



Performance audit report

New Zealand Blood Service: Managing the safety and supply of blood products





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New Zealand Blood Service: Managing the safety and supply of blood products

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report about a performance audit
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Contents

Auditor-General's overview	3
Part 1 – Introduction	5
The purpose of our audit	5
The New Zealand Blood Service's role	5
How we carried out our audit	6
What we did not audit	7
Part 2 – Keeping enough volunteer blood donors to meet the country's needs	9
How the New Zealand Blood Service understands what donors it needs to meet demand for blood and blood products	9
How the New Zealand Blood Service cares for donors	12
Ensuring that donors are satisfied with the quality of service	13
Communicating with donors and potential donors	13
Part 3 – Ensuring that blood and blood products are safe	15
Assessing and managing risks	15
Screening donors	16
Collecting blood safely	17
Testing blood donations	18
Tracking blood donations	18
Being prepared for disruptions to operations	19
Quality control, accreditation, and compliance with regulations	19
Best practice and safety in transfusion medicine	20
Part 4 – Supplying cost-effective blood products and services on time	23
Keeping operations cost-effective	23
Forecasting demand and managing the supply of blood products	25
Delivering blood products to hospitals	27
Monitoring, reporting, and managing performance	27
Part 5 – Keeping the New Zealand Blood Service in line with international best practice	29
International networking and monitoring	29
Benchmarking internationally	31
Appendices	
1 – What happens to blood donations	33
2 – Blood products, their uses, and how long they last	35
Figures	
1 – The actual and forecast number of whole blood and apheresis donors, 2008–2014	10
2 – New Zealand Blood Service input costs as a percentage of revenue, 2006/07–2010/11	24
3 – The New Zealand Blood Service's work with international organisations	30

Auditor-General's overview

Our health system needs a reliable supply of safe blood. Cancer, burns, and surgery patients and people with bleeding disorders all rely on blood products, which are vital medicines used to save lives. Each year, our hospitals use blood products to treat more than 40,000 people.

The New Zealand Blood Service (the Blood Service) is pivotal in effectively and safely providing blood and blood products, and is one of a few organisations in the world that provide a full “vein-to-vein” nationally integrated blood service. The Blood Service is involved in all stages of transfusing blood from donors to recipients. This includes collecting, testing, processing, and distributing blood and blood products.

My staff carried out a performance audit that found that the Blood Service effectively supplies safe blood and blood products to patients in our health system. This is a “good news” story. The Blood Service is a high-performing organisation and we have no improvements to recommend.

This country is fortunate in having enough blood for our needs. This self-sufficiency is the direct result of the generosity of volunteer blood donors. The success of the Blood Service in fostering and retaining volunteer donors has helped to achieve this.

The Blood Service is:

- planning well to meet future demand for different blood products;
- targeting younger people as potential donors; and
- working to encourage more Māori to become regular donors.

The Blood Service acts effectively and efficiently to meet the performance targets in its Statement of Intent. This includes accurately measuring how it performs and monitoring changes in demand for blood products. It uses the high-quality information this provides to support well-informed decision-making and make continuous improvement. It is also efficient in its operations.

The Blood Service manages its risks well by monitoring and analysing all incidents and knowing when it must treat such incidents more seriously. Hospitals' reports indicate that there are few transfusion-related incidents. The Blood Service reports regularly on all incidents that are escalated to senior managers and the Blood Service Board.

A meaningful core value – “Safety is our cornerstone” – guides the way that the Blood Service works and manages the safety of donors, blood and blood products, and the people who receive Blood Service medicines.

There is a strong sense of “customer care” throughout the Blood Service – staff recognise the generosity of donors and treat blood donations as gifts that they need to look after carefully and use effectively to help people. This has resulted in high levels of satisfaction among donors with the way that the Blood Service collects blood.

The Blood Service’s operations receive much external scrutiny. The Blood Service takes this scrutiny seriously, carefully considering all recommendations. Where relevant, it creates action plans to ensure that it acts on recommendations and improves.

Where appropriate, the Blood Service ensures that it operates in line with international best practice. It takes part in many international forums and groups that aim to make blood transfusion medicine and services better and safer.

I am pleased to report on this high-performing organisation. Some important success factors that I commend to other organisations underpin the Blood Service’s effectiveness and efficiency. These factors include:

- clear performance targets;
- planning and making decisions using accurate, relevant, and timely information about service demand and performance;
- managing risks effectively;
- a focus on managing issues and stakeholders critical to achieving its core purpose effectively;
- being open to scrutiny; and
- learning and making continuous improvements.

I thank the staff of the Blood Service and the Ministry of Health for their help with our audit.



Lyn Provost
Controller and Auditor-General

8 February 2012

Part 1

Introduction

- 1.1 In this Part, we discuss:
- the purpose of our audit;
 - the role of the Blood Service;
 - how we carried out our audit; and
 - what we did not audit.

The purpose of our audit

- 1.2 We carried out a performance audit to assess how well the Blood Service manages the safety and security of supply of blood products.
- 1.3 We assessed how well the Blood Service:
- ensures that it has enough volunteer blood donors to meet the country's needs (see Part 2);
 - manages the safety of blood and blood products (see Part 3);
 - supplies blood products and services in a cost-effective and timely way to meet needs (see Part 4); and
 - ensures that its operations and practices are in line with international best practice (see Part 5).

The New Zealand Blood Service's role

- 1.4 The Blood Service, a Crown entity, is the only provider of blood products to the health sector. Blood products, which are made from donated blood, are vital life-saving medicines for many illnesses and injuries, such as cancer, burns, and bleeding disorders such as haemophilia.¹ Surgeons use blood products to treat trauma victims and in organ transplant operations. Therefore, it is essential that the Blood Service ensures that it collects enough blood and always has enough blood products to meet needs.
- 1.5 The Blood Service operates an integrated national "vein-to-vein" blood service, which means that it is responsible for all stages of blood transfusion, including:
- collecting blood from voluntary donors;
 - testing donated blood and processing it into blood products;
 - managing the storage of blood and blood products in their blood banks and providing advice and guidance to hospitals about storing blood products;
 - selling and distributing blood products to hospitals; and
 - giving specialist advice about blood transfusion to hospitals.

¹ The Medicines Act 1981 considers blood to be medicine. Medsafe, a business unit of the Ministry of Health, is responsible for regulating therapeutic products, including medicines. Therefore, blood processing comes under Medsafe's regulatory scrutiny.

