



New Zealand Blood Service Statement of Intent

1 July 2014 – 30 June 2018

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1 INTRODUCTION

Purpose

This four year Statement of Intent (SOI) has been prepared in accordance with the Crown Entities Amendment Act 2013 and should be read in conjunction with each year's Annual Statement of Performance Expectations. It sets out the strategic direction for New Zealand Blood Service (NZBS) for four financial years through to June 2018 and outlines how NZBS will organise itself, prudently deploying resources to ensure transparency, collaboration and value for money in the support of New Zealand's healthcare sector. The SOI informs Parliament and the New Zealand public about the organisation, the strategic issues it faces and its response to those issues. Objectives and performance measures for each financial year will be updated annually in the Annual Statement of Performance Expectations, and will be reported on in the Annual Report.

Overview

NZBS is a Crown entity established under the New Zealand Public Health and Disability Act 2000. Its primary purpose and core activity is the safe, timely, high quality and efficient provision of blood and blood products and services to clinicians for the people of New Zealand. In addition to this, NZBS provides services for matching patients and donors prior to organ/tissue transplantation, tissue banking (skin and bone) and stem cell services. These activities, which are provided free of charge to all people in New Zealand, contribute to achievement of the organisation's single enduring Output Class and Outcome:

Health needs of people in New Zealand are supported by the availability of safe and appropriate blood and tissue products and related services.

Blood is a special kind of medical resource. The altruistic nature and unique attributes of the "gift" of blood is unlike most other therapeutic modalities. This requires that NZBS, - as a trusted partner in New Zealand's healthcare system, has in place a comprehensive donor recruitment programme and an integrated risk and safety management framework. Safety is at the heart of everything that NZBS does.

Strategic Direction

The organisation's seven strategic goals describe:

- our core activity
- our quality and safety focus
- the importance of blood donors to our activities
- our important relationship with the District Health Boards (DHBs)
- our focus on our people
- the need for on-going development
- financial sustainability

These strategic goals inform this SOI and will guide NZBS over the next four years as it makes the step changes necessary to ensure the organisation is appropriately positioned to meet the on-going needs of New Zealand's health and disability sector.

Government Expectations

NZBS is a Crown agent for the purposes of the Crown Entities Act 2004 and its 2013 Amendment. Pursuant to section 7 of the Act, NZBS will give effect to Government policy when directed by the Responsible Minister, the Minister of Health. Each year the Minister provides NZBS with a Letter of Expectation, which will be reflected in the Annual Statement of Performance Expectations.

Financial and Management Constraints

NZBS receives payment for its products and services on a fee-for-service basis from the DHBs, who are its principle customers. The financial plan each year will be included in the Annual Statement of Performance Expectations and will be prepared in line with the Minister's annual Letter of Expectations, ensuring:

- Management of safety and surety of supply at all times;
- Mitigation of risks related to the biological nature of blood products and variable product demand;
- The ability to review and address key infrastructure requirements;
- Adherence to existing banking credit facility and covenant obligations; and
- Maintenance of long term financial sustainability.

Business Improvement Activities

Ensuring appropriate blood product utilisation

NZBS is a demand driven service. It works in partnership with prescribing clinicians in the DHBs and with Hospital Transfusion Committees to ensure clinically appropriate utilisation of blood and blood products. This is very effective, as evidenced by the reduction in demand for Red Blood Cells (RBCs) between 2010-2014 as DHBs with the support of NZBS progressively implemented blood management programmes such as "Blood is a Gift – why use 2 when 1 will do?" This reduction in RBC prescribing, whilst good medical practise and reducing sector costs, does create financial challenges for NZBS with the associated loss of revenue.

Immunoglobulin product utilisation is also closely managed and monitored, as this drives plasmapheresis collection activity. Historically, the rate of growth in New Zealand has been lower than that seen in other countries; for example growth in Australia is consistently between 11-13% per annum, whereas up until 2010 NZBS growth was 8% per annum and since then it has reduced to between 0 – 4%.

These changes in demand are forecast to continue over the period of this SOI, therefore NZBS will flex its collection activity to align with actual demand in order to minimise expiry levels.

Collections and Facilities

NZBS regularly reviews its overall facility infrastructure in response to changes in forecast collection and manufacturing requirements. The last formal Facilities Review in 2009 led to the development focus of its two major hub-site facilities (which are leased) in Christchurch and Auckland taking account of:

- technology changes;
- space pressures and regulatory compliance requirements;
- reduced demand for RBC's;
- increasing requirements for plasma collection, to meet the growing demand for intravenous immunoglobulin; and
- in the case of Christchurch, issues arising from the earthquakes.

In November 2012 NZBS committed to a partnership arrangement with Ngāi Tahu Property Ltd to build and lease a purpose designed facility in Christchurch, which will be ready for occupation in late 2014.

With the relocation of National Office in mid-2012, the Donor Services area at the Auckland hub-site was reconfigured in 2013. This will be followed by extension of the Auckland Laboratory areas, which is likely to be completed in 2016.

NZBS plans to once again review its forecast future infrastructure requirements, taking into account the changes in Auckland and Christchurch and forecast product demand. This review will commence in the 2014/15 year.

Key Project and Sector Changes

In addition to continuing to work with the sector to improve blood product utilisation and reviewing our facility requirements; the key internal projects for NZBS over the period of this SOI include:

- Cost containment initiatives which will assist in off-setting increased infrastructure costs
- Technology replacements and upgrades
- A review of New Zealand's self-sufficiency status for plasma derived products
- Phase 2 of the Blood Management System upgrade that will see the implementation of new modules of eProgesa over the next 4 years in order to enhance safety and improve efficiency

The organisation will continue to participate in opportunities for joint procurement (in particular, participating in the All-of-Government procurement initiatives) and to share services (including back office functions) as these are identified and developed by the National Health Board and Health Benefits Ltd.



David Chamberlain
Chairman



David Wright
Deputy Chairperson



Fiona Ritsma
Chief Executive

27 February 2014

2 NZBS ORGANISATIONAL STRUCTURE AND CONTEXT

2.1 New Zealand Blood Service Outcome Statement

Health needs of people in New Zealand are supported by the availability of safe and appropriate blood and tissue products and related services

2.2 NZBS in the context of the New Zealand health and disability sector

NZBS is the only provider of blood and blood products and tissue typing services in New Zealand.

A collaborative relationship with both the prescribing clinicians in the DHBs and more than 120,000 loyal donors is at the heart of the organisation's success. Strong relationships also exist with DHB management; the Ministry of Health; CSL Behring in Australia; recipient organisations (in particular Leukaemia and Blood Cancer New Zealand, Immune Deficiencies Foundation of New Zealand and the Haemophilia Foundation of New Zealand); and international partners in the blood sector. Collectively our shared aim is to ensure that New Zealand continues to enjoy a safe and secure supply of blood and blood products and related services now and into the future.

2.3 NZBS Locations

NZBS was established in 1998 to integrate the formerly fragmented hospital based blood services into a single national organisation.

Current Locations

NZBS facilities are structured in a "hub and spoke" model (see Figure 1), with four major collections and manufacturing sites in Auckland, Hamilton, Wellington and Christchurch; supported by two collection co-ordinating centres in Palmerston North and Dunedin and three regional static collection sites located in Manukau, Takapuna and Tauranga. Regular mobile collections are also made in a number of cities and towns across New Zealand.

The national Tissue Typing, Component Development and Red Cell Reference Laboratories, and the administrative National Office are located in Auckland. NZBS also runs the hospital blood banks in Auckland, Hamilton, Palmerston North, Wellington, Christchurch and Dunedin Hospitals. All other hospital blood banks are staffed and operated by local DHB staff; however NZBS maintains overall responsibility for blood banking services across the country and has an active DHB oversight programme in place to achieve this.

Changes to Locations

Regional Donor Centres in Napier and Nelson were closed in 2013 in response to the decline in demand for RBCs. Mobile Blood Collection teams now visit these regions.

NZBS has embarked upon a relocation project for its Christchurch hub-site facility in partnership with Ngāi Tahu Property Limited, which will see it moving into a new purpose built leased facility in late 2014. Refurbishment is also underway in partnership with the Auckland hub-site landlord, the Dilworth School Trust Board, to future proof this facility; ensuring it is fit for purpose for the next 20 years as technologies change and that the requirement for additional donors (to meet the growing demand for fractionated product) can be accommodated in a Good Manufacturing Practice (GMP) compliant environment.

