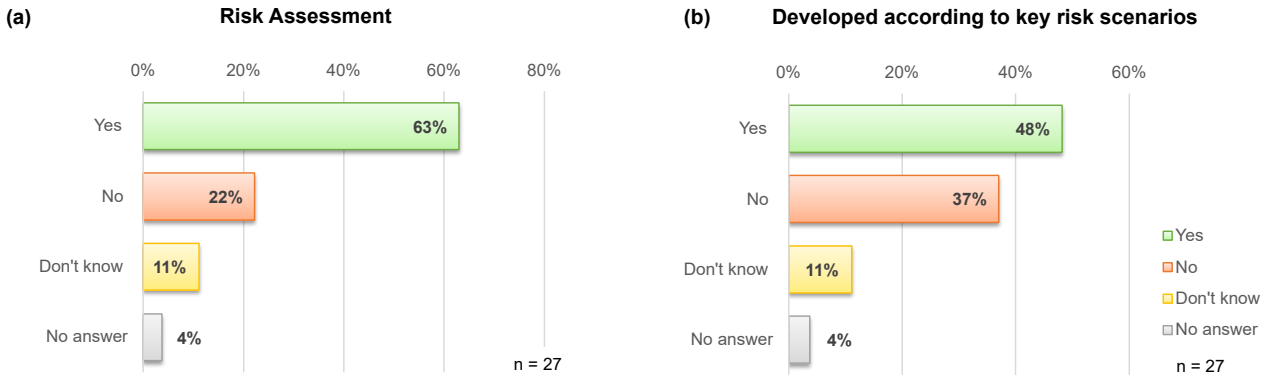


Figure 12 – *(a) Countries in which a risk assessment is performed pre-development of emergency preparedness and contingency plans (b) Countries in which the potential impact on the blood supply is analysed according to specific key risk scenarios*

Planning and mitigation: key priorities

In the emergency preparedness and contingency plans, the main priority is considered to be **prioritisation of activities** required to ensure the continuity of blood supply (85 %), followed by **preventative strategies and solutions** to avoid disruption of the supply (81 %) (Figure 13).

A majority of the countries (56 %) consider all of the options in the graph as main priorities.

Other main priorities include defined international and third-party collaborations.

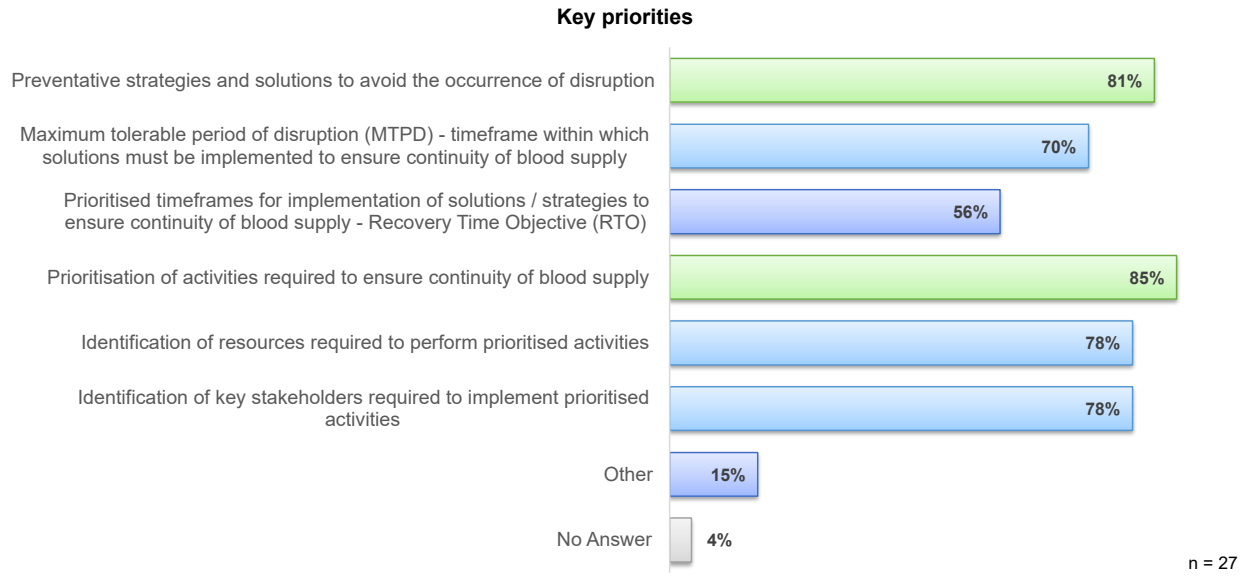


Figure 13 – *Key priorities or requirements to be considered in emergency preparedness and contingency plans*

Planning and mitigation: key stakeholders

Generally, **BEs** (93 %) and **hospitals/hospital blood banks** (74 %) are more frequently considered to be key stakeholders than the different regulatory bodies (Figure 14).

However, in 48 % of the countries, different key stakeholders are identified according to specific key risk scenarios.

The roles and responsibilities of all relevant stakeholders are defined in 43 % of the countries.

