



NATIONAL BLOOD AUTHORITY  
AUSTRALIA

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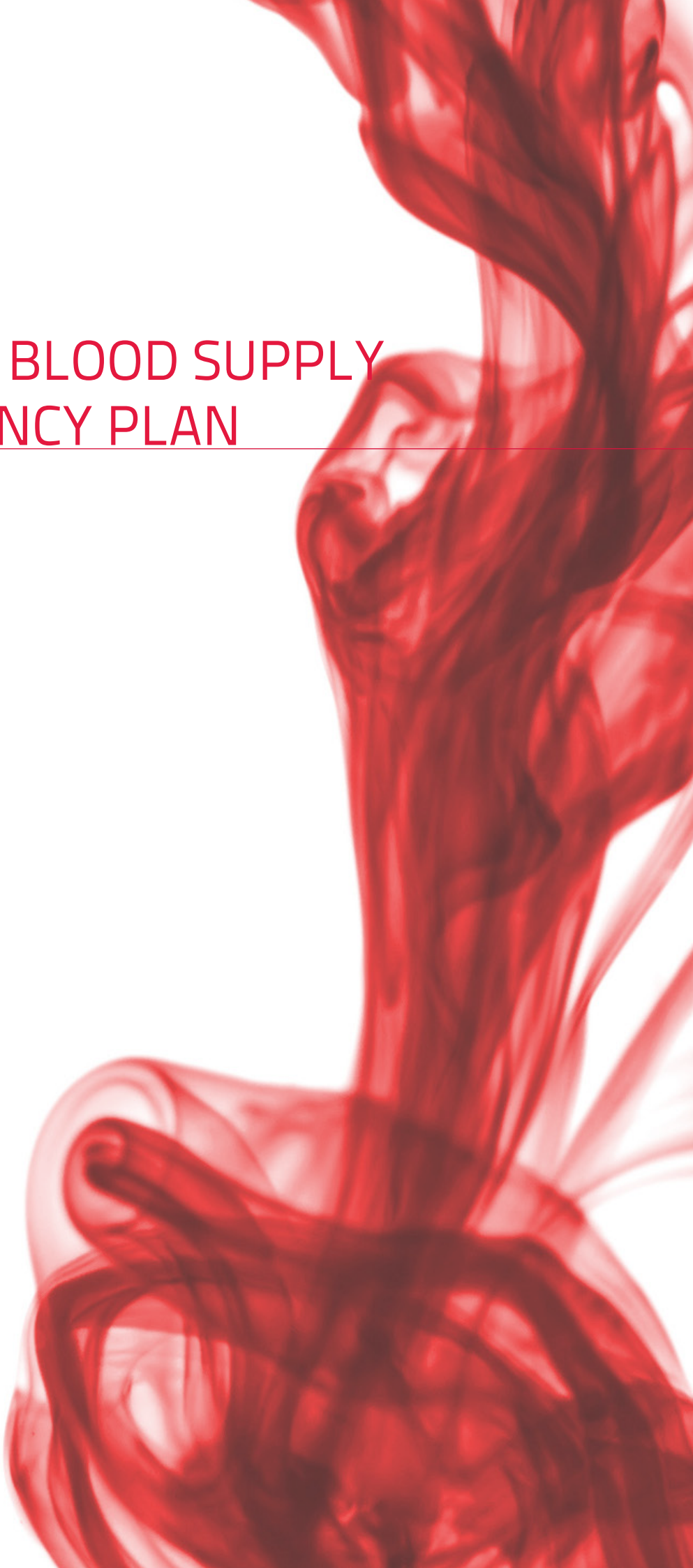
## NATIONAL BLOOD SUPPLY CONTINGENCY PLAN

> SAVING & IMPROVING AUSTRALIAN  
LIVES THROUGH A WORLD-CLASS  
BLOOD SUPPLY

# NATIONAL BLOOD SUPPLY CONTINGENCY PLAN

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July 2019





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# Acronyms

AHMAC	Australian Health Ministers Advisory Council
AHP	Approved Health Provider
AHPPC	Australian Health Protection Principal Committee
ANZSBT	Australian and New Zealand Society of Blood Transfusion
ARTG	Australian Register of Therapeutic Goods
Blood Service	Australian Red Cross Blood Service
BCP	Business Contingency Plan
CDNA	Communicable Diseases Network Australia
CHO	Chief Health Officers
CMO	Chief Medical Officer
COAG	Council of Australian Governments
DoH	Commonwealth Department of Health
Health	Commonwealth Department of Health or Australian Government Department of Health
HEMB	Health Emergency Management Branch
HLA	Human Leucocyte Antigens
HPA	Human Platelet Antigens
HTC	Haemophilia Treatment Centre
IEBMP	Interim Emergency Blood Management Plan
IPM	Intensive Product Management
JBC	Jurisdictional Blood Committee
NBA	National Blood Authority
NBSCP	National Blood Supply Contingency Plan
NBMS	National Blood Management System
NHEMS	National Health Emergency Management Sub Committee
NIR	National Incident Room
OHP	Office of Health Protection
QA	Quality Assurance
PMF	Plasma Master File

SMS	Short Message Service
TGA	Therapeutic Goods Administration
TMF	Technical Master File
TTI	Transfusion-transmitted Infection

# 1 Introduction

The National Blood Authority (NBA) is a statutory agency within the Australian Government health portfolio that manages and coordinates arrangements for the supply of blood and blood products and services on behalf of all Australian governments.

The primary objectives under the National Blood Agreement (the Agreement) are to:

- provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services; and
- promote safe, high quality management and use of blood products, blood related products and blood related services in Australia.

Under section 8 (1) of the *National Blood Authority Act 2003 (cth)* (the NBA Act) and clause 25 (i) of the Agreement, the NBA has a responsibility to establish and manage contingency and risk mitigation measures in relation to the national blood supply, including specific strategies developed in consultation with the Jurisdictional Blood Committee (JBC).

The National Blood Supply Contingency Plan (NBSCP) describes the context in which contingency planning is addressed, including guidance for interaction of contingency management with the NBSCP arrangements and the Commonwealth Department of Health (Health) where relevant. It specifies the arrangements for management of a crisis affecting or potentially affecting the supply of blood and blood products, including tailored and specific guidance on product groups in short supply and the management of other crises in a series of annexes:

- Annex A – Red Cell Response Plan;
- Annex B – Plasma & Recombinant Products Response Plan;
- Annex C – Platelets Response Plan;
- Annex D – Transfusion Transmissible Infection (TTI); and
- Annex E – Non Supply Crisis Management Event (to be developed).

The NBSCP aims to:

- provide an overarching framework for a rapid and coordinated response by the NBA, and other responsible agencies, to manage the consequences of a demand surge or supply failure at either a jurisdictional or national level;
- ensure appropriate preparation, mitigation and planning for the impact of blood crisis in the health sector;
- facilitate national decisions for an appropriate response during a supply and demand crisis, through clear communication and provision of relevant information and data;
- outline the approach to risk management as a basis for other similar interoperation plans such as those prepared by jurisdictions;



- ◆ guide stakeholders on specific roles and responsibilities during an activation of the NBSCP; and
- ◆ outline the modes of communication that will occur during an activation of the NBSCP.

## 1.1 Definition of a crisis

A crisis for the blood sector is defined as an event that causes a significant threat to the ability of the nationally coordinated and funded supply arrangements for blood and blood products in Australia to ensure supply to meet demand, through any of the following or a combination of these:

- ◆ a supply interruption;
- ◆ a surge in demand;
- ◆ a threat to patients; or
- ◆ other sudden and significant negative events that could potentially lead to a supply insufficiency or reputational damage.

Supply failure, demand surge, a risk to public health, or a sudden and significant negative event may require the NBSCP to be activated; these possible scenarios are summarised in Table 6. These events may occur in isolation, in tandem or sequentially, and may occur locally, regionally or nationally.

The responsibility for defining and responding to a crisis may at times not be aligned through the usual channels for blood product coordination and supply management chain. Ultimately, the NBA Chief Executive is responsible for activating the NBSCP. This will generally be in consultation with the Commonwealth Department of Health, state and territory governments and/or the Therapeutic Goods Administration.

Supply failures could arise from:

- ◆ significant decrease in the volume or quality of fresh blood components, or plasma-derived or recombinant products available for immediate distribution through the Australian blood products supply chain;
- ◆ manufacturer unable to produce a significant amount of product;
- ◆ significant delay or loss of product through a quality, storage or distribution issue;
- ◆ batch failure or batch recall; or
- ◆ contamination or suspected contamination of products.

Demand surges could arise from:

- ◆ multiple trauma patients;
- ◆ multiple burns patients;
- ◆ the response to the threat of a supply failure (local stock piling); or
- ◆ endemic disease burden (eg H1N1).

A demand surge can normally be managed through national redistribution of supplies or release of reserve stock; however this may require coordination under NBSCP arrangements.

A supply failure may also be triggered by a possible public health risk to patients arising from a transfusion-transmitted infection, because a product is withdrawn or recalled to prevent further contamination. This scenario is explained further in Annex D. A management response specific to these circumstances is required and to be effective, it must integrate the interdependencies of other contingency arrangements such as those outlined in the support document.

## 1.2 Non-supply crisis management event

A non-supply crisis management event arises as the result of an unpredictable event or an unforeseeable consequence of an event that had been considered a potential risk. In either case, decisions may need to be made quickly to limit impacts on the blood sector or organisations. A sudden and significant negative event could relate to the following types of scenarios, whether potential, perceived or real:

- ◆ negative media;
- ◆ information, data or privacy breach;
- ◆ a state or territory triggered event that could lead to a potential supply situation;
- ◆ public safety;
- ◆ financial loss and fraud;
- ◆ reputation loss; and
- ◆ legal proceeding and claims.

These types of events can have a sudden and significant negative impact in the sector that could potentially lead to a supply shortage or reputational damage and may lead to activating the NBSCP, or may trigger action that precedes an invocation of the NBSCP. A management response specific to these circumstances is required and to be effective, it must integrate the interdependencies of other contingency arrangements such as those outlined in the Non Supply Crisis Management Event Annex E. These events may occur in isolation, in tandem or sequentially.

## 2 Partners and stakeholders

This plan has been developed in conjunction with government and non-government stakeholders in the blood sector.

It is designed for those bodies involved in or associated with the management, supply and use of blood and blood products in Australia, in particular:

- ◆ signatories to the National Blood Agreement, represented by the Commonwealth state and territory health departments and Australian Health Ministers' Advisory Council (AHMAC);
- ◆ Australian Government Departments or agencies, including the Australian Government Department of Health (Health), in particular, the Office of Health Protection (OHP), and Health's blood policy area;

- key committees including the Jurisdictional Blood Committee (JBC) and Australian Health Protection Principal Committee (AHPPC) Standing committees such as Communicable Diseases Network Australia (CDNA) and National Health Emergency Management Standing Committee (NHEMS);
- the Therapeutic Goods Administration (TGA), as the regulator of blood and blood products;
- all suppliers, including Australian Red Cross Blood Service (Blood Service), CSL Behring and suppliers of imported products; and
- the clinical community, including the Australian and New Zealand Society of Blood Transfusion (ANZSBT), and all private and public hospitals, and associated public and private pathology laboratories in Australia.

## 2.1 National Blood Supply governance arrangements

The NBA governance arrangements are shown in Figure 1. The NBA is responsible for management of the supply of blood and blood products on behalf of all governments.

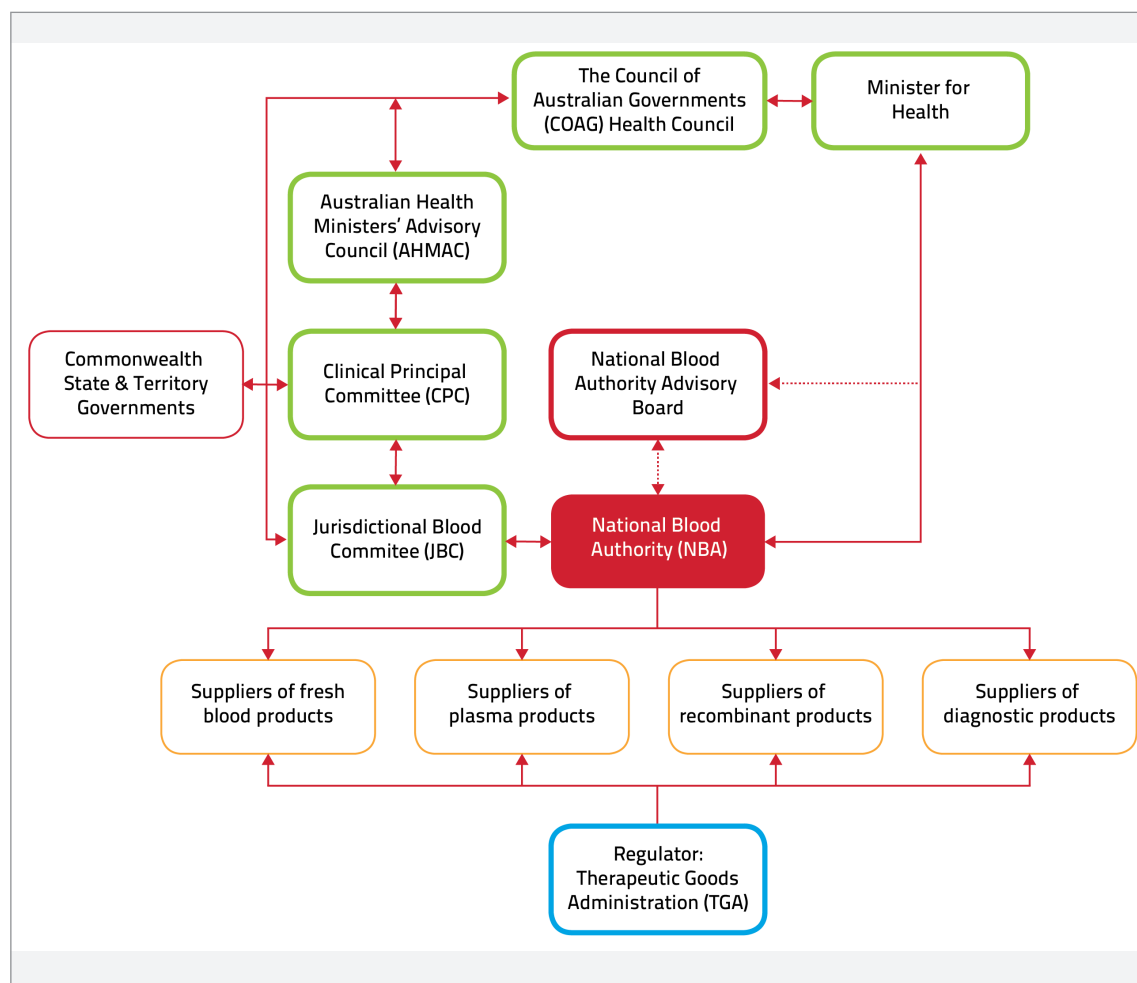


Figure 1 – NBA Governance Structure

### 2.1.1 National Blood Authority contingency planning responsibilities

Under section 8(1) of the NBA Act, the NBA has responsibilities to:

- carry out national blood arrangements to ensure that there is a sufficient supply of blood products and services in all the states and covered territories
- enter and manage contracts and arrangements for the collection, production and distribution of the blood products and services necessary to ensure a sufficient supply of blood products and services in all states and covered territories
- carry out national blood arrangements relating to safety measures, quality measures, contingency measures and risk mitigation measures for the supply of blood products and services

The NBA also has a responsibility under clause 25(i) of the Agreement for establishing and managing contingency and risk mitigation measures in relation to the national blood supply, including specific strategies developed in consultation with the JBC and approved by COAG.

A key challenge for the NBA is to ensure effective integration of these measures with the wider health sector contingency management arrangements, given the integral role blood and blood products play in the health sector.

### 2.1.2 Authority to activate the NBSCP

The NBA Chief Executive is responsible for activating the NBSCP. This will generally be in consultation with the Commonwealth Department of Health, state and territory governments and/or the TGA. The NBA Chief Executive will consult with JBC members (including their nominated representatives or advisors) and other relevant stakeholders to support decisions taken on activation of the NBSCP.

Decisions to change the status of the NBSCP are also made by the Chief Executive or nominated representative based on advice and if practicable consultation and agreement with the JBC. The authority for this plan remains with the NBA and may be activated or escalated / deescalated at different times to other plans such as supplier or jurisdictional contingency plans.

The NBA Chief Executive or other senior representative of the NBA will ordinarily attend AHPPC when relevant NBSCP information is presented. Other attendees will participate depending on the committee focus and agenda.

## 2.2 Wider Government focus for emergency management

The Australian Government Department of Health maintains a focus on national health and health emergency management. Some states and territories have moved towards an integrated emergency response framework, rather than just health or blood supply issues. These state based crisis management plans often include coverage of bush fire, flooding and similar incidents.

Figure 2 on shows the interdependencies between various government agencies in the event of a blood products incident requiring the activation of the NBSCP<sup>1</sup>.

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1. NBA Risk Management Framework and policy August 2017

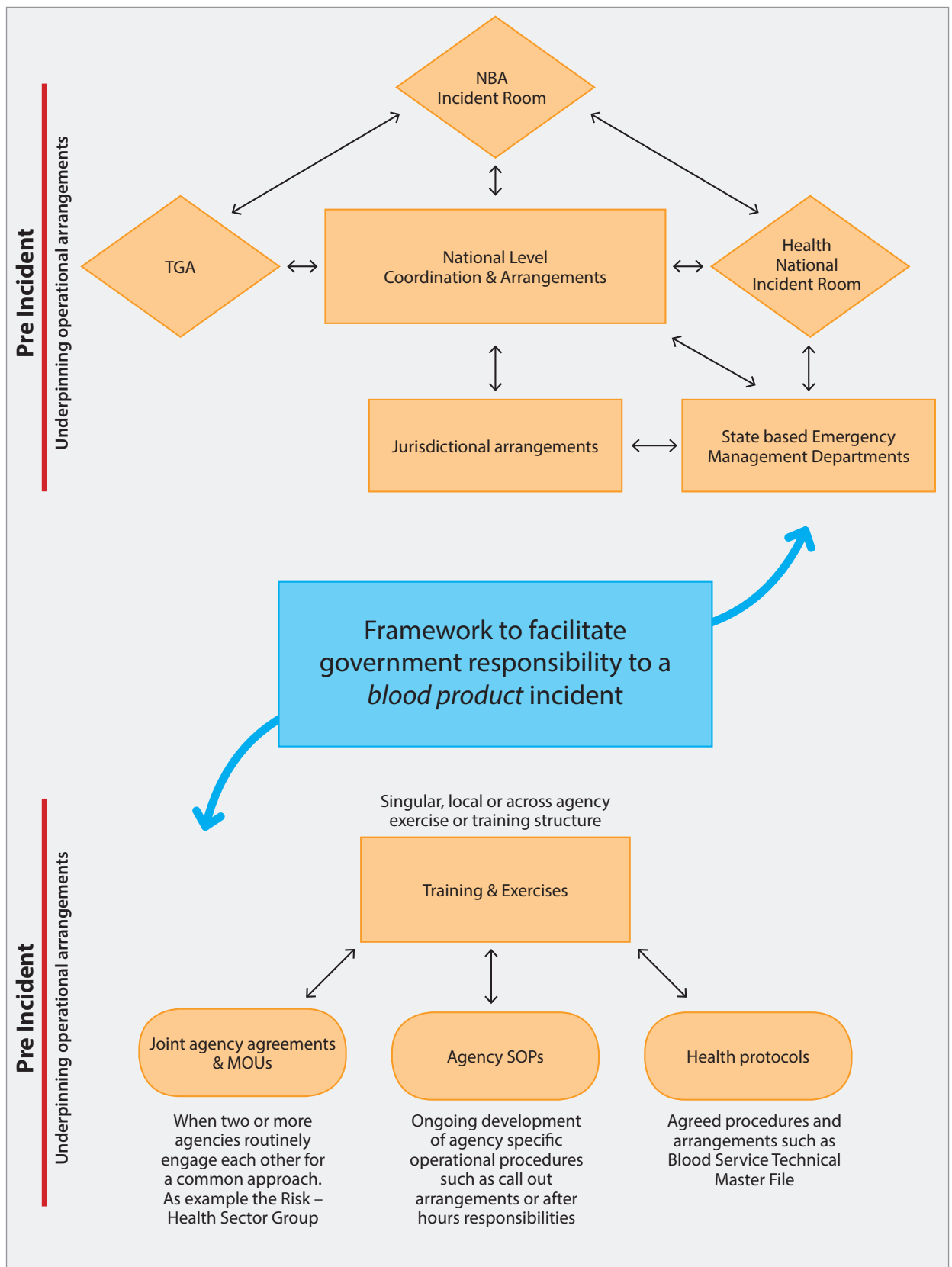


Figure 2 NBSCP Management Arrangement

## 2.3 Commonwealth Department of Health emergency management

The Commonwealth Department of Health, through AHPPC has responsibility for the development and management of a series of plans and arrangements around threats or emergencies in the health sector. This is achieved through a series of standing committees under the AHPPC. Key examples of AHPPC responsibility (relative to the NBSCP) are the development and oversight of the:

- ◆ Australian Health Management Plan for Pandemic Influenza;
- ◆ Contingency plans for variant Creutzfeldt–Jakob disease (vCJD);
- ◆ Communicable Disease Network;
- ◆ National Medical Stockpile; and
- ◆ Development of health-related risk context statements.

