Specialist Working Group

Terms of Reference

Overview

A Specialist Working Group (SWG) is established to provide support to the National Immunoglobulin Governance Advisory Committee (NIGAC) and the National Blood Authority (NBA) with respect to clinical considerations for the Immunoglobulin Governance Program in each of the speciality areas of Haematology, Immunology, Neurology and Transplantation. Representation will be sought from additional speciality areas (E.g. Rheumatology, dermatology) as required.

Role

The SWGs will:

1. Provide specialist clinical advice, feedback and make recommendations regarding changes to the *Criteria for the clinical use of Intravenous immunoglobulin in Australia (the Criteria)*
2. Provide specialist insight and advice on the development and commissioning of clinical treatment guidelines, research projects, consensus statements or other knowledge development in areas where prescribing variations exist with the potential for inappropriate use or regarding emerging areas of clinical practice
3. Define the relative prioritisation of each indication for eligibility during times of product shortage
4. Identify and recommend improvements to education and training regarding Immunoglobulin (Ig) and its use and provide education of clinicians regarding the Ig Program, as required
5. Provide advice and feedback regarding system values and modifications to the Immunoglobulin authorisation and outcomes database (BloodSTAR System)
6. Provide advice and contribute to Performance Improvement activities including the review of data and reports and identify, make recommendations and take action regarding opportunities for continuous improvement.
7. Contribute to the national body of knowledge and the broader Ig Governance Program including liaising as part of the national network of committees (including with NIGAC, other SWGs, and jurisdictional Ig advisory groups) as required.
8. Participate in specialist networks that may provide approval for use in specific conditions as required
9. Receive advice from jurisdictional clinical stakeholders regarding *the Criteria*.

Establishment and support

The SWGs will be established as autonomous committees supported by the NBA. Additional resources and support will be provided when required including specialist expertise for health economic assessments, epidemiological and other analysis. The SWGs will establish working relationships with each other and the network of national and jurisdictional committees and will provide regular updates to NIGAC regarding progress against their work program.

Membership

The membership of the SWGs will comprise:

Member	Nominating organisation or process
Chair	Medical Specialty Representative Member of NIGAC

Medical Specialty Representatives*: Each working group will have a minimum of 5-6 members and must include: – Representation from both adult and paediatric specialities (where relevant) – Members from at least 4 jurisdictions *Persons with clinical expertise and appropriate qualifications to consider the clinical appropriateness, safety and cost effectiveness of Ig, including comparative outcomes of different therapies. It is envisaged that these members may also participate in Jurisdictional Ig User/Governance Groups (as relevant)	NBA to appoint members based on consultation with Jurisdictional government health departments and other relevant stakeholders. Each relevant SWG will include at least 1 representative from: – Australian and New Zealand Association of Neurologists(ANZAN) – Haematology Society of Australia and New Zealand (HSANZ) – Australasian Society of Clinical Immunology and Allergy (ASCIA) – Transplantation Society of Australia and New Zealand (TSANZ)
Representative of national authoriser	Australian Red Cross Blood Service
NBA Representatives	Work Program development in line with government objectives and the broader Ig Governance program. Administrative support

Proxies, subcommittees and expert advice

Proxies for the Chair will be identified through the initial nomination and selection process for NIGAC. For other members, a proxy may be nominated as required.

The SWGs may request the establishment of further working groups or additional members for specific purposes. The SWGs may also request the assistance of other clinical specialists for advice on matters relating to specific conditions, or other expert advisers.

Frequency of meetings and teleconferences

Meetings will usually be held bi-monthly by teleconference including with 'WebEx' support where required. Face-to-face meetings may be required and where possible, will be linked to annual scientific meetings or similar. Additional teleconferences may also be organised including for urgent single-issue advice.

Duration of membership

Appointments to SWGs will be for a period of two years, with the possibility of reappointment. The process of reappointment may be staggered over a period of time to provide for continuity of membership, and incumbent appointments may be extended for this purpose.

Conflicts of Interest

All members (representatives and experts) are required to declare any conflicts of interest that may bias their input. The Chair examines conflicts of interest and makes decisions as to the member's ongoing participation or any limitation to participation.

Remuneration and allowances

The NBA will make best endeavours to ensure that members are not out of pocket when providing services to the working groups. Sitting fees will be paid in accordance with the NBA Management Instruction for remuneration for Non-NBA staff. For this committee the Remuneration Tribunal Determination for holders of part-time public office (category 3) applies. Expenses associated with travel will be managed in accordance with the NBA's travel policy for third parties.

