

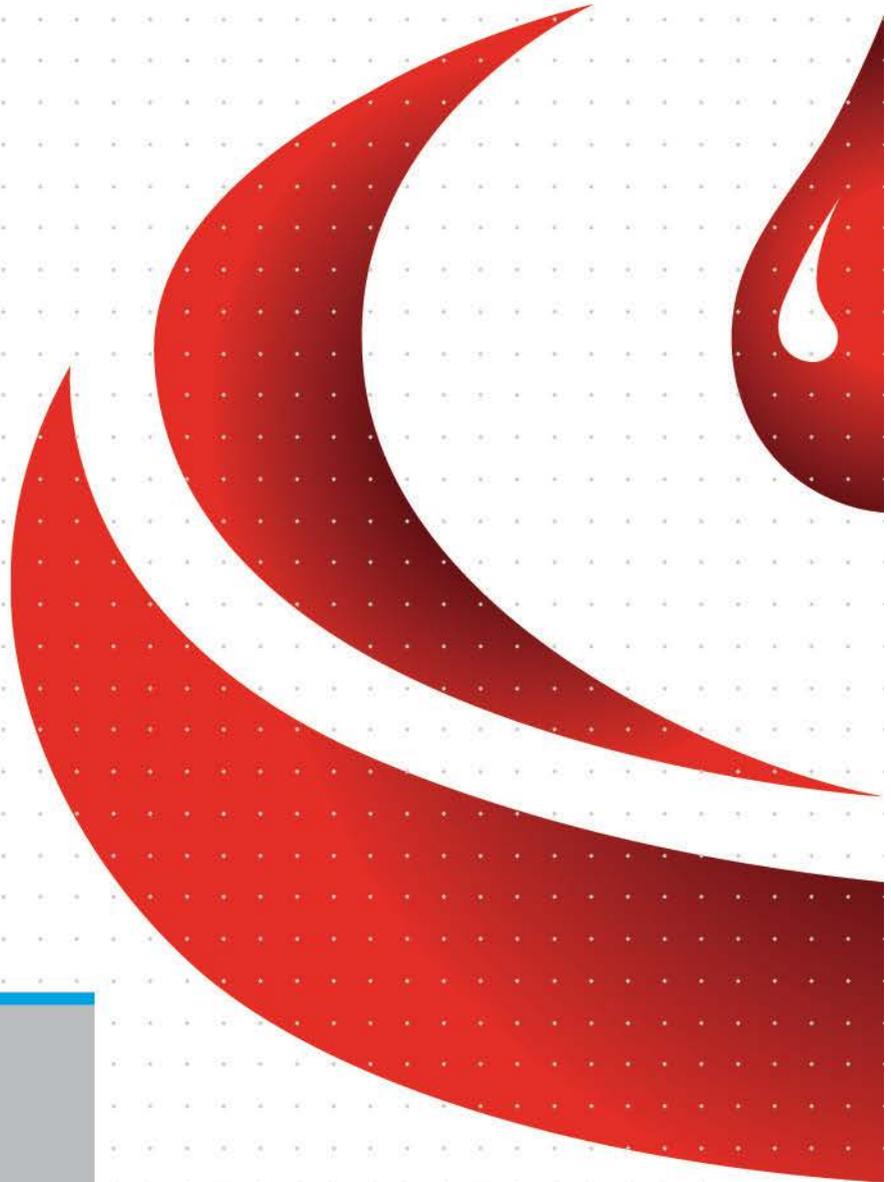


NATIONAL BLOOD AUTHORITY
AUSTRALIA

NATIONAL BLOOD SUPPLY CONTINGENCY PLAN

ANNEX C: PLATELETS
RESPONSE PLAN

December 2013



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> 1. Introduction

1.1 Purpose

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)

1.2 Background

The National Blood Supply Contingency Plan (NBSCP) supports the coordination of a rapid national response in the event of a threat or disaster that could affect the provision of a safe and adequate blood supply in Australia. This annex forms part of the NBSCP in relation to a platelet product supply incident response. It also provides guidance on the escalation of contingency management from NBSCP arrangements to the Office of Health Protection (OHP) where relevant.

As part of this framework the NBA has already released two annexes to the NBSCP, including:

- ◆ Annex A: Red Cells
- ◆ Annex B: Plasma and Recombinant products.

Annex C supports the sector-wide response to a range of risks identified for continued platelet supply as part the NBSCP.