The above health emergency arrangements should be read in conjunction with the NBSCP and other emergency response plans which may be interoperable with the NBSCP. The AHPPC is the policy and coordinating committee involved in planning and responding to a range of health emergencies. AHPPC meets quarterly and is chaired by the Commonwealth Chief Medical officer (CMO). Standing members include the, the Chief Health Officers (CHOs) of each jurisdiction, the heads of the Defence Health Service and Emergency Management Australia as well as experts in disaster medicine and mental health. The NBA Chief Executive or another senior representative of the NBA will ordinarily attend AHPPC when relevant NBSCP information is presented. Other attendees will participate depending on the committee focus and agenda.

In addition to managing the support functions for AHMAC, AHPPC works with the OHP who supports the administration of the AHPPC and maintains the National Incident Room (NIR). Activation of the NIR enables a coordinated national health response to an emergency or crisis and will work with and assist the NBA incident room where appropriate. These circumstances are outlined under Roles and Responsibilities within this document. An outline of the context and structure of the AHPPC are shown in Figure 3<sup>2</sup>. This figure 3 also indicates the levels of governance and engagement between state and territory, Commonwealth participants as well as the AHPPC escalation process.

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2. Australian Health Protection Principal Committee Strategic Plan 2014–18 p5

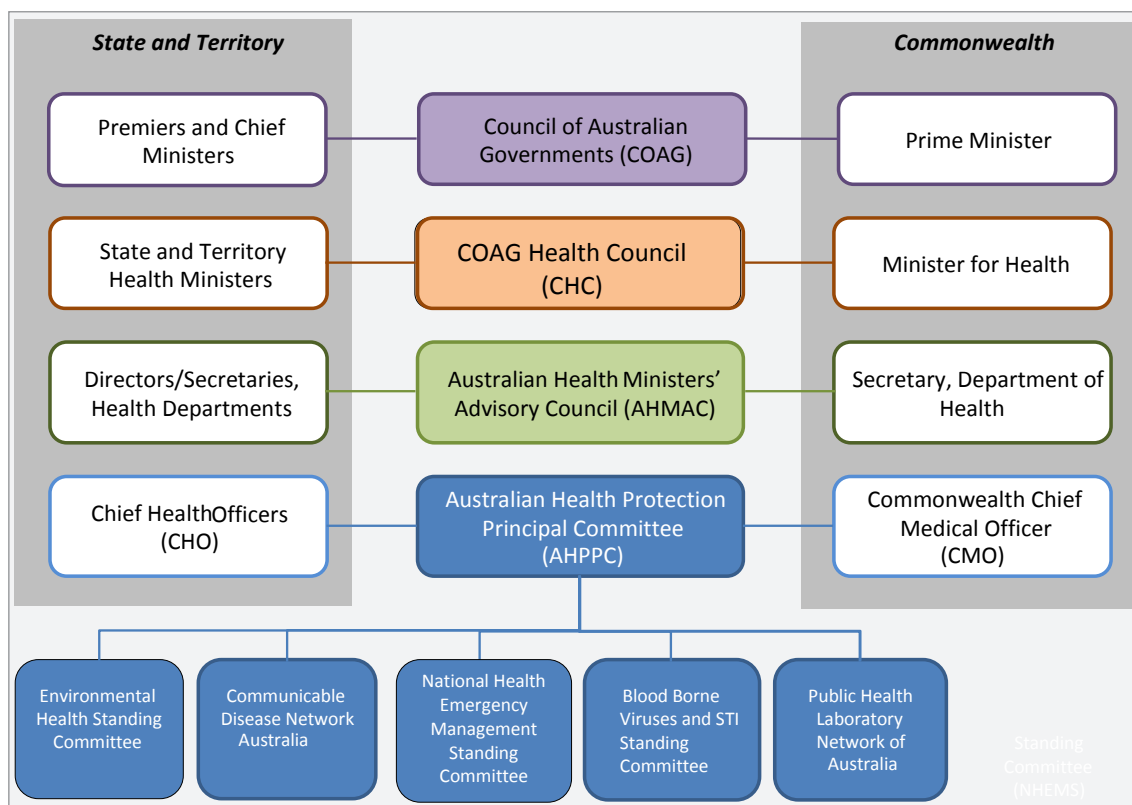


Figure 3 Governance of health protection in Australia

# 3 Blood and blood products

Blood and blood products are derived from blood donations, fractionation, and other manufacturing processes. An activation of the NBSCP could result from issues affecting one or more products.

## 3.1 Blood and blood products

Definitions of blood and blood products categories are shown in Table 1.

Table 1 - Blood and blood product categories

Category	Definition
<b>Fresh Blood Components</b>	Components of whole blood (red blood cells, platelets and fresh frozen plasma) are referred to as fresh blood components. The majority of these fresh components are collected by centrifuging the whole blood. The centrifugation process separates the whole blood into red blood cells, platelets and plasma. Platelets and plasma can also be collected by apheresis (a process where whole blood is removed from a donor and the required component(s) retained, while the remainder of the blood components are returned to the donor).
<b>Plasma-Derived Products</b>	These are products derived from plasma, using various techniques such as chromatography and Cohn cold-ethanol fractionation. Proteins are isolated from the plasma and processed into a range of plasma-derived products, such as albumin, immunoglobulin, and coagulation factors (including factors VIII, IX and XI).
<b>Recombinant Products</b>	Recombinant products are genetically engineered forms of plasma proteins and are not sourced from blood, but from host cells that contain an inserted copy of a human gene that produces the protein.

## 3.2 The role of blood and blood products in the health sector

Blood and blood products play a key role in the treatment and management of a range of clinical conditions. Blood transfusion and treatments are a critical part of modern health care. Many life-and-death situations rely on blood and blood products. Without them, there would be increased patient mortality and reduced clinical outcomes. Clinicians and hospitals rely on blood and blood products on a daily basis to treat and manage their patients.

Multiple factors influence the availability of products including the availability of voluntary blood donors, the shelf life of products and logistical supply issues including transport. Emergency situations such as tropical cyclones, floods, overseas incidents and flight interruptions such as volcanic ash can cause both short term and longer term interruptions to the availability of products. The shelf life of fresh blood components varies from five days to one year. As a consequence, supply chain and inventory management are key elements in ensuring continuity of supply.



An overview of the supply arrangements for blood and blood products is shown in Figure 4. The NBA, in conjunction with suppliers coordinates the day-to-day supply of blood and blood products within Australia. The roles of key supplier groups are as follows:

- Blood Service — responsible for the collection and management and distribution of all fresh blood components (red blood cells, plasma and platelets) from voluntary blood donations. It also supplies starting plasma for fractionation that CSL Behring manufactures into therapeutic plasma-derived products. The Blood Service distributes some plasma-derived products to hospitals and other users and provides transfusion medicine services.
- CSL Behring (Australia) — responsible for fractionating the plasma supplied by the Blood Service and providing finished plasma-derived products to the Blood Service for distribution.
- Contracted pharmaceutical companies — (including CSL Behring globally) responsible for the supply and some distribution of a range of imported or defined blood products not produced within Australia, or where domestic production capacity cannot meet demand.

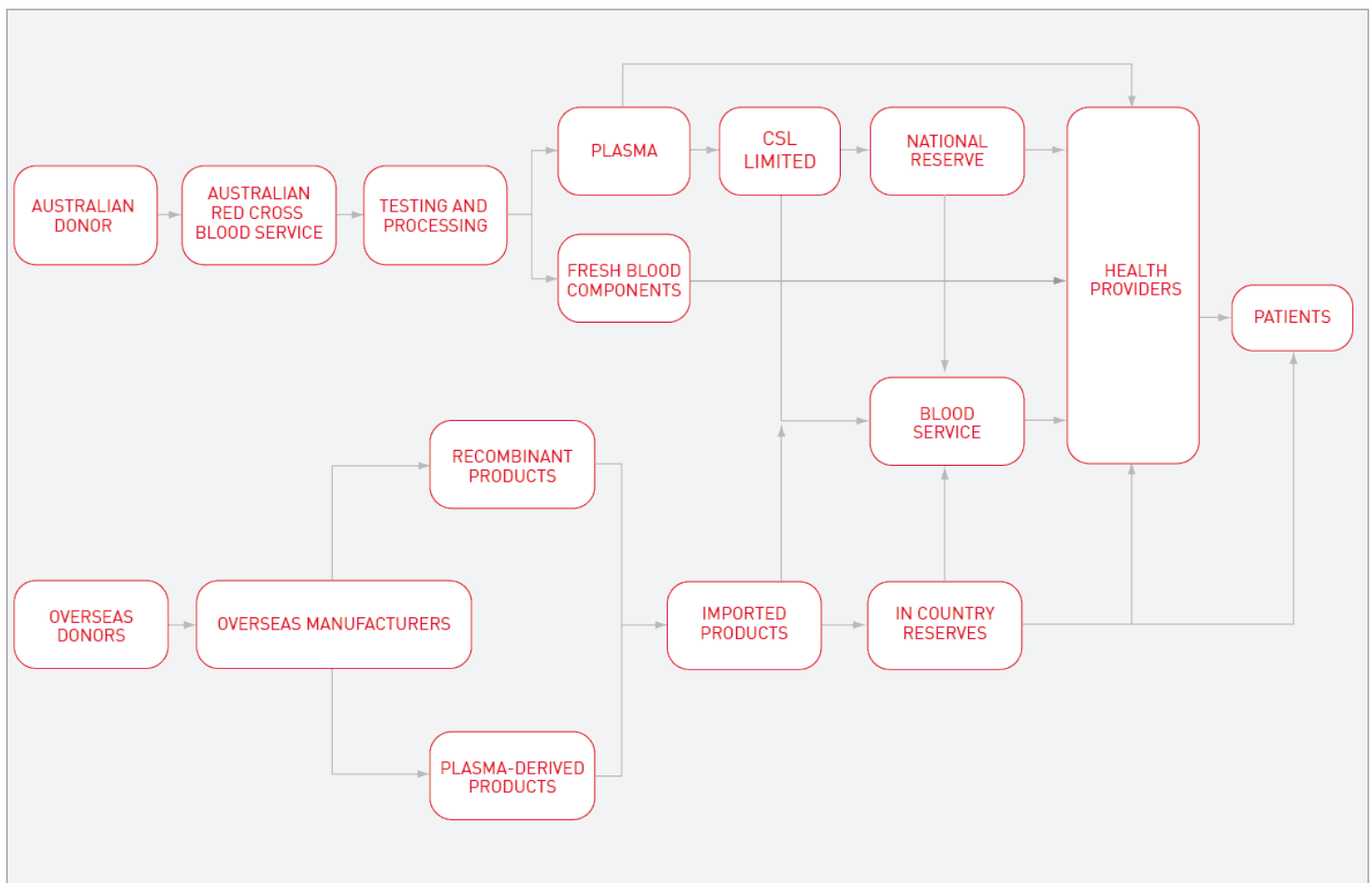


Figure 4 – National Blood Supply Arrangements

For health providers or health service organisations, the administration of blood and blood products is a

multistage process where each activity must be strictly controlled to ensure patient safety and to prevent adverse effects. At each stage it is necessary to consider issues as they relate to:

- ◆ patient factors such as clinical indications for transfusion, verification of identity at all stages, cross-matching procedures;
- ◆ blood product factors including identification, storage, transport and handling and management of used and unused products; and
- ◆ the interaction between the patient and blood product(s), traceability, treatment protocols and monitoring outcomes of the use of products.

## 4 Crisis Planning

Figure 5 – Activation Map is a flowchart of the process used to identify levels of activation. Note: Product shortages may or may not occur at the same time as other blood component shortages. The risk assessment process described below determines the alert levels at the time of activation.

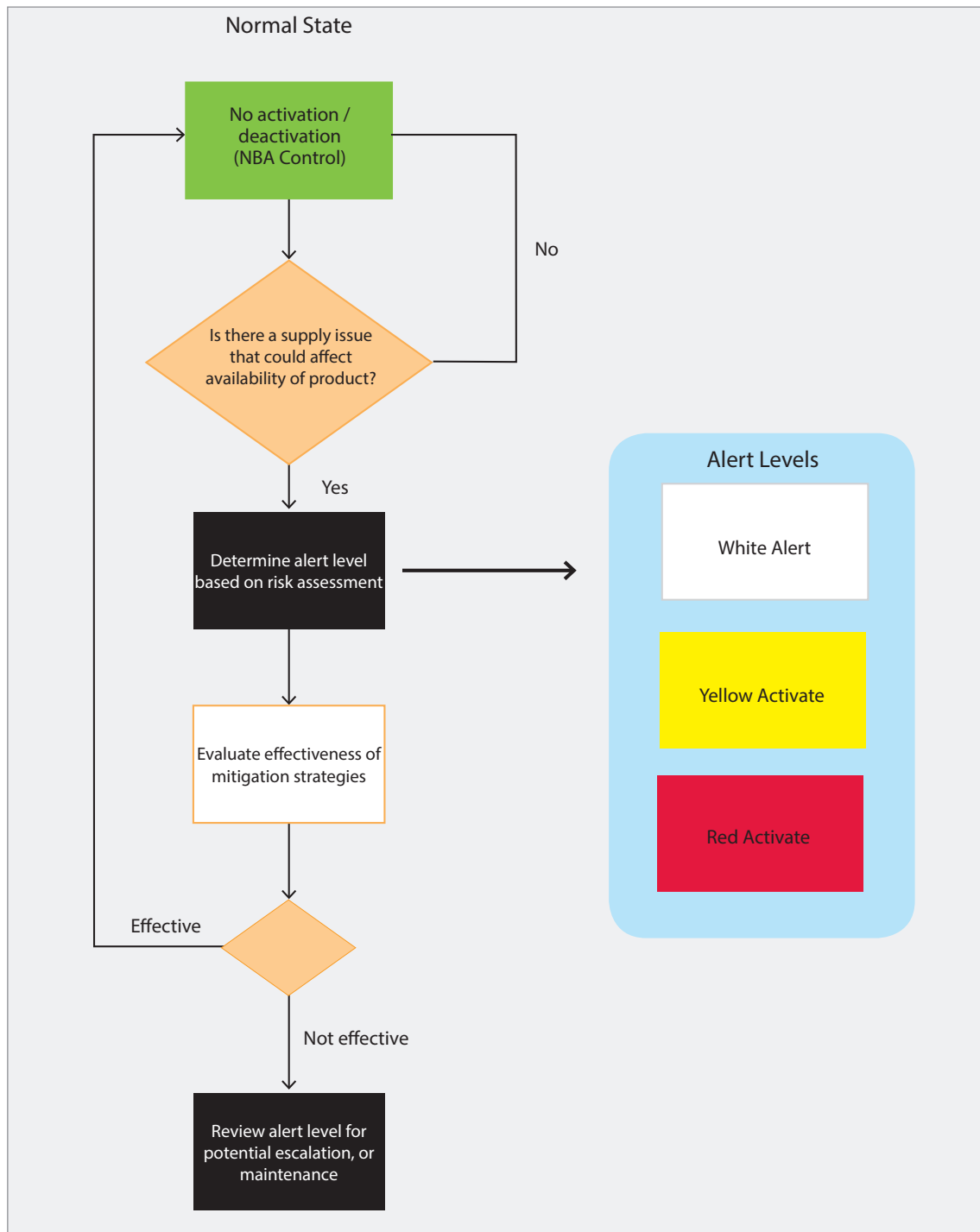


Figure 5 – Activation Map

## 4.1 Risk assessment and management

The NBA, together with key stakeholders, assesses the likelihood and potential impact of events that could affect the supply of, and demand for, blood and blood products. As part of this assessment, the following are analysed:

- ◆ possible scenarios;
- ◆ demand management;
- ◆ alternative product arrangements; and
- ◆ effectiveness of risk reduction strategies.

A key strategy is the management of reserves at different levels for different products. This will increase the capacity to mitigate supply-failure risks for that particular product. However, reserves are only feasible for products with longer shelf life.

A general approach to risk scenarios used by the NBA is to make an assessment of the 'Likelihood' of an event occurring and where that event does occur, to project the 'Consequence' of that event occurring. The process adopted by the NBA for assessing and managing risk is consistent with the Australian/New Zealand Standard for Risk Management (AS/NZS ISO 31000:2009) and the Commonwealth Risk Management Policy 2014. This process is also aligned with the NBA's Risk Management Policy Statement of 2017 which is consistent with the above standard and directives.

## 4.2 Rating the risk

In rating risks, the NBA uses a matrix and follows these steps:

- ◆ Step 1 – rank the consequence
- ◆ Step 2 – rank the likelihood
- ◆ Step 3 – classify the level of risk

Supply failure, demand surge, a risk to public health, or a sudden and significant negative event may require the NBSCP to be activated; these possible scenarios are summarised in Table 6.

### 4.2.1 Step 1 – Rank the consequence

For each identified risk, the consequence of a particular event occurring (from extreme to low) is determined using the guidance provided in Table 2. Table 2 provides a scale for the level of impact that an event would have on the available supply of blood and blood products. The fewer products that are available means the higher the potential impact could be, in particular, the ability to treat patients based on appropriate clinical need.

Table 2 - Consequence of a supply or demand crisis

Category	Indicator of impact
Extreme	<ul style="list-style-type: none"> <li>▪ Multijurisdictional or widespread national outage.</li> <li>▪ Blood stocks are below 24 hours.</li> <li>▪ Widespread loss of life will occur due to lack of product or from use of product.</li> </ul>
High	<ul style="list-style-type: none"> <li>▪ Multijurisdictional or national level blood issue.</li> <li>▪ Fresh blood stocks are below two days.</li> <li>▪ There is inadequate blood for emergency surgery.</li> <li>▪ Broad geographical product demand for recipients with severe morbidity.</li> </ul>
Medium	<ul style="list-style-type: none"> <li>▪ IPM and consequence strategies involving more than two external agencies.</li> <li>▪ Fresh blood stocks are less than three days.</li> <li>▪ There is a significant threat to elective surgery.</li> <li>▪ Localised product demand for recipients with minor morbidity.</li> </ul>
Low	<ul style="list-style-type: none"> <li>▪ Stock level and mitigation strategies are sufficient to manage situation with minor impacts on clinical practice.</li> <li>▪ Small concentrated product demand for recipients with minor morbidity.</li> </ul>

\*IPM = intensive product management

## 4.2.2 Step 2 – Rank the likelihood

For each identified risk, the likelihood (from extreme to low) that a particular event will occur is determined using the guidance provided in Table 3. The Probability of Occurrence or Frequency of Occurrence can be used.

Table 3 - Likelihood of a supply or demand crisis

Probability of Occurrence	Frequency of Occurrence
> 95–100% (Almost certain)	Event is a common or frequent occurrence (i.e. Several times a week)
> 70–95% (Likely)	Event is expected to or has occurred under some conditions (i.e. Monthly or several times a year)
> 30–70% (Possible)	Event will probably occur, or has occurred, under some conditions (i.e. once every 5 years)
> 5–30% (Unlikely)	Event could occur at some time, or has happened elsewhere (i.e. once every 10 years)
< 5% (Rare)	Event is not expected to occur, but may occur under exceptional circumstances (i.e. once every 25 years)

### 4.2.3 Step 3 – Classify the level of risk

Once the consequence and likelihood of each risk has been determined, the position on the NBA risk matrix is represented by a classification rating as depicted in Table 4. The matrix classification rating is used to determine the level of responsibility and the consequent level of action required, as shown in Table 5.