- 1.6 The Blood Service collects free donations from the New Zealand population. It then sells the blood products to district health boards (DHBs) to ensure that hospitals have appropriate and safe levels of these products. It sells the blood products to DHBs to cover its operating and manufacturing costs. Any financial surplus is returned to DHBs as a rebate or to offset price increases.
- 1.7 In the year ended 30 June 2011, the Blood Service had total expenses of \$93.0 million and total income of \$102.3 million, resulting in a net surplus for the year of \$9.3 million.
- 1.8 Appendix 1 has more details about how the vein-to-vein service works and describes how the Blood Service collects, tests, and distributes blood and blood products.
- 1.9 Blood products for many life-saving medical needs are expensive to make. They have different expiry dates or “shelf lives”, after which they are no longer safe to use. Depending on the type of blood product, these shelf lives range from five days to two years. Therefore, the Blood Service needs to ensure that it can supply blood products while minimising the discarding of expired blood products. Appendix 2 lists blood products, their main medical uses, and shelf lives.
- 1.10 As well as efficiently balancing supply and demand for blood products, the Blood Service must manage safety effectively at all stages of blood transfusion. The Blood Service has set “Safety is our cornerstone” as the core value for all that it does.

How we carried out our audit

- 1.11 We interviewed Blood Service staff who are responsible for managing the safety and security of supply of blood products, and officials in stakeholder entities responsible for the scrutiny and independent quality assurance of the Blood Service and its operations. These entities included the Ministry of Health (including Medsafe), and International Accreditation New Zealand (IANZ).²
- 1.12 We examined many documents relevant to the Blood Service’s operations, including:
- policy manuals and standards;
 - internal and external performance reports;
 - quality assurance reports; and
 - information about the safety and supply of blood products.
- 1.13 We visited the Blood Service’s national headquarters and collection and manufacturing hub in Auckland to learn about and observe how the Blood Service collects, tests, processes, stores, and distributes blood products.

² IANZ is the authority responsible for accrediting testing and calibration laboratories. It is the accreditation body of the Testing Laboratory Registration Council, which is an autonomous Crown entity established by the Testing Laboratory Registration Council Act 1972.

What we did not audit

- 1.14 The Blood Service helps the health sector match patients with donors before organ or tissue transplants, and provides tissue banking, products derived from bone, and stem cell services. We excluded these services from our audit because they do not directly relate to the safety and security of blood products.

Part 2

Keeping enough volunteer blood donors to meet the country's needs

- 2.1 In this Part, we set out our findings about how well the Blood Service:
- understands what donors it needs to meet demand for blood and blood products;
 - cares for blood donors;
 - monitors how satisfied donors are with the way they are treated when donating blood; and
 - informs donors and potential donors about the value of donating blood.

Our overall finding

- 2.2 The Blood Service fosters and maintains the sustainable voluntary donor population that it needs to meet the demand for blood products.

How the New Zealand Blood Service understands what donors it needs to meet demand for blood and blood products

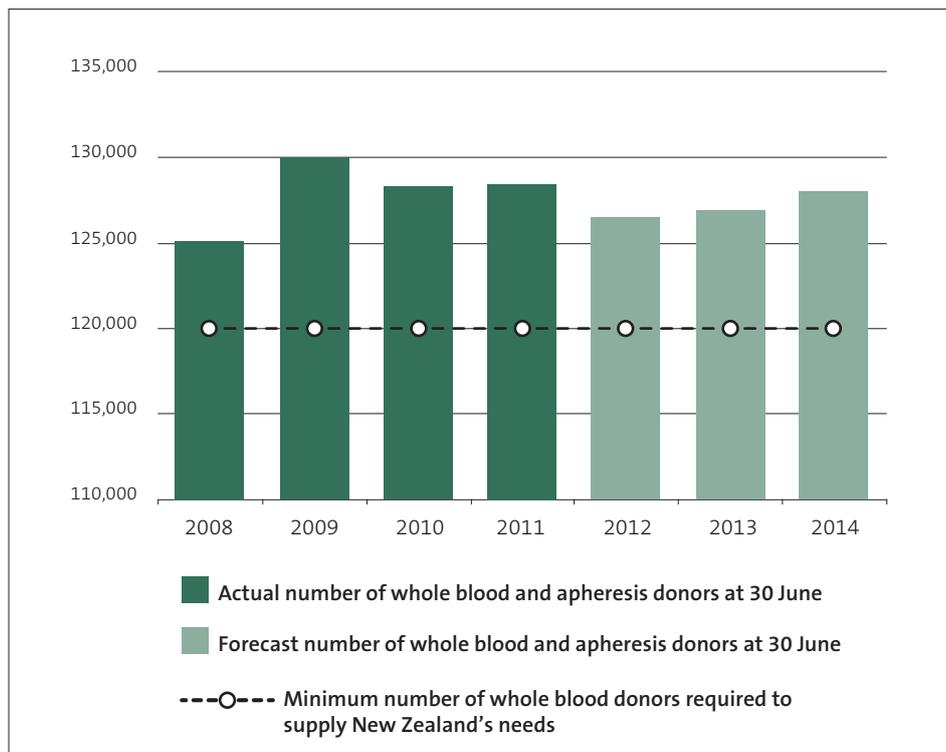
The Blood Service understands well how many and what kind of donors it needs to meet demand for blood products.

Keeping enough donors

- 2.3 The Blood Service successfully keeps enough donors to supply the country's demand for blood products. It forecasts that it will be able to keep doing so in coming years.
- 2.4 Figure 1 shows the number of whole blood and apheresis³ donors since 2008.

³ In apheresis, a machine first separates a donor's red blood cells from the plasma or platelets, and then returns the red cells to the donor. See Appendix 1 for more information.

Figure 1
The actual and forecast number of whole blood and apheresis donors, 2008–2014



Source: New Zealand Blood Service (2011), *Annual Report 2010/2011* and other information from the New Zealand Blood Service.

- 2.5 The Blood Service aims to have at least 120,000 donors of whole blood each year, the number it believes it needs to maintain a safe level of blood products to meet New Zealand's needs. This minimum number has been static in recent years.⁴
- 2.6 Collecting and analysing blood-type and other data from donors helps the Blood Service to identify and forecast trends and to redirect resources if the donor population changes.
- 2.7 We found that the Blood Service considers the wider effects on its business when it sets targets for collecting blood. These include:
- how targets will affect the need for current and future donors;
 - internal and external business implications;
 - logistics; and
 - costs.

