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## The development of a national New Zealand Blood Service

New Zealand Blood Service hosted our first seminar for 2003.

Dr Peter Flanagan, their National Medical Director; Jennifer Mitchell, the initial General Manager Operations; and Dr Judith McMorland, who teaches postgraduate students at the Auckland University Business School provided an interesting and entertaining presentation that traced the first three years of the N Z Blood Service and reflected on the critical issues of organisational and professional change that had to be addressed to achieve a world-class blood service. They said:

“The New Zealand Blood Service was established on 1 July 1998 by the Health Amendment Act 1998 and became the 23rd Health and Hospital Service (HHS). It functioned as a not for profit company under the Companies Act with two shareholders, the Ministers of Health and Finance. The Crown in establishing the National Blood Service identified a number of priorities.

- Minimise risk to recipients of blood products and to the Crown. It is noteworthy that one of the specific requirements in the legislation is that we must develop and maintain effective links with consumer organisations, including the Haemophilia Foundation New Zealand and Kids Foundation.
- Be responsive to situations such as emergencies or potential infection risks.
- Provide and ensure clear accountability from those who make decisions and how and on what basis were those decisions made.
- Provide strategic direction and leadership to overcome the problems encountered in 1992.
- Be a nationally consistent and accessible service and protect the gift status of blood



Judith, Peter and Jennifer

The context to this was the changes brought about by the 1992 Health Reforms. Pre-1991, transfusion services were the direct responsibility of 14 locally elected Area Health Boards. There were six regional blood centres at Auckland, Hamilton, Palmerston North, Wellington, Christchurch and Dunedin, with 18 sub centres in small local hospitals. There were no centralised databases and no integration of services. Oversight of the sector was through a “Transfusion Advisory Committee to Ministry of Health”.

The Health and Disability Services Amendment Act 1993 brought health reforms and a Purchaser - Provider split. Public hospitals (CHEs) were responsible for Blood Services and the 4 Regional Health Authorities that were established became purchasers of blood services from CHEs. A Blood Transfusion Trust was established

There were two pivotal events, which from an international and historical perspective demonstrate the failure of the model put in place in 1992. The first was the significant delay within New Zealand relating to the introduction of testing for HCV. The second was more subtle and took place in 1996 when a number of blood products were withdrawn because of a theoretical concern in relation to contamination.



## New Zealand Blood Service

*The gift of life*

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Although the withdrawal was undertaken with reasonable efficiency, the communication with the users of the products was not well handled at a number of sites and this created quite adverse media coverage for the Blood Service. The experience internationally is that when things go wrong in the Blood Service people want to know why.

Those two issues, coupled with increasing concerns within Medsafe (the regulatory arm within the Ministry of Health) led to the establishment of the Carter Marshall Review. John Carter is a haematologist in Wellington and Keith Marshall was from the Ministry of Health. The findings of their report were clear cut. There was a wide variation in both manufacturing and clinical standards, poor national inventory management, difficult communication lines at both operational and clinical levels, and a lack of sector wide planning and strategic direction.

The concept of establishing a national service was the prime Carter Marshall recommendation to government. As a result, the New Zealand Blood Service was established in order to:

- Ensure national consistency of service quality
- Establish a national strategic direction
- Achieve rationalisation of the service process and thereby a more efficient blood service

The key relationships that emerged for the NZBS were not that much different to that of the other HHSs. There was a relationship with the Ministry of Health, which was somewhat unclear, and oversight by CCMAU. The relationship with Medsafe is important and requires some explanation. In 1992 one of the strategies the Ministry put in place to safeguard the quality of blood components within New Zealand was to identify blood products as registered medicines and thereby bring them under the auspices of the Medicines Act and Medicines Regulations. As a result, each individual site required a licence from Medsafe to manufacture and issuance of that licence on an annual basis was determined by a satisfactory inspection. Therefore, at least in theory, the Ministry have control of the standards of the service through the licensing process. It is noteworthy that in the 6 years that the process was in place at no stage was a licence withdrawn, despite increasing concerns and correspondence between Medsafe and the Ministry.

#### NZBS Project Management

No matter what the size of a hospital, it has to meet the same regulations as a big institution. Similarly, we felt that as a small service in a small country we had a responsibility to cover off everything that the American Red Cross or the Australians or whoever also had to do. We were a 'minnow in a sea of sharks'. A small country, small service, with big aspirations

Our aim was to identify the best practice, gain access to the intellectual capital and implement with minimal alteration. This was not done in isolation. We were operational from day 1, and were operating from Auckland, Wellington and Christchurch so there was a bit of a flurry getting things under control.

