Accreditation of Blood Banks in Australia

First American Congress for the Accreditation of Medical Laboratories, Blood Banks and Haemopoietic Progenitor cells

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What will be covered:

The Regulation of the Blood Service – overview

The key stakeholders

NATA Accreditation and Standards for Blood Service accreditation

The Regulation of the Blood Service - overview

- Blood and blood components are donated voluntarily and free of payment to donors
- Blood and blood components are provided to patients free of charge and based on clinical need and appropriate clinical practice
- Regulation of the Blood Service is a fairly complex process with different stakeholder groups involved
- Australian based manufacturers of medicines and biologicals are required to hold a licence to manufacture.
- To obtain a licence, a manufacturer must demonstrate compliance with the relevant code of GMP. This is usually, but not always, done through an on-site inspection
- It is an offence in Australia to manufacture therapeutic goods for human use without a licence or certification unless the manufacturer is exempt from this requirement under the Therapeutic Goods Act 1989(link is external).

The Regulation of the Blood Service - overview

The Australian Red Cross Blood Service (ARCBS) is the principle body responsible for:

Donor collection of blood and blood components

Testing , processing and distribution of blood and blood components

Provide products such as Packed red cells, Platelets, Fresh Frozen Plasma etc

CSL Behring is the national provider of fractionated plasma components

Most plasma derived products used are manufactured by CSL Behring from plasma collected by the ARCBS under the CSL Australian Fractionation Agreement.

The Regulation of the Blood Service - overview

ARCBS and CSL Behring release Blood and Blood components to Pathology Immunohaematology (Transfusion) departments

Pathology transfusion departments perform supplementary testing prior to release for patient use

The Regulation of the Blood Service - overview

The ARCBS and CSL Behring are contracted to the NBA to produce Blood and blood components

The ARCBS and CSL Behring are licensed by the Therapeutic Goods Administration (TGA) to collection, process, test and release donated blood under the Therapeutics Goods Act

ARCBS are also Accredited by NATA for Testing activities

Pathology Immunohaematology (Transfusion) departments are accredited by NATA

The Key Stakeholders in the “Blood chain”

Regulators / Legislators / Licensing

Commonwealth & State Governments

The Therapeutic Goods Administration (TGA)

The National Blood Authority (NBA)

Standards and Standards writing bodies

TGA

ISO

National Pathology Accreditation Advisory Council (NPAAC)

Standards Australia

Accreditation Body

NATA

The Key Stakeholders in the "Blood chain"

Regulators / Legislators

<u>Commonwealth & State Governments</u>

- **Provide funding for Blood and blood component usage (through the NBA)**
- **<u>$1 billion</u> per annum funding the supply of blood and blood products.**
- **Provide directives on the use of Blood and blood components in their jurisdictions**
- **Mandate Licensing requirements**
- **Mandate accreditation for testing activities**

The Key Stakeholders in the "Blood chain"

Regulators and Licensing

The Therapeutic Goods Administration (TGA)

- **is a division of the Federal Government Department of Health**
- **is responsible for regulating medicines and medical devices (under which Blood and Blood products fall)**
- **TGA administers the Therapeutic Goods Act 1989**
- **TGA applies a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of**
    - **Quality**
    - **safety and**
    - **efficacy (performance), when necessary**

The Key Stakeholders in the "Blood chain"

The Therapeutic Goods Administration (TGA)

- **Blood and blood components are regulated under the *Therapeutic Goods Act* 1989 (Legislation)**
- **The TGA issue a License to ARCBS and CSL Behring in accordance with the Australian Code of Good Manufacturing Practice (cGMP) (2013) for the manufacture of human blood and blood components, human tissues and human cellular therapy products**
- **Good Manufacturing Practice (GMP) describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality**
- **There are different codes of GMP, depending on the type of therapeutic good**
    - **Good Manufacturing Practice for Medicines**
    - **Good Manufacturing Practice for Human Blood and Tissues**

The Key Stakeholders in the “Blood chain”

The National Blood Authority (NBA)

- **The National Blood Authority (NBA) is an independent statutory agency within the Federal Government Department of Health portfolio**
- **The NBA was established by the National Blood Authority Act 2003 following the signing of the National Blood Agreement by all state and territory health ministers in November 2002**
- **The NBA is separate and independent from TGA**
- **The NBA have no legislative powers**

The Key Stakeholders in the “Blood chain”

The National Blood Authority (NBA)

- **Manages and coordinates the national blood supply to ensure that healthcare providers have reliable and efficient access to blood and blood products**
- **Develops and implements national strategies to encourage better use of blood and blood-related products**
- **Supports the work of the jurisdictions to improve the way blood products are used - including developing and facilitating strategies and programs that will improve the safety, quality and effectiveness of blood usage, particularly in the areas of national standards, guidelines and data capture and analysis**
- **Tracks the usage and fate of Blood and Blood components**