⁴ In general, the Blood Service prefers regular repeat donors because they reduce the costs of recruiting donors, help maintain safety, and better understand the process of collecting blood.

Planning for changing demand

- 2.8 The Blood Service clearly plans to meet changing patterns in demand for blood products. For example, a notable trend – in New Zealand and internationally – is growth in demand for plasma. The Blood Service has analysed rates of plasma collecting and considered options for meeting the growing demand for plasma. It analysed trends and predicted demand using statistical data. As a result, the Blood Service has a clear preferred option for organising how it collects plasma and the facilities that it needs to meet the growing demand for plasma.

Targeting particular kinds of potential donors

- 2.9 The Blood Service targets specific groups as potential blood donors. Two major strategies it has put in place are a Māori Strategy and a Youth Strategy. The Blood Service introduced performance measures for these strategies in its *Statement of Intent 1 July 2011-30 June 2014* (SOI)⁵ and will report against them in future annual reports. This shows that the Blood Service recognises how important it is to identify and target groups that donate less, or that the country will need more from, to ensure that it has the right number and type of donors to meet demand.
- 2.10 The Blood Service's Māori Strategy aims to increase the number of Māori blood donors. The SOI contains a new performance target: to increase the percentage of Māori in the active donor population to more than the 6% recorded in 2010/11. The Blood Service aims to improve how it works with Māori groups and to introduce steps to make it easier for Māori to donate blood.
- 2.11 The Blood Service's Youth Strategy is an appropriate initiative to address the implications of an ageing population and probable increased demand for blood products. In 2010/11, 18.8% of donors were aged between 19 and 25 years. The Youth Strategy aims to increase the percentage of young donors.
- 2.12 Targeting young people will help replace the increasing number of donors who can no longer donate blood because of age restrictions. Donors can continue to donate blood up to their 71st birthday. If they pass a yearly Blood Service health assessment, they may continue to donate until they are 76. However, the Blood Service sets an age limit of 60 years for new donors.
- 2.13 As part of its Youth Strategy, the Blood Service gives its staff comprehensive and useful information about marketing and organising events, and resources to help them target and engage potential donors at tertiary institutions.

⁵ New Zealand Blood Service (2011) *Statement of Intent 1 July 2011-30 June 2014* is available at www.nzblood.co.nz.

How the New Zealand Blood Service cares for donors

The way that the Blood Service collects blood makes it convenient, safe, and comfortable for people to donate blood. Overall, the Blood Service has a clear focus on serving “customers” well and taking care of donors. The Blood Service acknowledges that donors volunteer their time and effort to give blood and that their contributions are essential.

Collecting blood conveniently and comfortably

- 2.14 The Blood Service has collection sites in the main urban centres. A mobile service collects blood from donors in smaller communities and some donors in the main cities. The Blood Service tries to ensure that its collection sites are comfortable and welcoming and reasonably meet the needs of donors. Collection sites are open on weekdays only, but have early opening times and are open at least one evening a week. The Blood Service does not currently collect blood on weekends, but, in 2012, will be investigating offering weekend appointments for apheresis donors.
- 2.15 To reduce waiting times for donors, the Blood Service uses a system of appointments. To fulfil collection targets, the Blood Service contacts and books appointments with specific donors according to their blood type or the blood product to be donated. The system is set up well to ensure that, to protect their safety, donors do not give blood again until they are eligible.⁶

Training staff to collect blood competently

- 2.16 The Blood Service thoroughly trains and assesses the competency of staff at its collection sites. As a result, the Blood Service can provide assurance that staff at collection sites are fully trained and competent in their roles to look after donors and ensure that procedures are as safe as possible.
- 2.17 All staff who collect blood must be registered nurses, enrolled nurses, or registered donor technicians. A comprehensive and well-structured module-based training programme for recruits includes rigorously assessing competency through self-study, classroom training, and on-the-job observing and examining.
- 2.18 Volunteers are valuable in helping to look after donors. They meet and greet donors at collection sites, and help with refreshments and administration. The Blood Service has a clear recruitment policy for volunteers and comprehensive guidelines to help volunteers fulfil their duties.

6 For more information about eligibility, see “Detailed eligibility criteria” at www.nzblood.co.nz.

Ensuring that donors are satisfied with the quality of service

Blood donors are satisfied with the quality of service they receive and there is an adequate complaints process.

- 2.19 The Blood Service recognises that it is important for people to have a positive experience when giving blood because this influences how willing they will be to donate again. It surveys donors to measure satisfaction and uses survey feedback to improve the way it looks after donors and runs collection facilities.
- 2.20 Survey results show that the way that the Blood Service collects blood satisfies donors. For example, results from surveys in 2009 and 2010 found that, on average, 93% of survey respondents were either “very satisfied” or “satisfied” with the overall quality of service (with most answering “very satisfied”).
- 2.21 The Blood Service has a nationally managed system for complaints and feedback from donors. This meets the Health and Disability Commissioner’s requirements for handling complaints. The Blood Service has processes in place to acknowledge, investigate, and answer all complaints.

Communicating with donors and potential donors

The Blood Service communicates effectively with donors and potential donors to ensure appropriate numbers of donors.

- 2.22 The Blood Service communicates with donors and potential donors in many ways. It uses these methods to recruit and retain blood donors, and to explain how important it is to donate blood to save lives.
- 2.23 The Blood Service’s marketing:
- explains clearly how important donating blood is to saving lives;
 - simply and effectively describes the process of donating blood and what happens with donated blood;
 - uses new ways, including online social networking sites, email, and texting, to reach donors and potential donors; and
 - targets new donors (such as in recruitment campaigns at tertiary institutions).
- 2.24 The Blood Service’s communications are guided by a detailed and thorough study of how best it can engage with donors and potential donors, especially through more use of electronic methods.

Part 3

Ensuring that blood and blood products are safe

- 3.1 In this Part, we discuss how the Blood Service manages the safety of blood and blood products by:
- assessing and managing risks;
 - screening donors;
 - having strong safety procedures for collecting blood;
 - testing all donations;
 - tracking all blood donations;
 - having contingency plans for managing blood;
 - controlling quality, maintaining accreditation, and complying with regulations; and
 - promoting good practice and safety in transfusion medicine.