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.

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.

> 2. NBSCP alert/activation levels

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

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

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

- Definition of the alert level, including the triggers that cause activation
- Patient category priorities to assist in the prioritisation of clinical use of platelets if needed
- Roles and responsibilities of key stakeholders, including examples of the types of actions that may be taken.

Whilst operational phase trigger points in this annex are identified as part days of stock of platelets, 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.

In preparing the NBSCP and previous annexes, the approach for the management of products was reviewed against work undertaken by the Australian Red Cross Blood Service (Blood Service) in developing their approach to emergency blood management planning.

The 'categorisation of patients' and suggested clinical actions in response to platelet shortages are based on preliminary work by NSW Health, which in turn drew on guidance from the United Kingdom National Health Service¹. The format for categorising patients under treatment and potential approaches to treatment on activation of the NBSCP Alert Levels is identified as part of the Platelets Categorisation Map.

¹ 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

> 3. Incident room activation

On activation of the NBSCP, the NBA will establish an NBSCP Operations Centre while the contingency is under the control of the NBA.

At any point in time, should the OHP decide that the severity of the incident demands that control be escalated to the OHP in order to develop national policies to protect public health, the NBA may close the NBSCP Operations Centre and transition to a support role under the OHP and Commonwealth of Australian Council Advisory Committee (CAC) emergency management arrangements. This will be communicated via the methods outlined in section 5. *Communications from NBA*.

> 4. Clinical advice and input during activation

Section 8. *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. Communications from NBA

Following activation of the NBSCP, the NBA will supplement existing routine communication channels and structures as follows:

5.1 Situation Report (SitRep)

NBA will issue a daily SitRep (more frequently if required) that provides an update of the situation. This includes a summary of required actions by stakeholders, associated roles and responsibilities and agreed media talking points. This SitRep will be circulated to the organisations set out in the Table 2 of this document and other identified stakeholders during the specific activation.

5.2 BloodNet Messaging

NBA will post an abbreviated Sit Rep and required AHP action messages on BloodNet. BloodNet is a web-based system that allows staff in hospital pathology laboratories to order blood and blood products and provides Australian health provider inventory levels in a standardised way. Blood Service inventory levels are provided to the NBA via the National Inventory Template (NIT). Messages are used in BloodNet to provide and receive information on status, developments and action items for those involved.

5.3 Direct targeted Communications

NBA will use a combination of fax, email and group text messaging (SMS) to provide high level information and advice on key changes in the situation or required actions by recipients. This includes advice on meeting schedules, changes in activation level or to flag the distribution of important information by email. This service is provided for NBSCP (and 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.

If at any time during activation, escalation or deactivation of the NBSCP, there is a need to hand over management of the incident to the OHP National Incident Room, the NBA will provide this detail via the above communication channels. Greater detail on the communications channel and flow is outlined in the NBSCP master document.

> 6. Alert levels - definitions and desired outcomes

To meet clinical demand for fresh blood components 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. *Figure 1 Platelet Activation Map* is a flowchart of triggers used to identify levels of activation during platelet shortages. Note: Platelet shortages may or may not occur at the same time as other fresh blood component shortages.

Potential actions are a suite of activities they 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 NBSCP arrangements, or with the Commonwealth OHP and CAC, 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 for national policies to protect public health.

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

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
WHITE ALERT (NBA Control)	<p>The NBA General Manager will determine that a national shortage of platelets has occurred, or is likely to occur</p> <p style="text-align: center;">and/or</p> <p>A shortage is recorded from the AHP inventory (sourced through BloodNet) and National Inventory Template indicating < 0.5 days stock nationally for 2 consecutive days</p> <p style="text-align: center;">and/or</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</p>	<ul style="list-style-type: none"> ◆ Blood Service calls for more donors ◆ Increase the number of whole blood donations collected into packs suitable for platelet production ◆ Extend shifts in the processing department to increase production of platelets ◆ Extend the opening times of static clinics for (the collection of platelet donations) ◆ Extend opening times of mobile sessions (for the collection of whole blood donations). ◆ 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 ◆ Alert AHP to focus on optimising platelet inventory management. For example, emphasise the 	To increase the collection and production to build stock levels while meeting demand for emergency services and other clinical requirements.