Table 4 - Classification ratings for risk management during activation of NBSCP

Likelihood	Consequence			
	Extreme	High	Medium	Low
Almost certain >95% to 100% or several times a week	Extreme	Extreme	High	Medium
Likely >70% to 95% or monthly or several times a year	Extreme	Extreme	High	Medium
Possible >30% to 70 % or once every 5 years	Extreme	High	Medium	Low
Unlikely >5% to 30 % or once every 10 years	High	High	Medium	Low

### 4.2.4 Alert levels

The NBSCP response framework is based on four escalating alert or activation levels:

- 🔴 WHITE Alert
- 🟡 YELLOW Activate
- 🔴 RED Activate
- 🟢 GREEN De-Activate

Table 5 - Classification ratings for risk management during activation of NBSCP as it relates to alert levels.

Risk Rating	Action Required
Red Activation	Escalate to NIR location with joint control – OHP/NBA Implement a detailed action plan to/ from Dept. of Health Report to governments as appropriate
Yellow Activation	Consider escalation to OHP location and joint control Implement a detailed action plan to reduce risk rating with daily Situation Reports (SitReps) Report to NIR as appropriate
White Activation	Specify management plans and accountability and responsibility Monitor trends and plan for improvement with potential activation of the NBSCP
Green De-Activation	Manage by routine procedures within the NBA such as Intensive Product Management (IPM) Monitor trends

Table 6 - Example of risk assessment, including possible causes of the scenario, likelihood, consequence and overall risk classification

Scenario	Possible cause	Likelihood	Consequence	Classification
Decrease in the available volume of any product	Any event that could reduce the collection of products, such as: <ul style="list-style-type: none"> <li>the introduction of a new test for infectious markers with a high Australian prevalence rate resulting in a greater number of donor deferrals</li> <li>significant reduction in donors such as from an avian influenza pandemic</li> </ul>	> 5–30% (Unlikely)	Medium	Low
Major interruption to the supply of product(s) due to technology failure	<ul style="list-style-type: none"> <li>failure of primary and backup capability to process / receive orders from Health service organisations such as the NBMS at the Blood Service</li> <li>QA control systems at the Blood Service or another supplier</li> </ul>	> 30–70% (Possible)	High	Medium
Manufacturer unable to produce products	Incident affecting production facility; for example: <ul style="list-style-type: none"> <li>corporate failure</li> <li>loss of facility</li> <li>inability to source consumables</li> <li>supply chain failure</li> </ul>	> 5–30% (Unlikely)	Medium	Low
Multiple trauma/burns patients	Large-scale catastrophic event such as; <ul style="list-style-type: none"> <li>airport, rail or infrastructure accident,</li> <li>natural disaster</li> <li>conflict-related event</li> </ul>	> 5–30% (Unlikely)	High	Medium
Cyber-attack	Cyber-attack leading to privacy breach	> 5–30% (Unlikely)	High	Medium

# 5 Supply risk mitigation

The NBA works with suppliers and other stakeholders to improve the preparedness of the sector to help prevent the activation of the NBSCP, as well as to support the development of sector infrastructure. This is to review and manage blood and blood products in a crisis situation, and on a daily basis.

## 5.1 National mitigation strategies

The NBA has put in place strategies to limit both the likelihood of a supply or demand failure, and to minimise the impact if there is such a failure. These activities include:

- ♦ risk management plans in supply contracts – the NBA requires as part of contract arrangements that each supplier provides a risk assessment which is used by the NBA as a basis of risk categorisation;
- ♦ cooperation in supplier contingency planning – the NBA continues to work with suppliers regarding stock levels and batch volumes to balance risk and commercial capabilities;
- ♦ product reserves and contingent supply arrangements – most contracts requires an amount of contingent stock above projected usage;
- ♦ promotion of best-practice use of blood and blood products – the NBA has implemented several blood wastage and patient blood management guidelines to assist in the reduction of product wastage of fresh products; and
- ♦ improvements in inventory management and reporting – BloodNet ordering and inventory management strategies are now in place across the majority of health service organisations providing visibility of stockholdings for fresh products in across Australia.

## 5.2 Therapeutic Goods Administration mitigation strategies

As part of this regulatory framework, all fresh blood components and plasma-derivatives are required to meet standards set by the TGA and to be manufactured under a TGA licence for Good Manufacturing Practice.

The Blood Service, as part of this regulatory framework is required to have a technical master file (TMF) for all fresh blood components. A TMF is a document describing the manufacturing process and scientific data or information from the manufacturer. The TMF shows that the blood components can satisfy the quality, safety and efficacy criteria specified by the TGA.

Under the Therapeutic Goods Act 1989 (TG Act), plasma-derived products are prescription medicines and are subject to full regulation provisions requiring standards, licensing of manufacture and inclusion on the Australian Register of Therapeutic Goods (ARTG) Unless exempt, therapeutic goods (including plasma-derived and recombinant products) must be entered on the ARTG as either 'registered' or 'listed' goods before they may be supplied in Australia.



### 5.3 Supplier mitigation arrangements

Most suppliers of blood and blood products have a range of business continuity planning mechanisms in place, including:

- ◆ robust risk management frameworks;
- ◆ risk assessment and management processes;
- ◆ disaster recovery arrangements;
- ◆ notification and reporting processes to identify impending risks;
- ◆ intensive product management mechanisms;
- ◆ commitments from suppliers to accord preferred customer status to supply for Australia;
- ◆ requirements for products to have a specified minimum level of shelf life at the time of supply in Australia;
- ◆ requirements for the holding of required levels of in-country reserves;
- ◆ provision for supply of alternative products, if triggered by the NBA;
- ◆ multiple supplier arrangements;
- ◆ donor screening and donor deferral;
- ◆ blood donation testing, and
- ◆ bacterial contamination screening

The integrity of the collection of blood and plasma in Australia is safeguarded by the requirements for donor questionnaires and associated offences and legal protections, in human tissue legislation in each state and territory.

All these continuity planning mechanisms are reviewed and updated regularly. Suppliers also work collaboratively with the NBA in ensuring that blood sector mitigation strategies, such as product reserves, are managed effectively and efficiently.

### 5.4 Health service organisations mitigation arrangements

Best practice management of blood and blood products suggests that Health Service Organisations should have a range of operational and governance mechanisms in place to guide the management of blood products. These mechanisms must be responsive to the specific circumstances of the institution, and maintain a high level of consciousness about the scarcity and cost of blood and blood products. The implementation of the National Safety and Quality Health Service Standards Second Edition (NSQHS) and in particular Standard 7 – Blood Management, and state-based safety and quality initiatives has promoted improvements in blood management practices. These arrangements are focused on:

- ◆ improving appropriateness of transfusion and transfusion procedures;
- ◆ aligning transfusion quality, safety and usage in hospitals to agreed standards;

- manage blood and blood products to minimise wastage and ensure that product is available to meet clinical demand in times of shortage improving;
- recording and documenting of the administration and use of blood and blood products;
- decreasing unnecessary transfusions and creating improved clinical outcomes;
- improving the reporting and management of adverse events; and
- fostering and developing better relationships across specialities and with pathology services, blood banks and the Blood Service, to ensure that patient needs are considered in a holistic manner.

For the purposes of this plan and relevant annexes, health providers (both public and private sector) are defined as individual hospitals, blood banks, pathology providers or a collection of these organisations working collaboratively that receive blood and blood products under the national blood arrangements.

Health governance arrangements are typically coordinated through a Blood Management Governance Group. The composition of a Blood Management Governance Group and its skills and expertise, will depend on the functions, activities, size and location of the institution. The Blood Management Governance Group, or its equivalent, are usually a multidisciplinary group that includes support from a variety of sources and include representatives from pathology or blood bank provider. Representatives may include:

- representatives from medicine, surgery or emergency departments;
- representatives from anaesthetics and theatre;
- representatives from intensive care;
- representatives from the institutional administration;
- representatives from risk or quality department;
- a transfusion medicine specialist (or haematologist);
- consumer representative; and
- a transfusion nurse or officer.

Typically, the responsibilities of a Blood Management Governance Group include:

- supporting compliance with the NSQHS standards; in particular, Standard 7 on Blood Management ; and
- promoting and educating the institution in the appropriate use of fresh blood products, consistent with the National Patient Blood Management Guidelines.

Further information to guide health service organisations in the appropriate use of blood and blood products and examples of blood governance arrangements are available at [www.blood.gov.au](http://www.blood.gov.au).

Implementation of effective health provider governance arrangements at health service organisations is essential for contingency preparedness in times of supply shortage and/ or NBSCP activation.

# 6 Response roles and responsibilities

## 6.1 Alert levels

The NBSCP response framework is based on four escalating alert or activation levels:

- ♦ WHITE Alert
- ♦ YELLOW Activate
- ♦ RED Activate
- ♦ GREEN De-Activate

The relationship between the levels is shown in Table 7. For each of the alert or activation levels the following are defined:

- ♦ management process;
- ♦ desired outcomes;
- ♦ required actions; and
- ♦ roles and responsibilities of relevant stakeholders.

## 6.2 Roles and responsibilities

A summary of the roles and responsibilities of key stakeholders is provided in Table 7. These roles and responsibilities may vary in detail depending on the products in short supply or the intensity of the supply crises. More detailed information relevant to the product in short supply is provided in the respective product annexes.

The NBA is responsible for the activation, escalation and de-escalation between alert levels and deactivation of the NBSCP. In most instances, this will be in consultation with key stakeholders, including the AHPPC, JBC, Commonwealth Department of Health, jurisdictional governments and suppliers.

The AHPPC may determine that, where decisions impact the capacity of the health sector to maintain normal practice, or where the shortage in product arises either rapidly or from a demand increase because of a wider health issue, this plan then provides for the engagement of and decision making, if required, by the AHPPC. The AHPPC will work with the NBA and may escalate and locate the management of a contingency from NBSCP arrangements to the National Health Incident Room based on significance or a widening health impact. In such instances, the NBA will work with the AHPPC throughout the incident, providing blood specific knowledge and remain within the incident management framework.

Table 7: Actions to be taken / roles and responsibilities during NBSCP activation

Organisations / Body	WHITE ALERT	YELLOW ACTIVATION Continue activities from White Alert, plus:	RED ACTIVATION Continue activities from White Alert and Yellow Activate, plus:	GREEN DE-ACTIVATION
Australian Government Department of Health: OHP activated NIR / AHPPC	<p>Liaise with NBA on NIR availability and status where NBA has established an Operations room for WHITE ALERT activities.</p> <p>Provide OHP status on alert situation to NBA for distribution.</p> <p>Establish communications with those jurisdictional bodies where central coordination of responses is relevant.</p> <p>Provide preparatory support to the NBSCP Operations room if escalation to Health NIR location is anticipated.</p>	<p>Establishes and coordinates incident room location handover from NBA incident room to NIR location (NBA will embed within NIR).</p> <p>Provide OHP directives including patient categories (if agreed/ activated) for communication with Stakeholders.</p> <p>Coordinates media activities, such as the provision of information and data to relevant bodies (Health, Blood Service or Suppliers) in accordance with an agreed Media Protocol.</p> <p>Coordinate combined response to issue.</p> <p>Determines possible impact on other products and whether need to activate further plan annexes.</p>	<p>Coordinates NIR participation in activation (NBA will remain embedded within NIR).</p> <p>Recommends to COAG Health Council cancellation of elective surgery requiring affected products nationally.</p> <p>Provide OHP directives for communication with Stakeholders.</p> <p>Re-evaluates the possible impact on other products and whether need to activate further plan annexes.</p> <p>Informs Minister of expected duration of impact on affected stocks.</p> <p>Sign off advice for COAG/ Health Ministers.</p>	<p>Advises NIR of deactivation.</p> <p>Provides directives on mitigation strategies and improvements to the plan that will improve future responses.</p>

Organisations / Body	WHITE ALERT	YELLOW ACTIVATION Continue activities from White Alert, plus:	RED ACTIVATION Continue activities from White Alert and Yellow Activate, plus:	GREEN DE-ACTIVATION
NBA	<p>Establish NBSCP Operations Room to coordinate Alert / Activation.</p> <p>Provide support and guidance to the OHP as required.</p> <p>Assess stock reporting and forecasts and notify all stakeholders of the activation of Plan.</p> <p>Assess impact on all products.</p> <p>Notifies relevant Stakeholders, Blood Service, Suppliers, JBC, OHP, TGA, Health, hospitals, pathology laboratories, associations and colleges of supply risk.</p> <p>Works with Blood Service/Suppliers to rectify situation.</p> <p>Work with Health to provide briefing to the Minister.</p> <p>Work with Health to coordinate national media advice on supply level.</p>	<p>Relocate to NIR consistent with any transfer of contingency requirements if applicable.</p> <p>Provide support with the OHP as required.</p> <p>Confirm escalation of NBSCP and maintain regular communications with all stakeholders on supply findings.</p> <p>Distribute OHP Categorisation of Patients Types document with instructions / status (if agreed/ activated).</p> <p>Undertakes agreed media activities in conjunction with Health, such as the provision information and data to relevant bodies in accordance with agreed Media Protocol.</p> <p>Considers possible impact on other products and whether need to activate further plan annexes.</p>	<p>Provide support and guidance with the OHP as required.</p> <p>Prepares advice for AHPPC/ COAG/ Health Ministers.</p> <p>Assist OHP to formulate instructions and distributes communications with Stakeholders.</p> <p>Works with TGA/Blood Service/ Suppliers on possible importation options and/or regulatory changes.</p> <p>Re-evaluates and advises OHP of the possible impact on other products and whether need to activate further plan annexes.</p>	<p>Inform stakeholders of deactivation.</p> <p>Manages and conducts debriefing session.</p> <p>Collects information to support improvements.</p> <p>Evaluate the outcomes of the activation and revise the NBSCP where necessary.</p> <p>Provides advice to JBC on new mitigation strategies that could be implemented, if appropriate.</p>

Organisations / Body	WHITE ALERT	YELLOW ACTIVATION Continue activities from White Alert, plus:	RED ACTIVATION Continue activities from White Alert and Yellow Activate, plus:	GREEN DE-ACTIVATION
Suppliers	<p>Provides relevant data and information to the NBA.</p> <p>Coordinates and provide daily advice on all inventories, including work in progress levels to NBA.</p> <p>Works with health service organisations and NBA to ensure the most effective distribution of available product based on taking into consideration patients as required.</p> <p>If arrangements have been agreed with an individual State or Territory, support and replicate communication with health service organisations (including health service organisations, clinicians and pathology providers using BloodNet where possible or relevant).</p>	<p>Comply with directions from the NBA/AHPPC. This may include gatekeeping of products to only provide product for particular patient categories (if this is appropriate for a product).</p> <p>Implement and advise NBA of status of management response required to address supply failure.</p> <p>Undertakes media activities in accordance with agreed media protocol.</p>	<p>Work with NBA and TGA on possible options for alternative arrangements or importation options.</p> <p>Works with the NBA to implement any government decisions.</p> <p>Assist with the distribution of any imported products.</p>	<p>Participates in briefing to improve plan and/or decrease the likelihood of future activation of the plan.</p>

Organisations / Body	WHITE ALERT	YELLOW ACTIVATION Continue activities from White Alert, plus:	RED ACTIVATION Continue activities from White Alert and Yellow Activate, plus:	GREEN DE-ACTIVATION
Blood Service	<p>Coordinates and provide daily advice on all inventories, including work in progress levels to NBA.</p> <p>Works with health service organisations and clinicians to ensure the most effective distribution of available product based on taking into consideration patient categories.</p> <p>If arrangements have been agreed with an individual State or Territory, the Blood Service or a supplier should assist the NBA with communications to health service organisations (including health service organisations, clinicians and pathology providers using BloodNet where possible). Increases donor recruitment activities to meet optimum product requirements, which may include:</p> <ul style="list-style-type: none"> <li>▪ Calling more donors;</li> <li>▪ Extending shifts in the processing department to increase production;</li> <li>▪ Extending the opening times of static or mobile clinics.</li> </ul>	<p>Comply with directions from the NBA/OHP. This may include gatekeeping of products to only provide product for particular patient categories.</p> <p>Launch national donor appeal, extend hours of operation and collection sites.</p> <p>Implements and advises NBA of status of management response required to address supply failure.</p> <p>Prioritise donors and donations based on product requirements.</p> <p>Undertake media activities in accordance with agreed media protocol.</p> <p>Provide regular updates on stock levels as requested.</p>	<p>Works with NBA and TGA on possible options for alternative arrangements.</p> <p>Consider other options under TMF/PMF with NBA and TGA.</p> <p>Provides expert advice to OHP.</p> <p>Considers activation of additional donor surge capacity, in jurisdictions where systems are in place.</p>	<p>Participates in briefing to improve plan and/or decrease the likelihood of future activation of the plan.</p>

Organisations / Body	WHITE ALERT	YELLOW ACTIVATION Continue activities from White Alert, plus:	RED ACTIVATION Continue activities from White Alert and Yellow Activate, plus:	GREEN DE-ACTIVATION
JBC/Health Departments/ Central Jurisdictional Incident Rooms	<p>Provide any critical information about their jurisdiction to NBA.</p> <p>If arrangements are not already in place and agreed with NBA, States and territories / Incident Rooms should assist the communication with Health Service Organisations including health service organisations, clinicians and pathology providers).</p> <p>Initiating jurisdiction supports NBA in analysis of initial information.</p> <p>Alert CMO/CHO and Jurisdictional emergency management or Incident Rooms arrangements of possible issue.</p>	<p>Support and works with health service organisations and clinicians as per jurisdictional Emergency Management Arrangements.</p> <p>Participate in regular communication with health service organisations on stock levels.</p> <p>Respond to media activities in accordance with agreed media protocol.</p> <p>Participate in regular communication to determine timing and nature of decisions to be taken to ensure understanding on impact on supply or demand.</p>	<p>Advises Jurisdictional Health Ministers of product stock status.</p> <p>Supports NBA in developing strategy recommendations to JBC/ AHPPC/ COAG.</p> <p>Communicate mandatory changes in clinical practice such as cancellation of elective surgery requiring affected product to health service organisations (including health service organisations, clinicians and pathology providers).</p>	<p>Inform health service organisations (including health service organisations, clinicians and pathology providers).</p> <p>Considers policy and funding options for additional mitigation strategies, if appropriate.</p> <p>Review and evaluate local emergency blood management plans.</p>



Organisations / Body	WHITE ALERT	YELLOW ACTIVATION Continue activities from White Alert, plus:	RED ACTIVATION Continue activities from White Alert and Yellow Activate, plus:	GREEN DE-ACTIVATION
Health Service Organisations/ Clinicians	<p>Reviews emergency product management arrangements to ensure currency.</p> <p>Activate emergency product management arrangements.</p> <p>Place institution on alert.</p> <p>Provide inventory levels to pathology provider, and specific batch details as required.</p> <p>Arrange inter-hospital product transfer to ensure equity of access nationally.</p> <p>Provide information to the NBA on inventory levels and demand trends as required.</p>	<p>Activate emergency product management arrangements, which should include only ordering product for specific patient categories, if requested to do this.</p> <p>Increase product minimisation strategies and treatment alternatives.</p> <p>Consider prioritising surgery to minimise product use.</p> <p>Commence centralised vetting process for all requests for products.</p> <p>Identify a clinician to coordinate and authorise all product orders.</p>	<p>Implements national strategies agreed by AHPPC/ COAG cancellation of elective surgery requiring affected product.</p> <p>Transfer product as directed by governments/NBA /Blood Service or Suppliers and update BloodNet, where relevant.</p>	<p>Participates in briefing if appropriate.</p> <p>Hospitals/ health service organisations blood management governance group or emergency product management teams to undertake internal debrief and evaluation of their process and amend as necessary.</p>
Pathology Providers	<p>Implements optimal inventory management practices such as reducing cross matching hold time.</p> <p>Notify customer base of status.</p> <p>Provide inventory levels to the NBA as requested by the NBA. This should be through BloodNet where available.</p> <p>Arrange inter-hospital transfer to ensure equity of access nationally.</p>	<p>Participate with health service organisations emergency product management arrangements, which should include only ordering product for specific patient categories (Refer to each Annex)</p> <p>Commence centralised coordination of request to all affiliated health service organisations.</p> <p>Identify internal triage clinicians to coordinate and authorise orders.</p>	<p>Implement strategies to assist in the implementation of approach agreed by AHPPC/ COAG.</p> <p>Transfer product as directed by governments or the Blood Service.</p>	<p>Participates in briefing if appropriate.</p> <p>Participate in affiliated hospital/ health service organisations debriefing arrangements, as necessary.</p>

Organisations / Body	WHITE ALERT	YELLOW ACTIVATION Continue activities from White Alert, plus:	RED ACTIVATION Continue activities from White Alert and Yellow Activate, plus:	GREEN DE-ACTIVATION
Australian Government Department of Health: Blood Policy	<p>Advise Departmental Executive and Communications area of situation.</p> <p>Provide briefing to the Minister.</p> <p>Coordinate national media advice on supply level.</p> <p>Coordinate jurisdictional analysis of public health impact.</p>	<p>Provide policy input where requested.</p> <p>Advises NBA/AHPPC for information and briefs Departmental Executive and Minister.</p> <p>Manages Media requirements in accordance with agreed media protocol.</p> <p>Considers budgetary matters, if required.</p>	<p>Activates NIR.</p> <p>Advises AHPPC to explore clinical options for reducing product use.</p> <p>Provides blood policy advice where requested.</p> <p>Communicate AHPPC/COAG decisions to NBA.</p> <p>Liaise with blood sector as requested/required.</p>	<p>Participates in briefing.</p> <p>Advises Departmental Executive and Minister of outcomes.</p>
Australian Government Department of Health: TGA	<p>Monitors situation and work with NBA and Blood Service/Suppliers as necessary.</p> <p>Supports/advises NBA in analysis of initial information.</p> <p>Expedite consideration of requests from the NBA and the Blood Service/Suppliers relating to manufacturing changes required to mitigate supply risks.</p> <p>Advises the NBA and the Blood Service on resolving regulatory matters as they arise.</p>	<p>Provides critical information on and makes regulatory decisions relating to use of product.</p> <p>Participates in media activities in accordance with agreed media protocol.</p>	<p>Works with NBA and Blood Service on options for importation of products.</p> <p>Provides input into briefings and media activities.</p>	<p>Participates in briefing if appropriate.</p>

Organisations / Body	WHITE ALERT	YELLOW ACTIVATION Continue activities from White Alert, plus:	RED ACTIVATION Continue activities from White Alert and Yellow Activate, plus:	GREEN DE-ACTIVATION
COAG (Health Ministers)	NIL	NIL	<p>Considers recommendations and provides direction.</p> <p>Outcomes communicated by Secretariat to stakeholders.</p> <p>Media activities.</p>	NIL

# 7 Notification and Communication

The normal operational daily communication channels will underpin communication with governments, the Blood Service, suppliers, health service organisations and pathology laboratories on activation of the NBSCP. To enhance the robustness of communication, these may be overlaid by additional measures, such as, through BloodNet and social media. However, the established communication channels will be the primary means of communication under the NBSCP.