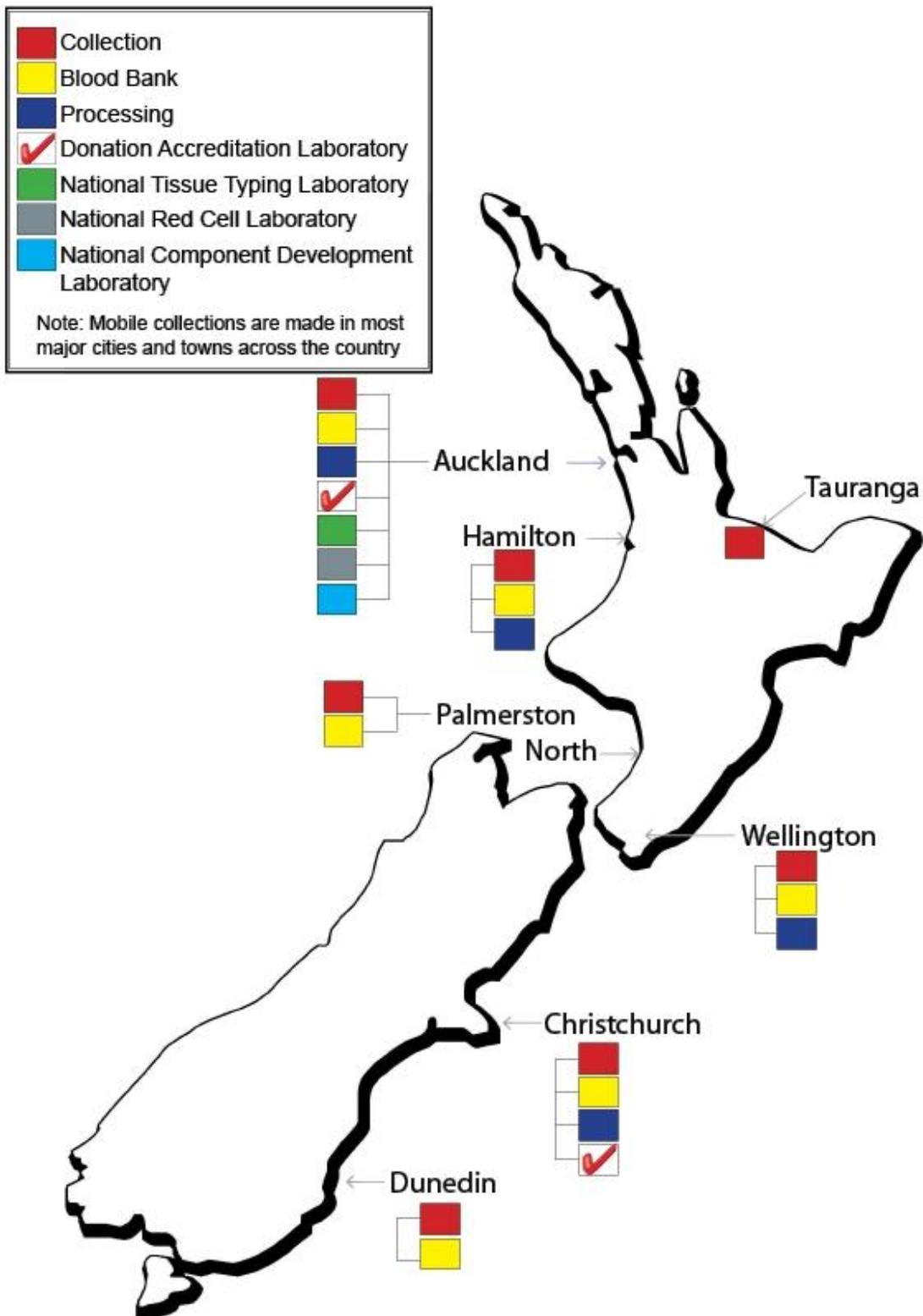


Figure 1: Distribution of NZBS activities across New Zealand

During the period of this SOI, NZBS will conduct a comprehensive Collections and Facilities Review (last completed in 2009) to model future requirements, ensuring the most cost effective and efficient national structure.

2.4 Process of providing blood products

Operationally, blood is collected either as whole blood (which is then separated into its component parts) or as individual components (plasma or platelets) via a process called apheresis. Figure 2 outlines the process for providing fresh and fractionated blood products to the DHBs.

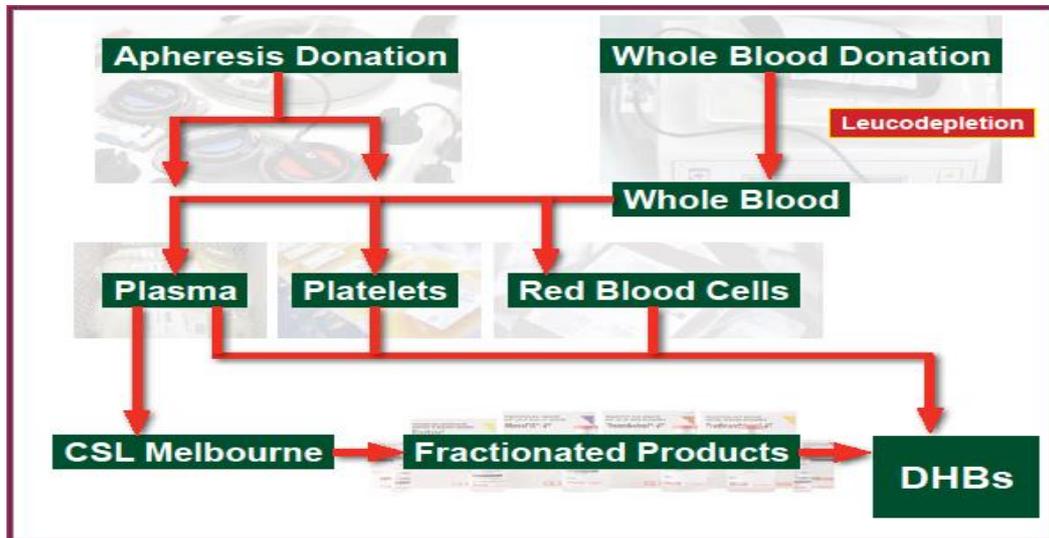


Figure 2: Flow of blood products to DHBs

2.5 NZBS Organisational Structure

NZBS is organised and supported by an established structure as outlined below.

Governance

NZBS is governed by a board appointed by and responsible to the Minister of Health. Current Board members have a range of appropriate and complementary skills and experience to govern what is a very complex technical manufacturing entity. It forecasts and reports on performance to the Minister through the Ministry of Health.

The NZBS Board performs the roles and responsibilities of a Crown Entity board as defined in the Crown Entities Act 2004, and its 2013 Amendment.

Management

While responsibility for overall NZBS performance rests with the Board, operational management is delegated to the Chief Executive.

The Chief Executive is supported by an Executive Team as shown in Figure 3. Reporting to the Executive Team are key national specialist roles, along with senior clinical and operational roles. National specialist roles include: National Manager Logistics; National Manager Marketing and Communications; National Manager Information Services; National Manager Procurement; National Manager Health & Safety, National Collections Co-ordinator, regionally based Area Managers, Transfusion Medicine Specialists and Nurses.

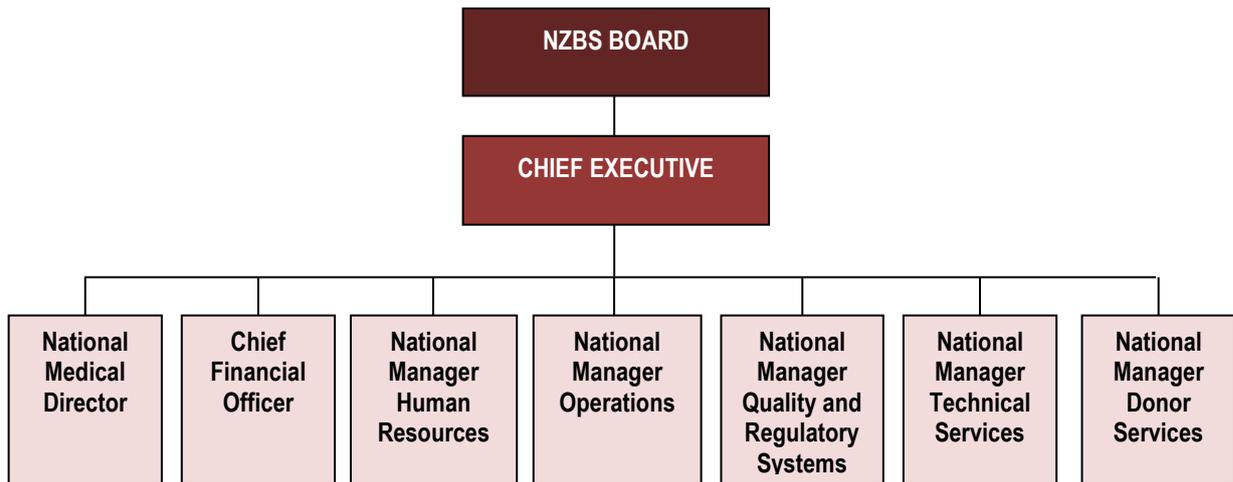


Figure 3: NZBS Board and Executive Management

Details about incumbents can be found on: www.nzblood.co.nz

NZBS Staff

Teamwork is fundamental to the success of NZBS. Eighty eight percent of NZBS staff are classified as “front-line” (i.e. staff whose role is directly related to the provision of NZBS products and services including maintenance of regulatory and GMP compliance). Front-line excludes Executive, National and Area Managers and staff employed in functions such as: Finance; Human Resources; Payroll; Information Services and Marketing.

Staff by Operational Area

Figure 4 provides an overview of NZBS staff groupings by operational area. “National” refers to the following national roles:

- National Management
- Finance and Procurement
- Information Services
- Marketing and Communications
- Human Resources and Payroll
- Operational Support Officers
- Training and Development Co-ordinators

This centralised national structure is an efficient management model and facilitates effective control and co-ordination of the national blood service.

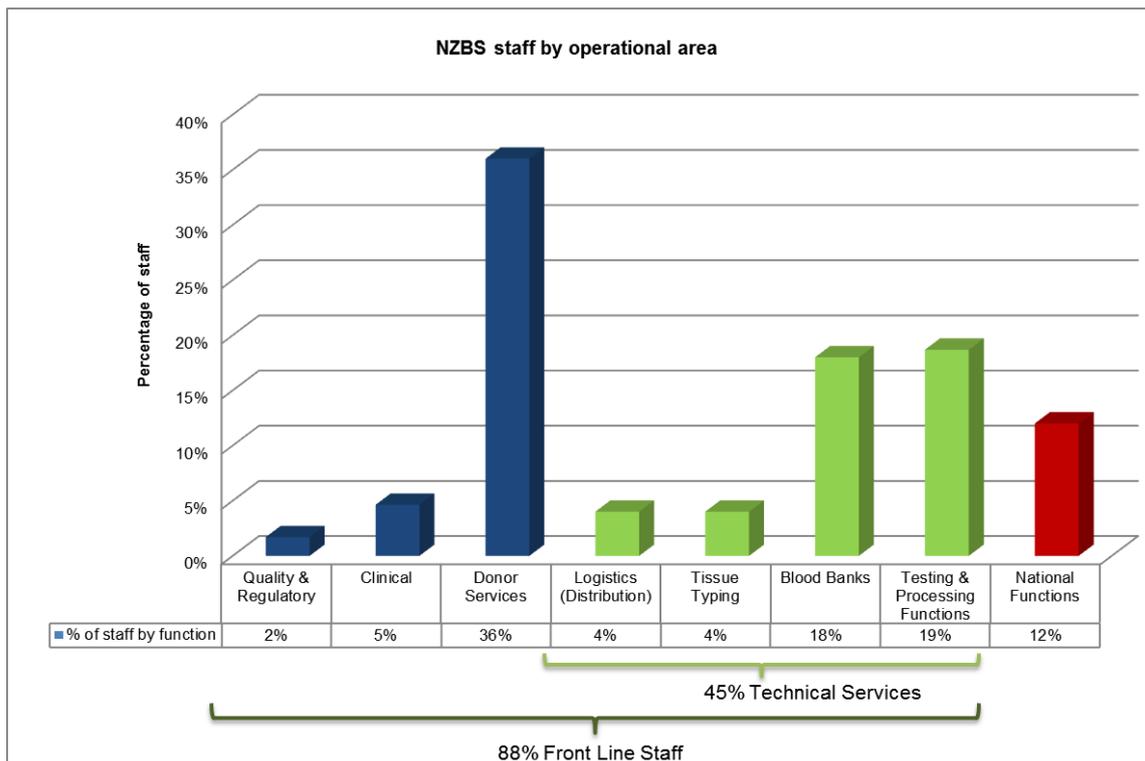


Figure 4: Composition of NZBS staff by operational area

Note:

Staff in Donor Services are predominantly Nurses, but also include Enrolled Nurses, Donor Technicians, Donor and Apheresis Recruiters, Drivers, Reception and Front-line Administration staff.