The Key Stakeholders in the “Blood chain”

The National Blood Authority (NBA)

- **Negotiates and manages national contracts with suppliers of blood and blood products to obtain the products needed**
- **Assesses blood supply risk and engages in contingency planning for risks arising in the sector and impacting on the sector**
- **Works with jurisdictions to determine the clinical requirements for blood and blood products to meet national clinical needs and develop an annual supply plan and budget**
- **Provides expert advice to support government policy development, including identification of emerging risks, developments, trends and new opportunities**
- **Manages the evaluation of proposals for blood sector improvements, including proposals for new products, technologies and system changes**

The Key Stakeholders in the “Blood chain”

Standards bodies – for Accreditation Activities

ISO, National Pathology Accreditation Advisory Council (NPAAC) and Standards Australia

NATA accreditation of all Pathology testing including ARCBS and Pathology laboratories is mandated by:

- **TGA for testing of In-house In-vitro diagnostics (In-house IVDs)**
- **Commonwealth Department of Human Services for activities involving Medicare reimbursement**

Accreditation activities and Accreditation Standards

ISO

NATA use of ISO 15189 for all Pathology related activities

National Pathology Accreditation Advisory Council (NPAAC)

In 1986, the Commonwealth introduced a compulsory accreditation system in relation to Medicare benefits for pathology.

In order to be accredited, a pathology laboratory must meet specified quality standards – these are defined by NPAAC

NPAAC is a division within the Federal Government Department of Health

Separate and independent from TGA and the NBA

Accreditation activities and Accreditation Standards

National Pathology Accreditation Advisory Council (NPAAC)

- **advises the Commonwealth, state and territory health ministers on matters relating to the accreditation of pathology laboratories**
- **plays a key role in ensuring the quality of Australian pathology services**
- **is responsible for the development and maintenance of standards and guidelines for pathology practices**
- **is comprised of representatives from all states and territories, nominees from peak professional bodies and the Department of Health.**

NPAAC Standards relevant to the Immunohaematology

Tier 2 - Standards and Supervisory Requirements for Pathology Laboratories

- **Requirements for Medical Pathology Services Requirements for the Supervision of Pathology Laboratories**

Tier 3 - Requirements for good medical practice in all Pathology Laboratories

- **Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials**
- **Requirements for Participation in External Quality Assessment**

NPAAC Standards relevant to the Immunohaematology

Tier 3 - Requirements for good medical practice in all Pathology Laboratories

- **Requirements for the Retention of Laboratory Records and Diagnostic Material**
- **Requirements for Information Communication**
- **Requirements for the Development and Use of In-House In Vitro Diagnostic Medical Devices**

Tier 4 - Specialised technical publications, intended to specify requirements in Pathology Laboratories undertaking testing in specific areas of pathology

- **Requirements for Transfusion Laboratory Practice**
- **Requirements for Medical Testing of Microbial Nucleic Acids**

NPAAC Standards relevant to the Immunohaematology

Requirements for Transfusion Laboratory Practice

Patient identification and labelling

Transfusion laboratory records

Pretransfusion testing

Antenatal and perinatal testing

Selection of blood components

Selection of red cells for transfusion

Selection of non-red cell blood components

Fresh frozen plasma, extended life plasma and cryoprecipitate

Platelet concentrates

Transfusion in special circumstances

- **Emergency transfusion**
- **Massive blood loss / critical bleeding**
- **Antenatal and neonatal settings**
- **Transfusion reactions**

Accreditation activities and Accreditation Standards

Standards Australia

Standards Australia is the nation's peak non-government Standards organisation

It is charged by the Commonwealth Government to meet Australia's need for contemporary, internationally aligned Standards and related services.

Standards Australia represents Australia on the two major International Standardizing bodies

- **the International Organization for Standardization (ISO)**
- **the International Electrotechnical Commission (IEC)**

Accreditation activities and Accreditation Standards

AS 3863 - Medical refrigeration equipment – For the storage of blood and blood products (2012)

Part 2 – User related requirements for care, maintenance, performance verification and calibration

Specifies user requirements of medical refrigeration equipment used for:

- **Blood and blood products in the temperature range 2ºC to 6ºC**
- **Frozen plasma and plasma products at a temperature -25ºC or lower**

Accreditation activities and Accreditation Standards

Australia and New Zealand Society of Blood Transfusion (ANZSBT)

Peak professional body and technical advisory group

ANZSBT offers

Provision and communication of independent expertise in transfusion medicine.

Seeks

To define and promote best practice in clinical and laboratory transfusion medicine.

To engage with stakeholders in all areas of transfusion through communication, representation and advocacy.