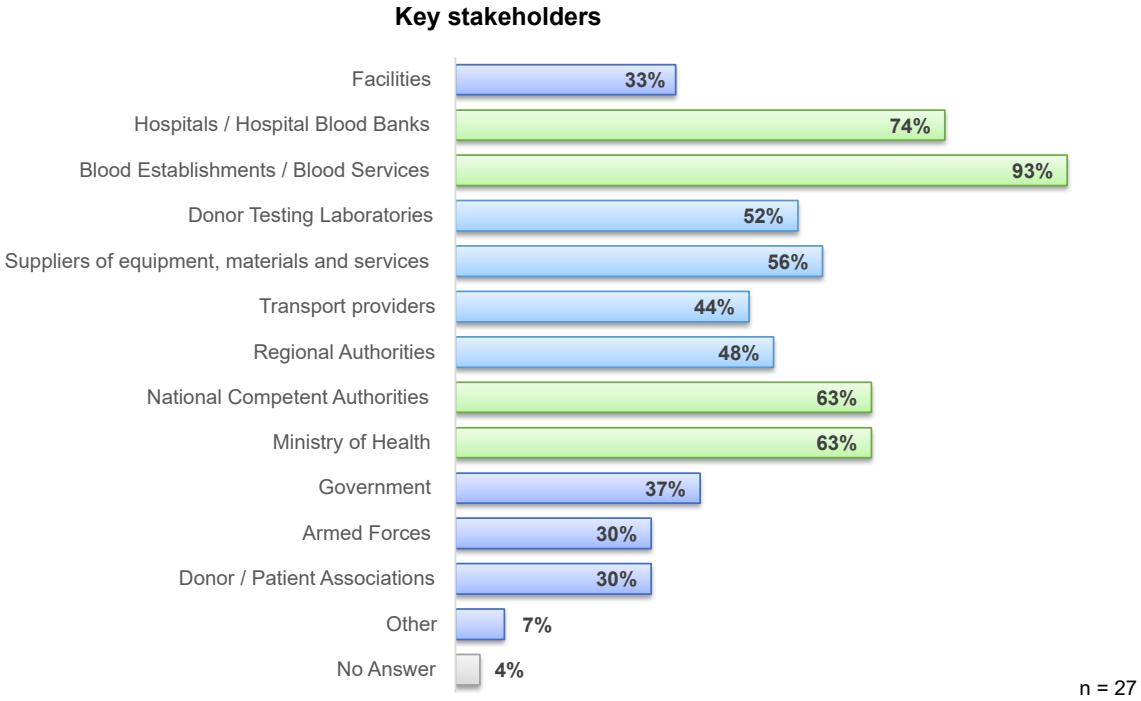


Figure 14 – *Key stakeholders for emergency preparedness and contingency plans*

Planning and mitigation: working groups and taskforces

Specific **working groups or taskforces**, responsible for emergency preparedness and contingency planning to ensure the continuity of blood supply, are established at national level in 59 % of the countries (Figure 15a).

There is no general trend in composition of the group; different countries have BE/transfusion committee alone, BE + national authority (often MoH) collaboration, or national authorities alone.

It is most common (39 %) that the group/taskforce has a fixed composition of members regardless of key risk scenarios, as opposed to different working groups/taskforces for different scenarios (33 %). Other countries may have a combination, i.e. fixed national taskforce with the option of expanding the group to include designated members for specific situations/ needs (Figure 15b).

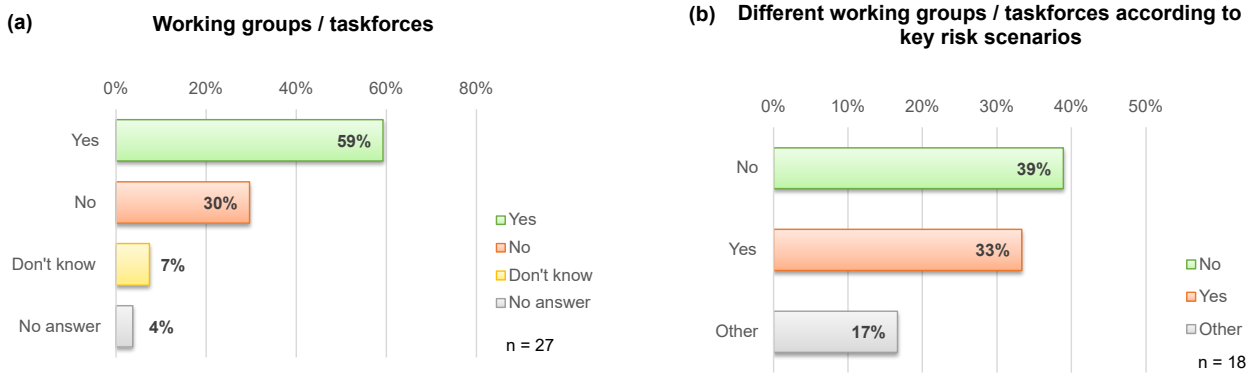


Figure 15 – *(a) Countries with specific national working groups or taskforces for emergency preparedness and contingency planning (b) Fixed or varying working groups/taskforces for different key risk scenarios*

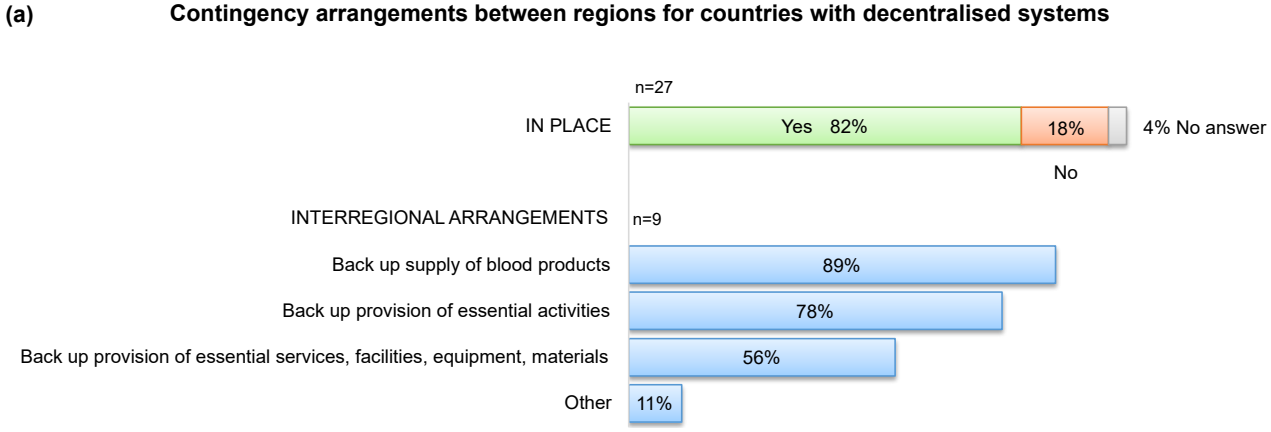
Planning and mitigation: collaborative contingency arrangements

It is more common among the European countries to have **interregional contingency arrangements** to ensure the continuity of the blood supply in emergency situations, than **corresponding cross-country arrangements** (Figure 16).