Staff in Technical Services are predominantly Medical Laboratory Scientists, but also include Medical Laboratory Technicians and Assistants and Clinical Scientists.

Over the period of this Statement of Intent NZBS will be progressively moving the skill mix of its staff through attrition to levels more consistent with international blood services. That will see:

- Donor Services moving to 60% Registered Nurses and 40% Enrolled Nurses and Donor Technicians; and
- Technical Service ratios will vary for the different laboratories, with a move to more Medical Laboratory Technicians and Assistants.

Principle front-line activities can be described as being either clinical, donor or technically related, as outlined in Figure 5.

	Key Activities	Responsible for	Location
Donor Services	Donor Recruitment	Maintaining a sustainable donor population - recruiting new donors and retaining existing donors through relationship development & scheduling appointments to achieve collection targets	All NZBS sites
	Collections	Collecting whole blood whilst ensuring maintenance of good donor health Collecting apheresis plasma and platelets whilst ensuring maintenance of good donor health	All NZBS sites Auckland Waikato Tauranga (plasma only) Palmerston North Wellington Christchurch Dunedin
Technical Services	Donation Accreditation Testing	Blood grouping and screening every blood donation for: HIV, HCV, HBV, syphilis, with selective testing for some donors	Auckland Christchurch
	NZBS Processing	Separating whole blood into: Red Cells, Plasma and Platelets through a range of manufacturing processes	Auckland Waikato Wellington Christchurch
	CSL Processing (Fractionation)	Frozen New Zealand plasma is sent to CSL Behring Australia, fractionated and returned to NZBS for distribution	CSL Behring, Australia
	Tissue Bank	The national skin bank in Auckland and bone banks at each of the Processing sites and in the blood banks in Palmerston North and Dunedin	Auckland Waikato Palmerston North Wellington Christchurch Dunedin
	Distribution	The logistics function in the 4 hub sites distributes product to each of the DHB hospital blood banks (NOTE: the DHB blood banks supply all private hospitals) and overseeing inventory management, minimising expiry and ensuring that product is always available to meet demand	Auckland Waikato Wellington Christchurch
	Blood Bank	Cross-matching and antibody screening to ensure compatibility between the donated blood and the patient (recipient) prior to dispatching to the appropriate hospital staff for transfusion	At the following hospitals: Auckland Waikato Palmerston North Wellington Christchurch Dunedin
	National Red Cell Reference Laboratory	Undertakes complex pre-transfusion testing and antibody identification. Runs a national quality assurance programme and inhouse reagent manufacturing	Auckland
National Tissue Typing Laboratory	Key testing and assessment services to DHBs undertaking organ and haemopoietic stem cell transplantation	Auckland	
Clinical Services	Clinical Support	Medical and transfusion nursing support to both DHB and NZBS staff on all transfusion medicine related issues	Auckland Waikato Palmerston North Wellington Christchurch Dunedin
	Clinical Services	Provision of therapeutic services such as plasma exchanges, stem cell harvests and therapeutic venesections	Auckland Waikato Palmerston North Christchurch
Supported by National functions of: Clinical, Quality & Regulatory Systems, Logistics, Marketing, Information Services, Finance and Human Resources			

Figure 5: Key front-line NZBS activities

Clinical Service

The NZBS Clinical Team plays a key role in maintaining clinical quality - ensuring that the right product is provided to the right patient at the right time. The clinical role within NZBS impacts on all areas in the “vein to vein” blood service from selection of donors to provision of advice and support for the management of patients with complex clinical problems requiring transfusion and analysis of any reported adverse transfusion events.

A multidisciplinary Clinical Advisory Group, chaired by the National Medical Director, oversees NZBS clinical activity; providing advice to the Chief Executive on clinical issues and taking a proactive role in setting clinical policy, standards and encouraging transfusion medicine best practice.

A clinical oversight programme enables NZBS to discharge its statutory responsibility for maintenance of effective blood banking and cross-matching systems in the DHB Blood Banks not operated by NZBS. The programme has been endorsed by International Accreditation New Zealand (IANZ). Active participation in the NZBS Clinical Oversight Programme is a key component to the DHB managed Blood Banks maintaining IANZ Accreditation.

A comprehensive twenty four hour national clinical advisory service is available to all hospital clinicians.

A national haemovigilance programme examines and reports annually on the frequency and causes of adverse transfusion related events, to help health professionals understand the risks associated with blood transfusion and assist development of improved systems for the safe delivery of blood products to patients.

Quality, Safety and Compliance – “Safety is our Cornerstone”

The NZBS Quality and Regulatory Systems team has a broad scope which includes ensuring organisational compliance with Good Manufacturing Practice (GMP) and maintenance of all required licences and accreditation through the development of robust quality systems. It maintains systems for document and records management, customer complaints, corrective action management, equipment management, validation management and conducting internal and external audits. The team works very closely with operational teams to ensure regulatory requirements are met.

The key external parties with whom the Quality and Regulatory Systems function interacts are: Medsafe; International Accreditation New Zealand (IANZ); the American Society for Histocompatibility and Immunogenetics (ASHI); the Australian Therapeutic Goods Administration (TGA); CSL Behring; Archives NZ and DHB Blood Banks.

NZBS Values

The NZBS organisational structure works within a values based framework. ***Safety is our Cornerstone (Ko te haumarū tā mātau mātapono taketake)*** is the overarching tenet to everything that NZBS does, cementing the four enduring values of:

- ***Striving for Excellence (Kia tau kite Tihi)***
Maximising the resources NZBS has to draw on, we strive for excellence in everything we do;
- ***Teamwork (Te Mahi Ngātahi)***
We value working towards and supporting each other to meet our common goal;
- ***Integrity and Respect (Te Pono me Te Tika)***
We value an environment where there is mutual trust and respect; and

- **Open Communication (Te Whakawhitiwhiti Whakaaro i runga i te Māharahara)**

We value sharing information and knowledge, thoughts and ideas, in an appropriate and timely manner.

2.6 Key External Relationships

NZBS has relationships with a number of different stakeholder groups (other than the Minister of Health). Key relationships exist between NZBS and:

- Donors
- DHBs and their patients
- Private hospitals
- Other users of blood products and services
- Ministry of Health
- Dilworth Trust Board (landlord for Auckland hub-site)
- Ngāi Tahu Property (developer and future landlord for Christchurch hub-site)
- CSL Behring Australia (plasma fractionator) based in Melbourne, Australia
- MAK-System (e-Progesa software provider) based in Paris, France
- Patient advocate groups (e.g. Leukaemia and Blood Cancer NZ; Haemophilia Foundation of NZ; and Immunodeficiency Foundation of NZ)
- National Haemophilia Management Group (NHMG)
- NZBS employees

The expectations of these stakeholders are assessed by a variety of means including regular contact (through routine service delivery and associated activities), focus group meetings, surveys and documented requests and requirements.

NZBS can be considered the custodian of more than 120,000 voluntary New Zealand blood and apheresis donors' "gift of life". In achieving its organisational goals and objectives, NZBS is mindful of its responsibility to these donors and the requirement to protect their taonga/gift through internal activities and by providing support to the prescribers of blood and blood products to ensure appropriate and cost-effective utilisation.

2.7 Statutory Obligations and Minister of Health's Expectations

The core functions of NZBS are specified in section 55 of the New Zealand Public Health and Disability Act 2000 (NZPHD Act) and subsequent Gazette Notices to that legislation.

The key function of NZBS identified in the NZPHD Act is:

To manage the donation, collection, processing, and supply of blood, controlled human substances, and related or incidental matters, in accordance with its statement of intent (including the statement of forecast service performance) and (subject to section 65 of the NZPHD Act) any [Ministerial] directions given under the Crown Entities Act 2004.

NZBS adheres to the fundamental principles contained in the New Zealand Health Strategy. In particular:

- NZBS provides blood, blood products and services to healthcare providers, thus contributing to the good health and well-being of all New Zealanders throughout their lives;
- NZBS delivers timely and equitable access to blood and tissue products and related services to all New Zealanders regardless of ability to pay;
- NZBS maintains a high level of public confidence;

- NZBS involves consumers through liaison with hospitals and recipient groups;
- The special relationship between Māori and the Crown under the Treaty of Waitangi is recognised through the NZBS Māori Responsiveness Strategy; and
- As a national entity NZBS seeks community involvement on key issues through consultative processes.

NZBS is committed to on-going organisation awareness of, and where appropriate taking actions to contribute to:

- The New Zealand Health Strategy (December 2000)
- The New Zealand Disability Strategy (April 2001)
- Recognition of the Government's requirements in regard to the Treaty of Waitangi.

This SOI reflects the expectations of its owner, the Crown, as documented in the June 2012 Enduring Letter of Expectations from the Ministers of Health and State Services and the Minister of Health's annual Letter of Expectations. NZBS will work with the Ministry of Health as the Minister's agent to ensure that each expectation is appropriately progressed.

3 HOW NZBS CONTRIBUTES

NZBS activities contribute to achievement of the government’s and health and disability system’s goals as detailed below.