Our overall finding

- 3.2 Safety is the cornerstone of the Blood Service's operations. The Blood Service has systems and controls to manage the safety of donated blood and processed blood products in all aspects of its operations.

Assessing and managing risks

The Blood Service uses a suitable framework to assess and manage risks to the supply of blood and blood products.

- 3.3 As part of its policy⁷ for assessing significant risks, the Blood Service uses a matrix to help work out how likely an adverse event is and what its consequences might be. The policy sets out the governance structure for managing risks. It also assigns responsibilities and accountabilities within the Blood Service for assessing and mitigating identified risks.
- 3.4 The Blood Service's framework for managing risks has five components. These are:
- the policy – setting out how to define, report on, and monitor risks;
 - assessing risks – in line with “Safety is our cornerstone”, with a formal process throughout the Blood Service's operations for reporting and dealing appropriately with significant incidents;
 - defining and ranking risks – scoring risks against how likely they are, their consequences, whether they are strategic or operational, and whether they concern safety, supply, or the sustainability of the business;
 - monitoring, managing, and controlling risks – using a risk register and regularly monitoring compliance with policies, standards, and legislative and regulatory requirements; and

⁷ The policy has been aligned to Risk Management Standard AS/NZS ISO 31000:2009 *Risk management – Principles and guidelines* and AS/NZS Handbook HB266:2010 – *Guide for managing risk in not-for-profit organisations*.

- reporting and review – including the Blood Service Executive Team’s formal quarterly review of the risk register and the Blood Service Board’s quarterly review of the “top 10” risks and all identified “high” or “very high” risks in the risk register.

3.5 The Blood Service’s framework for managing risks is particularly strong in dealing with significant incidents that have the potential to become major risks. Every quarter, the Blood Service’s Executive Team and Board receive a summary report of incidents that have been escalated for their attention. Relevant managers consider how to mitigate the risks. The Blood Service adds recurring escalated incidents to its risk register.

Screening donors

The Blood Service effectively screens all prospective blood donors.

Safety standards

- 3.6 Screening prospective donors is the first line of defence in managing blood safety. Screening helps to assess whether prospective donors are healthy and fit to donate blood, and helps to protect patients from infections, diseases, and adverse reactions to donated blood. The Blood Service identifies low-risk donors by learning about their behavioural and medical history.
- 3.7 The Blood Service uses strict standards to collect blood and guide how it screens people who donate blood. Appropriately, the Blood Service focuses on the safety of donors and the blood that it collects.

Screening process

- 3.8 A standard Donor Session Record form must be filled in every time a person presents to donate blood. A registered nurse interviews all prospective donors. The Donor Session Record contains a clear and detailed questionnaire about the interviewee’s eligibility to donate blood and appropriate requirements for donors to confirm that they understand the session record’s content. Prospective donors must sign a declaration stating that the information they provide is correct and accurate. The criteria that the Blood Service uses to assess eligibility to donate follow international best practice.
- 3.9 Effective checks identify donors and ensure that the Blood Service correctly links session records to donors and to blood products resulting from donations. For example, staff at collection sites:
- ask to see appropriate forms of personal identification; and
 - interview donors to verify information in the donor’s session records.

- 3.10 It is important to interview people preparing to donate blood. Staff at collection sites must have effective interpersonal skills because they must sometimes ask sensitive questions or explain tactfully to some would-be donors why they cannot donate blood. Effective interviewing skills are an important part of competency training for staff at collection sites. We observed that the training for donor selection interviews emphasises the importance of ensuring safety and making people feel at ease about donating blood (or being turned down). A rigorous competency assessment requires new staff at collection sites to successfully complete 15 interviews while an assessor watches.

Collecting blood safely

The Blood Service uses detailed and thorough procedures to ensure the safety and care of donors when it collects blood.

Procedures for collecting blood safely

- 3.11 These Blood Service's procedures for collecting blood include:
- training the registered nurses, enrolled nurses, and registered donor technicians who collect blood to observe donors during and after collecting blood, and to deal with any adverse reactions or events;
 - using a reporting system to record all serious incidents; and
 - enforcing strict hygiene standards and procedures while collecting blood.

Quality control

- 3.12 The Blood Service exercises strong internal and external quality control to safeguard the collecting and manufacturing of blood and blood products and to reduce the risk of unsafe blood products reaching patients. This quality control includes:
- the Blood Service's Quality Systems staff auditing the activities of all the Blood Service's departments, blood banks that the Blood Service runs, and aspects of manufacturing blood products from collecting to delivering (including testing, storing, and transporting);
 - Medsafe auditing the Blood Service's manufacturing and collections against internationally developed standards and the Code of Good Manufacturing Practice; and
 - IANZ auditing the Blood Service's laboratories and blood banks.
- 3.13 In paragraphs 3.15, 3.23-3.27, and 3.31, we discuss how Medsafe and IANZ assess and regulate the Blood Service.

Testing blood donations

The Blood Service tests all the blood donated to ensure that it is free of infectious diseases.

- 3.14 Blood is a biological resource. The Blood Service cannot eliminate all risks to recipients from infection, contamination, or adverse reaction. As discussed in paragraph 3.6, the Blood Service seeks to use only low-risk donors, whom it identifies through screening. Another vital measure to minimise risks is to test blood donations for infectious diseases.
- 3.15 The Blood Service tests every blood donation to confirm blood type, check for red cell antibodies, and screen for infectious diseases, including HIV, hepatitis B and C, and syphilis. The Blood Service tests donations in line with the Blood Service's manufacturing standards, which Medsafe approves.
- 3.16 The Blood Service has appropriate controls to ensure that it tests all donated blood. The Blood Service's computer system stops blood products from being labelled and released until it has completed all testing and has electronically collated and validated the results and medical information.

Tracking blood donations

The Blood Service can readily track all blood components (such as red blood cells or plasma) and blood products from donor to recipient.

- 3.17 The Blood Service uses Progesa, a comprehensive computer system, to manage blood donations by:
- storing all data about donors, donations, and patients, including donation history;
 - recording the results of donation and cross-matching tests;
 - tracking and controlling the movement of blood product stock;
 - recording when it supplies blood components and products to patients; and
 - providing the data it needs to recruit donors and correctly invoice hospitals for the blood products they receive.
- 3.18 By using Progesa in all its operations, the Blood Service can trace and recall any donated blood or blood product at any stage of the processing if there are concerns about safety.