Of the countries that have a regional/federal/decentralised blood system, 82 % (n = 9) have contingency arrangements in place **between regions**. In 8 out of 9 countries (89 %), the contingency arrangements include a **backup supply of blood products**, and in 7 out of 9 (78 %), a backup provision of essential activities.

Only 6 of the countries (22 %) have contingency arrangements in place with blood services or other organisations in **another country**.

All **cross-country arrangements** include **backup provision of essential activities** (testing, processing, etc.), whereas 50 % of the countries have backup arrangements for supply of blood products. Among other arrangements, two countries have backup for donor testing and one country has a safety stock of SD plasma.



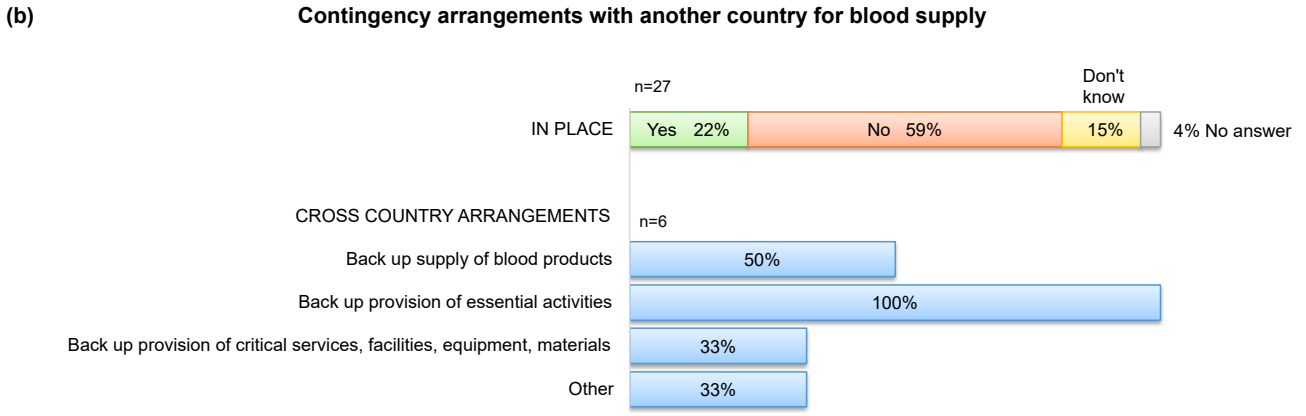


Figure 16 – *(a) Interregional contingency and (b) cross-country contingency arrangements*

Preparedness

Preparedness: Self-evaluation on quality indicators

In a self-evaluation on the quality indicators of emergency preparedness and contingency plans in place, considering the **specificity** of immediate steps to be taken, **flexibility** to respond to changing conditions, **focus** on incident impact, **efficacy** in minimising impact/implementing solutions, and **clearness** of roles, responsibilities and tasks during a disruption/emergency (Figure 17), it can be summarised that:

- When considering overall preparedness, the most favoured response among the European countries was "good" (26-44 %).
- More countries consider their plans "very poor" (15-22 %) than just "poor" (7-15 %).
- The mean percentage of countries considering their plans "very poor" (19 %) is higher than the mean percentage considering their plans "excellent" (15 %).
- Of the five categories, **flexibility** has the highest percentage when combining the "good" and "excellent" categories (56 % of the countries), whereas **focus** and **clarity** have the lowest percentage (48 %).
- Of the five categories, **efficacy** has the highest percentage when combining the "poor" and "very poor" categories (33 % of the countries), whereas **specificity** has the lowest percentage (26 %).