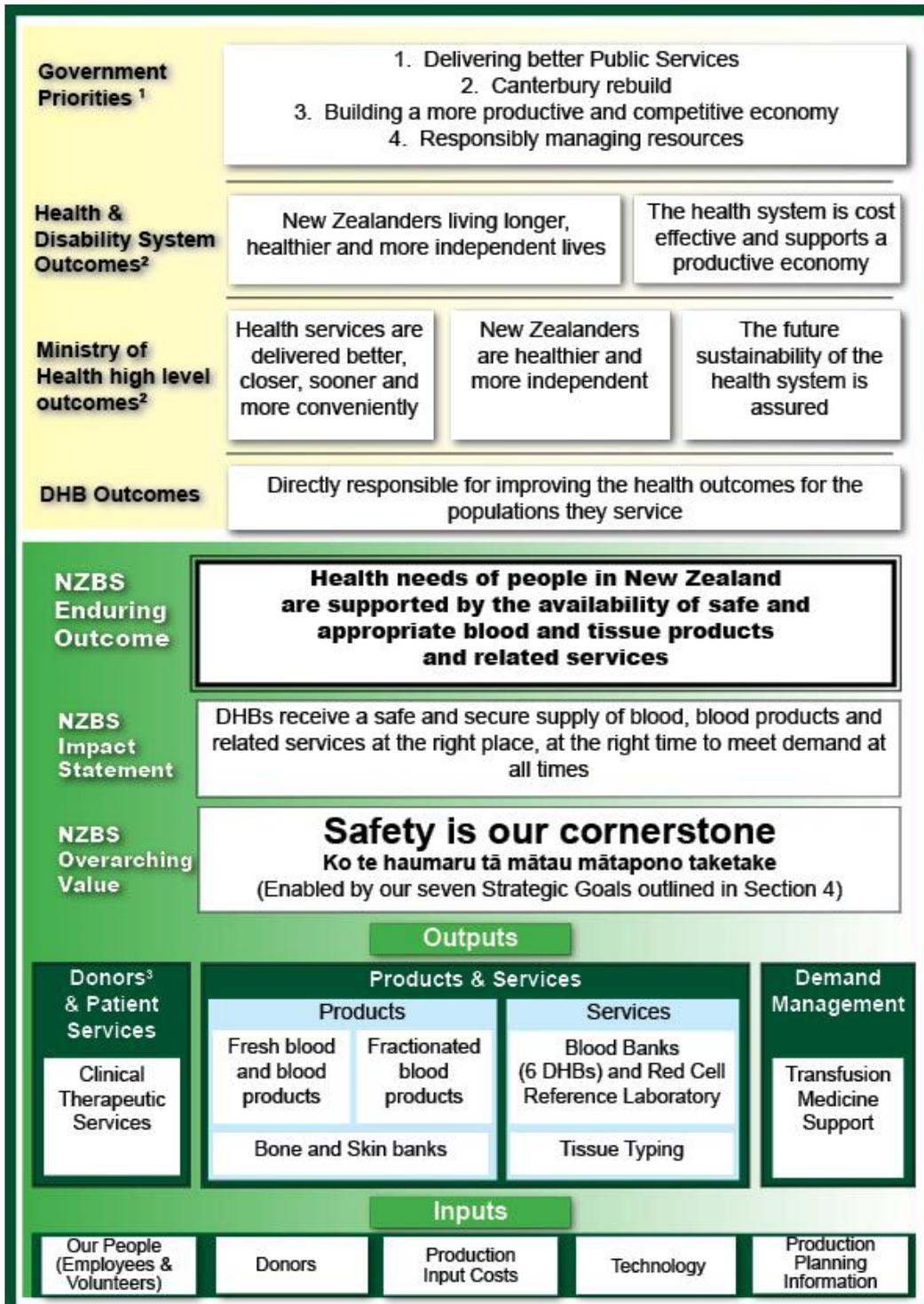


Figure 6: How NZBS contributes

¹ Budget 2014 Priorities (ref: <http://www.ssc.govt.nz/sites/all/files/budget2014-4year-plan-guide.pdf>)

² Ministry of Health Statement of Intent 2012/13 to 2014/15

³ These services refer to stem cell collections for transplantation and people with Haemochromatosis – in some situations their blood can be used for transfusion, hence referring to them as donors

4 NZBS STRATEGIC GOALS AND HOW THEY WILL BE IMPLEMENTED

The following section presents how NZBS intends to perform its functions and conduct its operations over the period of this SOI in order to achieve its strategic goals.

4.1 NZBS Strategic Goals

The NZBS Board and Executive have set the organisation’s strategic direction looking forward to 2018. The following seven strategic goals set the direction for NZBS’s core activity; quality and safety focus; recruitment and retention of blood donors; its important relationship with the DHBs; focus on NZBS staff; and the need for on-going development and financial sustainability.

Strategic Goal		Focus ⁴
1.	NZBS builds on core capabilities to provide a range of products and services which are appropriate to New Zealand health needs and priorities.	External
2.	NZBS achieves the highest possible Safety and Quality standards in all that it does.	Internal
3.	NZBS manages a sustainable donor population capable of supporting on-going product demand in New Zealand.	Internal
4.	NZBS relationships with other health sector entities are mutually supportive and productive.	External
5.	NZBS has a sustainable, competent and engaged workforce.	Internal
6.	NZBS uses international best practices and internal Research & Development capabilities to improve and develop products and services for the New Zealand health and disability sector.	Internal
7.	NZBS is a financially sustainable organisation operating effectively and efficiently.	Internal

The seven NZBS strategic goals collectively relate to three key areas of NZBS activity:

1. Donors and Patient Services

Collecting blood from donors, ensuring maintenance of their good health and that there are sufficient donors to support product demand, plus a small range of clinical therapeutic services.

2. Products and Services

Testing/manufacturing and supplying blood and tissue products together with related services.

3. Demand Management

Maintaining an excellent relationship with the DHBs as the primary NZBS customers; providing information to assist their management of product demand and informing NZBS production schedules to ensure 100% product availability at all times.

⁴ The differentiation of internal and external strategic goals assists the reader to identify those goals related to service provision (Goals 1 and 5) and those related to internal business activities to enhance that service provision.

4.2 How performance against strategic goals will be measured

The following section describes the activities related to each of the seven strategic goals and describes the key measures which will be reported in the Annual Report each year to demonstrate progressive achievement of the goals.

Strategic Goal 1

NZBS builds on core capabilities to provide a range of products and services which are appropriate to New Zealand health needs and priorities.

This strategic goal outlines NZBS's core activity as the only provider of blood and blood products and related services to the New Zealand health and disability sector. NZBS will utilise its core capabilities of specialist transfusion medicine knowledge and expertise to support the sector with a safe and appropriate range of products and services to meet New Zealand's changing health needs and priorities.

Leveraging off our unique competencies and capabilities, NZBS has a focus on:

- Ensuring the safety of the nation's blood supply;
- Respecting the gift status of every voluntary donation through minimising product expiry and maximising efficient utilisation;
- Ensuring certainty of supply of blood and tissue products and services to the healthcare community; and
- Meeting 100% of demand, 24 hours per day, 7 days per week, every year.

Measures and targets for achievement of Strategic Goal 1 are recorded in the Annual Statement of Performance Expectations and will be reported against in the Annual Report by:

Achievement of the NZBS Impact Statement – ensuring that DHBs receive a safe and secure supply of the right blood, blood products and related services at the right place at the right time to meet demand at all times.

Strategic Goal 2

NZBS achieves the highest possible Safety and Quality standards in all that it does.

Safety and quality are the over-riding principles of highly regulated blood services across the globe. To assure public confidence in the safety of New Zealand's blood supply, NZBS will ensure that regulatory accreditation and compliance requirements are maintained at all times in each of the four years of this SOI and beyond.

Facilities that are GMP compliant are an essential blood service requirement. During the period of this SOI NZBS will open a new leased facility in Christchurch (in partnership with Ngāi Tahu Property) and will upgrade its Auckland facility (in partnership with the Dilworth School Trust Board) to address both space and GMP compliance issues. It will also conduct a review of its other facilities to ensure that they remain compliant and appropriate for forecast requirements into the future.

In the NZBS setting, in addition to standard public sector legislative requirements, the following regulatory compliance is required:

- Annual Manufacturing Licences in the 6 NZBS collection and manufacturing sites audited by Medsafe against the Code of Good Manufacturing Practice (GMP);
- IANZ accreditation against International Standard ISO 15189 – “Medical Laboratories –requirements for quality and competence” in all NZBS diagnostic laboratories, including the six hospital Blood Banks run by NZBS.

- ASHI (American Society for Histocompatibility and Immunogenetics); and accreditation in the national Tissue Typing laboratory which requires annual monitored self-assessment and a formal inspection and external audit every two years (audits due in 2014 and 2016).

NZBS also complies with the requirements of:

- FACT (Foundation for the Accreditation of Cellular Therapy) for processing of haemopoietic progenitor cells in order to support the FACT accreditation held by the Auckland City Hospital and Starship Stem Cell Transplant Programme. Over the period of this SOI NZBS will be working with Christchurch Hospital transplant teams who are also seeking to achieve FACT accreditation. Because NZBS does not hold the accreditation, this is not listed as a measure below; and
- The Human Tissue Act 2008; as NZBS is the predominant supplier of human bone and sole supplier of human skin to DHBs and private healthcare providers. NOTE: as New Zealand is not self-sufficient in the supply of cadaver skin, NZBS co-ordinates importation of skin as required, supplementing domestic collection in order to meet demand. Due to global shortages, this does mean that NZBS does not have the same surety of supply that it has for blood and blood products.

In 2011 the Government announced that the Australia New Zealand Therapeutic Products Agency (ANZTPA) will be established by mid-2016. This will replace existing Medsafe regulation of blood and blood products. Initial consultation commenced in 2013, and this will become more active over the period of this SOI.

Achievement of Strategic Goal 2 is closely linked to Strategic Goal 1 and assures public confidence. It is in alignment with Ministry of Health's outcomes and is a fundamental requirement for any blood service; therefore, although an internal strategic goal, maintenance of the following safety and quality requirements will be measured and reported in the Annual Statement of Performance Expectations and Annual Report as achievement of:

1. Medsafe licences
2. IANZ accreditation
3. ASHI accreditation – next biennial audit in 2014
4. Testing of every donation prior to use
5. Reporting of transfusion related adverse events as part of the NZBS National Haemovigilance Programme

Strategic Goal 3

NZBS manages a sustainable donor population capable of supporting on-going product demand in New Zealand.