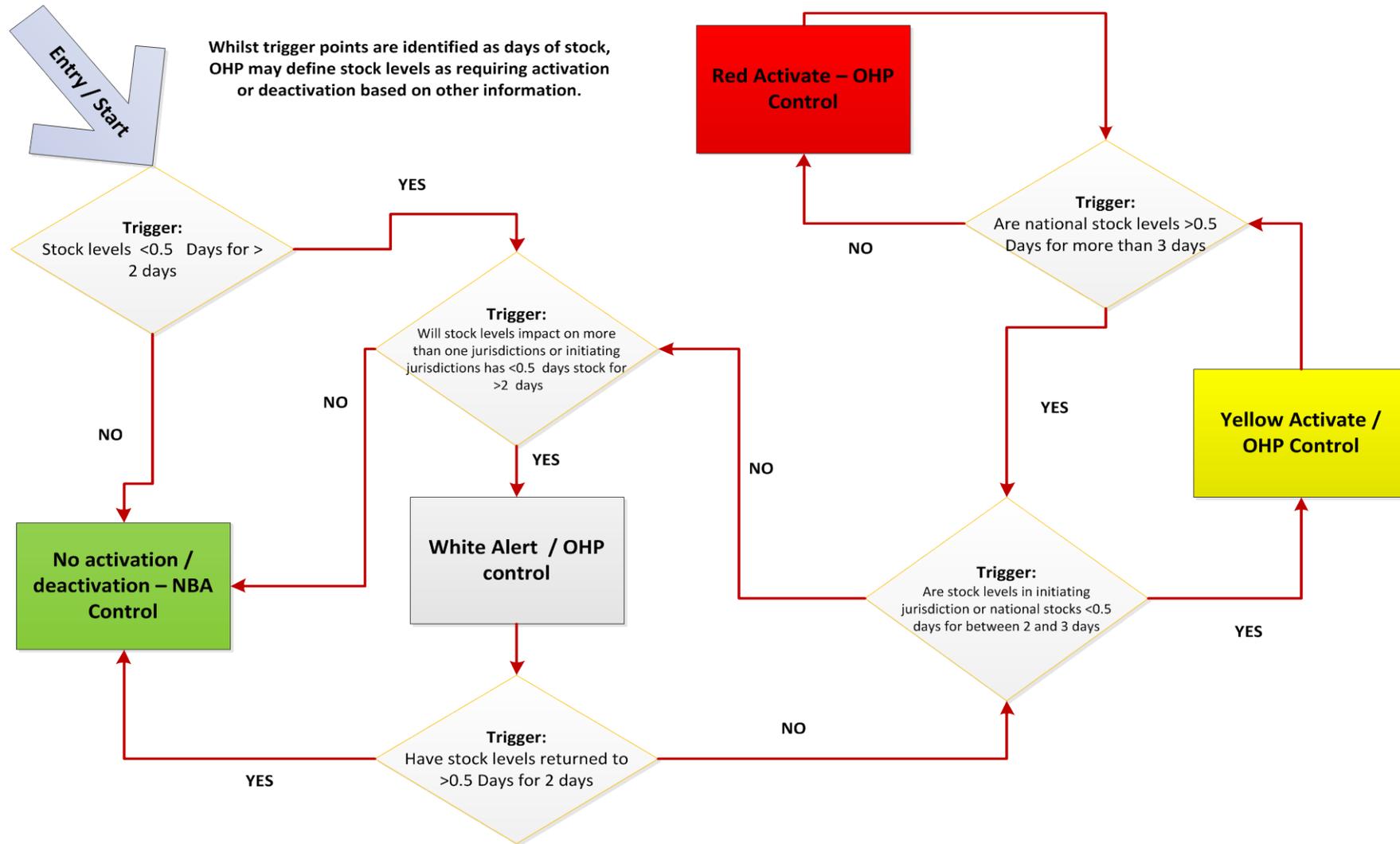
Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
	<p>outlined in Blood Access Priority 3 Treatment²</p>	<p>importance that hospitals/laboratories keep track of the status of the orders so that the same order is not requested twice for the same patient at times of change of shift etc</p> <ul style="list-style-type: none"> ◆ 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. 	
<p>YELLOW ACTIVATE (OHP or NBA Control based on Consultation)</p>	<p>Actions in WHITE ALERT phase have not rectified the situation allowing for the plan to be deactivated</p> <p style="text-align: center;">and/or</p> <p>The AHP inventory (sourced through BloodNet) and National Inventory Template continues to indicate stocking levels will continue at < 0.5 days of stock nationally</p> <p style="text-align: center;">and/or</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"> ◆ Decrease non-urgent product use in consultation with NBA / OHP as applicable. ◆ 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. ◆ Prioritise surgery to minimise platelet use in consultation with OHP to explore clinical options for reducing platelet use. ◆ 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 	<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>