## 7.1 Receipt and inventory management information system - BloodNet

BloodNet is the national online ordering and inventory management system, enabling staff in pathology laboratories to place orders online for blood and blood products, record inventory levels and to document the final fate of each unit (e.g. discarded, transferred, transfused). Over 95% of fresh blood units distributed by the Blood Service are ordered and processed through BloodNet.

Inventory levels held by health service organisations is collected through BloodNet and are used to develop reports identifying the inventory of blood and blood products held by health service organisations. The ongoing development of interfaces between health provider's laboratory information systems and BloodNet will allow in the future real time monitoring of inventory levels.

BloodNet also provides health service organisations inventory levels in a standardised way. Messages are used in BloodNet to provide and receive information on status, developments and action items for those involved.

## 7.2 NBSCP Blood Operations Centre

On activation of the NBSCP, the NBA will utilise the NBA Blood Operations Centre (BOC) while the contingency is under the control of the NBA. In addition to monitoring and supporting users, BOC also provides a single point of contact for staff from health service organisations and operates as the Incident Room when the NBSCP is activated.

At any point in time, should the AHPPC decide that the severity of the incident demands that control and or management location be escalated to the AHPPC in order to develop national policies to protect public health, the NBA may close BOC and transition to a collaborative role with the OHP and AHPPC emergency management arrangements.

## 7.3 Notification and communications scheduling

On activation of the NBSCP, a schedule of notification and communication to stakeholders will be established. The schedule will identify relevant stakeholders and required communications which could include:

- ◆ key messages, website updates and media releases;
- ◆ situation reports;
- ◆ incident logs;
- ◆ inventory reports; and
- ◆ contingency management meeting agenda, minutes and actions.

## 7.4 Media management and protocols

Media response should be a coordinated and combined response. The management and protocols should explicitly state that the key people (OHP/NBA/the Australian Government and the JBC) will work together to respond to media requests/release information. Additionally, any media activities and communications with clinical groups and health service organisations undertaken by the Blood Service need to be approved by the NBA or NBA/JBC.

In order to provide a common message to the clinical community, donors and the general public, the NBA will provide a contact point and timely media information released where appropriate on matters relating to the NBSCP. This will include facets of the daily SitRep framework and coverage of issues as presented from the media.

Other media communication from the TGA or jurisdictional Departments of Health may be available during an incident or activation. This would usually be in the form of product status or release from the TGA or matters pertaining to the Government or Minister regarding media communications from Health.

Suppliers may also be providing media information separate from that released by the NBA, Departments of Health or the TGA.

The release of information will be coordinated by the NBA to ensure accurate and standard communication.

The NBA can also use the National Health Emergency Media Response Network (NHEMRN) to ensure comprehensive sharing of information and consistent messaging across the Australian Government and jurisdictions. NHEMRN includes members from the Department of Health and all state and territory health department Media Units; relevant Australian Government agencies, national medical colleges and associations, National Aboriginal Community Controlled Health Organisations and select parts of the private sector directly involved in emergency health management. It is chaired and coordinated by the Commonwealth Department of Health. It is convened when needed.

## 7.5 Incident log

The NBA will maintain an incident log of events to ensure continuity of information as well as a reference to all issues, communications and decisions made throughout an activation of the NBSCP. The incident log will also play a vital role should activation be transferred to the AHPPC management structure.

The NBA will provide specific NBSCP information, comment and directions from AHPPC and jurisdictional decisions regarding action to be undertaken by all parties.

## 7.6 Situation reports (Sitreps)

Sitreps are usually provided daily. The SitRep will outline action items since the previous day and the roles and responsibilities in a standard template format.

## 7.7 Direct targeted communication

Using a combination of fax, email and SMS, the NBA can use a group text messaging (SMS) function to provide high level information such as meeting schedule and activation level usually with advice for text recipients to access their email inboxes for further detail. This service is provided for NBSCP (and the Business Continuity Plan (BCP)) purposes and has been populated with pre-defined templates for SMS messages for a variety of circumstances in addition to SMS distribution groups for the NBSCP.

## 7.8 OHP operational trigger

As outlined in Section 2 of this plan, the OHP has a wider range of responsibilities across the health sector in addition to blood and blood products. As such, the location of management for a blood or blood product contingency may be relocated to OHP and the NIR. In such an instance, the NBSCP will remain as the overarching contingency plan in place to avoid the duplication of management chains. Should this occur, a specific SitRep containing relevant information will be issued including:

- ◆ time of transfer of location to the NIR;
- ◆ contact point (numbers and physical location);
- ◆ contact name;
- ◆ position of responsibility;
- ◆ reason for escalation; and
- ◆ other relevant details.

At that point, the NBA NBSCP operational command will work with a component of the OHP management of an incident, with specific roles and responsibilities identified within the NBSCP communication to stakeholders. This arrangement will continue until further communication identifies a de-escalation of the issue and transfer back to NBA management and responsibility. This process will be recorded within the NBSCP incident log.

## 8 Recovery and Review

Following mitigation of a contingency, the status of the activation of the NBSCP will be returned to green, and a recovery process commenced.

A debrief across all stakeholders will be conducted to ensure strengths and weaknesses of an activation are captured in a timely manner. This will provide an opportunity to consider improvements to this plan and the annexes, as well as to recovery or make good activities.

As the impact on the supply of blood or blood products may reduce, but not necessarily cease as a risk, a staged approach to returning the NBSCP to green may occur and may include a period of post return intensive product management rather than a complete de-escalation of the plan.

As information gained through post incident analysis is vital to providing a context for future approaches to management of incidents, the NBA will conduct detailed forums post incident including a collection of stakeholders as appropriate.

Information and experience gained through activations or simulations of the NBSCP will be used as the basis for future refinements and revisions to the NBSCP or annexes.

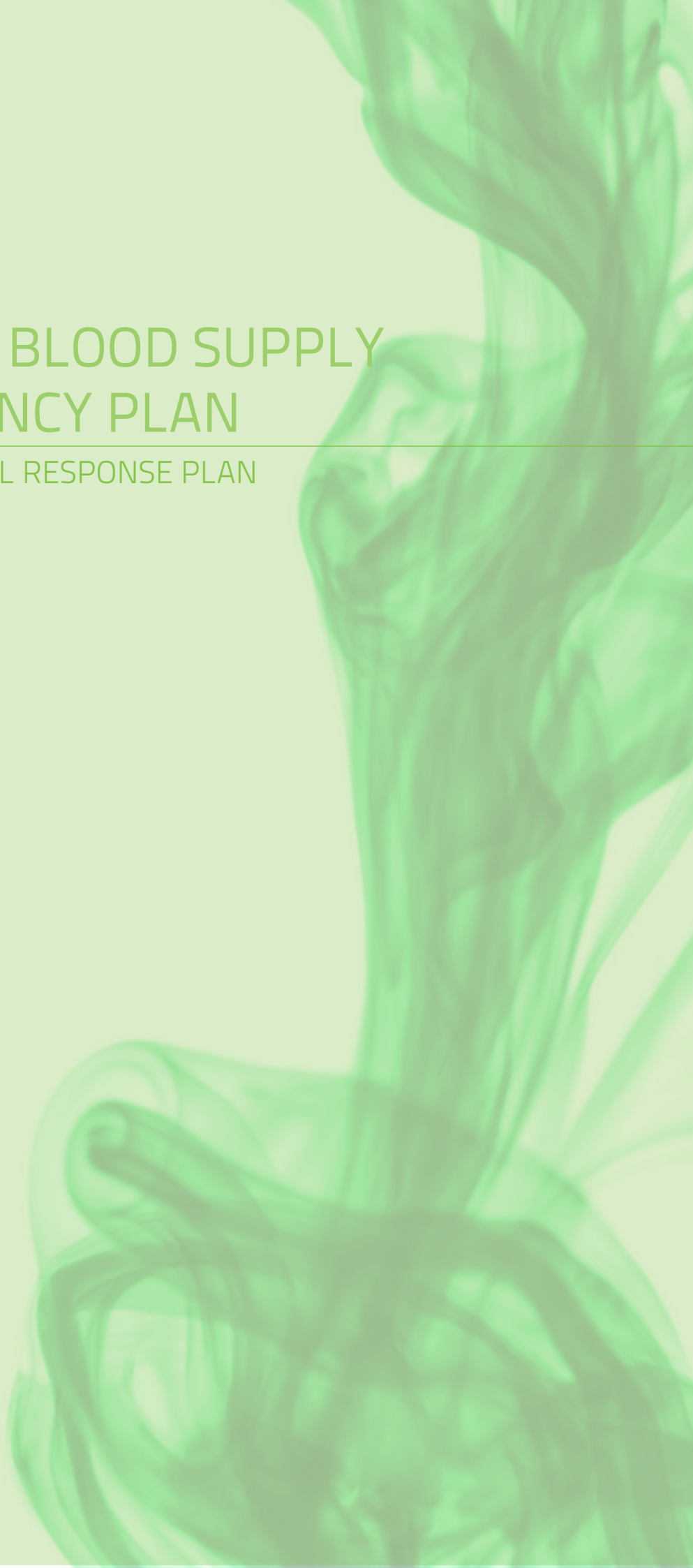




# NATIONAL BLOOD SUPPLY CONTINGENCY PLAN

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ANNEX A: RED CELL RESPONSE PLAN  
July 2019



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# 1 Introduction

The overarching document in this plan is the NBSCP master document which establishes the context in which contingency planning is addressed, with this document being an annex which deals specifically with red cell product shortages. It also provides guidance for the escalation of contingency management from NBSCP arrangements to the Australian Government Department of Health: Office of Health Protection (OHP) where relevant.

Governance of health protection in Australia is managed through a multiple set of state/ Commonwealth relationships.

The purpose of this annex is to outline the contingency planning response to a threat to the supply of red cells including the following products:

- ◆ Red cells leucodepleted
- ◆ Whole Blood (WB) paediatric red cells leucodepleted (Set of 4)
- ◆ WB washed red cells leucodepleted
- ◆ For a complete list of products supplied under the National Blood Agreement, visit the NBA website at: <http://www.blood.gov.au/national-product-list>

The day-to-day supply management of red blood cells is the responsibility of Australian Red Cross Blood Service (Blood Service), in accordance with the requirements under the Deed of Agreement with the NBA. This includes a responsibility to manage an acute shortage in a jurisdiction. This is defined as:

- ◆ stock levels in that jurisdiction being less than five days (or an acute shortage is predicted to occur);
- ◆ the incident is predicted to be resolved within eight days; and
- ◆ there will be no significant impact on the supply of products in any other jurisdiction.

This annex details the following for each alert and activation level:

- ◆ Definition of the alert level, including the triggers that cause activation;
- ◆ Potential actions and desired outcomes, including examples of the types of actions that may be taken can be found in Table 1; and
- ◆ Communication options during an activation.

## 2 Crisis Planning

### 2.1 Activation

Figure 1 - Activation Map is a flowchart of the process used to identify levels of activation. Refer to Section 4, Figure 5 Activation Map of the NBSCP Master Document for further details.

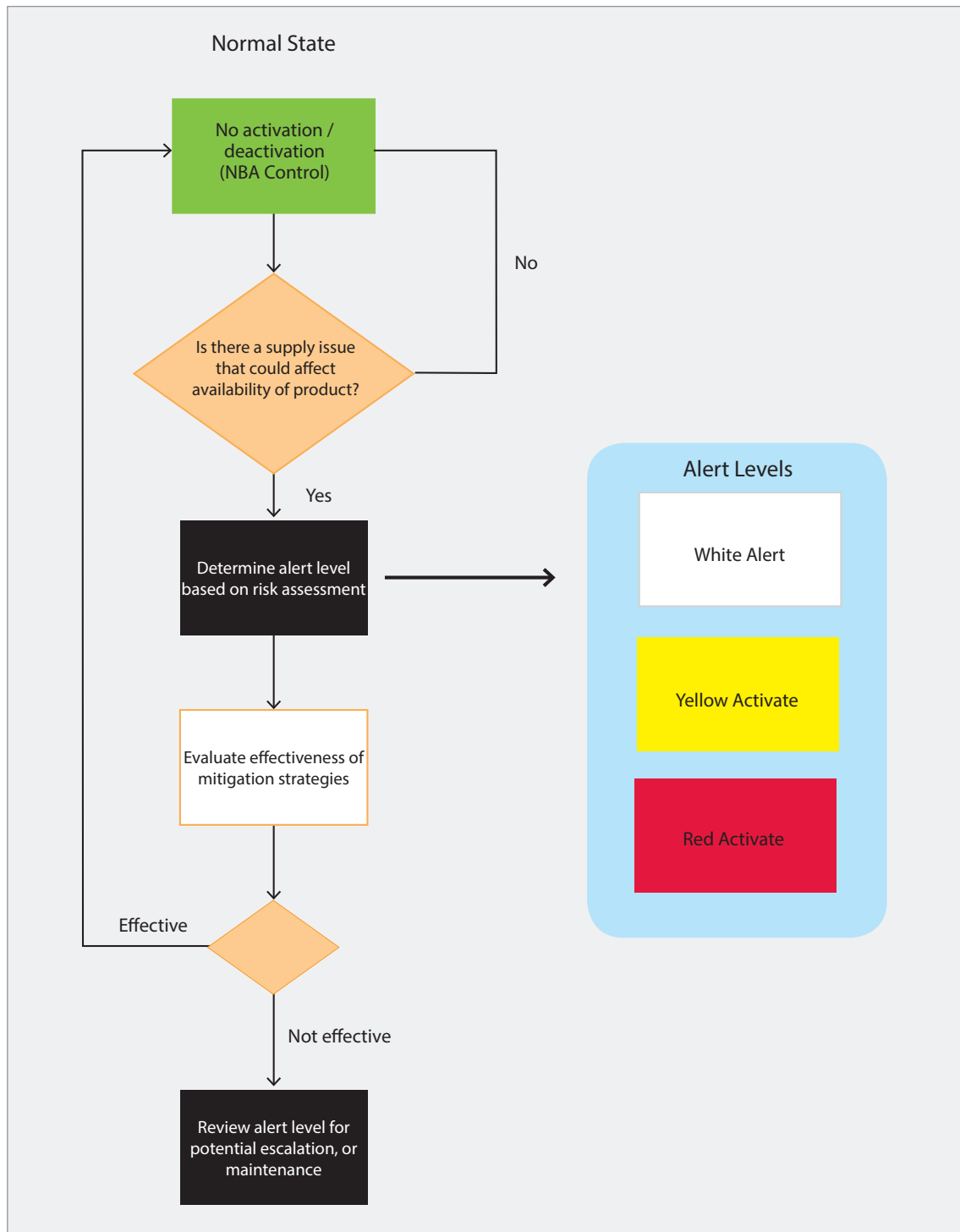


Figure 1 - Activation Map

## 2.2 Risk assessment and trigger points

Section 4 of the NBSCP Master Document provides a guide to how the risk is rated and assessed and then the alert level to be applied.

The operational phase trigger points in this annex are outlined specifically in Table 1 and Figure 2 of this document, which indicates the critical levels or activation points within the NBSCP.

The criteria for activation and deactivation may be varied by the NBA or OHP based on other information such as product availability for different patient priorities, or knowledge of future continued or anticipated supply chain shortages of product. This would override the 'stock level trigger point' listed in Figure 2 of this document.

In preparing the NBSCP and supplementary annexes, the approach for the management of products was reviewed against the National Service Requirements and Standards with the Australian Red Cross Blood Service (Blood Service) and approaches to emergency blood management planning.

## 2.3 Alert levels

The alert and activation levels defined under the NBSCP framework are as follows:

- ◆ WHITE Alert
- ◆ YELLOW Activate
- ◆ RED Activate
- ◆ GREEN De-Activate

To meet clinical demand for red cells in the event of a crisis, there is an escalation and de-escalation process to guide the blood sector's response. Table 1 Alert Levels – Definition, Potential Actions and Desired Outcomes provides a definition of each NBSCP alert level, a list of associated actions in response to that alert level and identifies the desired outcome sought.

Potential actions are a suite of activities that may be used depending on the circumstances. Actions undertaken in the activation of the NBSCP are not limited to the identified points below.

Responsibility for controlling the response to a crisis under each phase rests either, with the NBA under OHP arrangements, or with the AHPPC, depending on the seriousness of the incident. The OHP may make a decision to assume control of the incident at any point in time, should the OHP consider the need to apply national oversight to protect public health.

Figure 2 – Red Cell Activation Map is a flowchart of triggers used to identify levels of activation during product shortages.

Note: Product shortages may or may not occur at the same time as other blood component shortages.