New Zealand is primarily self-sufficient for blood and blood products; however, this does not preclude the procurement of imported product if clinically necessary and/or in exceptional circumstances. The active donor population is the source of the raw product that NZBS requires to manufacture its range of blood and blood products for transfusion; therefore, maintenance of good donor health is an essential requirement. To achieve this strategic goal NZBS will:

- Maintain a sustainable number of active donors (people who have donated whole blood and/or apheresis plasma/platelets at least once in the last 24 months) at the level of at least 120,000 donors (115,000 whole blood donors and 5,000 apheresis donors) over the four years of this SOI in order to meet demand. NOTE: this number is regularly reviewed and will be adjusted in-order to meet the changing demand for products. The annual target will be updated each year in the Annual Statement of Performance Expectations.

- Continue to develop donor recruitment and retention strategies to maintain sufficient voluntary donors to replace retiring or deferred donors including:
 - Maximising use of the Donor Relationship Management system and other electronic means for communicating with donors as we implement more blood-group specific strategies to better match collection with demand;
 - Monitoring and implementing strategies to maintain good donor health;
 - Targeting initiatives contained in the NZBS Māori Responsiveness Strategy (MRS) to improve engagement with Māori with the aim of increasing the number of Māori who donate blood; and
 - Targeting initiatives to recruit and retain youth donors (in particular between the ages of 19-25 years) to ensure a sustainable donor population into the future.

Figure 7 shows the current age profile of active donors (i.e. donors who have donated at least once in the last 24 months). Note:

- The decline in donors less than 20 years old is the result of a deliberate strategy to reduce school based collections to only one annual visit per school;
- The modest increase in donors aged 19 – 25 is in response to targeted marketing to New Zealand youth, in particular at tertiary institutions; and
- The general decline in the other age brackets is as a result of NZBS matching its new donor recruitment activities down in response to the declining demand for RBCs.

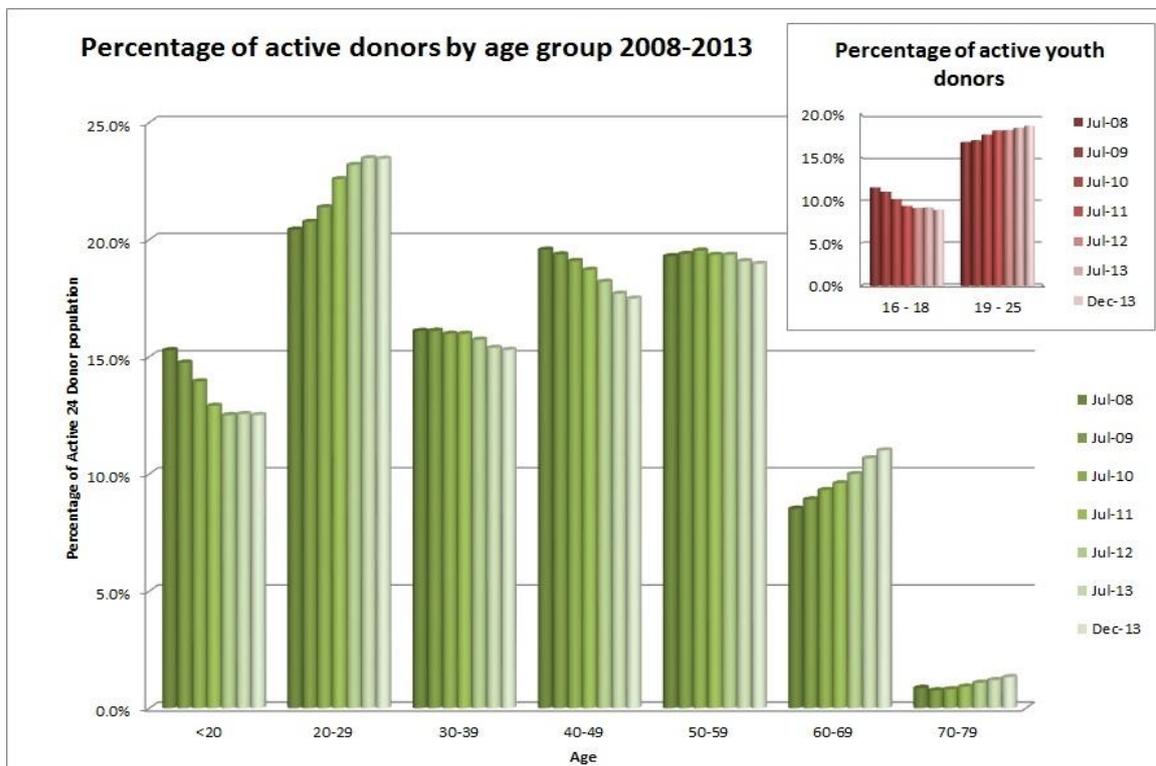


Figure 7: Active Donors by Year and Age Group for 2008- 2012

Measures and targets for achievement of Strategic Goal 3 are recorded in the Annual Statement of Performance Expectations and will be reported against in the Annual Report by:

1. Achieving annual donor population target numbers
2. Meeting youth and Māori donor growth targets
3. Meeting donor satisfaction targets

Strategic Goal 4

NZBS relationships with other health sector entities are mutually supportive and productive

Blood and blood products are provided free-of-charge to patients in New Zealand. NZBS is funded on a fee-for-service basis by its customers, primarily the DHBs. Note: the provision of blood and blood products to private hospitals and other users is coordinated and paid for by the DHBs.

As the only supplier of blood and blood products to the New Zealand health and disability sector, the fiscal and operating environments within the DHBs have a direct impact on NZBS. To successfully support the sector NZBS needs to work in partnership with the DHBs and ensure on-going efficient and effective management of its internal operations.

Activities related to NZBS's achievement of this Strategic Goal also contribute directly to supporting:

- a) The government's priority "Delivering better public services"⁵; and
- b) The Ministry of Health outcome that "Health Services are delivered better, sooner and more conveniently"⁶

NZBS Support to DHBs

NZBS supports the DHBs, who are the prescribers and purchasers of blood and tissue products and services (i.e. the DHBs determine demand). This support includes:

1. Provision of reports and analysis

- Monthly clinical product utilisation data assists DHB clinicians and management to maximise product utilisation, minimise expiry and cost;
- Ensuring appropriate blood product stock levels (and hence DHB expenditure) to most efficiently support anticipated clinical demand;
- Two to three clinical audit reports each year, based on work carried out by the NZBS clinical team (Transfusion Medical and Nurse Specialists) working in partnership with DHB clinical staff to assess targeted specific product utilisation;
- Monitoring with the aim of minimising adverse reactions in donors and in recipients (as identified by DHBs). This is achieved by analysis and publication of an annual Haemovigilance Report (a key tool used internationally by blood services) to help prescribers, treating clinicians and the blood service track trend changes and together ensure appropriate, clinically safe and efficacious product utilisation;⁷ and

⁵ Budget 2014 Priorities (ref: <http://www.ssc.govt.nz/sites/all/files/budget2014-4year-plan-guide.pdf>)

⁶ Ministry of Health Statement of Intent 2013 - 2016

⁷ More information about the Haemovigilance Report can be found on the NZBS website at: <http://www.nzblood.co.nz/Clinical-information/Haemovigilance-programme>

- Representation and reporting to the National Haemophilia Management Group (NHMG).
2. Clinical Oversight of DHB Blood Banks
- NZBS Transfusion Medicine Specialists visit all DHB Blood Banks not directly managed by NZBS to provide guidance and clinical oversight; ensuring that nationally consistent quality systems and processes are used in the provision of blood components and products to patients;
 - DHB blood bank responsiveness to NZBS clinical oversight visit recommendations enables them to meet the requirements for International Accreditation New Zealand (IANZ) accreditation; and
 - NZBS participation in the local DHB Hospital Transfusion Committees.
3. Planning and Communication
- The lead DHB CEO continues to be the key sector contact for NZBS to:
 - Agree the annual price engagement process in time for DHBs to budget for price and volume changes in their Annual Plans;
 - Identify and implement reporting change requirements, particularly to facilitate improved product utilisation; and
 - Identify business improvement opportunities, efficiencies and areas where working together can deliver savings to both DHBs and NZBS (e.g. in the management of Bone Banking Services) and any other mutually beneficial activities/projects.

Measures and targets for achievement of Strategic Goal 4 will be recorded in the Annual Statement of Performance Expectations and reported against in the Annual Report by the following key areas of interaction between the DHBs and NZBS:

1. Monthly distribution of the key product utilisation monitoring reports
 2. Production and circulation of an annual Haemovigilance Report
 3. A minimum of one clinical oversight visit to each DHB each year, including timely production of a report outlining any corrective actions and/or recommendations for improvement
- Note: implementation of recommendations is the responsibility of the DHBs.
4. Feedback on the NZBS : DHB relationship from the Lead DHB CEO.

Strategic Goal 5

NZBS has a sustainable, competent and engaged workforce.

NZBS people management strategies, policies, programmes and practices contributing to the achievement of this internal goal over the four year period of this SOI will:

- Be consistent with the Government's expectations for pay and employment conditions in the State Sector as required by the Minister's Annual Letter of Expectations;
- Promote the seven key elements of a "Good Employer"⁸
 1. Leadership, accountability and culture
 2. Recruitment, selection and induction

⁸ As defined by the Human Rights Commission in the published guidance from the Equal Employment Opportunities Commissioner (June 2006).

3. Employee development, promotion and exit
 4. Flexibility and work design
 5. Remuneration, recognition and conditions
 6. Harassment and bullying prevention
 7. Safe and healthy environment
- Demonstrate compliance with Equal Employment Opportunities policies and good faith and employment contract obligations in line with government expectations;
 - Align with NZBS vision and values;
 - Ensure sustainability through the development of a more diverse workforce reflective of the communities that we serve, including ethnic diversity;
 - Assist in the development of quality leaders (both management and clinical) attracting, optimising and retaining top talent to achieve strategic objectives; and
 - Support staff to achieve high safety and quality standards, including on-going professional development requirements to achieve annual professional registration.