Being prepared for disruptions to operations

The Blood Service has adequate contingency plans to protect and maintain its operations in the event of a major disruption to its system for managing blood.

- 3.19 Relying on Progesa throughout all stages of the vein-to-vein service means that it is vital that the Blood Service has plans to continue business when there are unplanned disruptions to its operation (for example, major malfunctions or natural disasters).
- 3.20 The Blood Service has adequate contingency plans to protect its operations in the event of major problems with Progesa. These include being able to switch to other computer servers in different parts of the country if its server were to fail. In addition, as part of standard operating protocols with district health boards (DHBs), the Blood Service regularly distributes an antibody database to hospitals. Therefore, hospital blood banks would have historical information about patient antibodies if Progesa were unavailable.
- 3.21 If there is a disaster or major malfunction of Progesa, the Blood Service has documented manual processes for:
- collecting, processing, and testing donations of blood components; and
 - cross-matching and issuing blood and blood products to patients.

Quality control, accreditation, and compliance with regulations

The Blood Service has effective systems and quality control to ensure that it safely converts blood into blood products. Blood Service staff and external agencies regularly scrutinise the operations of the Blood Service, which consistently maintains the accreditation it requires and complies with regulations.

- 3.22 The Blood Service uses National Collection and Manufacturing Standards to specify the technical requirements for the collecting, making, distributing, and storing of blood components and products. An internal Quality Systems team, which conducts regular audits across all operations of the Blood Service, monitors how the Blood Service adheres to the standards.
- 3.23 The Blood Service has ensured that it complies with good manufacturing practice by consistently maintaining Medsafe licences. The Blood Service is required to maintain these licences at all its sites where blood is processed and made into blood products. Every year, Medsafe audits each site against the Code of Good Manufacturing Practice.

- 3.24 We reviewed a small sample of Medsafe site audit reports and found that the results were highly favourable towards the Blood Service. Medsafe had identified only minor problems that, in our view, had no material bearing on how safe operations at the sites were.
- 3.25 Each year, International Accreditation New Zealand (IANZ) issues accreditation certificates to the Blood Service's diagnostic laboratories after its assessors survey the laboratories and the Blood Service carries out any corrective actions required. The Blood Service has met all the requirements for maintaining IANZ certificates for its laboratories.
- 3.26 The Blood Service has high operating standards in its diagnostic laboratories. In recent years, IANZ has identified few corrective actions for the Blood Service to take, at only a couple of sites. Since 2009, IANZ has not required the Blood Service to take any corrective action.
- 3.27 The Blood Service responds well to the findings of external quality assurance scrutiny. It formally responds to all Medsafe and IANZ recommendations, detailing the action it has taken or stating reasons for not acting. The Blood Service notes any concerns that IANZ has about its system for managing quality and assigns staff to address those concerns. This shows that, where relevant, the Blood Service acts on the recommendations of independent quality assurance inspectors to improve how it operates.

Best practice and safety in transfusion medicine

The Blood Service contributes to good transfusion medicine practices and the safe use of blood products.

Analysing adverse reactions

- 3.28 The Blood Service collects reports on adverse reactions in donors and recipients as part of a national haemovigilance programme. Haemovigilance means detecting, gathering, and analysing information about adverse and unexpected effects of blood transfusion. Under the haemovigilance programme, DHBs voluntarily report transfusion-related adverse events to the Blood Service.
- 3.29 The Blood Service's transfusion medicine specialists analyse and summarise adverse events related to transfusion and publish the findings each year in a haemovigilance report. This is in line with international best practice and is a valuable way for the Blood Service and DHBs to promote awareness of risks and best practice and safety in blood transfusion. It helps the Blood Service to identify ways to improve its internal systems and monitor the effects of using different blood products.

- 3.30 There are few transfusion-related adverse events. In 2011, there were only three life-threatening transfusion-related adverse events reported to the national haemovigilance programme and no transfusion-related deaths recorded.

Systems and processes for district health boards

- 3.31 The Blood Service has appropriate systems and processes in place to help DHBs to provide suitable transfusion services, including:
- a 24-hour transfusion medicine clinical advice service for DHB staff and blood banks;
 - yearly oversight review visits of DHB-run blood banks to help them meet and maintain all the requirements to get IANZ accreditation; and
 - working with Hospital Transfusion Committees to improve prescribing and how blood products are used.

Communicating with district health boards

- 3.32 The Blood Service uses a single main contact – a lead DHB chief executive – to plan and communicate with all DHBs. In our view, this is an efficient way to collaborate and helps the Blood Service to work consistently with DHBs.

Part 4

Supplying cost-effective blood products and services on time

4.1 In this Part, we set out our findings about how well the Blood Service:

- keeps its operations cost-effective;
- forecasts demand and manages supply of blood products;
- delivers blood products to hospitals; and
- monitors, reports, and manages performance.

Our overall finding

4.2 The Blood Service supplies blood products and services in a cost-effective and timely way that meets New Zealand's needs.

Keeping operations cost-effective

The Blood Service has kept its cost increases in recent years below those of the wider health sector. It uses efficient negotiating methods to achieve national consistency of product pricing, and manages its finances effectively.

4.3 DHBs pay a fee for each service they receive from the Blood Service. Most of the Blood Service's revenue comes from these fees (\$100.4 million in 2010/11), with no direct government funding. Each year, the Blood Service negotiates and agrees any cost increases with DHBs using a single main contact – a lead DHB chief executive. Using a single main DHB contact is an efficient way for the Blood Service to negotiate pricing of products with all DHBs and to ensure national consistency. The Blood Service's chief executive and the lead DHB chief executive communicate directly.

4.4 Formal policies define how the Blood Service manages finances and sets prices. A Financial Guidelines Policy guides how the Blood Service manages its financial operations. This includes expecting that the Blood Service will manage its financial affairs in line with financial best practice, as is appropriate for an efficient, well-managed manufacturer. The policy provides for the Blood Service to provide rebates to DHBs when there are any financial surpluses above its foreseeable financial need. This provision has been used twice in recent years, with rebates of \$2.4 million for 2008/09 and \$2.0 million for 2009/10. A Pricing Guidelines Policy states transparently to DHBs how the prices for products will be set.