Table 1: Alert Levels – Definition, Potential Actions and Desired Outcomes

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
<b>WHITE ALERT</b>	<p>The NBA Chief Executive will determine that a national shortage of red cells has occurred, or is likely to occur</p> <p><b>and/or</b></p> <p>A shortage is recorded from inventory (sourced through BloodNet) and National Inventory Template indicating current stock levels will not meet future demand (this may be opinion based by the NBA)</p> <p><b>and/or</b></p> <p>The product in stock or work in progress may be at a known or potentially high risk of 'failure'</p> <p><b>and/or</b></p> <ul style="list-style-type: none"> <li>▪ an acute shortage has occurred in more than one jurisdiction</li> <li>▪ a shortage in one jurisdiction will impact on more than one jurisdiction (i.e. initiating jurisdiction has had &lt;5 days stock for 8 days)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Blood Service give consideration to: <ul style="list-style-type: none"> <li>» Calling for more donors</li> <li>» Extend shifts in the processing department to increase production</li> <li>» Extend the opening times of static clinics for (the collection of donations)</li> <li>» Extend opening times of mobile sessions (for the collection of whole blood donations).</li> </ul> </li> <li>▪ Health service organisations confirm their inventory levels when requested, to the NBA and minimise the use of product, where appropriate, in accordance with Section 5 of this document without adversely impacting on patient outcomes</li> <li>▪ Alert health service organisations to focus on optimising product inventory management. For example, emphasise the importance that hospitals/laboratories keep track of the status of the orders.</li> <li>▪ Increase monitoring and movement of the national product stock ensuring wastage is kept to a minimum.</li> </ul>	<p>To increase the collection and production to build stock levels while meeting demand for emergency services and other clinical requirements.</p>

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
<b>YELLOW ACTIVATE</b>	<p>Actions in WHITE ALERT phase have not rectified the situation allowing for the plan to be deactivated</p> <p><b>and/or</b></p> <p>Inventory (sourced through BloodNet) and National Inventory Template indicating current stock levels will continue to not meet future demand (this may be opinion based by the NBA)</p> <p><b>and/or</b></p> <p>The product in stock or work in progress may be at a known or potentially high risk of 'failure'</p> <p><b>and/or</b></p> <ul style="list-style-type: none"> <li>the initiating jurisdiction has &lt;3 days stocks</li> <li>national stock levels are between 3–5 days.</li> </ul>	<ul style="list-style-type: none"> <li>Decrease non-urgent product use in consultation with NBA / AHPPC as applicable.</li> <li>At this point all requests for affected products from the hospital should be authorised by a named senior clinician within health service organisations.</li> <li>Recommendations from the OHP / NBA are put in place at either jurisdictional or national level so that available products can be redirected to meet life threatening and/or other agreed priorities based on appropriate clinical assessment.</li> <li>Prioritise surgery to minimise affected product use in consultation with AHPPC and to explore clinical options for reducing affected product use.</li> <li>NBA / OHP will inform Jurisdictions that affected products should be issued with an intention of reducing use in non-urgent situations.</li> <li>Extend the shelf life of affected products if the TGA approves.</li> </ul>	<p>Decrease non-urgent product use so that available products can be redirected to meet life threatening and/or other agreed priorities based on appropriate clinical assessment.</p> <p>Consider prioritising surgery to minimise product if applicable.</p>



Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
<b>RED ACTIVATE</b>	<p>Actions from WHITE ALERT and YELLOW ACTIVATE have not rectified the situation; <b>and/or</b> Inventory (sourced through BloodNet) and National Inventory Template indicates stocking levels will continue to not meet future demand (this may be opinion based by the NBA) <b>and/or</b> The product in stock or work in progress may be at a known or potentially high risk of 'failure' <b>and/or</b></p> <ul style="list-style-type: none"> <li>national stock levels are &lt;3 days</li> </ul>	<ul style="list-style-type: none"> <li>Actions as described for Yellow Alert.</li> <li>Close the NBSCP Operations Centre and NBA transition to a support role under Commonwealth Office of Health Protection and AHPPC incident management arrangements.</li> <li>Implement AHPPC national policies for prioritisation of affected product use.</li> <li>Affected product use triaged for life threatening and other clinical AHPPC recommendations and actions dependant on the situation.</li> <li>Restrictions imposed on affected product use in elective surgery.</li> <li>NBA support and replicate OHP communication and messaging using NBSCP communication arrangements.</li> <li>At this point all requests for affected products in the hospital are to be made via a named senior Clinician or treating physician. This will facilitate communication between the requestor and OHP / NBA / Blood Service.</li> <li>The NBA or if a National Incident Room is in place, the OHP, will take responsibility for facilitating the discussion and request for affected products between the treating clinician and the Blood Service. This will ensure that hospitals/laboratories can keep track of the status of the orders.</li> <li>Hospitals will be required to track closely the fate of each unit of affected products delivered to them. Information may be requested on each unit of affected products at regular intervals so that, if the product is not used, it can be retrieved and delivered to an alternative location for use. This will ensure that wastage of affected product is kept to a minimum and the most urgent cases are supported.</li> </ul>	<p>Affected products use is triaged for life-threatening and other clinically assessed priorities.</p> <p>Affected product use in elective surgery is restricted and procedures are compliant with jurisdictional emergency arrangements.</p> <p>If chronic, national consistency in triage of medical and surgical blood use.</p>
<b>DE-ACTIVATE</b>	<p>Affected products nationally have returned to a pre-WHITE alert level that is acceptable and the incident that led to the shortage has been resolved to the satisfaction of the NBA.</p>	<ul style="list-style-type: none"> <li>NBSCP improved for possible future crises and if possible new measures as recommended by AHPPC are introduced to decrease the likelihood or impact of a similar situation.</li> </ul>	<p>Evaluation of the activation for areas of NBSCP improvement and adoption of any new measures as recommended by AHPPC.</p>

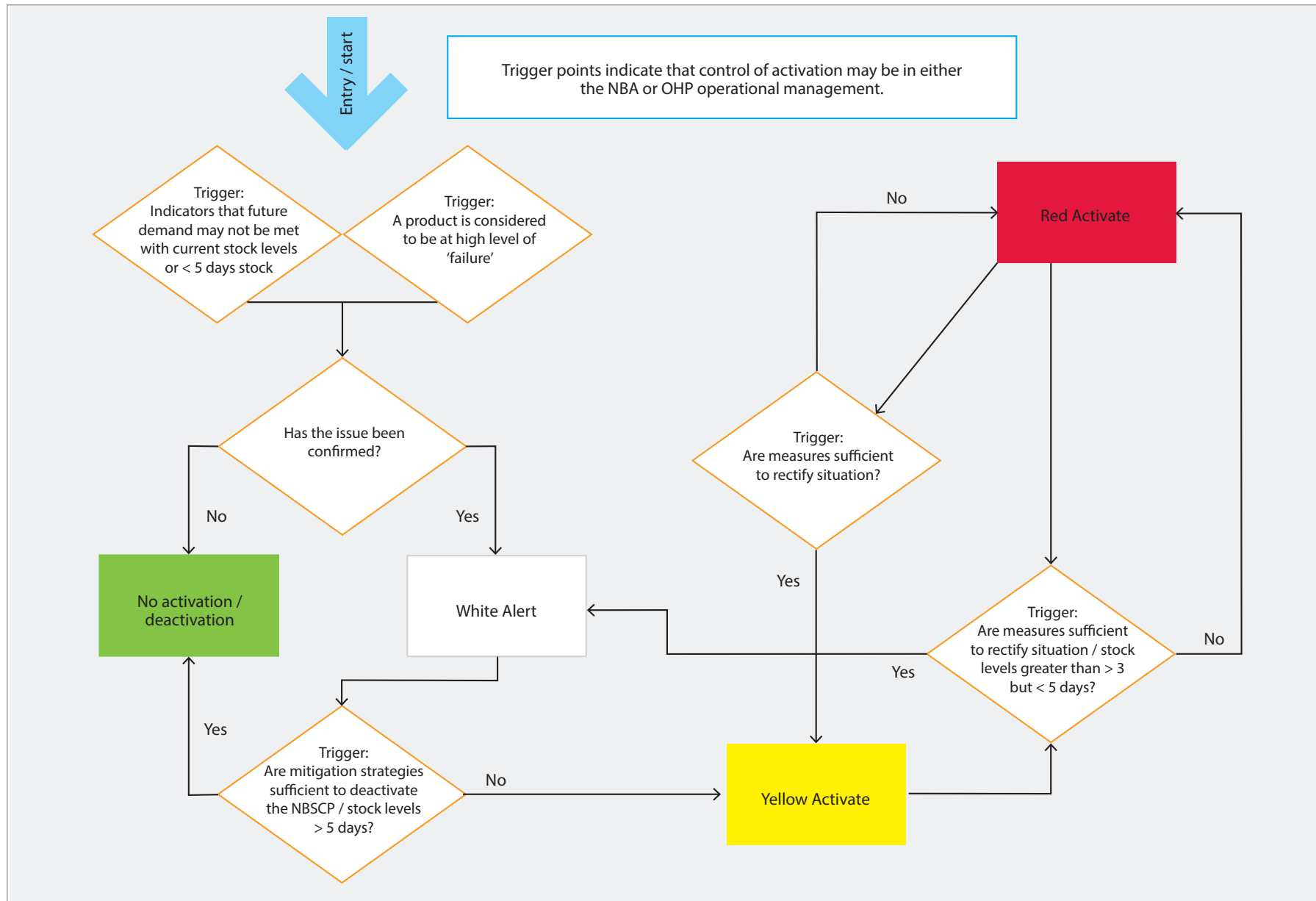


Figure 2 – Red Cell Activation Map

## 3 Response roles and responsibilities

Section 6, Table 7 of the NBSCP Master document outlines the roles and responsibilities of the key stakeholders involved in the management of activation of the NBSCP during each operational phase. It should be noted that these are high level descriptions of responsibilities and other roles may be required depending of the nature of the incident.

Directions from the NBA / OHP on levels of action and responsibilities will further guide all organisations / bodies involved in the NBSCP. The NBA will advise of the coordination and activation of the NBA incident room or the National Incident Room for OHP and other stakeholder's involvement.

If the contingency is escalated beyond White Alert, the actions required under other activation statuses include those described in previous levels, unless superseded by a new action.

More detailed information regarding roles and responsibilities is provided in the NBSCP master document.

## 4 Clinical advice and input during activation

Clinical Guidance for Patient Categorisation Priorities is outlined in Section 5 – Guidance for prioritisation of red cell transfusions.

The implementation of triage measures that involve a restriction on clinical practice will only occur following clinical advice appropriate to the measure/s being contemplated. The key sources of this advice include the relevant peak clinical bodies and Jurisdictional clinical experts at the time of activation.

Any decision to implement a clinical restriction on the use of red cells will only be made following consultation with all members of the JBC and/or Commonwealth Department of Health as appropriate.

# 5 Guidance for prioritisation of red cell transfusions

Governments cannot predetermine the treatment of patients nor generalise on what the most effective treatment regime may be, this is the responsibility of the treating clinician. In some circumstances such as those presented under an activation of the NBSCP, it may be necessary to restrict the availability of transfusions to patients with the greatest need. This decision should be made by the clinician, within the framework and arrangements established by the treating institution.

To support and assist clinicians and institutions with these decisions the following high level guide is suggested, which in descending order of urgency, classifies patients into Blood Accesses Priority levels 1 – 3, with patients in Blood Access Priority 1 having the highest priority for transfusion, noting these are suggested categories only and are not mandated. It is clearly the responsibility of the treating clinician and institution to determine the appropriate treatment of a patient based on available blood products.

## 5.1 Blood Access Priority 1

### Resuscitation

- ◆ Resuscitation from life threatening or ongoing blood loss from any cause, including major trauma and obstetric haemorrhage.

### Surgical support

- ◆ Emergency surgery (defined as a patient likely to die within 24 hours without surgery), including cardiac and vascular procedures.
- ◆ Urgent surgery (defined as a patient likely to have major morbidity if surgery not carried out).
- ◆ Organ transplantation that cannot be deferred.

### Nonsurgical anaemia

- ◆ Life threatening anaemia, including patients requiring in utero support or in neonatal intensive care.
- ◆ Support for stem cell transplantation or chemotherapy that cannot be delayed.
- ◆ Patients with severe bone marrow failure, haemoglobinopathies or other conditions who cannot tolerate any delay in transfusion.

## 5.2 Blood Access Priority 2

### Surgery and obstetrics

- ◆ Semi urgent surgery (defined as a patient likely to have minor morbidity if surgery is not carried out).
- ◆ Cancer surgery that cannot be deferred without risk to patient.
- ◆ Symptomatic, but non-life threatening, postoperative or postpartum anaemia.

#### Nonsurgical anaemia

- Symptomatic but non-life-threatening anaemia, (including postoperative) of any cause that cannot be managed by other means

### 5.3 Blood Access Priority 3

#### Surgery

- Elective surgery requiring cross matched red blood cell support of two or more units of homologous donor blood.

#### Nonsurgical anaemia

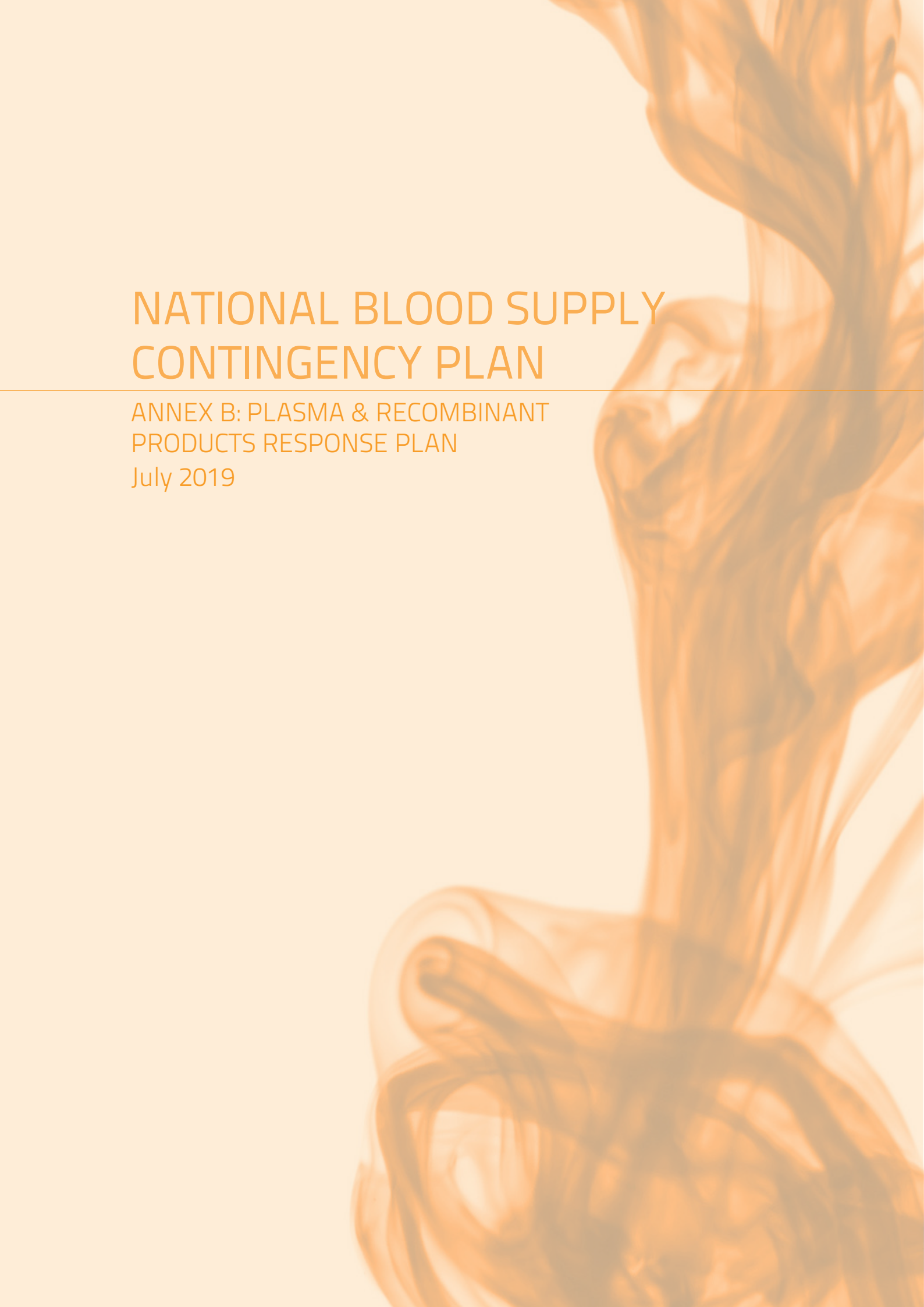
- Other non-urgent medical indications for transfusion.

**Note:** when considering priority of patients for transfusion, alternative actions may include:

- Transfusion alternatives e.g. erythropoietin, iron therapy, patient blood management
- Reduction in target post transfusion haemoglobin.



NATIONAL BLOOD AUTHORITY  
AUSTRALIA

An abstract, flowing, orange-colored graphic that resembles smoke or liquid, swirling upwards from the bottom right corner towards the top right. The background is a light cream color.

# NATIONAL BLOOD SUPPLY CONTINGENCY PLAN

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ANNEX B: PLASMA & RECOMBINANT  
PRODUCTS RESPONSE PLAN

July 2019

## Document Properties

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Version	2.0
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JBC Endorsement	March 2018
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November 2008	1.0	Initial approved document	NBA
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- 4 Clinical advice and input during activation ..... 12

# 1 Introduction

The overarching document in this plan is the NBSCP master document which establishes the context in which contingency planning is addressed, with this document being an annex that deals specifically with plasma and recombinant product shortages. It also provides guidance for the escalation of contingency management from NBSCP arrangements to the Australian Government Department of Health: Office of Health Protection (OHP) where relevant.

Governance of health protection in Australia is managed through a multiple set of state/ Commonwealth relationships.

The purpose of this annex is to outline the contingency planning response to a threat to the supply of one or more plasma or imported recombinant products including the following product categories:

- ◆ Domestically produced plasma derived products used in Australia which are manufactured by CSL Behring from plasma collected by the Australian Red Cross Blood Service (Blood Service)
- ◆ Imported plasma derived products used in Australia, including plasma derived Factor XI and XIII, anti-inhibitor coagulant complex concentrates, Protein C, plasma-derived Rh(D) immunoglobulin and immunoglobulin products. These products are imported because they are not manufactured in Australia or they are manufactured in insufficient quantities to meet clinical need
- ◆ Recombinant clotting factor products which are also imported. These products are also not manufactured in Australia

For a complete list of products supplied under the National Blood Agreement, visit the NBA website at: <http://www.nba.gov.au/national-product-list>.

Day-to-day management of plasma-derived and recombinant products are handled by a range of suppliers in accordance with contractual requirements with the NBA.

Day-to-day management arrangements for plasma-derived or recombinant products is defined as the sufficient supply to meet the appropriate clinical demand in accordance with the annual supply plan agreed by all governments. Long-term supply management is undertaken by the NBA. Occasionally products may be under an intensive product management (IPM) process. During IPM, the NBA works with suppliers and clinicians to manage the available supply to best meet demand. Using IPM arrangements is considered a part of day-to-day management if risk of supply failure is assessed as being negligible. Different information contributes to this assessment and can be highly dependent on the type of product, the circumstances, production information and whether there is an alternative product available.

This annex details the following for each alert and activation level:

- ◆ Definition of the alert level, including the triggers that cause activation
- ◆ Potential actions and desired outcomes, including examples of the types of actions that may be taken can be found in Table 1.
- ◆ Communication options during an activation

## 2 Crisis Planning

### 2.1 Activation

Figure 1 – Activation Map is a flowchart of the process used to identify levels of activation. Refer to Section 4, Figure 5 Activation Map of the NBSCP Master Document for further details.