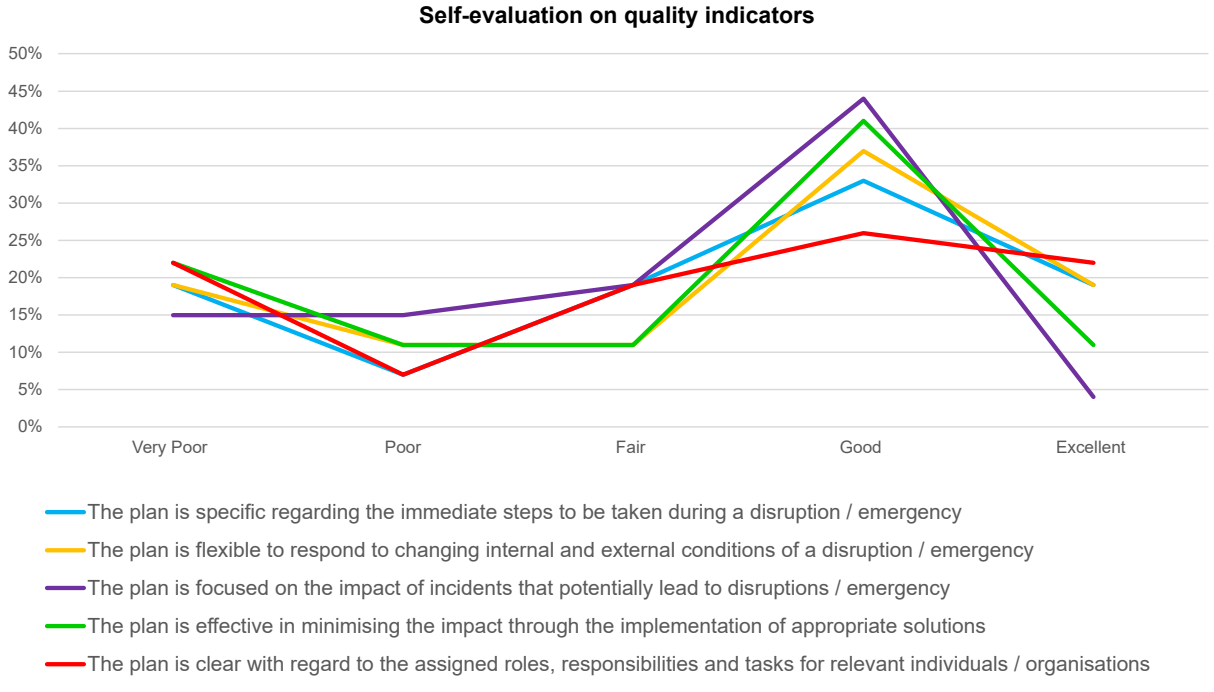


Figure 17 – *Self-evaluation on quality indicators of existing emergency preparedness and contingency plans*

Preparedness: content of the emergency preparedness and contingency plans

The emergency preparedness and contingency plans most commonly include **purpose, scope and objectives** (74 %), followed by **defined actions to implement proposed solutions** (70 %) (Figure 18).

Less than half of the countries (48 %) have plans that contain key stakeholder interdependencies and organisation and/or a process for recovery (44 %).

The organisation level differs: in some countries, plans containing the mentioned details exist only on a national level, whereas in other countries, this level of detail exists only on a local hospital/BE level.

Preparedness: testing of the emergency preparedness and contingency plans

Less than half of the countries (44 %) **test the procedures** stated in the emergency preparedness and contingency plans regularly (Figure 19). Almost all tests are performed through **periodic practical exercises** (92 %), complemented by **periodic desk-based review** in two-thirds of cases. Four countries perform only practical exercises, while one country carries out desk-based reviews alone.

It is most common to test the plans **every second year**. However, testing intervals of up to five years exist. No countries test the plans in intervals shorter than one year.

Fifteen percent of the countries do not know whether their plans are regularly tested or not.

Preparedness: reviewing of the emergency preparedness and contingency plans

Once established, emergency preparedness and contingency plans are subject to **periodic review** in 59 % of the countries (Figure 20). They are most commonly reviewed **annually** (38 %) or upon **significant change** (31 %).

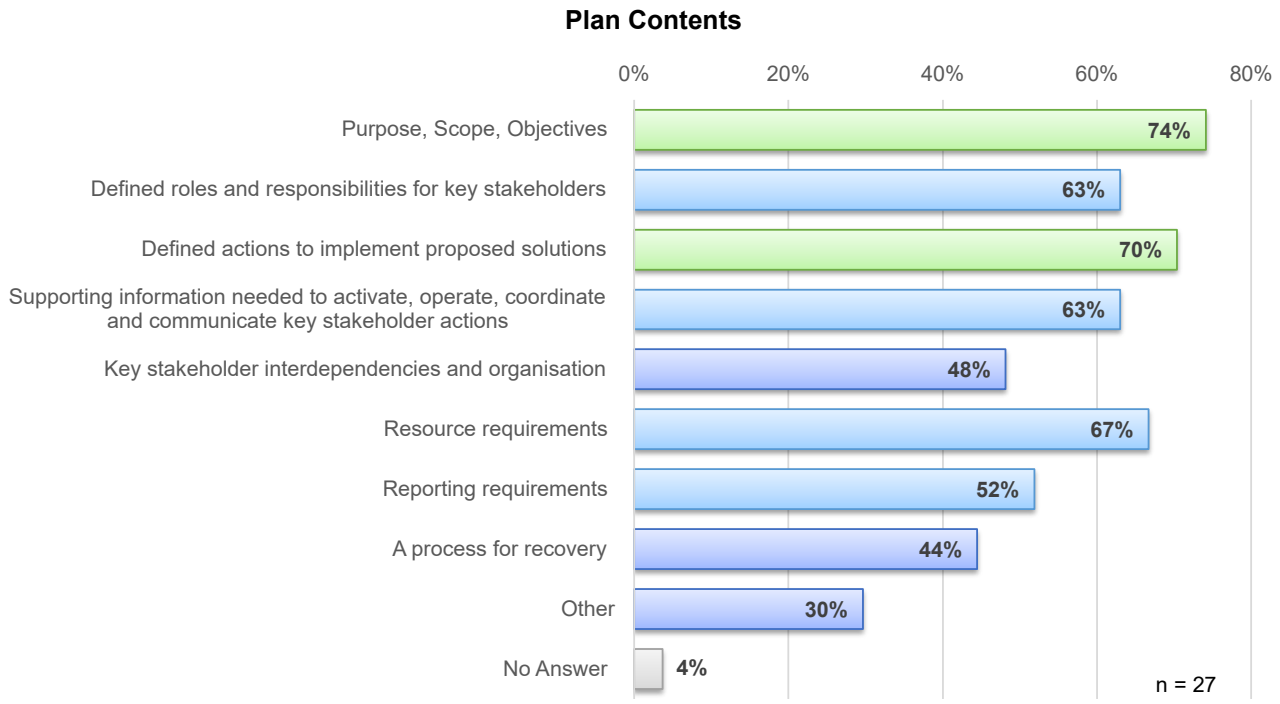


Figure 18 – *Content of the emergency preparedness and contingency plans*

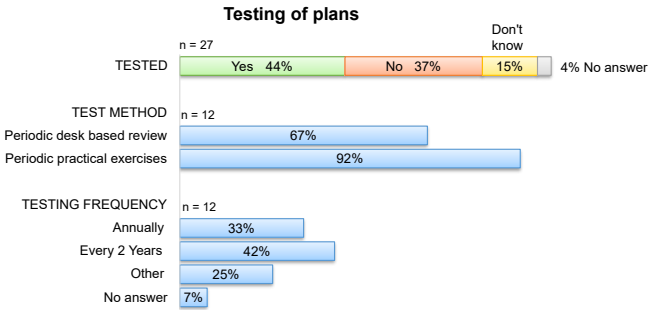


Figure 19 – *Testing, test method and testing frequency of the emergency preparedness and contingency plans*