² 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

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
		<p>within the AHP.</p> <ul style="list-style-type: none"> ◆ The interchangeable use of apheresis and pooled platelets (except for HLA/HPA matched platelets). Requests for long dated platelet units is restricted. ◆ 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. ◆ Accepting platelets of a different ABO group (in line with adult and paediatric guidelines). ◆ Accepting leucodepleted platelets instead of CMV negative / non-reactive platelets where clinically appropriate. ◆ Accepting RhD positive platelet units where RhD negative platelets are not available and administering anti-D where applicable. ◆ Extend the shelf life of platelets to seven days if the TGA approves. ◆ Consider selective variation of bacterial testing requirements to reduce processing time following consultation with the TGA. 	
RED ACTIVATE (OHP Control)	<p>Actions from WHITE ALERT and YELLOW ACTIVATE have not rectified the situation;</p> <p style="text-align: center;">and/or</p> <p>The AHP inventory (sourced through BloodNet) and National Inventory Template indicates stocking levels will continue at < 0.5 days of stock nationally and may</p>	<ul style="list-style-type: none"> ◆ Actions as described for Yellow Alert. ◆ Close the NBSCP Operations Centre and NBA transition to a support role under OHP and CAC incident management arrangements. ◆ Implement CAC national policies for prioritisation of platelet use using Platelet Activation Map. ◆ Platelet use triaged for life threatening and other clinical CAC recommendations and actions dependant 	<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</p>

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
	<p>deteriorate further</p> <p style="text-align: center;">and/or</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>	<p>on the situation.</p> <ul style="list-style-type: none"> ◆ Restrictions imposed on platelet use in elective surgery. ◆ NBA support and replicate OHP communication and messaging using NBSCP communication arrangements. ◆ 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. ◆ 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. 	<p>jurisdictional emergency arrangements.</p> <p>If chronic, implement national consistency in triage of medical and surgical blood use.</p>
DE-ACTIVATE (NBA Control)	<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"> ◆ NBSCP improved for possible future crises and if possible new measures as recommended by CAC are introduced to decrease the likelihood or impact of a similar situation. 	<p>NBSCP improved and if possible new measures as recommended by CAC are introduced.</p>

> 7. Platelet activation map



> 8. Clinical guidance for patient category priorities – to assist in 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.

8.1 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 bleeding³

- 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 surgery⁴
- Patients who require immediate or urgent surgery with a platelet count $<50 \times 10^9/L$ or with functional platelet defects.

³ Webert Bleeding Severity Measurement Scale defines clinically significant bleeding (Grade 2). Webert KE, Arnold DM, Lui Y, Carruthers J, Arnold E, Heddle NM. A new tool to assess bleeding severity in patients with chemotherapy-induced thrombocytopenia (CME). *Transfusion*. 2012 Nov; 52 (11): 2466-2474

⁴ **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.

- 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.

8.2 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 $<20 \times 10^9/L$.

8.3 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 surgery⁵ 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 surgery⁶

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

⁵ **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.

⁶ **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.

> 9. CMV seronegative blood component prioritisation

Supply constraints for CMV seronegative blood components may occur alone or in association with a general shortage of blood components. Within either of these scenarios, platelets are most commonly impacted because of their short shelf-life followed by Group O RhD negative red cells.

During periods where CMV seronegative blood component supply constraints occur in isolation, it may be necessary to prioritise supply of such components to patients with the greatest clinical need. In this scenario, all clinically appropriate requests for the supply of blood components are able to be met, albeit the supply of CMV seronegative blood components for some patients may be briefly delayed or may need to be met with CMV untested or CMV seropositive leucodepleted blood components. (Note: The Blood Service specifically labels components that test CMV seronegative. Components that test CMV seropositive are not labeled as such). Prioritisation of supply in this scenario is undertaken by medical staff at the Australian Red Cross Blood Service in consultation with the treating clinician.