4.5 In its policies and performance reporting, the Blood Service emphasises minimising cost increases to the health sector, and keeping them within the sector's cost increases. In recent years, the Blood Service has achieved this. Its 2010/11 annual report stated that (after rebates to DHBs) the Blood Service passed on to the health sector a 7.61% compound increase in costs during the five

financial years to 2011/12.⁸ This compared favourably with a 13.61% compound increase during the same period in the overall health sector's contribution to cost pressures, as measured by a Contribution to Cost Pressures index.⁹ This indicates that the Blood Service provides blood products cost-effectively without compromising safety or supply.

- 4.6 The Blood Service has effectively managed input costs and overheads. As Figure 2 shows, during the past five years, the six major Blood Service input cost categories have shown a slight decrease as a percentage of costs to revenue. By keeping production and other overhead cost increases low, the Blood Service can deliver value for money in providing blood products to DHBs. Price increases in 2011/12 were set at 0.65%, below the rate of inflation. Meanwhile, demand for blood products has increased slightly.

Figure 2

New Zealand Blood Service input costs as a percentage of revenue, 2006/07–2010/11

Identified costs to revenue	Actual for financial year				
	2006/07 %	2007/08 %	2008/09 %	2009/10 %	2010/11 %
Indirect overheads to revenue	28.3	28.2	28.5	28.8	28.7
Production consumables to revenue	24.9	23.0	22.9	21.6	22.4
Production labour to revenue	19.3	20.0	19.8	19.9	20.4
Other production costs to revenue	1.8	2.0	1.9	1.7	1.9
Depreciation costs to revenue	5.0	4.0	3.4	3.2	3.1
Financing/capital charge costs to revenue	2.1	2.2	2.7	2.1	2.6
	81.4	79.4	79.2	77.3	79.1

Source: New Zealand Blood Service Chief Financial Officer (December 2011).

- 4.7 The cost of making blood products has increased only slightly during the last four years. The cumulative increase of 9.6% can be attributed to complying with improved safety processes and adopting new proven technologies.

⁸ The figure includes 2011/12 because negotiation and setting of cost increases for products and services occur at the start of the financial year.

⁹ Each year, the Treasury sets the Contribution to Cost Pressures index, an annual inflation allowance made to Vote Health.

Forecasting demand and managing the supply of blood products

The Blood Service forecasts, plans collection of blood, and monitors inventory and demand appropriately to effectively meet demand for blood products. It wastes little product.

Forecasting demand

- 4.8 The Blood Service must ensure that the supply of blood and blood products meets the needs of DHBs, while aiming to minimise the amount of donated blood that is discarded because it has not been used by its expiry date.
- 4.9 To manage supply, the Blood Service must:
- accurately forecast demand for blood products;
 - plan how to collect donations to meet forecast demand; and
 - constantly monitor demand for blood products against stock inventory and forecasts, and use this information, as required, to:
 - redistribute stocks of blood products;
 - adjust how much of different blood products it makes; and
 - revise national and regional collection targets for collecting blood.
- 4.10 Senior Blood Service staff forecast demand. The forecasting is critical for the Blood Service's operations. Staff frequently and regularly analyse suitable information sources to help forecast demand for blood products. This work includes:
- collaborating with DHBs to get their forecasts of product demand (and providing them with monthly product usage reports to help them understand demand and plan their budgets);
 - carefully reviewing sales and product demand statistics for each blood product to identify trends and patterns;
 - considering events, such as medical trials in hospitals, that are likely to change the usual demand for blood products; and
 - analysing international and long-term trends in the use of different blood products.

Monitoring and adjusting stocks of blood products

The Blood Service monitors stock levels effectively. Actual use is usually close to what the Blood Service forecasts, although changes in what medical staff prescribe can significantly affect demand for some of the lesser-used blood products.

- 4.11 The Blood Service continuously and closely monitors its stock of blood products and changes in demand. This helps to set collection targets, control inventory, and forecast.
- 4.12 Every day, the Blood Service monitors stocks of blood products nationally, regionally, and locally. If available stocks fall to certain levels, the Blood Service assesses what it must do. When it has to, the Blood Service redistributes stock to meet demand, or to reduce the amount of product expiring.
- 4.13 The Blood Service makes plans for collecting each blood component based on forecast demand. These plans determine how many whole blood, and plasma and platelet apheresis donations the Blood Service must collect, and tightly link collecting and processing to demand. We found that the Blood Service tightly monitors stocks of blood components that have the shortest shelf life – red blood cells (35 days) and platelets (five days). As a result, the Blood Service can adjust collection plans when demand for a product changes.
- 4.14 The Ministry of Health has received no reports of the Blood Service being unable to supply its main products or services. This means that the Blood Service effectively meets demand for blood and blood products. Maintaining supply is reported as a performance measure in the Blood Service's SOI and annual report.

Minimising the expiry and discarding of blood products

- 4.15 The Blood Service knows how important it is to minimise, where possible, the discarding of expired blood components and processed blood products. Underpinning this, the Blood Service recognises that donors have voluntarily given blood components that it should value and respect.
- 4.16 Blood banks manage stocks of blood products to maximise shelf life. The blood banks supply red blood cells for routine orders on a first in, first out basis to properly rotate stock. The Blood Service aims to supply red blood cells that are less than 15 days old to fill routine orders. In 2010/11, 93% of the red blood cells that the Blood Service distributed were less than 15 days old.
- 4.17 The Blood Service sensibly uses a returns scheme to reduce the amount of blood products expiring. This allows hospitals to return products that are near expiry to the Blood Service so that it can redistribute them to larger hospitals, where they

are more likely to be used before they expire. The Blood Service has controls in place to work with DHBs to avoid over-ordering.

- 4.18 In practice, discarding some blood donations and products through expiry is unavoidable. Hospitals, especially in smaller and more remote regions, need to keep stocks of red blood cells and platelets above their usual usage volumes in case of major unexpected medical events. However, less than 10% of fresh blood products are wasted.
- 4.19 The Blood Service allows some expired blood components or products to be used non-therapeutically (for example, in education or medical research). This is a good way to reduce wastage of expired blood products. The Blood Service's Medical Director formally assesses all requests for expired blood products to ensure that those products will be used ethically, reasonably, and not for profit.

Delivering blood products to hospitals

The Blood Service has effective systems and processes to ensure accurate and timely delivery of blood products to hospitals.