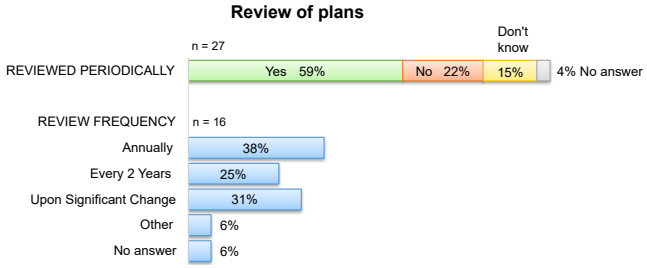


Figure 20 – *Review of the emergency preparedness and contingency plans*

Significant changes may be reported to the relevant stakeholders: 41 % of the countries have a system in place for **communicating significant changes** to the **relevant stakeholders** and 26 % do not know whether such a reporting system exists in their country (Figure 21).

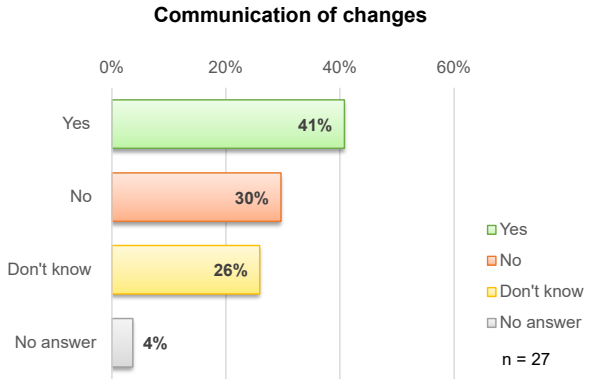


Figure 21 – *System for communication of significant changes to stakeholders*

Response

Response: stakeholders

In 52 % of the countries, relevant stakeholders have been provided with documented plans to guide their actions (activation, operation, co-ordination and communication of their response) in response to a disruption/emergency situation (Figure 22).

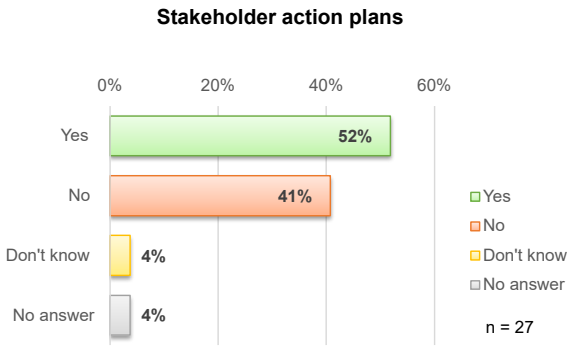


Figure 22 – *Provision of documented action plans for stakeholders*

Response: communicative approach

There is a defined approach for communication to ensure the continuity of the blood supply in emergency situations in 7 out of 10 countries (Figure 23a). All relevant stakeholders have been made aware of communication procedures in 59 % of the countries (Figure 23b).

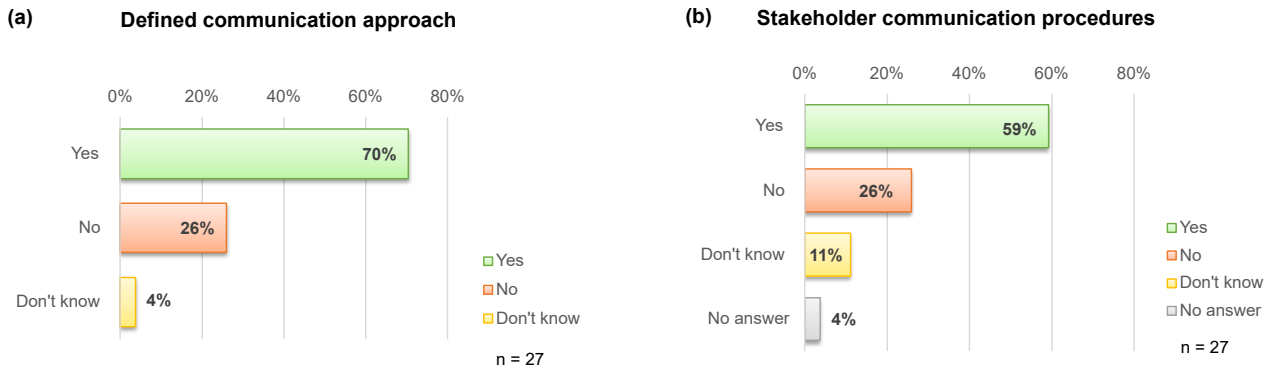


Figure 23 – *(a) Defined communication approach and (b) stakeholder awareness of communication procedures*

What, **when** and **with whom** to communicate is defined in 95 % of the countries, whereas **who** will communicate and **how** to communicate is lacking in 15 % and 21 % of the countries, respectively (Figure 24).