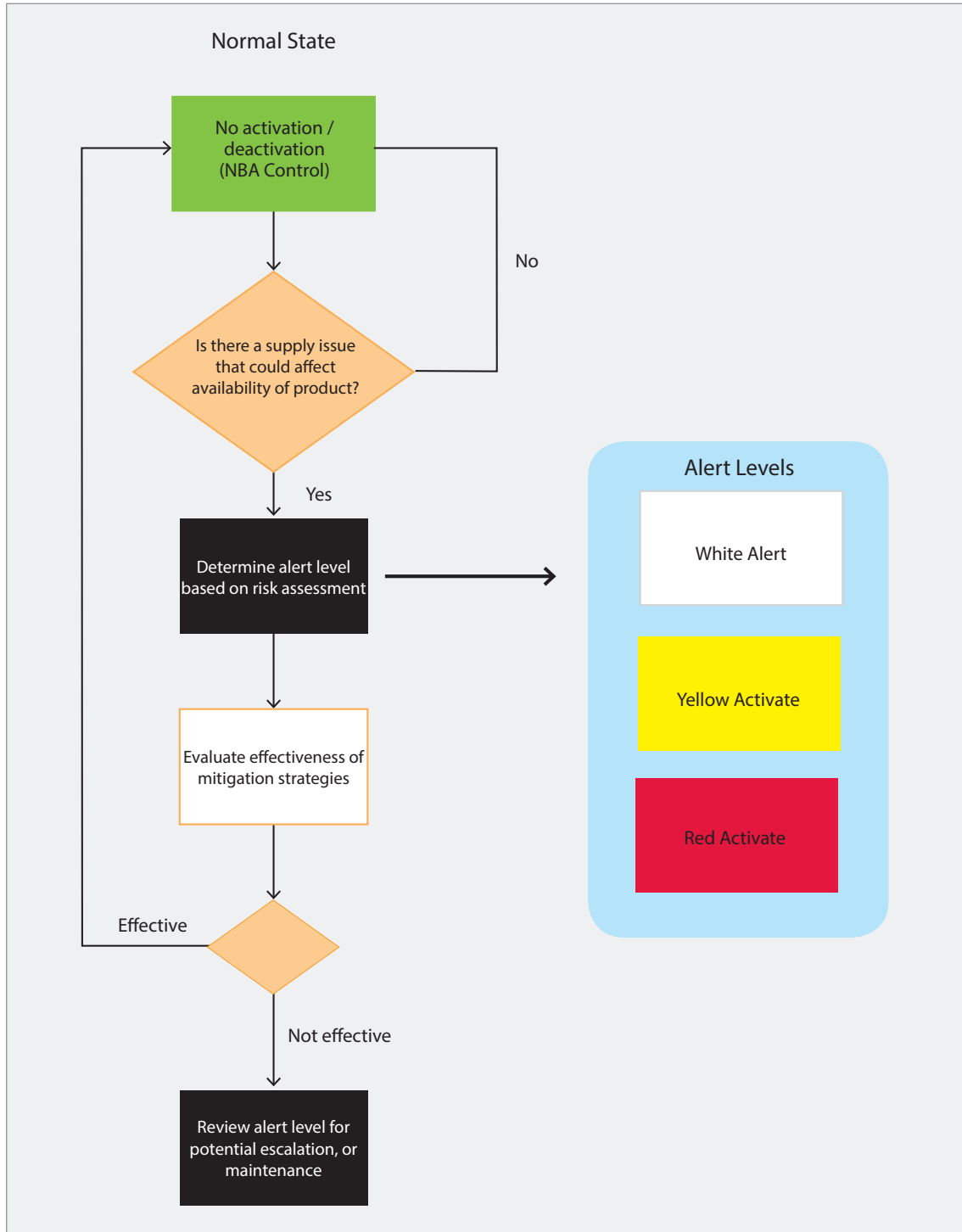


Figure 1 – Activation Map

## 2.2 Risk assessment and trigger points

Section 4 of the NBSCP Master Document provides a guide to how the risk is rated and assessed and then the alert level to be applied.

The operational phase trigger points in this annex are outlined specifically in Table 1 and Figure 2 of this document, which indicates the critical levels or activation points within the NBSCP.

The criteria for activation and deactivation may be varied by the NBA or OHP based on other information such as product availability for different patient priorities, or knowledge of future continued or anticipated supply chain shortages of product. This would override the 'stock level trigger point' listed in Table 1 and Figure 2 of this document.

In preparing the NBSCP and supplementary annexes, the approach for the management of products was reviewed against the National Services and Standards with the Australian Red Cross Blood Service (Blood Service) and approaches to emergency blood management planning.

## 2.3 Alert levels

The alert and activation levels defined under the NBSCP framework are as follows:

- 🔴 WHITE Alert
- 🟡 YELLOW Activate
- 🔴 RED Activate
- 🟢 GREEN De-Activate

To meet clinical demand for plasma and recombinant products in the event of a crisis, there is an escalation and de-escalation process to guide the blood sector's response. Table 1 Alert Levels – Definition, Potential Actions and Desired Outcomes provides a definition of each NBSCP alert level, a list of associated actions in response to that alert level and identifies the desired outcome sought.

Potential actions are a suite of activities that may be used depending on the circumstances. Actions undertaken in the activation of the NBSCP are not limited to the identified points below.

Responsibility for controlling the response to a crisis under each phase rests either, with the NBA under OHP arrangements, or with the AHPPC, depending on the seriousness of the incident. The OHP may make a decision to assume control of the incident at any point in time, should the OHP consider the need to apply national oversight to protect public health.

Figure 2 – Plasma and Recombinant product Activation Map is a flowchart of triggers used to identify levels of activation during product shortages. Note: Product shortages may or may not occur at the same time as other blood component shortages.

Table 1: Alert Levels – Definition, Potential Actions and Desired Outcomes

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
<b>WHITE ALERT</b>	<p>The NBA General Manager will determine that a national shortage of a plasma or recombinant product has occurred, or is likely to occur</p> <p><b>and/or</b></p> <p>A shortage is recorded from inventory (sourced through BloodNet), the National Inventory Template and commercial supplier inventory reports indicating that current stock levels will not meet future demand (this may be opinion based by the NBA)</p> <p><b>and/or</b></p> <p>The product in stock or work in progress may be at a known or potentially high risk of failure.</p>	<ul style="list-style-type: none"> <li>▪ If impact is plasma focused, benefit may be from: <ul style="list-style-type: none"> <li>» Blood Service calls for more donors</li> <li>» Increase the number of donations collected into packs suitable for production</li> <li>» Extend shifts in the processing department to increase production</li> <li>» Extend the opening times of static clinics for (the collection of donations)</li> <li>» Extend opening times of mobile sessions (for the collection of whole blood donations).</li> </ul> </li> <li>▪ Health service organisations confirm their inventory levels when requested, to the NBA and minimise the use of product where appropriate, and without adversely impacting on patient outcomes</li> <li>▪ Access commercial suppliers contractual arrangements including Intensive Product Management (IPM) and reserves including (but not limited to) In Country Reserves (ICR), minimum product inventory (MPI) and CSL Behring National Reserve (NR).</li> <li>▪ Alert health service organisations to focus on optimising product inventory management. For example, emphasise the importance that hospitals/laboratories keep track of the status of the orders so that the same order is not requested twice for the same patient at times of change of shift etc.</li> <li>▪ Increase monitoring and movement of the national product stock ensuring wastage is kept to a minimum.</li> </ul>	<p>To increase collection and production to build stock levels while meeting demand for emergency services and other clinical requirements.</p>

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
<b>YELLOW ACTIVATE</b>	<p>Actions in WHITE ALERT phase have not rectified the situation allowing for the plan to be deactivated</p> <p><b>and/or</b></p> <p>Inventory (sourced through BloodNet), National Inventory Template and commercial supplier inventory reports indicating current stock levels will continue to not meet future demand (this may be opinion based by the NBA)</p> <p><b>and/or</b></p> <p>The product in stock or work in progress may be at a known or potentially high risk of 'failure'.</p>	<ul style="list-style-type: none"> <li>▪ If not already utilised under IPM, access remaining commercial supplier reserves/measures including committed global stock (CGS), contractual Australian preferred customer status and alternative product supply requirements.</li> <li>▪ Decrease non-urgent product use in consultation with Jurisdictions / AHPPC as applicable.</li> <li>▪ Recommendations from the AHPPC / NBA are put in place at either jurisdictional or national level so that available products can be redirected to meet life threatening and/or other agreed priorities based on appropriate clinical assessment.</li> <li>▪ Prioritise surgery to minimise affected product use in consultation with Jurisdictions/AHPPC and to explore clinical options for reducing affected product use.</li> <li>▪ NBA / OHP will inform Jurisdictions that affected products should be issued with an intention of reducing use in non-urgent situations.</li> <li>▪ At this point all requests for affected products from the hospital should be authorised by a named senior clinician within the health service organisation.</li> <li>▪ Work with commercial suppliers and TGA to import alternative products</li> <li>▪ Extend the shelf life of affected products if the TGA approves.</li> </ul>	<p>Decrease non-urgent product use so that available products can be redirected to meet life threatening and/or other agreed priorities based on appropriate clinical assessment.</p> <p>Consider prioritising surgery to minimise product if applicable.</p>

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
<p><b>RED ACTIVATE</b></p>	<p>Actions from WHITE ALERT and YELLOW ACTIVATE have not rectified the situation; <b>and/or</b></p> <p>Inventory (sourced through BloodNet), National Inventory Template and commercial supplier inventory reports indicates stocking levels will continue to not meet future demand (this may be opinion based by the NBA)</p> <p><b>and/or</b></p> <p>The product in stock or work in progress may be at a known or potentially high risk of 'failure'.</p>	<ul style="list-style-type: none"> <li>▪ Actions as described for Yellow Alert.</li> <li>▪ Close the NBSCP Operations Centre and NBA transition to a support role under the Commonwealth Office of Health Protection and AHPPC incident management arrangements.</li> <li>▪ Implement AHPPC national policies for prioritisation of affected product use.</li> <li>▪ Affected product use triaged for life threatening and other clinical AHPPC recommendations and actions dependant on the situation.</li> <li>▪ Restrictions imposed on affected product use in elective surgery.</li> <li>▪ NBA support and replicate OHP communication and messaging using NBSCP communication arrangements.</li> <li>▪ At this point all requests for affected products in the hospital are to be made via a named senior Clinician or treating physician. This will facilitate communication between the requestor and OHP / NBA / Blood Service or other relative medical advisory body.</li> <li>▪ At this point, the NBA or if a Health NIR is in place, the OHP, will take responsibility for facilitating the discussion and request for affected products between the treating clinician and the relevant product supplier Blood Service or relevant medical advisory body such as AHDCO. This will ensure that hospitals/laboratories can keep track of the status of the orders so that the same order is not requested twice for the same patient at times of change of shift etc.</li> <li>▪ Hospitals will be required to track closely the fate of each unit/vial/ bottle of affected products delivered to them. Information may be requested on each unit/vial/bottle of affected products at regular intervals so that, if the product is not used, it can be retrieved and delivered to an alternative location for use. This will ensure that wastage of affected product is kept to a minimum and the most urgent cases are supported.</li> </ul>	<p>Affected product use in elective surgery is restricted and procedures are compliant with jurisdictional emergency arrangements.</p> <p>If chronic, national consistency in triage of medical and surgical blood use.</p>

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
<b>DE-ACTIVATE</b>	Affected products nationally have returned to a pre-WHITE alert level that is acceptable and the incident that led to the shortage has been resolved to the satisfaction of the NBA	<ul style="list-style-type: none"> <li>NBSCP improved for possible future crises and if possible new measures as recommended by AHPPC are introduced to decrease the likelihood or impact of a similar situation.</li> </ul>	Evaluation of the activation for areas of improvement and possible adoption of any new measures as recommended by AHPPC.



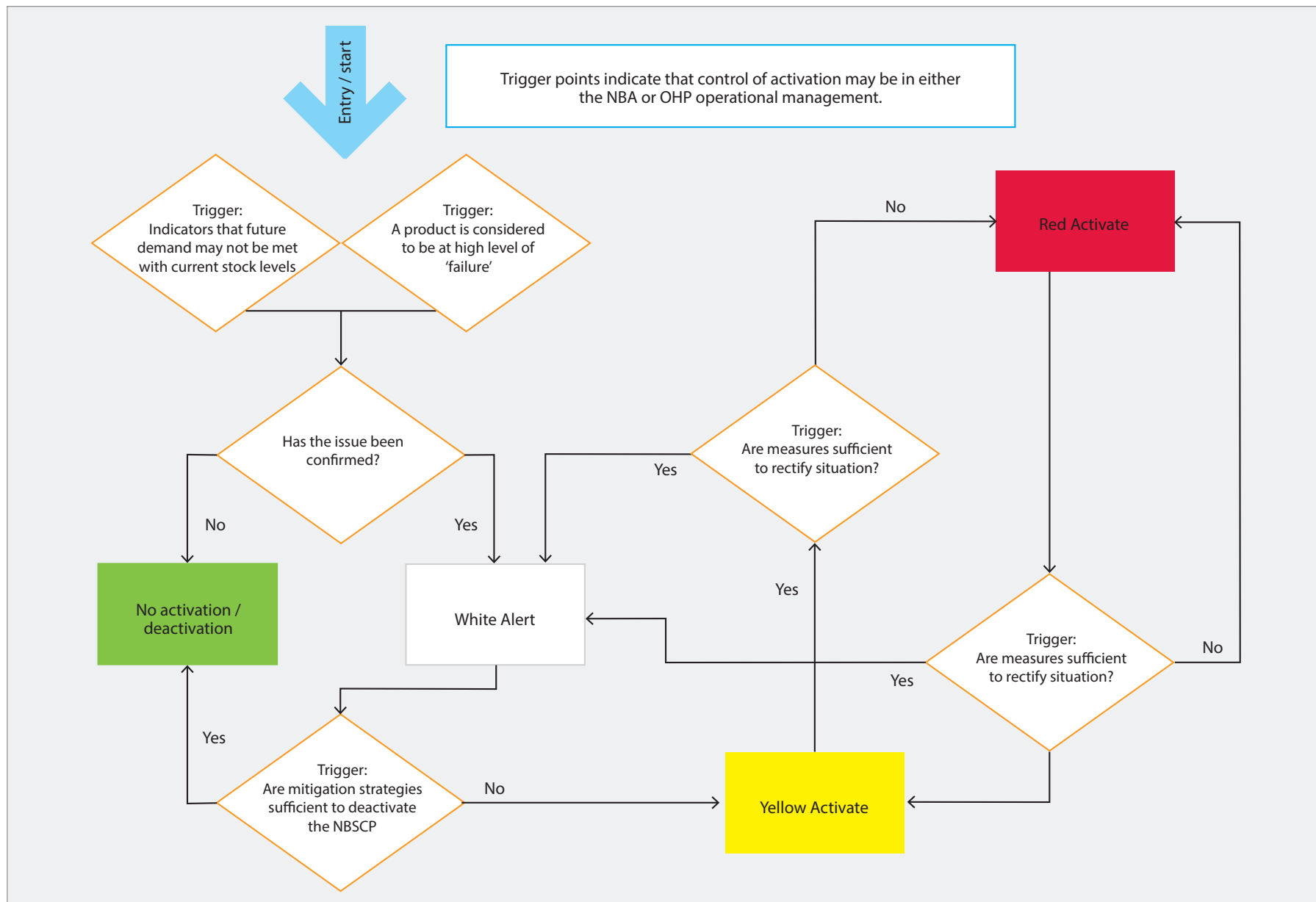


Figure 2 – Plasma and Recombinant Product Activation Map

## 3 Response roles and responsibilities

Section 6, Table 7 of the NBSCP Maser document outlines the roles and responsibilities of the key stakeholders involved in the management of activation of the NBSCP during each operational phase. It should be noted that these are high level descriptions of responsibilities and other roles may be required depending of the nature of the incident.

Directions from the NBA / OHP on levels of action and responsibilities will further guide all organisations / bodies involved in the NBSCP. The NBA will advise of the coordination and activation of the NBA incident room or the National Incident Room for OHP and other stakeholder's involvement.

If the contingency is escalated beyond White Alert, the actions required under other activation statuses include those described in previous levels, unless superseded by a new action.

More detailed information regarding roles and responsibilities is provided in the NBSCP master document.

## 4 Clinical advice and input during activation

Given the diverse range of products and associated clinical indications for this product group, the document does not specify *Clinical Guidance for Patient Categorisation Priorities* as in other NBSCP Annexes.

The implementation of triage measures that involve a restriction on clinical practice will only occur following clinical advice appropriate to the measure/s being contemplated. The key sources of this advice will include the relevant peak clinical bodies and Jurisdictional clinical experts at the time of activation.

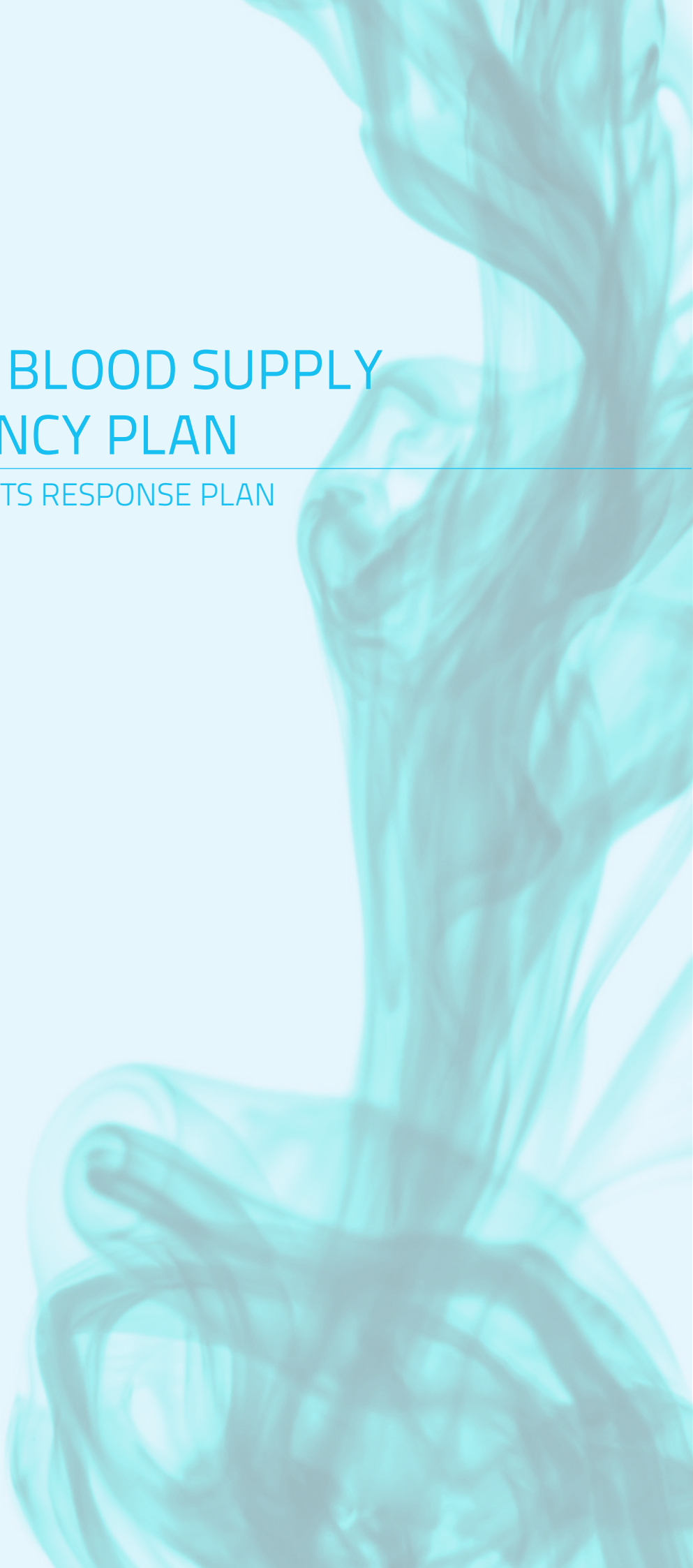
Any decision to implement a clinical restriction on the use of a plasma or recombinant product will only be made following consultation with all members of the JBC and/or Commonwealth Department of Health as appropriate.



# NATIONAL BLOOD SUPPLY CONTINGENCY PLAN

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ANNEX C: PLATELETS RESPONSE PLAN  
July 2019



## Document Properties

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December 2013	1.0	Initial approved document	NBA
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# 1 Introduction

The overarching document in this plan is the NBSCP master document which establishes the context in which contingency planning is addressed, with this document being an annex which deals specifically with red cell product shortages. It also provides guidance for the escalation of contingency management from NBSCP arrangements to the Australian Government Department of Health: Office of Health Protection (OHP) where relevant.

Governance of health protection in Australia is managed through a multiple set of state/ Commonwealth relationships.

The purpose of this annex is to outline the contingency planning response to a threat to the supply of platelets, including the following product categories:

- ◆ Whole Blood Platelet Pool – Leucodepleted
- ◆ Apheresis Platelet – Leucodepleted
- ◆ Paediatric Apheresis Platelet – Leucodepleted (Set of 4)
- ◆ For a complete list of products supplied under the National Blood Agreement, visit the NBA website at: <http://www.blood.gov.au/national-product-list>

The use of platelets is indicated for the prevention and treatment of haemorrhaging in patients with thrombocytopenia or platelet function defects. The platelet count is the primary trigger for the use of platelets in a patient, with clinical risk factors for bleeding and the extent of bleeding also influencing the decision to transfuse.

The day-to-day supply management of platelets is the responsibility of the Australian Red Cross Blood Service (Blood Service) in accordance with the requirements under the Deed of Agreement with the NBA. This includes a responsibility to manage acute shortage in a jurisdiction. If an acute shortage occurs, the Blood Service would be expected to manage the process without the activation of the NBSCP.

Platelets have a short shelf-life (5 days, further reduced by pre-release bacterial testing) from collection – hence an interruption to production or distribution or a sudden, large unexpected increase in use will have a rapid impact on supply. Similarly their shorter shelf life makes redistribution between centres and between jurisdictions within a useful timeframe more challenging than for other blood products.