Overview of National Immunoglobulin (Ig) Governance Program

Objectives

The National Ig Governance Program is established to achieve governments' objectives for immunoglobulin products funded and supplied under the national blood arrangements, namely to:

- ensure immunoglobulin product use and management reflects appropriate clinical practice and represents efficient, effective and ethical expenditure of government funds, in accordance with relevant national safety and quality standards for health care
- ensure that access to immunoglobulin products is consistent with the criteria for access determined by governments
- improve the capture of information on the need for, use of, and outcomes of treatment (including adverse events) with immunoglobulin products to inform future changes to the criteria

Description

The Program will be delivered through a package of measures which will implement an integrated national framework for governance and management of immunoglobulin products.

The integrated national framework will provide the following benefits for the governance and management of immunoglobulin products under the national blood arrangements:

- greater clarity in the roles, responsibilities, authority and accountability of those involved in authorising, supplying, managing and using the products throughout the supply chain and within health services
- integration of specialist clinical expertise with policy, analysis and health economist perspectives to support and improve the governance and management
- the consistent and efficient collection of authorisation, supply, use and outcomes data through a national system
- progressive updating of governments' criteria for access to the products under the national blood arrangements, based on improvements in data, knowledge and practice
- agreed indicators and processes to report on, evaluate and improve both clinical practice and outcomes in relation to the products, and the performance of the arrangements for governance and management of the products
- coordinated processes to define, prioritise and deliver an improved knowledge base in relation to the products through well-directed research, education and training
- the potential to consider and, if approved, implement efficiency improvements in the processes for management of the products, including:
    - an appropriate level of automated authorisation of access to the products through the national system, within appropriate safeguards
    - streamlined product distribution.

Implementation

Implementation of the Program will be managed and coordinated through the NBA, under the policy oversight of governments through the Jurisdictional Blood Committee, and working in conjunction with the range of participants involved in the governance and management of immunoglobulin products including health consumers, clinicians, health services, jurisdictional health departments, and product suppliers, distributors and authorisers.

The specific implementation arrangements may vary according to the circumstances of different jurisdictions or health services, within the objective of ensuring nationally consistent governance and management outcomes.

Program measures

The specific National Ig Governance Program measures are:

Development and maintenance of policies and procedures for access to Ig products - A defined set of policies and associated procedures will be developed and maintained, describing the roles and responsibilities of key participants in the governance and management framework for immunoglobulin products.

Establishment and support of a national network of committees – It is envisaged that an integrated network of committees will be established, including the National Immunoglobulin Governance Advisory Committee and specialist working groups. These committees will be integrated with a network of existing or new local governance committees and Ig user groups. The advice and recommendations of this committee network will fundamentally inform the development, implementation and ongoing operation of the other governance program measures.

Developing the criteria for access - The *Criteria for the clinical use of intravenous immunoglobulin in Australia* (*Criteria*) were issued in 2007 and updated in 2012, and have been successful in defining the eligibility for access to product funded under the national blood arrangements. The Criteria will be further developed through the improved governance framework, in particular through the role of the national committee network, improved data collection and analysis, and clinical practice development and targeted research. Considerations for the evolution of the *Criteria* will include appropriate clinical practice, alternative therapies and health economic aspects.

Development and implementation of a national ordering and outcomes database - A national Ig ordering and outcomes database will support and contribute to the effectiveness of the program. The database will support the implementation of the *Criteria*, policies and processes for access to immunoglobulin products, and will generate clinical and management information to support improved patient care and efficient and effective product management and usage. Improved national data will enhance the ability to further develop the *Criteria*, and provide an improved evidence base for practice improvement and research.

Development and implementation of a performance improvement program – It is envisaged that under the guidance of the national committee network, and utilising the *Criteria* and governance policies, and the outcomes and ordering database, and other sources which may provide relevant information, a program will be developed to monitor, assess and improve the performance of the governance system and identify improvements to systems and processes. This will include the development of indicators, reports and benchmarking processes, and an appropriate framework for auditing.

Facilitate knowledge development - A knowledge development program will identify priorities for the development of better knowledge to support more informed decision making both at the clinician and system-wide management levels. In particular, it will identify areas of need and evaluate the value of investment in research and in education and training to improve clinical practice, governance and management.

Potential efficiency improvements - In light of the other elements of the improved governance and management framework, consideration will be given to:

- automated authorisation of access to products through the national system, within appropriate safeguards, for conditions where use is sufficiently established and indications robust enough to ensure that automated approval is feasible and appropriate
- improved efficiency through streamlined product distribution.