- 4.20 The Blood Service prioritises orders and has different ways to deliver, depending on how urgently DHBs need the products. In many ways, this is similar to how postal and courier companies dispatch and deliver products effectively.
- 4.21 The Blood Service rigorously maintains a controlled environment for all blood products that it transports to hospitals. To ensure the safety of products, all product delivery containers have devices to monitor temperatures. This results in tight quality and safety control when storing and transporting blood products.
- 4.22 The incidence of failures to deliver products is low. Each year, the Blood Service dispatches about 40,000 consignments. In 2010/11, the Blood Service recorded only 49 handling and transport incidents. Of these, only 12 were directly related to failures to deliver products.

Monitoring, reporting, and managing performance

The Blood Service monitors and reports appropriately and in a relevant way so that it and stakeholders can keep track of its performance.

Reporting public accountability

- 4.23 The Blood Service monitors the performance measures that are in its SOI and reports on them every year. This helps stakeholders and the public assess how well the Blood Service manages the safety and security of blood products. In general,

the Blood Service meets the performance measures that it sets. These measures include:

- reporting revenue against budget;
- retaining enough donors to meet demand for blood products;
- counting the number of donations compared with the target number of donations;
- measuring the quantity of fresh blood components produced compared with the target;
- testing all donations before issue;
- showing productive relations with DHBs by agreeing pricing of products and services;
- not having to report to the Ministry of Health any cases of being unable to supply important blood products or services; and
- complying with regulations by:
 - maintaining certification with Medsafe licences at required sites; and
 - ensuring that all of its diagnostic laboratories have ongoing IANZ accreditation.

4.24 As noted in paragraph 2.9, in its SOI for 2011-2014, the Blood Service has introduced useful new performance measures to report how well it targets Māori and younger people as potential donors. The Blood Service also uses survey results about donors' satisfaction to improve its services (see paragraph 2.20).

Other reporting to stakeholders

4.25 As well as public accountability reporting, the Blood Service reports to important stakeholders on how well it is managing. These reports include:

- quarterly performance reports to the Ministry of Health – these monitor performance against the same performance measures used in the SOI, and help the Ministry to monitor the Blood Service's performance regularly; and
- monthly reports about each blood bank, which include information about how the blood bank uses blood products – this includes the age of red blood cells that the blood banks receive, the volume of expired red blood cells, the volume of red blood cells that are returned, and how quickly the Blood Service provides quantities for routine and urgent orders.

Part 5

Keeping the New Zealand Blood Service in line with international best practice

5.1 In this Part, we discuss how the Blood Service keeps its operations in line with international best practice. We focus on:

- international networking and monitoring; and
- benchmarking internationally.

Our overall finding

5.2 The Blood Service improves its services and systems – as appropriate – in line with international best practice.

International networking and monitoring

The Blood Service keeps strong relationships with international organisations relevant to transfusion medicine and blood services. This includes being involved in international forums and conferences covering best practice and improving the safety and provision of blood services.

- 5.3 The Blood Service’s international relationships help it to effectively:
- build networking opportunities with blood service providers in other countries;
 - access international experts in blood transfusion medicine and blood products;
 - monitor, and contribute to, international advances in transfusion medicine and blood products; and
 - keep its standards and operations in line with international best practice.
- 5.4 In particular, the Blood Service’s standards – which state technical requirements for collecting, making, distributing, and storing blood and blood components – use as an external reference the European Directorate for the Quality of Medicines & HealthCare’s *Guide to the Preparation, Use and Quality Assurance of Blood Components*.¹⁰ This guide, updated every year, sets and updates international best practice in blood transfusion medicine, and the safety and quality of blood components. The Blood Service is a member of the guide’s drafting group.
- 5.5 Figure 3 summarises the Blood Service’s main international relationships.

¹⁰ European Directorate for the Quality of Medicines & HealthCare (2010), *Guide to the Preparation, Use and Quality Assurance of Blood Components* – 16th edition, available at www.edqm.eu.

Figure 3
The New Zealand Blood Service's work with international organisations

Organisation	Nature of involvement
European Directorate for the Quality of Medicines & HealthCare	The Blood Service is a member of the drafting group for the <i>Guide to the Preparation, Use and Quality Assurance of Blood Components</i> . This guide is one of the main international standards for blood services. The Blood Service's Medical Director chairs a working group on Quality Management Systems, which keeps the guide's chapters on quality in line with a European Union directive on quality systems.
International Plasma Fractionation Association (IPFA)	The Blood Service is a member of the executive board of IPFA, a professional association for not-for-profit organisations that separate blood plasma into its components.
International Society of Blood Transfusion (ISBT)	The Blood Service's Medical Director is currently the President Elect of ISBT, an international professional organisation for blood transfusion services.
Biological Excellence for Safer Transfusion (BEST) collaborative	The Blood Service is a member of BEST, a professional organisation that focuses on blood components and clinical transfusion.
International Haemovigilance Network (IHN)	The Blood Service is a full international member of IHN, a forum for those working in haemovigilance.
Australia and New Zealand Society of Blood Transfusion	The Blood Service holds one of six positions on the council of this professional organisation for blood transfusion services.
World Health Organization (WHO)	The Blood Service is a member of the WHO Expert Panel on blood transfusion.
American Association of Blood Banks (AABB)	The Blood Service is a member of the AABB. This provides access to AABB's latest information about blood transfusion.
Asia Pacific Blood Network (APBN)	The Blood Service is a member of APBN, which promotes blood safety and efficient blood service operations. Every year, APBN compares its members' benchmarking.

Benchmarking internationally

The Blood Service works with other blood service providers to create international performance benchmarks, although large differences in how blood services operate in different countries mean useful international benchmarking is difficult to achieve.

- 5.6 Directly benchmarking the Blood Service's performance against that of other blood service providers is inherently difficult. This is because of differences in:
- the policy, medical, and regulatory frameworks under which blood service providers operate;
 - the products they provide; and
 - the number of organisations involved in providing a blood service. (New Zealand is one of a few countries where a single organisation runs a vein-to-vein blood service.)
- 5.7 In 2007, Australia's National Blood Authority found it difficult to compare international performance after it had commissioned a detailed study to compare the costs and performance of Australia's fresh blood products services with those of other countries. The Authority concluded that:
- It is important that these benchmarking data [presented in the study's report] are treated with caution ... we have not been able to apply robust data definitions or guarantee we are comparing 'like' with 'like'.*
- 5.8 However, we note that the Blood Service is working with other countries to internationally benchmark some indicators and understand reasons for differences. As a member of the Asia Pacific Blood Network, the Blood Service takes part in benchmarking that compares practice.