NZBS recognises the importance of listening to staff and understanding what they see as important in order to enhance:

- Engagement
- Participation
- Productivity
- Retention and reduction in staff turnover
- Achievement of strategic and operational objectives

Employee commitment will be measured biennially through a workforce engagement survey which will be conducted in 2014 and 2016; enabling internal benchmarking by identifying the percentage of staff in each of three defined engagement categories - engaged, ambivalent and disengaged over time.

As New Zealand's only blood service, international collaboration at both a clinical and management level ensures that the nation's transfusion service and blood safety standards continue to be contemporary and cost-effective.

Measures and targets for achievement of Strategic Goal 5 will be recorded in the Annual Statement of Performance Expectations and will be reported against in the Annual Report by:

1. An improvement in the Employee Engagement Index in FY14 and FY16.
2. Annual Employee turn-over of 12% or less.⁹

Strategic Goal 6

NZBS uses international “best practices” and internal Research and Development capabilities to improve and develop products and services for the New Zealand health and disability sector.

Activities associated with achievement of this internal goal contribute to the government's policy driver for growth of “support for science, innovation and trade” and are aligned with the health and disability sector's National Health IT Plan and Health

⁹ The level determined by NZBS management to be appropriate.

Quality and Safety Commission's aspirations. NZBS activities related to the achievement of this goal include:

- Monitoring and, where appropriate, prioritising internal activities/projects to keep abreast of international developments in transfusion medicine practise and deliver business improvements. For example:
 - Use of a Platelet Additive Solution which delivers both patient safety and efficiency gains;
 - The move to male only plasma and cryoprecipitate for transfusion and screening plateletpheresis donors to reduce the risk of transfusion related acute lung injury (TRALI); and
 - Implementation of plateletpheresis technology which enables triple doses to be collected from one donor.
- Adherence to the *Council of Europe Guide to the preparation, use and quality assurance of blood components* ("The Guide") as NZBS's external reference standard. The Guide is reviewed annually by an expert internationally constituted committee. By undertaking its own regular review of this internationally recognised Guide, NZBS will assure relevance and appropriate alignment of New Zealand blood safety standards with standards applied in European countries and Australia.
- Benchmarking with international blood services. NZBS is a member of the Asia Pacific Blood Network (APBN) and participates in an annual Comparison of Practise benchmarking analysis looking at metrics such as:
 - Issues of components per 1,000 population;
 - Overall population participation rate in blood donation, including analysis in specific age bands;
 - Donor deferral rates, with more analysis being conducted about reasons for deferral;
 - Donor and recipient adverse events; and
 - FTE / specific outputs.
- Upgrading facilities to ensure a sustainable infrastructure to meet forecast demand and enable adoption of new technologies, systems and processes.
- Ensuring up-to-date versions of key software packages and maximising functionality. For example, the 2012 upgrade of the blood management system Progesa to the web-based e-Progesa, and plans throughout the period of this SOI to implement additional modules to enhance functionality and improve safety and efficiency.

Achievement of Strategic Goal 6 will primarily be monitored through internal organisational measures; however, achievement of the Christchurch Facility project, which is a key strategic project for the organisation in 2014/15, will be reported in the 2014/15 Annual Report by:

- Successful completion of key project milestones in accordance with Board approved project plan.¹⁰

Strategic Goal 7

NZBS is a financially sustainable organisation operating effectively and efficiently.

This strategic goal is in accordance with the Minister's expectation that financial sustainability is a critical part of all crown entities strategy. NZBS's "vein-to-vein" business model is the envy of many blood services around the world. In particular the

¹⁰ See 2014/15 Annual Statement of Performance Expectations, Measure 6.1

close relationship this model promotes between the DHBs and NZBS, which ensures a good alignment of priorities and on-going focus on cost control. The underlying principles of the business model will continue to be reviewed over the four years of this SOI to ensure that NZBS continues to meet the nation's requirement for a high quality, safe, cost effective and financially sustainable demand driven support service to the New Zealand health and disability sector.

Key principles within the current model include:

- Self Sufficiency where clinically appropriate (to ensure surety of supply) whereby NZBS collects sufficient blood to meet all of New Zealand's requirements for blood and blood products. This self-sufficiency principle will be reviewed over the period of this SOI to ensure that it remains an appropriate strategy for New Zealand; and
- Plasma fractionation contractual arrangements with CSL Behring which was renegotiated in 2014 and extends to June 2017.

NZBS acknowledges the financial pressures on the country and the health and disability sector in particular and will:

- Ensure prudent financial management, operating in a financially responsible manner and keeping expenditure under review to ensure provision of value for money;
- Maintain financial sustainability in response to any change in product mix and volumes, limiting any price increases to DHBs through a strong focus on cost containment and internal business improvement activities; and
- Provide to the DHBs, by way of rebate, the portion of any unbudgeted annual surplus delivered which is not required by NZBS in discharging its own financial obligations and responsibilities, in accordance with the NZBS Financial Guidelines Policy introduced in 2009.

Measures and targets for achievement of Strategic Goal 7 will be recorded in the Annual Statement of Performance Expectations and will be reported against in the Annual Report by:

- Meeting budget each year whilst continuing to implement internal initiatives to ensure on-going safety and surety of supply.

5 ORGANISATIONAL CAPABILITY – STRATEGIC ISSUES AND HOW THEY WILL BE MANAGED

To achieve the outputs and strategic goals outlined in this document NZBS must maintain and continue to enhance its organisational capability, operating effective systems to help in the early identification and management of any issues that may arise as external or internal business needs/conditions alter. Organisational capability in 2014 and the key strategic issues identified at that time are discussed in the table below, along with management activities planned over the period of this SOI in order to manage them.

Strategic Issue	Status in 2014 and management activities to manage issue
<p>Cost and supply difficulties due to unexpected changes in demand</p>	<p>Like blood services all over the world, NZBS is vulnerable to unexpected or unmanaged changes in the mix or volume of products utilised by its customers. Even small changes in mix, volume or fractionation yield have the potential to affect both supply and revenue and can result in significant over or under recovery of operating costs.</p> <p>Working in partnership with DHB clinicians, NZBS plays an active role in product management activities to ensure appropriate utilisation of blood and blood products (i.e. demand management).</p> <p>Some issues in respect of key products and a brief discussion of their management are presented below:</p> <p><u>Red Blood Cells (RBCs)</u></p> <p>Each year since 2010 has seen a reduction in demand for RBCs as DHBs working in partnership with NZBS implement improved blood management systems. Demand for RBCs is forecast to plateau at a new reduced level by 2017, increasing slowly from that time in alignment with population growth. In response to this decline, Whole Blood (WB) collection levels have been progressively reduced, with the closure of two Donor Centres in 2013 and an ongoing conversion of WB donors to Plasmapheresis.</p> <p><u>Immunoglobulin products</u></p> <p>Consistent with blood services around the world, immunoglobulin continues to be the primary product driver for plasma collection in New Zealand.</p> <p>NZBS works closely with DHBs to manage use of intravenous immunoglobulin (IVIg) and regular clinical audits indicate that the prescribing of IVIg in New Zealand is largely consistent with published international guidelines.</p> <p>In response to demand from patient groups and their managing clinicians NZBS added Evogam (a dedicated subcutaneous immunoglobulin manufactured from NZ plasma) to its product list in 2013.</p> <p>Historically the rate of growth of immunoglobulin prescribing has been lower than that seen in other countries, for example growth in Australia has increased between 11-13% per annum, whereas in 2012/13 in New Zealand prescribing was 3% less than in 2011/12. This picked up in 2013/14 to be close to 8% growth, in part due to an uptake in the new Evogam product, and is forecast to continue to grow at 2.00% annually for the period of this SOI. Plasmapheresis collections will be adjusted up or down if there is a sustained change in demand; however, it is important to understand that there is a lead time from any change in donor collection activity (which cannot be easily “turned on and off”) to the provision of finished product.</p> <p>NZBS plans to review its strategy of self-sufficiency for immunoglobulin products during the term of this SOI, to ensure that it is still appropriate and cost effective in meeting sector requirements.</p>

	<p><u>Biostate (a Factor VIII product)</u></p> <p>Volumes are determined by the National Haemophilia Management Group (NHMG). All people with Haemophilia who elected to, have changed from plasma derived Biostate to recombinant product; therefore stable utilisation is expected.</p> <p>Prior to 2014/15 CSL Behring purchased surplus Biostate from NZBS, ensuring that the donor's gift was maximised and providing revenue of around \$475k per annum for a surplus product not required in New Zealand. However, with the global shift to recombinant product, the market for NZBS's surplus Biostate has evaporated; therefore, with renewal of the Fractionation Agreement in July 2014 this arrangement has stopped.</p>
<p>DHB Relationship and price increase expectations</p>	<p>Recovering its costs on a fee-for-service basis from its customers, NZBS acknowledges the sector expectation to ensure any price increase is kept to the absolute minimum required to fund business-as-usual" and NZBS controlled activities. NZBS works hard to meet this sector expectation without compromising NZBS financial viability (Crown expectation).</p> <p>The relationship that exists between NZBS and the nominated "Lead DHB CEO" is well maintained and provides an effective channel for communication, on-going planning and issue resolution for both NZBS and the DHBs. Through this communication channel NZBS will continue to provide early indications to the DHBs about annual price movements to inform their annual budget planning process.</p> <p>The annual NZBS budget incorporates its financial policy settings, internal efficiencies and anticipated volume growth / decline for specific products and services. It also ensures all specific funding requirements under Ministerial directive are complied with, together with the requirement to meet all capital expenditure requirements out of operating cash flows.</p> <p>A mechanism exists to share with the DHBs the portion of any unbudgeted annual surplus that NZBS may achieve due to changed product mix demand, improved fractionation yields and cost efficiencies; and which is not required by NZBS in discharging its own financial obligations and responsibilities.</p>
<p>Ensuring sufficient blood donors to meet ongoing changes in demand</p>	<p>A total donor panel of at least 120,000 active donors will be sufficient to meet projected requirements for 2014/15. The apheresis donor panels (for Platelets and Plasma) will need to increase by 300 from 2013/14 levels to 5,355 by the end of 2014/15 to meet the forecast growth in plasma required primarily due to the increasing demand for IntragamP.</p> <p>Donor recruitment and retention will be a focus for NZBS over the period of this SOI. There are a number of new and on-going initiatives to support optimal utilisation of the donor panel. In particular, the focus on blood-group specific donor appointments to better match collections with demand and youth recruitment to address the generally aging demographic of New Zealand blood donors.</p> <p>NZBS committed to a defined Māori Responsiveness Strategy in 2010 to improve its engagement with Māori. This strategy will be reviewed over the period of this SOI to ensure that it remains current and continues to compliment targeted initiatives to encourage Māori support for the New Zealand Bone Marrow Donor Registry (NZBMDR) for which NZBS (working in partnership with Leukaemia and Blood Cancer New Zealand) carries out both recruitment and tissue typing services for potential donors.</p> <p>Regular use of computer surveys and targeted focus groups will enable NZBS to ensure donor satisfaction and to assess donor views on selected issues, facilitating service improvement.</p>