The key challenges we faced in the development of a National Blood Service for New Zealand are encompassed in 3 key projects we needed to complete within a 3 year timeframe:

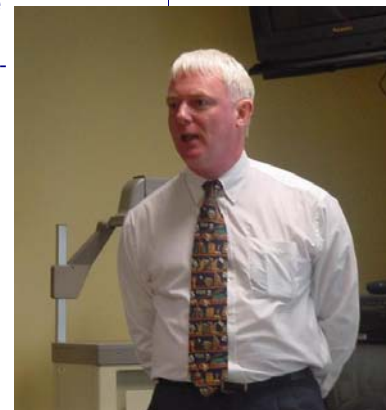
The Blood Management System Project, which is the computer system needed to manage the national blood system; the Hospital and Health Service Integration Project, which was to get all the other Blood Services into NZBS ; and the Service Development Project, which was to develop an organisation that could support the infrastructure of the Service.

Prior to the establishment of NZBS there was a whole range of different facilities up and down the country doing a range of things. In every centre there was a differing range of activities, including some we did not know about and were not necessarily related.

We now have a centralised structure incorporating accreditation testing sites at Auckland and Christchurch, 4 processing sites where blood products are manufactured, and 6 sites co-ordinating collections throughout the country. NZBS was established with 'vein to vein' responsibility. It directly manages Hospital Blood Banks at the 6 manufacturing sites and contracts responsibility for Blood Banking to other DHBs under Supply Agreements.

We developed three interdependent projects to establish the integrated national service:

A Service Development Project allowed us to go from our blank start to develop a national organisation. We started off by going overseas to look at international services. We looked at places that had a similar sized population, a health system not too dissimilar to New Zealand,



Peter Flanagan in full flight

There was a whole range of different facilities up and down the country doing a range of things. In every centre there was a different ratio of activities, including some we did not know about

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and was a long thin country with a 'coal pit' at the end because we have a geography issue to consider. We looked at Norway, Finland and Scotland as countries that fitted those requirements. From that we came back to a conceptual design in which there was a requirement for centralisation and for manufacturing in certain places. That concept was tested through workshops and logistical and financial analysis. The result was the "2-4-6" model outlined above.

We then looked at integrating the HHS based transfusion services into that format. As we brought them into the NZBS we changed them to fit the desired format. By August 2000 we were manufacturing all blood products in New Zealand so all of the collection and manufacturing was being managed through our planned structure.

That unbundling of services was very complex. The transferring of a service – the contracts, the assets, the people, and then contracting back the supply of blood and everything that entails, coupled with the local variations, was a massive project.

A number of the larger centres had been looking at a blood management system but none of them could afford the kind of blood system that was required. We looked at a number of systems, put out an RFP and got three major responses. The one we chose was the one in Scotland and Finland - we had seen it and it worked. It is an interesting system, written by a Macedonian, sold out of Paris, converted into English in Scotland and managed in New Zealand by the Spanish. We outsourced the hardware and facility management and were lucky to be able to start with a clean slate.

It is interesting that up to 12 months after establishing the service we did not know how much blood there was in New Zealand. It was almost impossible to find out in a timely manner because there was no existing infrastructure to enable that type of data to be put together.

We went to Scotland and acquired their intellectual capital. We did ratification between the two countries and they came out to New Zealand and looked at what we had and we imported it pretty much unchanged.

Integration was completed by the end of August 2000. We had developed an integrated national service able to supply to everyone whether they were in Tairāwhiti or Auckland, ensuring quality, safety and supply and positioned to meet the challenges of the future as a world class service.

While the NZBS was trying to put itself together to manage the future risks that were identified as a priority, the future risks were no longer the future. Within a very short space of time a number of significant developments took place. The challenge of change hit us through a requirement to meet international standards.

EC CPMP/BWP/390/97(rev6) – which is something no one in New Zealand had heard of, is a requirement to apply nucleic acid testing to plasma fractionation pools. It was by definition a European requirement and because it was a European requirement it was a requirement of any product that might be imported into Europe so the United States was forced to follow.

Six months after this became effective in Europe, it became a European Pharmacopoeial requirement and a European requirement is an Australian TGA requirement in relation to the manufacturing activities of CSL. We send our plasma to CSL in Australia and therefore if we wished to continue to have our plasma fractionated by CSL we had to follow this regulation.

This is an example of the international harmonisation of blood service decision making arising from the international market for plasma, which is a commodity on the world stage.