Appendix 1

What happens to blood donations?

The Blood Service uses what it calls a “vein-to-vein” business model. This means that it is responsible for all aspects of blood transfusion, from collecting blood, testing it and processing it into blood products, to distributing blood products to hospitals. This Appendix outlines the main processes involved.

Collecting blood

The Blood Service contacts registered donors and asks them to make an appointment to donate their blood at one of 11 Blood Service blood donation centres or at a mobile collection site.

Blood Service staff interview donors, who are then required to fill in an eligibility and health check questionnaire each time they arrange to donate. A successful whole blood donation results in a completed questionnaire, the collection of one unit (470 millilitres) of blood in a sterile bag, and a small amount (15 millilitres) for testing. The Blood Service then dispatches the collected blood units under controlled conditions to one of its four processing centres (in Auckland, Hamilton, Wellington, and Christchurch). At the same time, the Blood Service sends the test samples to one of its two testing centres (in Auckland and Christchurch).

Processing donations

All whole blood donations go through a filtering process called leucodepletion. This removes most white blood cells (leucocytes). Research has shown that doing this reduces the risk of certain diseases and adverse transfusion reactions in patients who receive donated blood.

Blood units then go into a specialist centrifuge machine that spins them at a controlled speed and temperature. Centrifugation separates the main (remaining) components of blood. Specialist machines then extract and bag these separated components.

The relatively heavy **red blood cells** settle at the bottom of the bag, where they can be carefully removed. Red blood cells carry oxygen and carbon dioxide through the body. They are used during surgery, and for treating people who get anaemia from diseases such as cancer.

A lighter component of blood called **plasma** moves towards the top of the bag. Plasma, a straw-coloured fluid, makes up more than half the volume of blood. It contains and carries water, proteins, white blood cells, red blood cells, and platelets around the body. Plasma is used to treat burns victims and people who have had surgery or organ transplants. Plasma can be made into many specialist products using a process called fractionation. Fractionated plasma products can last up to two years and are used for many purposes, including:

- treating burns or acute blood loss;
- transplant surgery; and
- helping people with bleeding disorders, infection, or immunity issues.

Centrifugation creates a thin layer between the red cells and plasma. This “buffy coat” contains **platelets** and white blood cells. Platelets (and some important clotting factors found in plasma) play a major role in blood clotting. They are used to treat blood diseases, cancer, and for controlling bleeding after surgery or trauma. There are not enough platelets in a single whole blood donation unit to treat a patient. Therefore, platelets are pooled and processed further.

Apheresis

Apheresis is an automated alternative to collecting whole blood. After the Blood Service collects blood, a special cell separator machine separates the red blood cells from the plasma or platelets. The red blood cells are then returned to the donor. Apheresis provides larger quantities of plasma or platelets than standard whole blood donation. Because apheresis donors do not give red blood cells, they can donate more often than donors of whole blood.

Testing blood products

At the Auckland and Christchurch testing centres, the Blood Service tests samples of donated blood in parallel to processing the donated unit of blood. It tests every donation to confirm blood type, check for red cell antibodies, and screen for infectious diseases. Blood Service staff do not label blood products until after all processing and testing, and the electronic collating and validating of results and medical information.

Storing and distributing

The Blood Service must store blood products in strictly controlled temperatures and conditions, from collecting them to their being issued for use in patients. For example, red blood cells, which have a shelf life of 35 days, must be stored at between 2°C and 6°C. Platelets, which can only be used within five days of being donated, must be kept at 22°C and agitated gently and continuously. Fresh plasma must be frozen at a controlled temperature of below -25°C and may be stored for up to two years.

Hospital blood banks order final products, which are distributed by logistics teams in the Blood Service's "hubs" at Auckland, Hamilton, Wellington, and Christchurch. These teams manage inventory, seek to minimise waste because of product expiring, and ensure that supply meets demand.

Delivering blood products from blood banks to hospitals and patients

The Blood Service has blood banks in six of the country's largest hospitals: Auckland City, Waikato, Palmerston North, Wellington, Christchurch, and Dunedin. The blood banks ensure that patients get the right product, on time, and in good condition. This includes pre-transfusion testing to determine patients' blood types and to match them to blood products. Local DHB staff run all other hospital blood banks, but the Blood Service has overall responsibility for national blood banking services and oversees these other blood banks. After blood products have been dispatched from the blood banks to hospitals, medical staff prescribe and infuse the products into patients.

Appendix 2

Blood products, their uses, and how long they last

Fresh blood products

	Medical use	Shelf life
Plasma	For patients after trauma or transplants	Up to two years if stored below -25°C
Platelets	For patients with some blood diseases or cancer, and to control bleeding after surgery or trauma	Up to five days if stored at 22°C and constantly moved
Red blood cells	For patients with chronic anaemia resulting from disorders such as kidney failure or cancer, and acute blood loss from trauma or surgery	Up to 35 days when stored at 4°C

Products manufactured from plasma

	Medical use	Shelf life
Albumex [®] 4	In patients with burns or in shock from blood loss	Up to two years
Albumex [®] 20	To treat liver failure or renal failure associated with severe protein deficiency	
Rh(D) Immunoglobulin-VF (Anti-D)	To prevent haemolytic disease in newborns whose blood type is incompatible with their mother	
Cryoprecipitate	For helping blood to clot in trauma patients and during cardiac surgery or transplants	
Biostat [®] (Factor VIII)	To manage haemophilia A, an inherited bleeding disorder that requires lifelong treatment	
MonoFIX [®] -VF (Factor IX)	To treat haemophilia B, an inherited bleeding disorder	
Prothrombinex-VF (Factors II, IX, and X)	To reverse the anticoagulant effect of warfarin in bleeding patients	
Hyperimmune globulins	To temporarily protect from a specific infection, such as tetanus or hepatitis B	
Intragam [®] P	To treat patients with immune deficiencies or those whose immune system has been compromised	
Normal immunoglobulin	To protect travellers from contracting hepatitis A when visiting high-risk areas	

Source: New Zealand Blood Service (2011), *New Zealand Blood Service Annual Report 2010/11*.

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