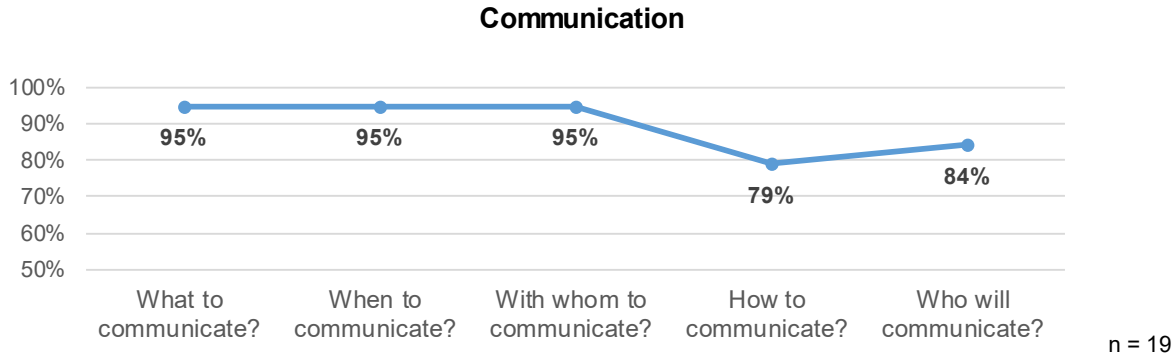


Figure 24 – *Definition of who, what, when, with whom and how to communicate*

Recovery

Recovery: tools for recovery and effectiveness assessment

The number of countries that have a documented process or strategy to restore and return activities back to routine after the adoption of any temporary measures in response to a disruption or emergency is equal to the number of countries that have no such strategy in place (44 %) (Figure 25a).

There is a similar situation for a defined process assessing the effectiveness of the response to a disruption or emergency (both 41 %); however, fewer countries are aware of whether it exists or not, compared to the knowledge of a recovery process (Figure 25b).

In all, 30 % of the countries have both a documented return process and an effectiveness assessment process in place.

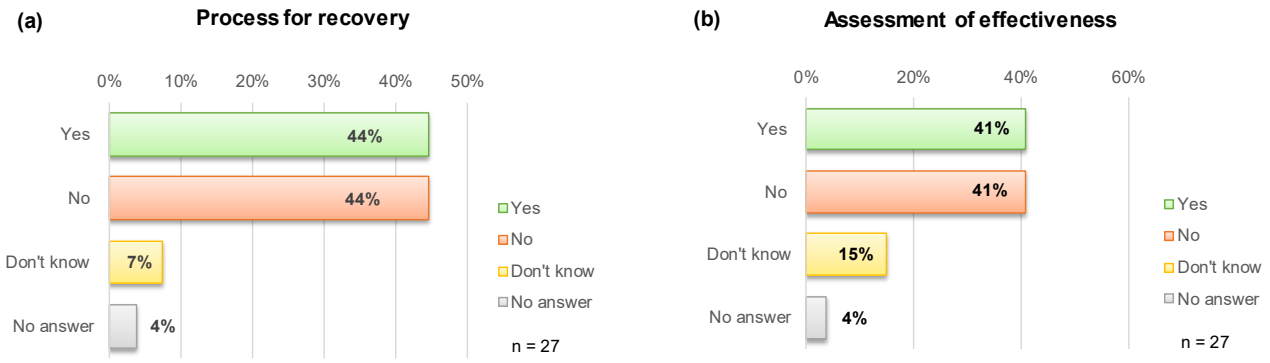


Figure 25 – *Documented recovery routine and (b) effectiveness assessment process*

Survey summary and general comments

The majority of the European countries participating in the survey have contingency and emergency preparedness plans in place, although there is no joint structure for the plans. The contents vary from general to specific for blood supply, from covering a wide range of emergencies to single-scenario preparedness (typically COVID-19), and from being established in co-operation with authorities on a national level to being part of local hospital general emergency plans. Although the range of potential key stakeholders is wide, the countries agree that the Blood Establishment should always be involved in the plans.

Currently, there are no provisions in EU legislation relating to contingency and emergency planning to ensure the continuity of the blood supply. However, a majority of the countries have national legislation in place for contingency and emergency preparedness. This needs to be taken into account by the European Commission if any legislative provisions are being considered in the revised European blood legislative framework. With regard to what is in place in the respective countries today, there is a stronger interest in guidelines than in further legislation.

Contingency and emergency preparedness plans are subject to regulatory oversight/inspection in a majority of the countries, but in most cases are not needed in order to obtain Blood Establishment authorisation. Furthermore, concrete systems for allowing necessary derogations from the authorisation are rare.

Both a potential blood supply decrease and blood demand increase should be considered in the contingency and emergency preparedness plan. Key risk scenarios vary greatly with individual experience and geographical location of the countries. Therefore, choice of key risk scenarios to be included in the contingency and emergency preparedness plan must be individually assessed by each member state. Several countries expressed a wish for a risk assessment tool, which the Model Preparedness Plan may help with.

More countries mention that they have emergency donation plans than backup processing arrangements. There is an overall potential to increase intercountry contingency arrangements.

Contingency and emergency preparedness plans should, once established, be subject to recurring testing, yet only a minority of the countries currently do this. Other areas of uncertainty/improvement include communication strategies and recovery process/assessment of effectiveness after a plan has been put into action and a key risk scenario has been mitigated. Recommendations and a Model Preparedness Plan can facilitate strategies in these areas.

Appendix 1: Survey questions

Section A: Section 1 – Emergency Preparedness and Contingency Planning Frameworks

To characterise and collect qualitative information on the emergency preparedness and contingency planning frameworks in place at national level for ensuring the continuity of the blood supply in European countries.

A1. Responding country?
A2. Name of responding organisation and contact email address.
A3. Role of responding organisation?
- Local Blood Establishment
- Regional Blood Establishment
- National Blood Establishment
- Regional Authority for Blood
- National Competent Authority for Blood
- Ministry of Health
- Other, comment

A4. In your country, how is your blood transfusion system organised? (Please provide details)
- Local Model (i.e. Independent Local Blood Establishments), comment
- Regional Model (i.e. Decentralised/Regional Blood Service), comment
- National Model (i.e. Centralised/National Blood Service), comment
- A combination of the above, comment
- Other, comment

A5. Who are the main blood operators within your country?
- Public (or belonging to the Ministry of Health), comment
- Supranational (e.g. Red Cross, Red Crescent), comment
- Private Operators, comment
- Hospital-Based Operators, comment
- Military Operators, comment
- Other, comment