However, where the supply constraint is more severe and is in association with a general shortage of blood components, it may be necessary to restrict the supply of blood components to particular patient categories. In these situations, the NBSCP will be activated and there will be communication between stakeholders, including the National Blood Authority (NBA), Jurisdictional Blood Committee (JBC), COAG Advisory Committee (CAC) and the Blood Service. Prescribing clinicians will be informed about the necessity to reduce the demands for blood components.

This document provides guidance for the prioritisation of the supply of CMV seronegative blood components during periods when activation of the NBSCP is required as well as during periods when activation is not required. In descending order of urgency, patients can be classified in CMV Seronegative Priority 1-3, patients classified in CMV Seronegative Priority 1 have the highest priority for transfusion of CMV seronegative blood components.

9.1 CMV Seronegative Priority 1

During periods when supplies of CMV seronegative blood components are constrained, the following patients have the highest priority for transfusion of these blood components and are classified as “CMV Seronegative Priority 1”.

- Intra-uterine transfusions and neonates
- CMV seronegative pregnant women having antenatal transfusion with ongoing pregnancy

As noted in the SaBTO statement, CMV is the commonest cause of congenital infection in the developed world, affecting 1-2% of infants worldwide. Up to 20% of babies who acquire congenital CMV die, and CMV is estimated to cause up to 12% of all sensorineural hearing loss and 10% of cerebral palsy. Primary infection is more likely to cause symptomatic congenital CMV and long term sequelae than reactivation of infection. CMV infection of the fetal brain causes microcephaly and hydrocephalus. Eye involvement (chorioretinitis, cataract and blindness) occurs in 10-20% of cases presenting in the neonatal period. Mortality from symptomatic neonatal CMV infection is between 10% and 30%, although much higher if the baby is premature.

As noted in the SaBTO statement, primary CMV infection in pregnancy is associated with a 40% risk of transmission to the foetus. Following primary maternal infection in pregnancy, 18% of neonates have clinical manifestations at birth. In a recently published systematic review of antenatal interventions for preventing transmission of CMV from mother to foetus, the authors found no randomised controlled trials meeting the criteria for conclusion. This contrasts with the successful prevention of CMV infection/disease by routine or pre-emptive prophylactic strategies in the post-transplant setting. Therefore, emphasis has been placed on the importance of avoiding CMV infection during pregnancy.

9.2 CMV Seronegative Priority 2

During periods when supplies of CMV seronegative blood components are constrained, the following patients have moderate priority for transfusion of these blood components and are classified as “CMV Seronegative Priority 2. If however, these patients are subject to routine CMV quantitative PCR monitoring and pre-emptive therapy, CMV seronegative blood components may not be required.

- CMV seronegative recipients of allogeneic stem cell, bone marrow or solid organ transplants receiving a seronegative transplant
- CMV seronegative recipients of highly immunosuppressive chemotherapy

In the setting of organ donation there are three potential sources of infection – endogenous reactivation, the donor organ and cellular blood components; with the donor organ being the most important source. As noted in the SABTO review, in the era of effective viral prophylaxis (Mitsani et al, 2010; Manuel et al 2009), this risk has almost but disappeared. The reduction in risk is also seen in organ transplantation in children, traditionally the most vulnerable group (Danziger-Isakov et al 2009). Exposure to CMV seropositive blood in a seronegative patient receiving a CMV positive donation does not appear to increase risk of CMV related seroconversion or disease (Preikaitis et al 2002).

The only large prospective randomised trial comparing the efficacy of CMV seronegative blood components with leucocyte-depleted blood components for haemopoietic stem cell transplants was conducted by Bowden et al in 1995. It is important to note that this study used bedside filtration which is less effective compared with the current Australian practice of pre-storage leucodepletion. The study concluded that the two methods were equivalent in mitigating the risk of transfusion-transmitted CMV infection. However the secondary analysis of all infections occurring within the first 100 days of transplant showed that the probability of CMV disease in the leucodepleted arm was greater, although infection rates were similar in both arms. The authors noted that there were possible explanations for this outcome and concluded that leucodepletion was an effective strategy to reduce transfusion-transmitted CMV. A later study in 2003 by Nichols et al found that the use of filtered red cells was the primary predictor of transfusion-transmitted CMV, however the use of ganciclovir prevented all but one case of CMV disease. This study highlighted the importance of early CMV detection and effective treatment. Other studies have not shown any differences in infection or disease in CMV seronegative patients receiving CMV seronegative blood components versus leucodepleted blood.