It was recognised in Europe that the regulation was before its time. The technology wasn't there to easily deliver what was required of us. Both the NZBS and the Australians analysed the options and made recommendations for change but there was little political will for change until a young girl in Melbourne acquired HIV through a blood transfusion. The Australians were directed to take an expensive option, developed by a company called Klyron, which tested for HIV and HCV. Our Minister of Health attended a conference in Australia about this time and in November 1999 identified a requirement for New Zealand to follow the Australian approach. That is an example of how regulatory requirements can become embroiled in political decision making and makes transfusion services such an interesting place to work.

At the same time there was an increasing international concern in relation to variant CJD. In 1998, some 10 years after the disease was first identified, the UK introduced 'precautionary measures' to prevent transmission by blood. Since 1998 the UK has burned 550 metric tonnes of plasma each year. It imports paid donor plasma from the United States and manufactures that into products to be used in the United Kingdom.

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They could not import red cells and therefore implemented Universal Leucodepletion in the belief that it might be beneficial. This got the international community quite excited and in 1999 the US Federal Drug Agency and Health Canada announced an intention to introduce UK donor deferral to reduce their risk. This was a very pragmatic approach. They said, “we can not do anything about this disease, we can’t test for it, we do not know if it is there, but just in case any one who has been to the UK we would like to exclude. They could not do that so they said, “how much can we afford to lose?” They decided 2½% so they did a travel survey and that corresponds to 6 months so the 6 months UK donor referral was set in stone.

The question was, what should New Zealand do? We had done our survey and knew that 1 in 3 New Zealand donors had visited the UK between 1980 and 1996 and 10% had visited for more than 6 months. At that point we did not have a mechanism to make a decision but decided that we could cope with a 10% donor loss and made a recommendation to the Minister. As a result, in November 1999 MoH announced package of measures. UK donor deferral (10% of donors excluded) was introduced. At the same time, recognising that 1 donor in 5 still had a link to the UK, Universal Leucodepletion was part of the package.

At this stage we still did not have a national service. Testing was still taking place at a number of sites. Processing integration had not been completed. The only effective measure we could put in place to see what was happening was to require everyone to submit a daily summary of what blood they had. By November 1999 we had a daily inventory sheet.

Coming back to Nuclear Acid Testing, the reality is that we had to test for this viral genetic material using technology that had not been used on such a scale before. The samples were tested in pools rather than individually because the technology allowed that. We faced patent issues. We had two potential suppliers. After due diligence we selected one and then were told that they could not supply because of patent issues and the other supplier had taken out a world wide patent. After designing a NAT suite in our new building to suit the technology, we had to turn around and negotiate with a monopolistic supplier. Thankfully, we received moral support from the international blood community, which made our negotiations with that supplier easier than might have been the case.

Universal Leucodepletion makes manufacturing much more expensive. However, the change provided an opportunity to standardise component processing systems across the four processing sites. Statistical process control used to monitor performance. The NZBS approach is based on English NBS models

The deferral of “UK donors” was an interesting experience. We put in place a vigorous campaign to recruit replacement donors. The response was good. The difficulty was replacing long term donors with a high return rate with new donors with a much lower return rate. Although this was a difficult time for us, in international terms, we survived this period quite well.

We have moved from being a company to a Crown Entity. Largely as a response to pressure from the hospitals, we have removed the service from hospitals into our own sites where we are more accessible to the public. After 3 years we are established, running and able to make decisions about blood services in a much more mature way. The solution identified by Government to form the New Zealand Blood Service has worked to reduce the risk to recipients of blood products.

So, science, medicine, the regulator or whatever, the simple plan of the NZBS to establish itself in 3 years was hijacked by the reality of bureaucrats, mad cow disease and nuclear acid testing. Never the less we have achieved our goal, for the first time New Zealand has a truly national blood service.

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Judith McMorland

## The best laid plans of mice and men so often go awry

Robert Burns's cautionary proverb was amply illustrated on March 12, scheduled as a "sentinel event" seminar for the Institute. The first Auckland seminar beamed live into Wellington through video conferencing facilities provided by Minter Ellison. Our guest speaker, Colin Feek, Deputy Director General Clinical Services at the Ministry of Health, speaking on Strategy drew a good number of registrants for the seminar to both the Auckland and Wellington locations.

### Problem No 1

Colin became ill. Demonstrating his grasp of the need for a 'Plan B' back up strategy he quickly arranged for Judy Glackin, Manager, Health of Older People Policy, to take his place and speak on the Ministry's Health of Older People Strategy. Her presentation was prepared and copied and seminar rooms were set up with drink and nibbles at hand for attendees to enjoy during our important networking session.

### Problem No 2

A Cathay Pacific pilot bent the tail of his 747 on the tarmac at Auckland International Airport. With debris all over the tarmac and the bent 747 at the end of the runway the airport was closed. Judy got no closer to Auckland than a 7000 feet fly over as her flight was diverted back to Wellington.