A6. In your country, are emergency preparedness and contingency plans in place to ensure the continuity of blood supply?
- Yes
- No

A7. If yes, how are the emergency preparedness and contingency plans co-ordinated? (Please provide details)
- Local level (i.e. each individual Blood Establishment), comment
- Regional level (a co-ordinated regional approach), comment
- National level (a co-ordinated national approach), comment
- Other (e.g. Military Level, Commercial Level), comment

A8. If no, please provide details
A9. In your country, which organisations/institutions/bodies are actively involved in emergency preparedness and contingency planning in the blood sector?
- Hospitals/Hospital Blood Banks
- Blood Establishments
- Regional Authorities
- National Competent Authority – Blood
- Ministry of Health (or equivalent)
- Government
- Armed Forces
- Other, comment

Section B: Section 2 – Legislation and Guidelines

To collect qualitative information on the legislation, standards and guidelines in place at national level relating to emergency preparedness and contingency planning to ensure the continuity of blood supply.

B1. In your country, is there legislation/legislative provisions related to emergency preparedness and contingency planning to ensure the continuity of blood supply?
- Yes
- No
- I don't know

B2. Is this legislation;
- Specific for ensuring the continuity of blood supply?
- General for ensuring the provision of critical health services?
- Other, comment

B3. Does the legislation provide for the following;
- A definition of what constitutes an emergency situation?, comment
- Designation of the relevant stakeholders involved?, comment
- The obligations and actions required for the relevant stakeholders involved?, comment
- None of the above (provide details), comment

B4. In your country, are there guidelines in place relating to emergency preparedness and contingency planning to ensure the continuity of blood supply?
- Yes
- No
- I don't know

B5. Are the guidelines;
- Specific to ensuring continuity of blood supply?
- General for the provision of critical health services?
- Other, comment

B6. Do the guidelines provide for the following;
- A definition of what constitutes an emergency situation?, comment
- Identifying the relevant stakeholders involved?, comment
- The obligations and actions for the main stakeholders involved?, comment
- None of the above (provide details), comment

B7. In your country, are there any other guidelines, recommendations or standards on emergency preparedness or contingency planning to ensure continuity of the blood supply? (If yes, please provide details)
- Yes
- No
- I don't know

B8. Do you consider that there is a need for legislation outlining the obligations for emergency preparedness and contingency planning to ensure continuity of blood supply?
- Yes
- No
- I don't know

B9. Do you consider that there is a need for defined guidance or recommendations on emergency preparedness and contingency planning to ensure the continuity of blood supply?
- Yes
- No
- I don't know

Section C: Section 3 – Regulatory Oversight

To collect qualitative information on the regulatory oversight of emergency preparedness and contingency planning to ensure continuity of blood supply.

C1. In your country, are emergency preparedness and contingency plans subject to inspection by the relevant blood regulatory authority/inspectorate?
- Yes
- No
- I don't know

C2. In your country, in order to obtain a blood establishment authorisation, are you required to have emergency preparedness and contingency plans to ensure the continuity of blood supply?
- Yes
- No
- I don't know

C3. If yes, are emergency preparedness and contingency plans required to be submitted to the relevant regulatory authority for their review and approval?
- Yes
- No
- I don't know

C4. In your country, is there a system to allow for specific derogations to blood establishment authorisations, where required, to ensure the continuity of blood supply in emergency situations?
- Yes
- No
- I don't know

C5. In your country, are the national competent authority for blood/relevant regulatory authorities, involved in the development of emergency preparedness and contingency plans for ensuring continuity of blood supply?
- Yes
- No
- I don't know

C6. Are emergency preparedness and contingency plans for ensuring continuity of the blood supply shared with the blood national competent authority/relevant regulatory authorities, for their review/approval or awareness?
- Yes
- No
- I don't know

Section D: Section 4 – Key Risk Scenarios

To collect qualitative information on the type of key risk scenarios covered by national emergency preparedness and contingency plans to ensure continuity of blood supply.

D1. In your country, are emergency preparedness and contingency plans in place to ensure continuity of blood supply, to manage;
- a decrease in the blood supply?
- an increase in the demand for blood?
- both a decrease in the blood supply and an increased demand for blood?
- none of the above. There are no emergency preparedness or contingency plans in place.

D2. In your country, are there emergency preparedness and contingency plans in place to ensure the continuity of blood supply for the following key risk scenarios?
- Interruption in the supply of critical services, equipment, or devices, comment
- Disruption or damage to premises or facilities, comment
- Epidemics/Pandemics, comment
- Loss of working staff, comment
- Adverse weather conditions, comment

- Terrorist attacks, comment
- War, comment
- Other (please specify) , comment

Section E: Section 5 (a) – National Approach – Planning and Mitigation

To collect qualitative data on the national approach to emergency preparedness and contingency planning to ensure the continuity of the blood supply.

To collect qualitative and quantitative data on the planning and mitigation stage of emergency preparedness and contingency planning.

E1. What factors are taken into account in establishing emergency preparedness and contingency plans to ensure continuity of blood supply?
- Legal and regulatory requirements
- National guidelines
- Type of blood products or services provided
- Type of activities performed
- Relevant stakeholders involved
- Human, equipment and material resources
- Public health obligations
- Needs of the public
- Specific key risk scenarios
- Other, comment

E2. In developing emergency preparedness and contingency plans, is there a risk assessment performed on the likelihood that specific disruptions or emergency situations will occur?
- Yes
- No
- I don't know

E3. If yes, are there any specific risk assessment principles used? Please provide name and link for information if available

E4. In developing emergency preparedness and contingency plans, is the potential impact on the blood supply analysed according to specific key risk scenarios?
- Yes
- No
- I don't know