This annex details the following for each alert and activation level:

- ◆ Definition of the alert level, including the triggers that cause activation;
- ◆ Potential actions and desired outcomes, including examples of the types of actions that may be taken can be found in Table 1; and
- ◆ Communication options during an activation.

## 2 Crisis Planning

### 2.1 Activation

Figure 1 – Activation Map is a flowchart of the process used to identify levels of activation. Refer to Section 4, Figure 5 Activation Map of the NBSCP Master Document for further details.

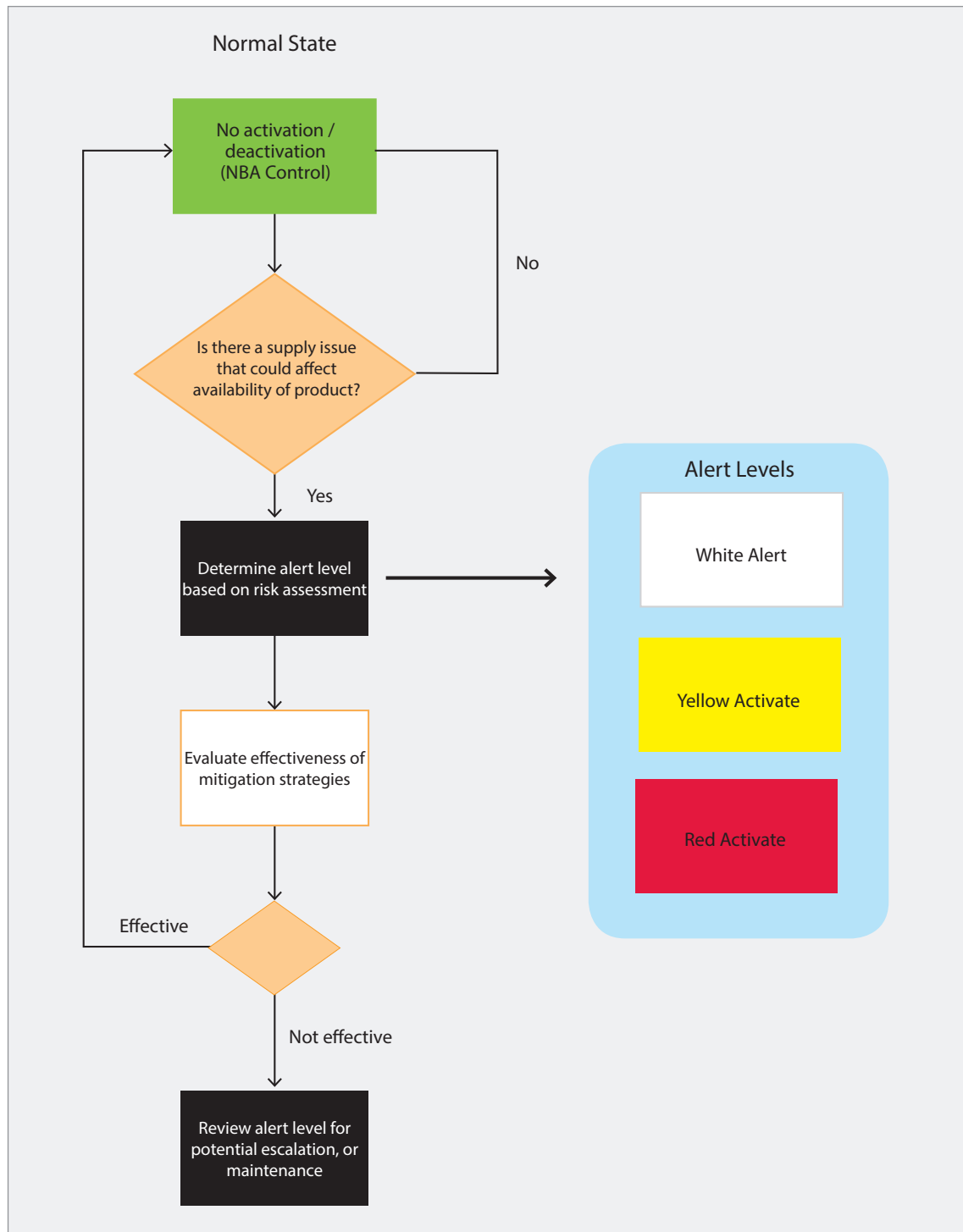


Figure 1 – Activation Map



## 2.2 Risk assessment and trigger points

Section 4 of the NBSCP Master Document provides a guide to how the risk is rated and assessed and then the alert level to be applied.

The operational phase trigger points in this annex are outlined specifically in Table 1 and Figure 2 of this document, which indicates the critical levels or activation points within the NBSCP.

The criteria for activation and deactivation may be varied by the NBA or OHP based on other information such as product availability for different patient priorities, or knowledge of future continued or anticipated supply chain shortages of product. This would override the 'stock level trigger point' listed in Table 1 and Figure 2 of this document.

In preparing the NBSCP and supplementary annexes, the approach for the management of products was reviewed against the National Service Requirements and Standards with the Blood Service and approaches to emergency blood management planning.

## 2.3 Alert levels

The alert and activation levels defined under the NBSCP framework are as follows:

- ◆ WHITE Alert
- ◆ YELLOW Activate
- ◆ RED Activate
- ◆ GREEN De-Activate

To meet clinical demand for platelets in the event of a crisis, there is an escalation and de-escalation process to guide the blood sector's response. Table 1 Alert Levels – Definition, Potential Actions and Desired Outcomes provides a definition of each NBSCP alert level, a list of associated actions in response to that alert level and identifies the desired outcome sought.

Potential actions are a suite of activities that may be used depending on the circumstances. Actions undertaken in the activation of the NBSCP are not limited to the identified points below.

Responsibility for controlling the response to a crisis under each phase rests either, with the NBA under OHP arrangements, or with the AHPPC, depending on the seriousness of the incident. The OHP may make a decision to assume control of the incident at any point in time, should the OHP consider the need to apply national oversight to protect public health.

Figure 2 – Platelet Activation Map is a flowchart of triggers used to identify levels of activation during product shortages.

Note: Product shortages may or may not occur at the same time as other blood component shortages.

Table 1. Alert Levels – Definition, Potential Actions and Desired Outcomes

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
<b>WHITE ALERT</b>	<p>The NBA Chief Executive will determine that a national shortage of platelets has occurred, or is likely to occur</p> <p><b>and/or</b></p> <p>A shortage is recorded from the AHP inventory (sourced through BloodNet) and National Inventory Template indicating &lt; 0.5 days stock nationally for 2 consecutive days</p> <p><b>and/or</b></p> <p>The supply of platelets to jurisdictions has been compromised to a level requiring an ALERT response. This would most likely be through the inability to deliver treatment as outlined in Blood Access Priority 3 Treatment<sup>1</sup>.</p>	<ul style="list-style-type: none"> <li>▪ Blood Service calls for more donors</li> <li>▪ Increase the number of whole blood donations collected into packs suitable for platelet production</li> <li>▪ Extend shifts in the processing department to increase production of platelets</li> <li>▪ Extend the opening times of static clinics for (the collection of platelet donations)</li> <li>▪ Extend opening times of mobile sessions (for the collection of whole blood donations).</li> <li>▪ AHPs confirm their inventory levels when requested, to the NBA and minimise the use of platelets where appropriate, and without adversely impacting on patient outcomes</li> <li>▪ Alert AHP to focus on optimising platelet inventory management. For example, emphasise the importance that hospitals/ laboratories keep track of the status of the orders so that the same order is not requested twice for the same patient at times of change of shift etc</li> <li>▪ Increase monitoring and movement of the national platelet stock ensuring units of platelets are distributed according to age and group mix, to ensure wastage is kept to a minimum.</li> </ul>	<p>To increase the collection and production to build stock levels while meeting demand for emergency services and other clinical requirements.</p>

<sup>1</sup> Categorisation of patients extracted from 'Proposed generic actions for hospitals at each phase' A Plan For NHS Blood and Transplant and Hospitals to Address Platelet Shortage  
[http://hospital.blood.co.uk/library/pdf/nbtc\\_platelet\\_shortages\\_plan\\_09\\_10.pdf](http://hospital.blood.co.uk/library/pdf/nbtc_platelet_shortages_plan_09_10.pdf)

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
<b>YELLOW ACTIVATE</b>	<p>Actions in WHITE ALERT phase have not rectified the situation allowing for the plan to be deactivated</p> <p><b>and/or</b></p> <p>The AHP inventory (sourced through BloodNet) and National Inventory Template continues to indicate stocking levels will continue at &lt; 0.5 days of stock nationally</p> <p><b>and/or</b></p> <p>NBA estimates the current and anticipated supply of platelets to jurisdictions has been compromised to a level requiring an ACTIVATE response. This would most likely be through the inability to deliver treatment as outlined in Blood Access Priority 2 Treatment.</p>	<ul style="list-style-type: none"> <li>▪ Decrease non-urgent product use in consultation with NBA / AHPPC as applicable.</li> <li>▪ Recommendations from the OHP / NBA are put in place at either jurisdictional or national level so that available products can be redirected to meet life threatening and/or other agreed priorities based on appropriate clinical assessment.</li> <li>▪ Prioritise surgery to minimise platelet use in consultation with OHP to explore clinical options for reducing platelet use.</li> <li>▪ NBA / OHP will inform Jurisdictions that units of platelets should be issued for use in accordance with identified categories of patient as defined in the Blood Access Priority Levels 1-3. If a reduction in usage is required at this stage, restrictions to supply will be limited to Blood Access Priority 1 and 2 (including HLA/HPA matched platelets). At this point all requests for units of platelets from the hospital should be authorised by a named senior clinician within the AHP.</li> <li>▪ The interchangeable use of apheresis and pooled platelets (except for HLA/HPA matched platelets). Requests for long dated platelet units is restricted.</li> <li>▪ It is important that hospitals/laboratories keep track of the status of the orders so that the same order is not requested twice for the same patient at times of change of shift etc.</li> <li>▪ Accepting platelets of a different ABO group (in line with adult and paediatric guidelines).</li> <li>▪ Accepting leucodepleted platelets instead of CMV negative / non-reactive platelets where clinically appropriate.</li> <li>▪ Accepting RhD positive platelet units where RhD negative platelets are not available and administering anti-D where applicable.</li> <li>▪ Extend the shelf life of platelets to seven days if the TGA approves.</li> <li>▪ Consider selective variation of bacterial testing requirements to reduce processing time following consultation with the TGA.</li> </ul>	<p>Decrease non-urgent product use so that available products can be redirected to meet life threatening and/or other agreed priorities based on appropriate clinical assessment.</p> <p>Consider prioritising surgery to minimise blood use.</p> <p>If chronic shortage, consider triage of medical indications for transfusion.</p>

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
<b>RED ACTIVATE</b>	<p>Actions from WHITE ALERT and YELLOW ACTIVATE have not rectified the situation; <b>and/or</b></p> <p>The AHP inventory (sourced through BloodNet) and National Inventory Template indicates stocking levels will continue at &lt; 0.5 days of stock nationally and may deteriorate further <b>and/or</b></p> <p>The supply of platelets to jurisdictions has been compromised to a level requiring an ACTIVATE response. This would most likely be through the inability to deliver treatment as outlined in Blood Access Priority 1 Treatment.</p>	<ul style="list-style-type: none"> <li>▪ Actions as described for Yellow Alert.</li> <li>▪ Close the NBSCP Operations Centre and NBA transition to a support role under OHP incident management arrangements.</li> <li>▪ Implement OHP national policies for prioritisation of platelet use using Platelet Activation Map.</li> <li>▪ Platelet use triaged for life threatening and other clinical OHP recommendations and actions dependant on the situation.</li> <li>▪ Restrictions imposed on platelet use in elective surgery.</li> <li>▪ NBA support and replicate OHP communication and messaging using NBSCP communication arrangements.</li> <li>▪ At this point all requests for units of platelets in the hospital are to be made via a named senior Clinician, such as a Consultant Haematologist. This will facilitate communication between the requestor and OHP / NBA / Blood Service. At this point, the NBA or if a National Incident Room is in place, OHP, will take responsibility for facilitating the discussion and request for platelets between the treating clinician and the Blood Service. This will ensure that hospitals/laboratories can keep track of the status of the orders so that the same order is not requested twice for the same patient at times of change of shift etc.</li> <li>▪ Hospitals will be required to track closely the fate of each unit of platelets delivered to them. Information may be requested on each unit of platelets at regular intervals so that, if the unit is not used, it can be retrieved and delivered to an alternative location for use. This will ensure that wastage of platelet units is kept to a minimum and the most urgent cases are supported.</li> </ul>	<p>Platelets use is triaged for life-threatening and other clinically assessed priorities.</p> <p>Platelets use in elective surgery is restricted and procedures are compliant with jurisdictional emergency arrangements.</p> <p>If chronic, implement national consistency in triage of medical and surgical blood use.</p>
<b>DE-ACTIVATE</b>	<p>Platelets nationally have returned to a pre-WHITE alert level that is acceptable and the incident that led to the shortage has been resolved.</p>	<ul style="list-style-type: none"> <li>▪ NBSCP improved for possible future crises and if possible new measures as recommended by OHP are introduced to decrease the likelihood or impact of a similar situation.</li> </ul>	<p>NBSCP improved and if possible new measures as recommended by OHP are introduced.</p>

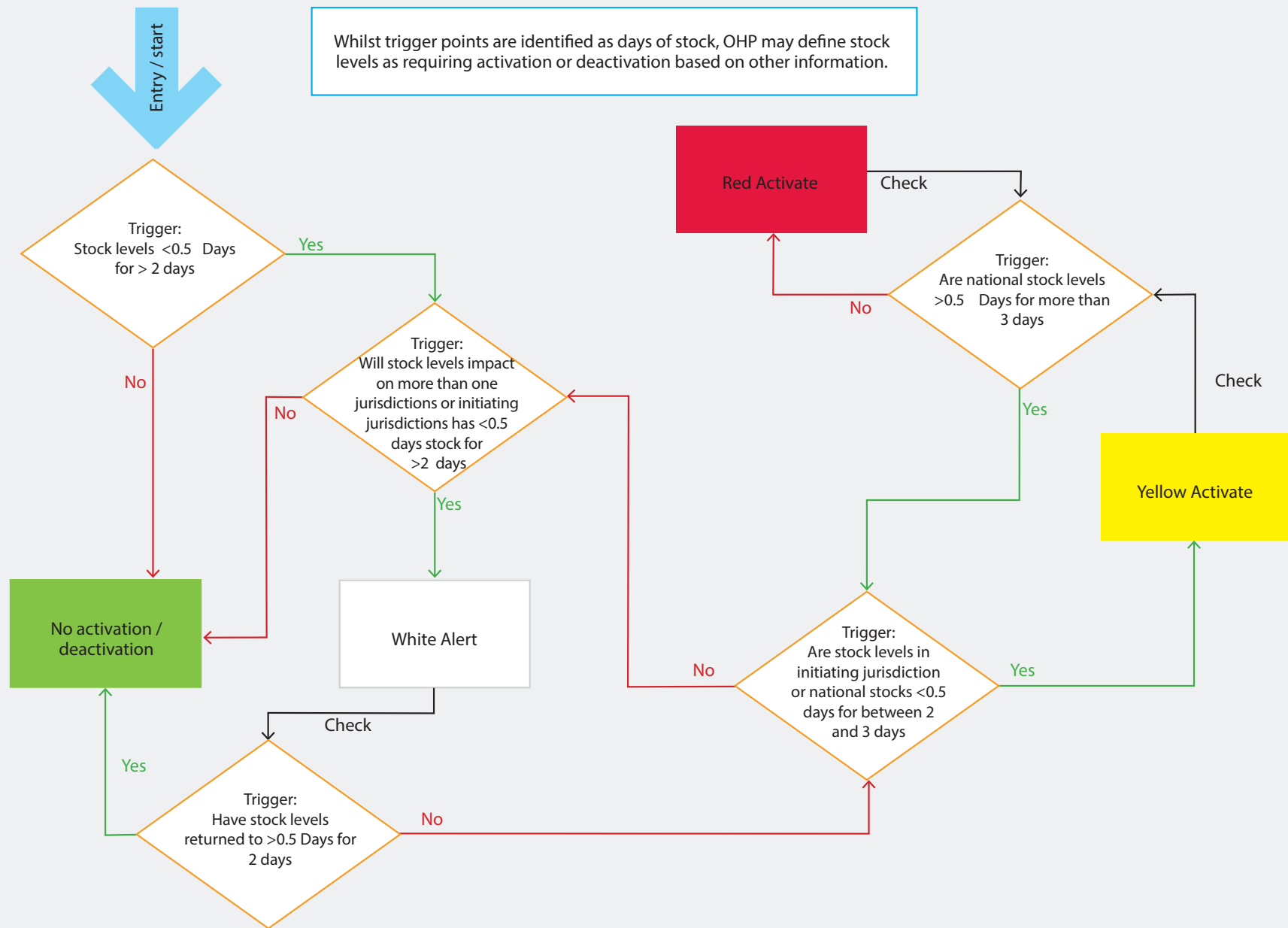


Figure 2 – Platelet Activation Map

## 3 Response roles and responsibilities

Section 6, Table 7 of the NBSCP Master document outlines the roles and responsibilities of the key stakeholders involved in the management of activation of the NBSCP during each operational phase. It should be noted that these are high level descriptions of responsibilities and other roles may be required depending of the nature of the incident.

Directions from the NBA / OHP on levels of action and responsibilities will further guide all organisations / bodies involved in the NBSCP. The NBA will advise of the coordination and activation of the NBA incident room or the National Incident Room for OHP and other stakeholder's involvement.

If the contingency is escalated beyond White Alert, the actions required under other activation statuses include those described in previous levels, unless superseded by a new action.

More detailed information regarding roles and responsibilities is provided in the NBSCP master document.

## 4 Clinical advice and input during activation

Section 5. Clinical Guidance for Patient Categorisation Priorities provides a guide to the potential clinical approach and treatment that may be used during reduced availability of platelets.

The implementation of triage measures that involve a restriction on clinical practice will only occur following clinical advice appropriate to the measure/s being contemplated. The key sources of this advice include the Blood Service Transfusion Advisory Service, NBA and OHP Advisory Clinicians and Jurisdictional clinical experts.

Any decision to implement a clinical restriction on the use of platelets will only be made following consultation with all members of the JBC and/or OHP as appropriate.

# 5 Guidance for prioritisation of platelet transfusions

During periods of platelet supply constraints, it may be necessary to prioritise the supply of platelet transfusions to patients with the greatest clinical need and to delay the supply of platelets to other patients pending stock availability (such as when infectious disease screening is completed). In this scenario, all clinically appropriate requests for platelet supply are able to be met, albeit the supply for some patients may be briefly delayed. Prioritisation of platelet supply in this scenario is undertaken by medical staff at the Blood Service.

However, where the supply constraint is more severe, it may be necessary to restrict the supply of platelets to particular patient categories. In these situations, the NBSCP will be activated and there will be communication between stakeholders, including the NBA, Jurisdictional Blood Committee (JBC), OHP and the Blood Service. Prescribing clinicians will be informed about the necessity to reduce the demands for platelets.

This document provides guidance for the prioritisation of requests for platelets during periods when platelet supply is constrained. In descending order of urgency, patients can be classified in Platelet Priority 1–3, with patients in Platelet Priority 1 having the highest priority for transfusion.

## 5.1 Platelet Priority 1

During periods when platelet supply is constrained, the following patients have the highest priority for platelet transfusion and are classified as “Platelet Priority 1”.

Patients with clinically significant bleeding<sup>2</sup>

- ◆ Patients with clinically significant bleeding in whom thrombocytopenia or platelet dysfunction is thought to be a major contributory factor.
- ◆ Patients with critical bleeding requiring massive blood transfusion.
- ◆ Patients with clinically significant bleeding in the presence of acute Disseminated Intravascular Coagulopathy (DIC) and a platelet count  $<50 \times 10^9/L$ .
- ◆ Patients requiring platelet support for immediate or urgent surgery<sup>3</sup>
- ◆ Patients who require immediate or urgent surgery with a platelet count  $<50 \times 10^9/L$  or with functional platelet defects.
- ◆ Patients who require immediate or urgent neurosurgery, intraocular or neuroaxial surgery with a platelet count  $<100 \times 10^9/L$  or with functional platelet defects.