To promote and support education and research.

The advancement of knowledge in blood transfusion and transfusion medicine.

The promotion of improved standards in the practice of blood transfusion

Accreditation activities and Accreditation Standards

ANZSBT Guidelines:

- **Extended Life Plasma: A Framework for Preparation, Storage and Use, Administration of Blood Products**
- **Prevention of Transfusion-Associated Graft-Versus-Host Disease**
- **Pretransfusion Laboratory Practice**
- **Blood Grouping & Antibody Screening in the Antenatal & Perinatal Setting**
- **Laboratory Assessment of Fetomaternal Haemorrhage**
- **Autologous Blood Collection**

Accreditation of Blood Donor Services and Immunohaematology

NATA accredits:

ARCBS

Pathology Immunohaematology laboratories

To – ISO 15189, NPAAC and ISO Requirements

Also uses ANZSBT Guidelines

Accreditation of Blood Donor Services and Immunohaematology

Accreditation of Blood Donor Services (ARCBS) includes

Assessment teams include:

Haematologists/ Immunohaematologists

Immunologists

Microbiologists

Biochemists

Some areas of discussion surrounding patient/donor identification and sample identification – no donor information included on testing specimens

By screening donors for infectious diseases are ARCBS acting as a "diagnostic laboratory"

Accreditation of Blood Donor Services and Immunohaematology

10.80 Blood donor services

- **.01 Collection of blood from donors, routine**
- **.02 Collection and storage of autologous blood donations**
- **.03 Collection and storage of directed/dedicated blood donations**
- **.04 Collection of cells or plasma by automated means**
- **.06 Operation of a mobile collection unit**
- **.10 Preparation of blood components**
- **.11 Storage and distribution of blood and blood components**
- **.12 Freezing and thawing of cellular components for transfusion**
- **.13 Preparation of leucocyte-poor red cells**
- **.35 Screening of donor blood for markers of transfusion transmitted disease**
- **.80 Tissue typing - donor specific antibody detection and antibody identification**

Accreditation of Blood Donor Services and Immunohaematology

10.10 Microbiology

10.11 Bacteriology

.02 Inoculation of cultures
10.16 Serology of infection

.02 Extended serological testing
.03 Specialised or uncommon serological testing procedures
10.17 Detection and characterisation of microbial DNA/RNA
.02 Detection and characterisation of parasitic DNA/RNA

.03 Detection and characterisation of viral DNA/RNA
10.20 Immunohaematology
.04 Identification of blood group antibodies
.05 Determination of compatibility of donor units
.06 Red cell phenotyping
.07 Antibody elution
.18 Blood grouping including ABO, Rh(D) and other antigens and antibody screening by manual methods
.80 Molecular Genetic Studies (Platelet Antigens)

.16 Blood grouping including ABO, Rh(D) and other antigens and antibody screening by automated methods

Accreditation of Blood Donor Services and Immunohaematology

10.30 Haematology
.01 Blood counts
.02 Visual examination of blood films
.05 Automated differential leucocyte counts
10.40 Immunopathology

.12 Detection of autoantibodies in body fluids and biopsy material

.40 Human Leucocyte Antigen (HLA) typing

.41 HLA Single Antigen Tests

HLA B27, B57

.80 Molecular genetic studies

.99 Miscellaneous tests

Histocompatibility Testing

Accreditation of Blood Donor Services and Immunohaematology

10.60 Chemical pathology

10.61 General chemistry
.01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies

.02 Proteins, quantitative analysis

10.80 Blood donor services

.12 Freezing and thawing of cellular components for transfusion

Accreditation of Blood Donor Services and Immunohaematology

355 accredited laboratories

Public & Private Pathology

10.20 Immunohaematology

- **.01 Blood grouping including ABO, Rh(D)**
- **.03 Blood group antibody screening**
- **.04 Identification of blood group antibodies**
- **.05 Determination of compatibility of donor units**
- **.06 Red cell phenotyping**
- **.07 Antibody elution**
- **.08 Antibody titration**
- **.10 Storage and distribution of blood and blood components**
- **.15 Blood grouping including ABO, Rh(D) and other antigens by automated methods**
- **.17 Blood grouping including ABO, Rh(D) and other antigens by manual methods**
- **.19 Investigation of transfusion reactions**
- **.20 Direct Antiglobulin Test (Poly and monospecific)**
- **.80 Molecular genetic studies**
- **.99 Miscellaneous tests**

Resources

ARCBS - www.donateblood.com.au

NATA – www.nata.com.au

NBA - www.blood.gov.au

NPAAC - www.health.gov.au/npaac

TGA - www.tga.gov.au

Standards Australia - www.standards.org.au

Thank you for your attention

Any questions?