### Problem No 3

The wine and nibbles were nice but where were we going to find a speaker? Emboldened by a little of our sponsors delightful smooth red I noted that Judy's presentation was on older people. As demonstratedly the oldest person present I felt I should offer to fill the gap. The ladies present humoured a vain old man and gave me the floor.

I am told my impromptu presentation on bioterrorism was well received and generated vigorous debate in Wellington after we closed. A week later I would have changed the subject to "whatever happened to bioterrorism when SARS came along?"

I can report that the video link with Wellington was excellent. A wonderful way to communicate without leaving town. The good news for members is that we always have plans B and C to guarantee a speaker at our seminars. Not only will there be food, fellowship and networking, there will be a little stimulus for the mind.

Helene Lipton Professor of Health Policy and Pharmacy, University of California at San Francisco will present at our next seminar on April 3rd. I look forward to seeing you there.

Bruce Parkes

MinterEllisonRuddWatts  
LAWYERS



## Contributions Welcome

1. The Auckland Branch welcomes contributions to **Inform** on subjects of interest to managers in the health and disability sector. Articles may be longer researched contributions, comments on current practice, or shorter notes and/or reviews. The range of possible subjects is very wide.
2. The maximum length is generally 3000 words. Shorter contributions are very welcome. Please include an e-mail address so authors can be contacted and a brief list of key points or an abstract.
3. Copy should be provided by e-mail or on a computer disk.
4. Contributions may be passed to the Editorial Committee for consideration.
5. Make submissions or contact the Editor for more information at [nzihm@xtra.co.nz](mailto:nzihm@xtra.co.nz)



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## Up coming Seminars

April 3rd

@ Birthcare

20 Titoki St, Parnell  
5.30m. for 6 p.m.

### Drug risk relationships between physician groups and funders”

Helene Lipton Professor of  
Health Policy and Pharmacy,  
University of California at  
San Francisco

### Non Members Welcome

Cost

Members \$20

Non Members \$30

Light refreshments supplied

## Profile

Fiona Ritsma joined NZIHM in 1990 and was elected on to the Auckland Branch Committee in 1998. Her ability and willingness to put her “shoulder to the wheel” were quickly recognised as she was elected to the National Council in 2000 and appointed National President in 2001. Despite her heavy workload as our President and her senior management position, Fiona remains a committed and active member of our Branch Committee.

Fiona grew up in Hawkes Bay then moved south to Christchurch to train as a radiographer. After graduation she undertook her “obligatory OE” working in London, Westminster and Kings College Hospitals in London. She returned to Christchurch for a few years before being enticed by the challenges available in Auckland.



Starting as a Charge Radiographer in the Oncology Department at Auckland Hospital, Fiona has moved through management position to her present position of General Manager, Clinical Support Services at the Auckland District Health Board (ADHB), where she is responsible for Radiology, LabPlus, Pharmacy, Nutrition, Clinical Engineering and Clinical Genetics Services.

While Service Manager, Oncology, Haematology and Palliative Care, a role she held for eight years, she was responsible for significant expansion of radiation oncology facilities and the fundraising, design, building and commissioning of a purpose built adult bone marrow transplant unit. Fiona moved on to become the Auckland Hospital Manager of Acute and Allied Health. This was a broad portfolio, which at times included Emergency Medicine, Critical Care, Neuro Services, Allied Health, Clinical Records, A+ Links (gerontology and community based nurses and Allied Health), Pain Service and Administration Services.

Fiona has undertaken study tours of Hong Kong – Great Britain and Europe, and Australia. She has a Diploma in Business Administration from Massey University and is sought after as a speaker and author for sector publications. She is an Associate Fellow of ACHSE, a Fellow of the NZ Institute of Medical Radiation Technology and a member of the Auckland Division of Cancer Society of New Zealand.

Fiona is a “people person”. Always ready to listen and communicate, her humour and enthusiasm is an effective motivator of team activity. She is a keen traveller and somehow finds time for cycling, walking and reading.

In her role as National President Fiona looks forward to working with the New Zealand National Council to further develop the range of services available to NZIHM members, working closely with ACHSE and contributing to a raised standard of health management in New Zealand.

## 2003 Conference

### Note your diaries now

Health New Zealand Conference & Exhibition 2003  
NZIHM continues its strategy of adding value for members by holding a combined conference with other healthcare special interest groups. Our 2003 Conference will be a combined conference with Health Informatics New Zealand.



Theme Advancing Knowledge for Quality Healthcare  
Date 6–7 August  
Location Hyatt Regency Auckland  
More information in later editions of Inform and by special flyer