There are several factors which influence the likelihood of a patient acquiring CMV infection and CMV disease, including the chemotherapy protocol, the patients underlying disease and their ability to tolerate side effects of therapy, the institutional CMV monitoring strategy, as well as the use of prophylaxis vs pre-emptive CMV treatment preferences. The risk of CMV disease is considerably mitigated by CMV DNA screening and pre-emptive therapy with ganciclovir or valganciclovir. More recently a test that measures CMV T-cell responses (CMV QuantiFERON) might better define the group at risk of CMV disease. It is also important to note however that the use of CMV quantitative PCR monitoring for at risk patients is not routinely available in Australian hospitals. For this reason it is not feasible to further prioritise within these groups of patients.ⁱ

9.3 CMV Seronegative Priority 3

During periods when supplies of CMV seronegative blood components are constrained, the following patients have the lowest priority for transfusion of these blood components and are classified as “CMV Seronegative Priority 3. If however, these patients are subject to routine CMV quantitative PCR monitoring and pre-emptive therapy, CMV seronegative blood components may not be required.

- CMV seronegative recipients of autologous stem cell or bone marrow transplants
- CMV seropositive pregnant women having antenatal transfusion with ongoing pregnancy
- CMV seronegative recipients of allogeneic stem cell, bone marrow or solid organ transplants receiving a seropositive transplant.

Following primary infection with CMV, the individual becomes CMV seropositive and is thus both infected and potentially infective for life. Lifelong infection and reactivation facilitates transmission to intimate contacts. Women who are already CMV seropositive can also transmit infection, in some cases following reinfection with a different strain of CMV (Boppana et al, 2001). To reduce the risk of foetal/neonatal CMV infection, it is recommended that all pregnant women, including those who are CMV seropositive receive CMV seronegative blood components.

Neither the provision of CMV seronegative blood components nor the provision of leucodepleted blood components completely eliminates the risk of CMV transmission. It is acknowledged that the rates of transfusion-transmitted CMV are both very low, and the two techniques are probably equivalent. However, data to confirm equivalence is not yet available and would require large clinical trials. The Blood Service is undertaking modeling to derive residual risk estimates to inform clinical decision making. The use of CMV quantitative PCR monitoring for at risk patients is not routinely utilised in Australian hospitals

> 10. Roles and Responsibilities

Table 2 Roles and responsibilities specific to platelet contingencies outlines the roles and responsibilities of key stakeholders involved in the management of platelets at each alert level.

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.

The role of the Commonwealth Office of Health Protection (OHP) and relationship with Commonwealth of Australian Council Advisory Committee (CAC), National Health Emergency Management Subcommittee (NHEMS) and National Incident Room are identified within the NBSCP communications document. Within any activation, the individual roles and responsibilities of all organisations and bodies are subject to the specific circumstances as presented at the time of activation of the NBSCP.

Table 2. Roles and responsibilities specific to platelet contingencies

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
OHP	<ul style="list-style-type: none"> > Liaise with NBA on incident room status and use, where NBA has established, an Operations room for WHITE ALERT activities. > Provide OHP directive/status on alert situation to NBA for distribution. > Establish communications with those jurisdictional bodies where central coordination of responses is relevant. > Provide preparatory support to the NBSCP Operations room if escalation to OHP commences. 	<ul style="list-style-type: none"> > If control elevated to OHP, establish and coordinate incident room activation and handover arrangements from NBA. 	<ul style="list-style-type: none"> > Establish and coordinate incident room activation and handover arrangements from NBA. > Manage the contingency under OHP arrangements. > Direct NBA on support and communication requirements. 	<ul style="list-style-type: none"> > Advises of National Incident Room handover of deactivation. > Provides directives on mitigation strategies and improvements to the plan that will improve future responses.