E5. What are the main priorities or requirements to be considered in emergency preparedness and contingency plans?
- Preventative strategies and solutions to avoid the occurrence of disruption
- Maximum tolerable period of disruption (MTPD) – timeframe within which solutions must be implemented to ensure continuity of blood supply
- Prioritised timeframes for implementation of solutions/strategies to ensure continuity of blood supply – Recovery Time Objective (RTO)
- Prioritisation of activities required to ensure continuity of blood supply
- Identification of resources required to perform prioritised activities
- Identification of key stakeholders required to implement prioritised activities
- Other, comment

E6. In your country, who are the key stakeholders for emergency preparedness and emergency planning for ensuring the continuity of blood supply?
- Facilities
- Hospitals/Hospital Blood Banks
- Blood Establishments/Blood Services
- Donor Testing Laboratories
- Suppliers of equipment, materials and services
- Transport providers

- Regional Authorities
- National Competent Authorities
- Ministry of Health
- Government
- Armed Forces
- Donor/Patient Associations
- Other, comment

E7. Are different key stakeholders identified according to specific key risk scenarios?
- No
- Yes, depending on the specific risk scenario, different key stakeholders have been identified
- I don't know

E8. Have specific working group(s)/taskforce(s) been established at national level, responsible for emergency preparedness and contingency planning to ensure the continuity of blood supply?
- Yes
- No
- I don't know

E9. If yes, are there different work groups/taskforces established according to specific key risk scenarios?
- No, there is one national emergency preparedness and contingency planning work group/task force
- Yes, depending on the different scenarios, different working groups/taskforces have been established
- Other, provide details

E10. Have the roles and responsibilities for all relevant stakeholders been established at national level with respect to emergency preparedness and contingency planning to ensure the continuity of blood supply?
- Yes
- No
- I don't know

E11. In your country, are there contingency arrangements in place with another country (or organisations/blood services in another country) to ensure the continuity of blood supply in emergency situations?
- Yes
- No
- I don't know

E12. If yes, what arrangements are in place?
- Back up supply of blood products, comment
- Back up provision of essential activities (e.g. testing, processing etc.), comment
- Back up provision of critical services, facilities, equipment, materials, comment
- Other, please provide details

E13. For countries with regional/federal/decentralised systems, are there contingency arrangements in place between regions (organisations/blood establishments in other regions) to ensure continuity of blood supply in emergency situations?
- Yes
- No
- Not applicable

E14. If yes, what arrangements are in place?
- Back up supply of blood products, comment
- Back up provision of essential activities (testing, processing, etc.), comment
- Back up provision of essential services, facilities, equipment, materials, comment
- Other, please provide details

Section F: Section 5 (b) – National Approach – Preparedness

F1. According to the quality indicators below, how would you evaluate the emergency preparedness and contingency plans for ensuring the continuity of blood supply in your country?
- Very Poor – Poor – Fair – Good – Excellent

- The plan is specific regarding the immediate steps to be taken during a disruption/emergency
- The plan is flexible to respond to changing internal and external conditions of a disruption/emergency
- The plan is focused on the impact of incidents that potentially lead to disruptions/emergency
- The plan is effective in minimising the impact through the implementation of appropriate solutions
- The plan is clear with regard to the assigned roles, responsibilities and tasks for relevant individuals/organisations

F2. In your country, do emergency preparedness and contingency plan(s) include the following elements?
- Purpose, Scope, Objectives
- Defined roles and responsibilities for key stakeholders
- Defined actions to implement proposed solutions
- Supporting information needed to activate, operate, co-ordinate and communicate key stakeholder actions
- Key stakeholder interdependencies and organisation
- Resource requirements
- Reporting requirements
- A process for recovery
- Other, comment

F3. In your country, are relevant stakeholders informed and prepared in emergency preparedness and contingency planning procedures?
- Yes
- No
- I don't know

F4. If yes, how is this preparation performed (please provide details)?
- Theoretical, awareness preparation?, comment
- Practical exercises?, comment
- Other?, comment

F5. If yes, how often is this preparation performed? (please provide details)

F6. If no, have relevant stakeholders been made aware of their roles and responsibilities with regard to emergency preparedness and contingency planning to ensure continuity of blood supply?
- Yes
- No
- I don't know

F7. In your country, are emergency preparedness and contingency plans tested?
- Yes
- No
- I don't know

F8. If yes, how are they tested? (Please provide details)
- Periodic desk-based review, comment
- Periodic practical exercises, comment
- Other, comment

F9. If yes, how often are emergency preparedness and contingency plans tested?
- Annually
- Every 2 Years
- Upon Significant Changes
- Other, comment

F10. In your country, are emergency preparedness and contingency plans subject to periodic review?
- Yes
- No
- I don't know

F11. If yes, how often are they reviewed?
- Annually
- Every 2 Years
- Upon Significant Change

- Other, comment

F12. In your country, where significant changes have been made to emergency preparedness and contingency plans, is there a system in place for communicating these changes to relevant stakeholders?
- Yes
- No
- I don't know

Section G: Section 5 (c) – National Approach – Response

G1. In your country, have relevant stakeholders involved in ensuring continuity of blood supply, been provided with documented plans to guide their actions in response to a disruption/emergency situation? (Actions including the activation, operation, co-ordination and communication of their response)
- Yes
- No
- I don't know

G2. In your country, is there a defined approach for communication, to ensure the continuity of blood supply in emergency situations?
- Yes
- No
- I don't know

G3. If so, are the following defined;
- What to communicate?
- When to communicate?
- With whom to communicate?
- How to communicate?
- Who will communicate?

G4. Have all relevant stakeholders been made aware and prepared in communication procedures to be followed to ensure continuity of blood supply in emergency situations?
- Yes
- No
- I don't know

Section H: Section 5 (d) – National Approach – Recovery

H1. In your country is there a documented process/strategy to restore and return activities back to routine after the adoption of any temporary measures in response to a disruption/emergency?
- Yes
- No
- I don't know

H2. As part of emergency preparedness and contingency planning, is there a defined process for assessing the effectiveness of the response to a disruption or emergency?
- Yes
- No
- I don't know

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