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2 Webert Bleeding Severity Measurement Scale defines clinically significant bleeding (Grade 2). Webert KE, Arnold DM, Lui Y, Carruthers J, Arnold E, Hedde NM. A new tool to assess bleeding severity in patients with chemotherapy-induced thrombocytopenia (CME). *Transfusion*. 2012 Nov; 52 (11): 2466–2474

3 **Immediate:** Immediate life, limb or organ-saving operation. Resuscitation simultaneous with surgical treatment. Operation within minutes of decision to operate (e.g. laparotomy / thoracotomy for control of haemorrhage).  
**Urgent:** Acute onset or deterioration of conditions that threaten life, limb or organ survival or for relief of distressing symptoms. Operation within hours of decision to operate and normally once resuscitation completed (e.g. laparotomy for perforation). Australia & New Zealand Gastric & Oesophageal Surgery Association Audit Data Dictionary. Version 3. Morbidity Audits Department Research, Audit and Academic Surgery Division; Jan 2013. Urgency of Surgery; p. 43.

## 5.2 Platelet Priority 2

During periods when platelet supply is constrained, the following patients have moderate priority for platelet transfusion and are classified as "Platelet Priority 2".

Patients at high risk of critical bleeding

- Patients with head injury and a platelet count  $<100 \times 10^9/L$ .
- Neonates with Neonatal Alloimmune Thrombocytopenia (NAIT) (platelet count  $<30 \times 10^9/L$ ).
- Neonates with severe thrombocytopenia ( $<25 \times 10^9/L$  for term neonates and  $<30-50 \times 10^9/L$  for preterm neonates).
- Patients requiring prophylactic platelet transfusion for prevention of bleeding
- Patients with severe thrombocytopenia undergoing chemotherapy and haematopoietic stem cell transplantation with a platelet count of  $<10 \times 10^9/L$  in the absence of risk factors and at  $<20 \times 10^9/L$  in the presence of risk factors (e.g. fever).
- Critically ill patients with a platelet count of  $<20 \times 10^9/L$ .

## 5.3 Platelet Priority 3

- During periods when platelet supply is constrained, the following patients have the lowest priority for platelet transfusion and are classified as "Platelet Priority 3".
- Patients requiring platelet support for expedited surgery<sup>4</sup> or invasive procedures
- Patients who require expedited surgery with a platelet count  $<50 \times 10^9/L$  or with functional platelet defects.
- Patients who require expedited neurosurgery, intraocular or neuroaxial surgery with a platelet count  $<100 \times 10^9/L$  or with functional platelet defects.
- Patients requiring expedited invasive procedure or biopsy with a platelet count  $<50 \times 10^9/L$  or with functional platelet defects.

**Patients requiring platelet support for elective surgery<sup>5</sup>**

- Elective surgery in patients who may require platelet support for thrombocytopenia or functional platelet defects.

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4 Expedited: Stable patient requiring early intervention for a condition that is not an immediate threat to life, limb or organ survival. Operation within days of decision to operate). Australia & New Zealand Gastric & Oesophageal Surgery Association Audit Data Dictionary. Version 3. Morbidity Audits Department Research, Audit and Academic Surgery Division; Jan 2013. Urgency of Surgery; p. 43.

5 Elective: Surgical procedure planned or booked in advance of routine admission to hospital. Operation at a time to suit both patient and surgeon. ). Australia & New Zealand Gastric & Oesophageal Surgery Association Audit Data Dictionary. Version 3. Morbidity Audits Department Research, Audit and Academic Surgery Division; Jan 2013. Urgency of Surgery; p.43.



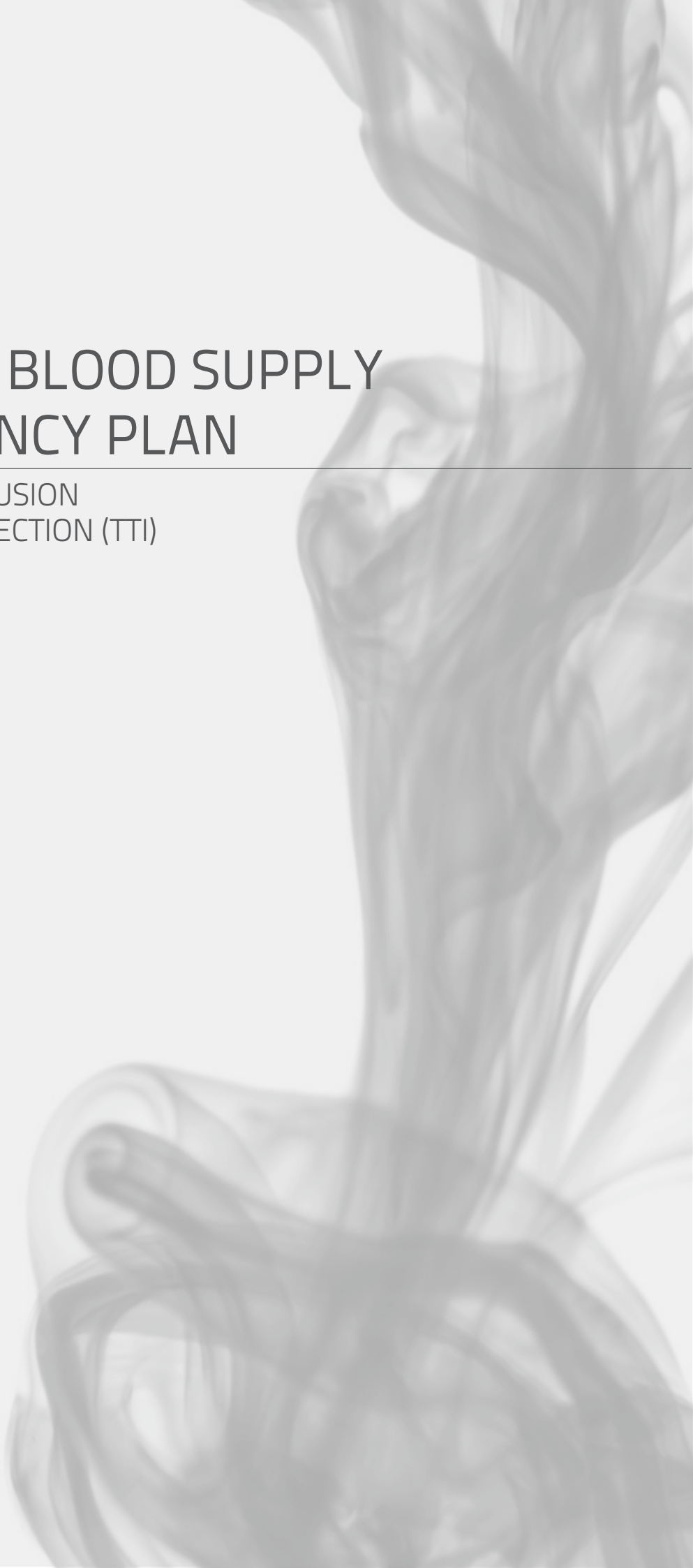


NATIONAL BLOOD AUTHORITY  
AUSTRALIA

# NATIONAL BLOOD SUPPLY CONTINGENCY PLAN

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ANNEX D: TRANSFUSION  
TRANSMITTED INFECTION (TTI)



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# 1 Introduction

The overarching document in this plan is the NBSCP master document which establishes the context in which contingency planning is addressed, with this document being an annex which deals specifically with product shortage as a result of Transfusion Transmitted Infections (TTI). It also provides guidance for the escalation of contingency management from NBSCP arrangements to the Australian Government Department of Health: Office of Health Protection (OHP) where relevant.

Governance of health protection in Australia is managed through a multiple set of state/ Commonwealth relationships.

The purpose of this supporting document is to outline the arrangements the NBA uses for the ongoing monitoring of risks associated with TTIs, including:

- ◆ Public Health Response and a Supply Failure response
  - monitoring the two distinct channels under the Department of Health that indicate actions for either supply failure or public health responses
- ◆ Interactions across the AHPPC framework
  - focus of relevant subcommittees, publications and information that are in place and how the NBA reviews and shares available information
- ◆ Issues that eventuate and can be considered on the emergence of a TTI risk
- ◆ Critical methods on how TTI risks are monitored
  - detailed approach to monitoring for transfusion transmitted infection
- ◆ Roles and responsibilities

A TTI within the Australian blood supply may cause any number of supply issues in the availability blood and blood products. This may be the result of any single or multiple infections becoming evident within the donation or transfusion process. A widespread outbreak of TTI can affect the availability of donors and the number of donor deferrals, which in turn can create a product shortage.

## 2 Supply Failure Response

An incident that affects blood donations would be considered a supply failure response. An incident of TTI will be addressed by the applicable NBSCP annex or annexes depending on those blood product(s) affected by a TTI.

To ensure a proactive approach to TTI incidents, the NBA and the Australian Red Cross Blood Service (Blood Service) actively monitor world and Australian events for issues that may contribute to a TTI. This approach to horizon scanning is shown in Figure 1, which indicates the formal interaction across the Department of Health framework of information, meetings, and publications covering many aspects of potential TTI issues.

In addition, the NBA has formal channels in place for monitoring TTI via the Blood Service and associated contracted suppliers. The Blood Service has an extensive surveillance programme for transfusion transmissible infections<sup>1</sup> which may impact on the blood supply.

This support document for a TTI is an additional source of detail focusing on the origins of information available at the time of an incident rather than an action plan that would be put in place during a specific product shortage or impact to the Australian blood supply.

A range of documents are used to inform the NBA's approach to transfusion transmitted infection. These documents include:

- ◆ Review of Risk Management in the Blood Sector Outcomes
- ◆ Health Sector Groups Trusted Information Sharing Network (TISN)
- ◆ Blood Service Annual Transfusion Transmission Infection (TTI) Surveillance Report

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<sup>1</sup> Australian Red Cross Blood Service; Transfusion transmissible infections in Australia 2012, Surveillance Report.

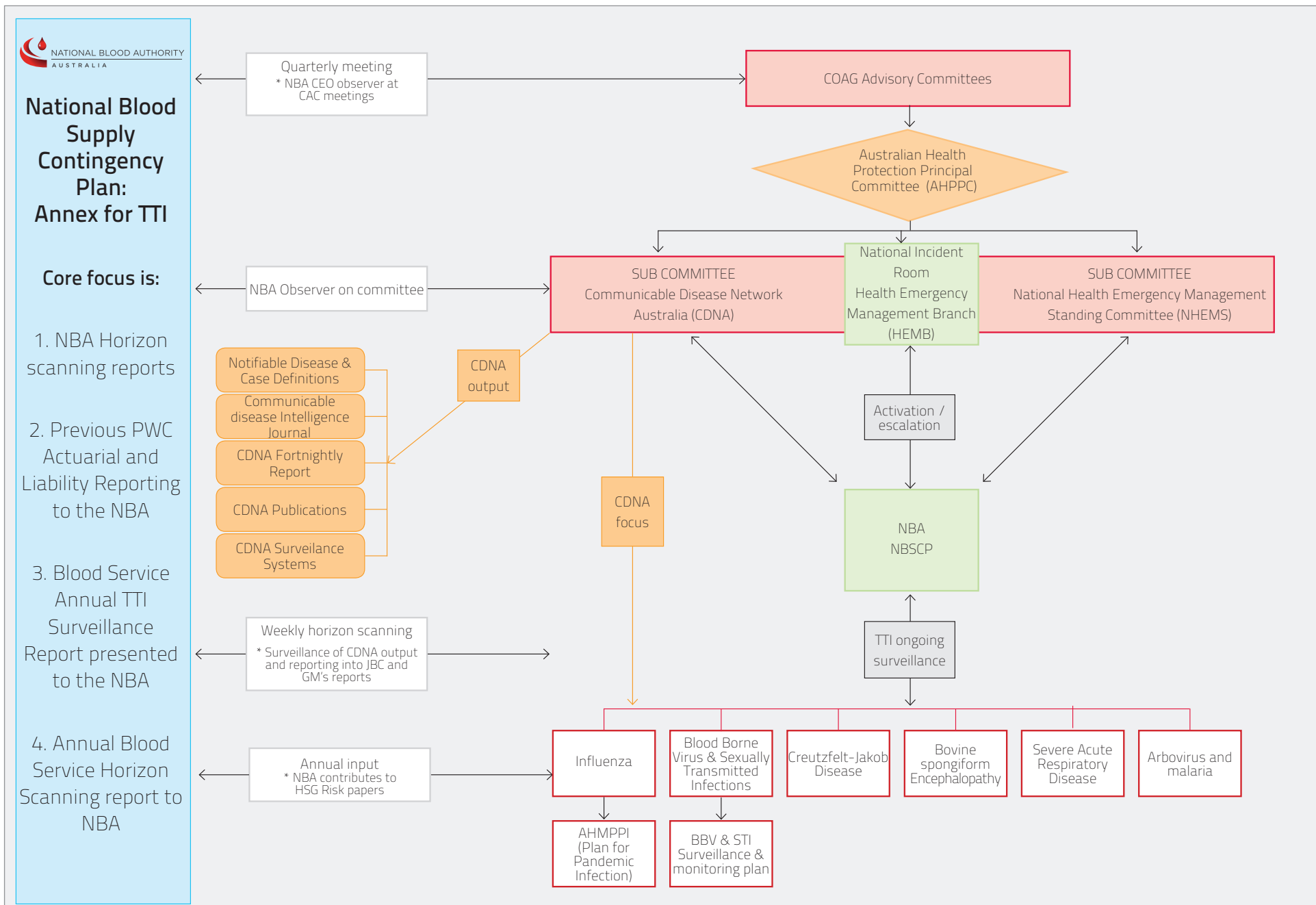


Figure 1 – Overview of the Australian Health Protection Principal Committee (AHPPC) framework and interdependencies

# 3 How TTI Risks Are Managed

## 3.1 TTI Occurrence

The risk or occurrence of TTI could potentially impose limitations on supply because of the limitations it may place on the availability of suitable donors or safe blood. There are a range of scenarios where an incident of TTI affecting the Australian blood supply could occur. These include the following

- ◆ Failure to positively identify the presence of a known and relevant infection that is presently part of the pre-screening and testing regime within the Australian blood collection process.
- ◆ Failure to positively identify the presence of a known and relevant infection that is not presently part of the pre-screening and testing regime within the Australian blood collection process but is part of other pre-screening and testing regimes of another country, such as the U.S. FDA screening and testing process.
- ◆ The presence of a relevant infection that is not part of the pre-screening and testing regime within Australian or other countries pre-screening and testing regime.

Early interception of any contaminated blood products and avoidance of the transmission of contaminants through the blood supply (where possible) is managed through the regulatory framework and quality assurance and/or testing processes used by Blood Service and is not addressed via this support document.

As an example, contaminated platelets; where a small number of units are affected, the recall of those units from a limited number of health facilities and limited look back investigation fits within the established parameters of the required risk mitigation framework for dealing with blood and blood products.

The regulatory framework is enforced and overseen by the Therapeutic Goods Administration (TGA) and implemented by the Blood Service as covered in the Therapeutic Goods Order (TGO) 88. There are two parts to this framework:

- ◆ Initial screening of blood donors is done by questionnaire and interview — designed to mitigate the risk of a Transfusion-Transmitted Infection (TTI) in a donation.
- ◆ Mandatory testing of donated blood for TTI's as listed in TGO 88<sup>2</sup>.

Table 1 outlines the level of risk associated with a TTI in Australia from a transfusion-transmissible infection calculated on Blood Service data.

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<sup>2</sup> <https://www.comlaw.gov.au/Details/F2013L00854/Explanatory%20Statement/Text>



## 3.2 Horizon Scanning

The major concern in recent years for the blood sector has been the ability to detect and then adequately deal with contamination by a previously unknown virus or from a bacterial contamination in a blood product or from consumable products involved in the donation that emerge post donation.

The NBA and Blood Service conduct horizon scanning for a variety of potential impacts that may cause a TTI such as, but not limited to:

- ◆ Arbovirus and malaria
- ◆ Pandemic Influenza
- ◆ Bovine spongiform encephalopathy (BSE)
- ◆ Variant Creutzfeldt – Jakob disease (vCJD)
- ◆ Severe acute respiratory disease (SARS)
- ◆ Blood borne virus and sexually transmitted infections

Although the residual risk of TTI is very low, this support document has been developed to provide a framework to guide the management of a potential or real incident of contamination within the Australian blood supply. The guidance may operate prior to formal activation of the NBSCP, which may only be activated in the event that a TTI or the public health response to an incident (eg recall of a large proportion of all products) impacting on the ability of the Blood Service to maintain a normal supply level for all fresh components.

## 3.3 Testing Regime

The present testing regime for blood donations by the Blood Service is by testing all donations for 5 transfusion-transmissible infectious diseases, using the following screening tests:

Mandated donor blood screening serology (antibodies):

- a. Hepatitis B surface antigen
- b. Antibody to HIV 1 and 2
- c. Antibody to Hepatitis C
- d. Antibody to Human T-Lymphotropic Virus (HTLV) 1 and 2
- e. Antibody to Syphilis

Mandated donor blood screening Nucleic Acid Testing (NAT):

- a. Hepatitis B
- b. HIV 1 RNA
- c. Hepatitis C RNA

### 3.4 Residual Risk Estimates for Transfusion-transmissible infections

The Blood Service estimates of residuals risk of transfusion-transmissible viral infection are presented in the table below.

Table 1: Screening tests for transfusion transmissible infections.

Agent and testing standard**	Window period	Estimate of residual risk 'per unit' (a)
HIV (antibody/p24Ag + NAT)	5.9 days	Less than 1 in 1 million(1)
HCV (antibody + NAT)	2.6 days	Less than 1 in 1 million(1)
HBV (HBsAg + NAT)	15.1 days	Approximately 1 in 557,000(1,4)
HTLV 1 & 2 (antibody)	51 days	Less than 1 in 1 million(1)
vCJD* [No testing]		Possible, not yet reported in Australia
Malaria (antibody)	7–14 days	Less than 1 in 1 million(2)

**Notes to Table 1:**

\* vCJD –variant Creutzfeldt-Jakob Disease;

\*\*The testing regime may change over time due to testing improvements or further opportunity to identify risks in the blood supply. For further information or standards, visit: [http://www.transfusion.com.au/fact\\_sheets](http://www.transfusion.com.au/fact_sheets)

(a) The risk estimates for HIV, HTLV and HCV are based on Blood Service data from 1 January 2013 to 31 December 2014. As no HTLV incident donors were recorded for the period, the residual risk estimate was derived from one model only and based on first-time donor risk calculation. The HBV WP and OBI risk function (ref 4) estimated on Blood Service data from 1 January 2014 to 16 April 2015.

(b) The Blood Service residual risk figures are updated annually and the most recent data can be found at the relevant pages of the Blood Service website [http://www.transfusion.com.au/adverse\\_events/risks/estimates](http://www.transfusion.com.au/adverse_events/risks/estimates)

The Blood Service also performs other recommended and desirable tests for TTIs, such as CMV and bacterial testing as well as performing leucodepletion, processes which are outlined in the TMF and audited by TGA. Testing for a range of TTIs is also undertaken by CSL Behring as part of their manufacturing process for plasma-derived products. This includes HIV, HCV, HBV serology and HIV and HCV NAT.

## 4. Horizon scanning

The risk of a TTI in the Australian blood sector is constantly changing as a result of Australia's exposure to the international environment. The NBA and the Blood Service look to prevent an incident of a TTI through a range of operational mechanisms in place such as annual reporting on the risks of a TTI to the Australian blood supply. This approach is further strengthened by the regulatory framework of the TGA.

The Department of Health also has an extensive framework in place, managed by the Office of Health Protection (OHP). This framework has broad coverage of issues that could potentially affect public health such as pandemic influenza or Creutzfeldt-Jakob disease that could affect either the donation process or create a TTI within the Australian blood supply.

Many of these potential risks have specific internet sites containing the latest information on potential risks. See link. <http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-about.htm>

## 5. Response roles and responsibilities

Section 6, Table 7 of the NBSCP Master document outlines the roles and responsibilities of the key stakeholders involved in the management of activation of the NBSCP during each operational phase. It should be noted that these are high level descriptions of responsibilities and other roles may be required depending of the nature of the incident.

Directions from the NBA / OHP on levels of action and responsibilities will further guide all organisations / bodies involved in the NBSCP. The NBA will advise of the coordination and activation of the NBA incident room or the National Incident Room for OHP and other stakeholder's involvement.

If the contingency is escalated beyond White Alert, the actions required under other activation statuses include those described in previous levels, unless superseded by a new action.

More detailed information regarding roles and responsibilities is provided in the NBSCP Master document.