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	<ul style="list-style-type: none"> > Establish NBSCP Operations Room to coordinate alert/activation. > Provide support to the OHP as required. > Assess stock reporting via BloodNet and National Inventory Template and forecasts and notify the activation of plan. > Assess impact on all products > Notify relevant jurisdictions, Blood Service, JBC, OHP, TGA, Health, Private hospitals associations and colleges of supply risk. > Support and interface with extant jurisdictional contingency management arrangements. > Work with Blood Service to rectify situation. > Work with Health to provide briefing to the Minister. > Work with Health to coordinate national media advice on supply level. > Re-evaluate and advise OHP of the possible impact on other products and whether need to activate further plan annexes. 	<ul style="list-style-type: none"> > Prepare to handover Incident Room responsibilities to OHP consistent with any transfer of contingency control. > Confirm escalation of Plan and maintain regular communications with all stakeholders on supply findings. > Commence work with TGA/Blood Service on possible TMF changes > Distribute CAC Categorisation of Patients Types – Platelets Document with instructions / status to AHPs and other jurisdictional requested stakeholders if required. > Undertake media activities, such as the provision information and data to relevant bodies (Health and Blood Service) in accordance with an agreed Media Protocol. > Consider possible impact on other products and whether need to activate further plan annexes. 	<ul style="list-style-type: none"> > Provide support to the OHP as required. > Prepares advice for CAC / COAG/ Health Ministers. > Respond to OHP instructions and distribute communications with Stakeholders. > Work with TGA/Blood Service on possible TMF changes. > Re-evaluate and advise CAC of the possible impact on other products and whether there is a need to activate further plan annexes. 	<ul style="list-style-type: none"> > Inform stakeholders of deactivation. > Manage and conduct debriefing session. > Collect information to support improvements. > Revise plan, if necessary. > Provide advice to JBC on new mitigation strategies that could be implemented, if appropriate.

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	<ul style="list-style-type: none"> > Provide daily advice on all inventories, including work in progress levels to NBA. > Work with AHPs to ensure the most effective distribution of available product based on taking into consideration patient categories (section 6). > Increases donor recruitment activities to meet optimum product requirements, which may include: <ul style="list-style-type: none"> > Calling more donors > Extending shifts in the processing department to increase the production of platelets > Extending the opening times of static or mobile clinics > Transferring donors to plateletpheresis (where considered appropriate based on assessment of red cell inventory) 	<ul style="list-style-type: none"> > Comply with directions from the NBA/OHP. This may include gatekeeping of platelets to only provide product for particular patient categories (as per Section 6). > Launches national donor appeal, extend hours of operation and collection sites. > Advise the NBA of the status of Blood Service management response required to address supply failure > Prioritise donors and donations based on product requirements. > Undertakes media activities in accordance with agreed media protocol. > Facilitate inter-jurisdictional stock transfers as required to ensure national equity of supply. 	<ul style="list-style-type: none"> > Work with NBA and TGA on possible options for alternative platelet processing arrangements. > Provide details of any other options under TMF to the NBA and TGA. > Support activation of additional donor surge capacity, in jurisdictions where such systems are in place. 	<ul style="list-style-type: none"> > Participate in briefing to improve plan and/or decrease the likelihood of future activation of the plan.
JBC/Health Departments/ Central Jurisdictional Incident Rooms	<ul style="list-style-type: none"> > Facilitate the interfacing of NBSCP requirements with jurisdictional contingency management arrangements. > Provide any critical information about their jurisdiction to NBA. 	<ul style="list-style-type: none"> > Support and work with NBA, OHP, institutions and clinicians as per jurisdictional Emergency Management Arrangements. > Implement regular communication with AHPs on stock levels in 	<ul style="list-style-type: none"> > Advise Jurisdictional Health Ministers of product stock status. > Support NBA in developing strategy recommendations to JBC/ CAC/ COAG. 	<ul style="list-style-type: none"> > Considers policy and funding options for additional mitigation strategies, if