	<p>A Facebook site launched in mid-2009 to communicate with youth donors has more than 27,600 “fans” and is proving to be an effective means of retaining engagement with this demographic.</p> <p>In response to donor requests and to reduce postal costs, NZBS has increased the use of text and email to contact donors. Electronic communication will continue to be promoted as the preferred contact method during the period of this SOI.</p>
<p>Fractionated product supply</p>	<p>NZBS contracts with a third party fractionator (CSL Behring in Australia) to manufacture fractionated products of required specifications, prepared from New Zealand plasma.</p> <p>NZBS and its predecessors have had a long standing relationship with CSL Behring and they are responsive to the changing needs of NZBS. Key staff at NZBS and CSL Behring work together to manage production of fractionated products by altering the amount or timing of plasma fractionation pools to most effectively meet New Zealand’s product requirements at all times.</p> <p>Unlike a standard manufacturing environment, the protein composition of raw plasma entering each fractionation batch is determined by the individual donors contributing to it. This introduces an unknown biological variable into the production model which adds complexity and risk to forecasting exact yield and hence the amount of manufactured product ultimately derived from each pool of plasma fractionated. Variations in product yield can have significant impacts upon per unit costs of production and production volumes. Additionally there is a risk that a fractionation pool of plasma may be “contaminated” and need to be withdrawn. NZBS mitigates this risk by having a three month supply of fractionated products in New Zealand and a “buffer” stock of frozen NZ plasma at CSL Behring, which would enable an urgent fractionation pool to be commenced in the event that this situation occurred.</p>
<p>Escalating lease costs</p>	<p>NZBS is not financially resourced to own any property and is consequently in a tenant/landlord relationship for all of its facilities. All leased premises¹¹ are fitted-out to meet NZBS specialist requirements for the collection, processing and distribution of blood and blood products, noting blood is classified as a medicine in New Zealand and regulated accordingly.</p> <p>Regular internal and external audit of how facilities meet GMP requirements and organisational needs is undertaken.</p> <p>During the period of this SOI, NZBS will complete a comprehensive Collections & Facilities Review (last conducted in 2009) to model future requirements and to ensure continuation of the most cost-effective and efficient methods of collection as New Zealand’s blood service requirements change. The review will take in to consideration GMP and other regulatory compliance requirements, technology changes and forecast collection and manufacturing activity.</p> <p>Contributing to the Canterbury Rebuild, GMP compliance issues identified in the Christchurch facility are being addressed through a partnership arrangement with Ngāi Tahu Property which will result in the opening in late 2014 of a new purpose built, leased facility within close proximity to Christchurch Hospital.</p> <p>Refurbishment has already commenced at the Auckland hub site working with landlord, Dilworth Trust Board, to future-proof the existing investment in this leased premises. As an interim measure the NZBS National Office has temporarily relocated to a building within 10 minutes’ walk of the hub-site.</p> <p>The Blood Banks in Auckland and Christchurch hospitals are too small to</p>

¹¹ Details about the location of NZBS facilities can be found on page 8.

	<p>meet the volume of activity. Negotiations are underway with both District Health Boards to find a larger more suitably placed accommodation within both DHBs planned facility upgrades.</p> <p>Planned changes to facilities all add cost which will be off-set by a range of on-going efficiencies and other money-saving initiatives within NZBS.</p>
<p>Labour cost escalations</p>	<p>Labour is the largest single cost in running the blood service.</p> <p>Staffing numbers are flexed depending on forecast product demand. With the sustained decline in demand for RBCs the fixed site Donor Centres in Napier and Nelson were closed in 2013 and staffing numbers at other centres in both Collections and Technical services have been managed down by attrition.</p> <p>Operating in the same labour market, NZBS employment terms and conditions are consistent with health and disability sector collectives that have been negotiated by the DHBs. For some employee groups NZBS is directly linked as part of sector wide Multi Employer Collective Agreements.</p> <p>NZBS is required under the NZPHD Act to consult with the Director-General of Health on its bargaining strategy prior to commencing any Collective Agreement negotiations and settlement with staff on Individual Employment Agreements. This bargaining strategy also needs to be consistent with the Government’s regularly published expectations for pay and employment conditions in the State Sector.</p> <p>Recognising the significant impact that DHB employment relations practices and collective agreement negotiations have on the organisation, NZBS actively participates in sector forums whenever possible and seeks to keep abreast of employment relations matters in the wider DHB health and disability sector.</p> <p>With changing product demand, both staffing levels and skill-mix will continue to be regularly reviewed over the period of this SOI.</p>
<p>Retention of specialist trained staff (Being a “Good Employer”)</p>	<p>It is critical that NZBS can attract and retain skilled, committed employees to ensure that the on-going viability and safety of the blood supply are not compromised. Therefore, consistent with government expectations and to achieve its Strategic Goal 5, NZBS Human Resource policies, practices and programmes ensure legislative requirements are met and that there is alignment with the seven key elements of being a “Good Employer”.</p> <p>Learning and Development initiatives and attention to succession planning also mitigate the risks inherent in loss of key personnel and ensure best utilisation of financial resources in respect of labour costs. NZBS has an integrated Learning and Development framework which supports appropriate development of the skills and talent necessary to maximise employee potential.</p> <p>NZBS works collaboratively with the key training agencies (especially in the area of laboratory scientist training) to ensure that under-graduate teaching is aligned with the future industry requirements. NZBS provides BMLSc students with clinical experience opportunities as part of their degree training and employs graduates where suitable vacancies exist.</p> <p>Employee turnover in recent years has been low. NZBS regularly reviews its recruitment policies to ensure they meet best practice and are non-discriminatory. Training is provided to relevant staff on recruitment practices to ensure that the organisation’s obligations as an equal opportunity employer are met. The NZBS Recruitment strategy streamlines recruitment processes, helping to attract and retain key talent. This will continue to be monitored and developed over the period of this SOI</p> <p>Staff consultation and involvement has been factored in to planning for facility upgrades in Auckland and Christchurch.</p>

	Biennial Staff Engagement Surveys will be conducted in 2014 and 2016.
Ability to deal with “the unexpected”	<p>A comprehensive organisational risk management framework ensures that all significant NZBS risks are effectively identified, assessed, managed and monitored.</p> <p>NZBS also has a robust emergency management plan which was well tested in 2011 in response to the earthquakes in Christchurch.</p> <p>Risk identification and escalated incident management are agenda items at each Executive Team meeting. The NZBS Board receives regular reports on any major incidents, reviews the Risk Register and Organisational Health and Safety metrics on a quarterly basis and the Risk Management Policy annually.</p>
Retention of regulatory compliance	<p>All NZBS manufacturing sites are GMP compliant and hold licences to manufacture blood components. NZBS diagnostic laboratories, including the 6 hospital Blood Banks, are IANZ accredited. The National Tissue Typing laboratory is also accredited by ASHI.</p> <p>NZBS works closely and successfully with regulators/ auditors to ensure that all manufacturing centres retain required licences to manufacture blood components, and all diagnostic laboratories hold appropriate accreditation at all times. Maintaining registration and appropriate licences is part of “business as usual” with continuous quality improvement fundamental to the organisation at all levels.</p> <p>The 2011 announcement to work towards the establishment of a joint Australia New Zealand Therapeutics Products Agency (ANZTPA) by mid-2016 is noted. It is too early to know the full implications of the transition from Medsafe to ANZTPA; however, NZBS will be actively involved in the consultation process and will update budget and operational assumptions in the Annual Statement of Performance as they become better known.</p>
Affordability of required capital investment	<p>Blood Service activities are capital intensive (for context, the 2013/14 book value is \$14.3m) with capital expenditure being funded out of operating cash-flows. GMP requirements ensure that all equipment is well maintained and replaced as required.</p> <p>All NZBS properties are leased; therefore, the capital component of the Christchurch and Auckland developments will be funded on “pay-as-you-go” lease arrangements as outlined above.</p> <p>Over the term of this SOI the key capital investments will include:</p> <ul style="list-style-type: none"> • eProgesa (Blood Management System) enhancements - \$1.8m. • Key Equipment Replacements - \$2.1m • Blood Bank Automation - \$1.0m • Auckland Facilities Upgrade - \$2.5m. • Christchurch Facilities - \$1.8m. • IT Infrastructure - \$1.1m

