

## COMPLETION OF THE REVIEW OF THE AUTHORISATION AND CLINICAL GOVERNANCE FRAMEWORK FOR INTRAVENOUS IMMUNOGLOBULIN

The National Blood Authority (NBA), on behalf of all Australian governments under the national blood arrangements, commissioned a review of the adequacy of the current Intravenous Immunoglobulin (IVIg) authorisation and clinical governance arrangements, with a view to recommending options for improvements to delivering governments' goals for the management of IVIg. The review also analysed the issues, benefits and risks of potentially including Normal Immunoglobulin (NIg) and Subcutaneous Immunoglobulin (ScIg) in the IVIg management framework.

Governments' goals for the management of these products are to:

- ensure that funded immunoglobulin use reflects best clinical practice and is cost effective
- ensure that the outcomes of decision making regarding access to IVIg funded under the national blood arrangements are consistent with the [Criteria for the clinical use of intravenous immunoglobulin in Australia](#) (the Criteria) determined by governments
- improve the capture of information on the need for, use and outcomes of treatment with immunoglobulin and to improve the evidence base that will inform future changes as to what is regarded as best practice in immunoglobulin use and prescribing.

### How the review was conducted

The NBA engaged Ernst & Young to conduct the review in three parts, as follows:

- Part 1 reviewed and analysed the current processes for accessing IVIg and NIg to determine the extent of compliance, efficiency and satisfaction of all stakeholders with the current IVIg authorisation and clinical governance arrangements. Part 1 also identified and analysed the information and data that is currently available at each step in the process to support decision-making.
- Part 2 reviewed and analysed clinicians' IVIg and NIg prescribing and patient treatment review practices and compared these to known practices and attitudes in prescribing other blood products and high cost therapeutic products.
- Part 3 drew on the findings of Parts 1 and 2, and taking this information and other research and consultation advice into account, developed options for a nationally consistent authorisation and clinical governance framework.

The review included a significant amount of consultation with clinicians, nurses, scientists, jurisdictional health departments, and other stakeholders, including surveys and structured interviews and group discussions. Throughout the review process, Ernst and Young was also assisted by advice from a Review Advisory Group with the following membership:

- Chair – Dr Stephen Christley, Chief Public Health Officer and Executive Director, Public Health and Clinical Coordination, SA Department of Health
- Clinical Community - Associate Professor Robert Heddle, Professor John Gibson; and Associate Professor Lynette Keirs
- Health Consumer representative - Ms Helen Mikolaj
- Patient representative - Ms Jackie Murphy
- Large jurisdiction representative - Dr Jan Fizzell
- Small jurisdiction representative - Ms Carolyn Duck
- Department of Health and Ageing - Ms Sharyn McGregor
- Australian Red Cross Blood Service - Dr Joanne Pink
- IVIg Nurse - Ms Linley Bilby
- Health Economist - Ms Liliana Bulfone

## **Review findings and recommendations**

The review highlighted significant variation in IVIg management processes nationally, with process inefficiencies, under investment in integrated data systems and limited evidence of alternative therapies being considered before prescription. It also found variation in diagnoses, high prescription rates in some conditions compared to international rates of use, limited transparency of cost implications and no accountability for cost with the prescriber.

The model recommended by Ernst and Young in Part 3 of the review is a centralised approach to demand management, to formalise and centralise clinical governance at a national level in order to gain efficiencies and ensure equity of product use across Australia.

To implement the recommended model, Ernst and Young recommended an integrated package of short term improvement projects and longer term strategic projects. The following recommended short term projects target five areas identified for improvement of current arrangements:

- Describe the functional model for the current authorisation and clinical governance arrangements, and formally allocate responsibility and authority in each jurisdiction;
- Introduce new management processes to include Nlg and SClg in IVIg authorisation process;
- Improve patient information to ensure patients are aware of the Criteria requirements for eligibility and ongoing therapy;
- Centralise hospital ordering and product management at the blood bank or pharmacy for improved management; define when and how emergency stock should be managed; and
- Define and deliver a package of information concerning current IVIg products and arrangements, particularly for junior medical and nursing staff.

The longer term strategic projects recommended by Ernst and Young include projects to establish the knowledge base and decision making processes to allow further improvement, and strategic projects targeted at transitioning arrangements to a more self-supporting and continuously improving mode. Further work is continuing to consider these recommendations within the proposed centralised model and provide more detailed advice to governments. Any proposed structural changes to the current IVIg arrangements would require governments' endorsement.

## **Implementation of review recommendations**

In March 2013 the Jurisdictional Blood Committee considered the final report of the review and endorsed the NBA commencing work to implement the five short term improvement projects above. These will be undertaken within 2013, and further updates will be available as this work unfolds.

The three reports submitted by Ernst and Young form a comprehensive and well conducted review by means of positive engagement and involvement of key stakeholders. The enthusiasm shown by all parties involved in the review was particularly encouraging and the NBA was very pleased to note the willingness of participants to embrace change and seek further improvement on current arrangements.

The NBA intends to keep all stakeholders informed and involved in the implementation of any of the agreed recommendations of the review and welcomes feedback on any aspects of the project (contact [IVIgReview@nba.gov.au](mailto:IVIgReview@nba.gov.au)).

The [Executive Summary](#) of the review is available for further information.

March 2013