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
	<ul style="list-style-type: none"> > If arrangements are not already in place and agreed with NBA, States and territories / Incident Rooms should assist with NBA communication with Approved Health Providers (including institutions, clinicians and pathology providers). > Alert CMO/CHO and Jurisdictional emergency management or Incident Rooms arrangements of possible issue. 	<ul style="list-style-type: none"> accordance with jurisdictional contingency management arrangements. > Respond to media activities in accordance with agreed media protocol. > Participate in regular communication to determine timing and nature of decisions to be taken to ensure understanding on impact on supply or demand. 	<ul style="list-style-type: none"> > Communicate mandatory changes in clinical practice such as cancellation of elective surgery requiring platelets to AHP's (including institutions, clinicians and pathology providers). 	<ul style="list-style-type: none"> appropriate. > Works with NBA to Inform AHPs (including institutions, clinicians and pathology providers).
Health Service Organisations and clinicians	<ul style="list-style-type: none"> > Review emergency platelets management arrangements issued by the NBA or OHP to ensure currency. > Activate emergency platelet management arrangements. > Place institution on alert. > Provide inventory levels to the NBA for upload into BloodNet and specific batch details as required. > Facilitate requested inter-hospital transfer to ensure equity of access nationally. 	<ul style="list-style-type: none"> > Activate emergency platelet management arrangements, which should include only ordering platelets for specific patient categories (Section 6), if requested to do this. > Increase platelet minimisation strategies and treatment alternatives. > Consider prioritising surgery to minimise platelet use. > Commence centralised vetting process for all requests for platelets. > Identify a clinician to coordinate and authorise all platelet orders. 	<ul style="list-style-type: none"> > Implements national strategies agreed by CAC/COAG cancellation of Elective Surgery requiring platelets. > Transfer product as directed by NBA through BloodNet or direct communications. 	<ul style="list-style-type: none"> > Participate in debriefing if appropriate. > Hospitals/ institutions TGGs or emergency platelet management teams to undertake internal debrief and evaluation of their process and amend as necessary.

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
Pathology provider	<ul style="list-style-type: none"> > Notify customer base of status. > Provide inventory levels to the NBA at the frequency requested. This should be through BloodNet where available. > Facilitate inter-hospital transfer as requested to ensure equity of access. > Not requesting long dated platelet units. 	<ul style="list-style-type: none"> > Participate with institutions emergency platelet management arrangements, which should include only ordering platelets for specific patient categories (Section 6), if requested to do this. > Commence centralised coordination of request to all affiliated institutions. 	<ul style="list-style-type: none"> > Implement strategies to assist in the implementation of approach agreed by OHP > Transfer product as directed by NBA or OHP 	<ul style="list-style-type: none"> > Participates in briefing if appropriate. > Participate in affiliated hospital/ institutions debriefing arrangements, as necessary.
Health	<ul style="list-style-type: none"> > Advise Departmental Executive and Communications area of situation. > Provide briefing to the Minister. > Coordinate national media advice on supply level. > Coordinate jurisdictional analysis of public health impact. 	<ul style="list-style-type: none"> > OHP advises NBA and CAC for information and briefs Departmental Executive and Minister. > Manages Media requirements in accordance with agreed media protocol. > Considers budgetary matters when provided by the NBA, if required. 	<ul style="list-style-type: none"> > Considers activating NIR to explore clinical options for reducing platelet use. > Communicate OHP/CAC/COAG decisions to NBA. 	<ul style="list-style-type: none"> > Participates in briefing. > Advises Departmental Executive and Minister of outcomes.
TGA	<ul style="list-style-type: none"> > Monitors situation and work with NBA and Blood Service as necessary. > Supports NBA in analysis of initial information. > Expedite consideration of requests from the NBA/Blood Service relating to manufacturing changes required to mitigate supply risks. 	<ul style="list-style-type: none"> > Provides critical information on and makes regulatory decisions relating to use of product. > Undertakes media activities in accordance with agreed media protocol. 	<ul style="list-style-type: none"> > Works with NBA, OHP and Blood Service on options for importation of platelets or removal of bacterial testing. 	<ul style="list-style-type: none"> > Participates in briefing if appropriate.

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
	<ul style="list-style-type: none"> > Works with the NBA and Blood Service on resolving regulatory matters as they arise. 			
COAG (Health Ministers)	NIL	NIL	<ul style="list-style-type: none"> > Considers and endorses CAC decisions. > Outcomes communicated by Secretariat to stakeholders. > Media activities. 	NIL

> 11. Acronyms and references

ANZSBT	Australian and New Zealand Society of Blood Transfusion
Blood Service	Australian Red Cross Blood Service
BCP	Business Contingency Plan
CAC	Commonwealth of Australia Council Advisory Committee
CHO	Chief Health Officers
COAG	Commonwealth of Australia Council
CMO	Chief Medical Officer
Health	Dept. of Health
HLA	Human Leucocyte Antigens
HPA	Human Platelet Antigens
HTC	Health Treatment Centre
IEBMP	Interim Emergency Blood Management Plan
JBC	Jurisdictional Blood Committee
NBA	National Blood Authority
NBSCP	National Blood Supply Contingency Plan
NIR	National Incident Room
OHP	Office of Health Protection
TGA	Therapeutic Goods Administration
TMF	Technical Master File

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