GLOSSARY

TERM	DEFINITION
Accreditation Testing	Testing carried out on all blood donations involving two distinct processes: blood grouping and screening for infectious markers.
Albumex	Albumin product manufactured by fractionation process from New Zealand plasma by CSL Behring in Australia. Used to treat patients suffering burns or shock due to blood loss and treatment of liver and/or renal failure associated with severe protein deficiency.
Albumin	The major protein in plasma that is important in maintaining blood volume.
ANZTPA	Australian New Zealand Therapeutic Products Agency – a proposed joint agency with Australia to regulate therapeutic products (including blood) which is planned to be established by mid-2016. Will replace Medsafe.
Apheresis	A procedure in which blood is temporarily withdrawn, one or more components are selectively removed, and the remainder of the blood is re-infused back into the donor. Used in NZ to collect plasma and platelets.
ASHI	American Society for Histocompatibility and Immunogenetics. An international society of professionals dedicated to advancing the science, education and application of immunogenetics and immunology.
ASHI Accreditation	The ASHI accreditation program determines whether laboratory procedures meet documented ASHI standards and requirements. ASHI conducts a biennial audit of the NZBS Tissue Typing Laboratory.
Biostate (Factor VIII)	Biostate® is freeze dried, high purity, plasma-derived human Factor VIII concentrate, manufactured by fractionation process from New Zealand plasma by CSL Behring Australia. Manufacturing process incorporates two specific viral inactivation steps (solvent detergent treatment and dry heat). Biostate is used in the management of Haemophilia A, an inherited bleeding disorder requiring life-long treatment.
Blood	Consists of cellular components (red cells, white cells and platelets) suspended in plasma.
Blood Group	Complex chemical substances found on or in the surface of red cells which distinguish each blood group. The two more important blood group systems in transfusion work are the ABO (blood types A, B O and AB) and Rh D (positive or negative) systems.
Blood Product	Products manufactured from donated blood.
Code of Good Manufacturing Practice	A set of standards that provide assurance that a manufacturer has a quality system in place that meets the requirements for the product being made.
CSL / CSL Behring Australia	CSL is a company that develops, manufactures and markets pharmaceutical products of biological origin through a process called fractionation. NZBS contracts with CSL Behring Australia (previously CSL Biotherapies) to manufacture a range of products derived from New Zealand human plasma which NZBS collects and ships to Melbourne for fractionation. Finished product is returned to NZBS for distribution to the New Zealand health sector.
Cross-match	A term used when testing the patient's serum against the donor's red cells.
Cryoprecipitate	A clotting factor preparation derived from plasma and used in the treatment of trauma patients and during cardiac / transplant surgery.
DHB	District Health Boards are responsible for providing, or funding the provision of health and disability services in their district.
Donor	A person who gives blood or tissues to be used in another person.
eProgesa	Name given to the MAK-System blood management software, which tracks

TERM	DEFINITION	
	product from donation through the testing and manufacturing process, to issuing to a recipient (patient) in the hospital blood banks.	
FACT Accreditation	The Foundation for the Accreditation of Cellular Therapy (FACT) is a voluntary professional programme involving setting of standards and accreditation of bone marrow transplant facilities. This encompasses collection, processing and clinical transplantation activities.	
Factor VIII	Product used to treat certain types of haemophilia with a deficiency of the blood clotting factor VIII. It can be derived from blood plasma or produced synthetically using recombinant DNA technology.	
Factor IX	Product used to treat haemophilia B (Christmas disease) which is caused by a deficiency in blood clotting factor IX. It can be derived from blood plasma or produced synthetically using recombinant DNA technology.	
Fractionation	Fractionation involves separating substances (e.g. proteins in the case of plasma) by changing the conditions such as temperature or acidity. In the NZBS setting, CSL Behring fractionates New Zealand plasma to produce a range of plasma derived products to treat New Zealand patients.	
Fresh Frozen Plasma (FFP)	Used to treat patients following trauma or transplantation. Frozen plasma is also sent to CSL Behring in Australia for manufacture into fractionated products.	
GMP	Good Manufacturing Practice. A prerequisite of licensing.	
Good Employer	As defined by the Human Rights Commission in the published guidance from the Equal Employment Opportunities Commissioner (June 2006).	
Haematopoietic Stem Cells	Cells found in the bone marrow capable of the formation of all blood cell types.	
Haemophilia	A hereditary deficiency of clotting factors in blood.	
Haemovigilance	Organised surveillance procedures related to serious adverse or unexpected events or reactions in relation to any aspect of transfusion medicine.	
Haemovigilance Imputability Score Definitions	<p>NA Not assessable</p> <p>1 Excluded</p> <p>2 Unlikely</p> <p>3 Possible</p> <p>4 Likely, probable</p> <p>5 Certain</p>	<ul style="list-style-type: none"> ▪ When there is insufficient data for imputability assessment. ▪ When there is conclusive evidence beyond reasonable doubt for attributing the event to alternative causes ▪ When there is conclusive evidence beyond reasonable doubt for attributing the event to alternative causes. ▪ When the evidence is indeterminate for attributing the event either to the transfusion or alternative causes. ▪ When the evidence is clearly in favour of attributing the event to the transfusion. ▪ When there is conclusive evidence beyond reasonable doubt for attributing the event to the transfusion.
Haemovigilance Severity Score Definitions	Grade 1	The recipient may have required treatment but lack of such would not have resulted in permanent damage or impairment of a body function.
	Grade 2 (severe)	The recipient required hospitalization or prolongation of hospitalization directly attributable to the event; and/or the adverse event resulted in persistent or significant disability or incapacity; or the event necessitated

TERM	DEFINITION	
		medical or surgical intervention to preclude permanent damage or impairment of a body function.
	Grade 3 (life-threatening)	The recipient required major intervention following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.
	Grade 4 (death)	The recipient died following an adverse transfusion reaction. <i>Grade 4 should only be used if death is probably or definitely related to transfusion. If the patient died of another cause, the severity should be graded as 1, 2 or 3.</i>
HBL	Health Benefits Ltd – formally the Shared Service Establishment Board. Created to help reduce the cost of non-clinical support functions in health and to harness the benefits of bulk purchasing.	
HBV	Hepatitis B is an infectious illness caused by the hepatitis B virus (HBV) which infects the liver and causes an inflammation called hepatitis.	
HCV	Hepatitis C is an infectious disease affecting the liver, caused by the hepatitis C virus (HCV). The infection is often asymptomatic, but once established, chronic infection can progress to scarring of the liver (fibrosis), advanced scarring (cirrhosis) or liver failure.	
HIV	Human Immunodeficiency Virus – a virus that causes Acquired Immunodeficiency Syndrome (AIDs) in humans.	
HWNZ	Health Workforce New Zealand - set up in 2009 to provide national leadership on the development of the country's health and disability workforce.	
IANZ	International Accreditation New Zealand is the national authority for accreditation of testing and calibration laboratories, inspection bodies and radiology services. IANZ promotes the development and maintenance of good practice testing and inspection and maintains a registration scheme for organisations that comply with the practice.	
Immunoglobulins	Proteins that combat infection.	
Intragam P	An immunoglobulin product manufactured by fractionation process from New Zealand plasma by CSL Behring Australia and used to boost the immune system of patients with immune deficiencies or in the treatment of a range of diseases where the immune system is compromised.	
Intravenous	Within or administered into a vein.	
IU (International Unit)	In pharmacology an International Unit (abbreviated to IU) is a unit of measurement for the amount of a substance producing a specified effect when tested according to an internationally accepted biological procedure. There is no equivalence among different substances.	
MOH	Ministry of Health is the Government's principal advisor on health and disability policy.	
MonoFIX (Factor IX)	MonoFIX is a Factor IX product manufactured by fractionation process from New Zealand plasma by CSL Behring in Australia. It is used for the treatment of the inherited bleeding disorder Haemophilia B, also known as Christmas Disease.	
MRS	NZBS's Māori Responsiveness Strategy developed in 2010 provides a framework and identifies areas where NZBS can progress its approach to produce benefits for Māori.	
NHMG	National Haemophilia Management Group – established in 2007 to take overall responsibility for the national management and oversight of the provision of services to people with haemophilia and allied bleeding disorders.	
NHB	National Health Board - established in November 2009 to improve the quality, safety and sustainability of health care for New Zealanders.	

TERM	DEFINITION
NZBS	New Zealand Blood Service.
NZ GAAP	New Zealand Generally Accepted Accounting Practices.
NZIFRS	New Zealand Equivalents to International Financial Reporting Standards.
Output Agreement	This Agreement is required pursuant to section 170 of the Crown Entities Act 2004 and assists the Minister and NZBS to clarify, align, and manage their respective expectations and responsibilities.
Plasma	Liquid portion of blood that contains antibodies and other proteins.
Plasmapheresis	A procedure where blood is temporarily withdrawn, plasma is selectively removed, and the remainder of the blood is re-infused back into the donor.
Platelets	One of the cellular components of blood that contributes to clotting. Used to support patients who are bleeding, or at risk of bleeding and those undergoing treatment for some blood diseases, cancer, following cardiac surgery and in massive transfusion and trauma.
Platelet Additive Solution (PAS)	PAS is a synthetic additive solution used as a substitute for plasma when storing platelet concentrates.
Plateletpheresis	A procedure where blood is temporarily withdrawn, platelets are selectively removed, and the remainder of the blood is re-infused back into the donor.
Red Blood Cells (RBC's)	The most common type of blood cell which delivers oxygen to the bodies tissues. Used for treatment of people with chronic anaemia resulting from disorders such as cancer and kidney failure; also for acute blood loss as a result of surgery or trauma.
Recombinant product	Synthetic or manufactured blood products – as opposed to products derived from plasma (e.g. Factor VIII).
Self-sufficiency	A fundamental principle in the operation of NZBS, “self-sufficiency” involves collection and manufacturing to meet all blood product demand in New Zealand from blood and plasma collected solely in this country.
Serology	The science of measurement and characterisation of antibodies and other immunological substances in body fluids, particularly serum/plasma.
Serum	The clear, straw coloured fluid portion of the blood that remains after coagulation and removal of cellular blood components by centrifugation.
TGA	Therapeutic Goods Administration - Australian regulatory body assessing and monitoring activities to ensure therapeutic goods are of acceptable standard.
Therapeutic Services	Includes: <ul style="list-style-type: none"> i) Therapeutic apheresis - the separation and removal of one component of blood from a patient as part of a treatment regime. Therapeutic apheresis procedures include plasma exchange (Plasmapheresis) for the treatment of acute conditions such as Guillain-Barré or chronic disorders like Myasthenia Gravis and the removal of white cells (Leukapheresis) used to support the clinical treatment of Leukaemia. ii) Therapeutic venesection predominately as a treatment for haemochromatosis, a hereditary disease which sees a build-up of iron in the blood.
Transfusion Related Acute Lung Injury (TRALI)	Transfusion Related Acute Lung Injury (TRALI) is a complication of blood transfusion characterised by the acute onset of pulmonary oedema (i.e. swelling and/or fluid accumulation in the lungs). This is now recognised to be one of the most frequent severe complications of transfusion.
Vein to Vein Blood Service	The responsibility for the full supply-chain of blood from blood donor selection and collection of blood, through manufacturing and testing, storage and transportation, through to final administration of blood products to patients and analysis of any reported adverse transfusion events.