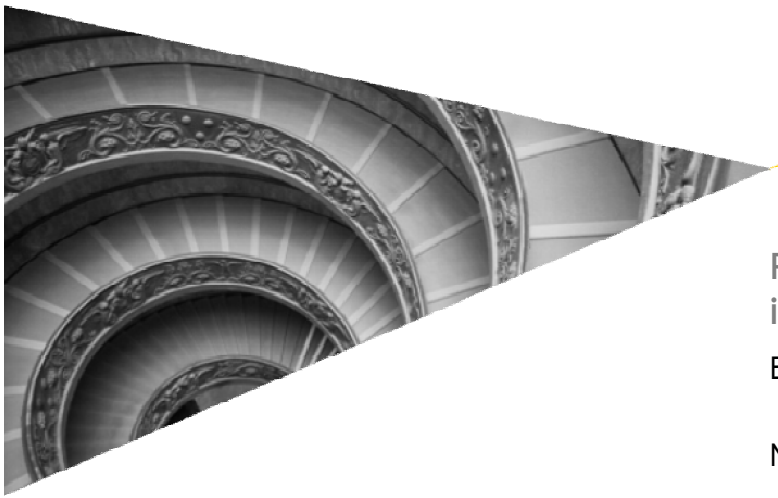

Review of the clinical governance and authorisation process for intravenous immunoglobulin

Executive Summary

National Blood Authority

November 2012

IMPORTANT NOTE: This review was undertaken independently by Ernst and Young on the request of the NBA (acting on behalf of all governments) with the support of an Advisory Group comprising jurisdictional and consumer representatives and expert members. The Executive Summary of the Review report outlines the adequacy of the current IVIg authorisation and clinical governance arrangements and may inform any decisions on proposed changes to the current arrangements. While the Executive Summary has been approved for publication, this does not signify that the contents necessarily reflect the policies, views or approval of governments.

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Foreword

Ernst and Young have pleasure in submitting a suite of three reports that constitute a Review of the Authorisation and Clinical Governance process for Intravenous Immunoglobulin in Australia.

Immunoglobulin replacement or immune modulation therapy is an effective treatment for a wide range of clinical indications with the majority use being within the specialties of Immunology, Haematology and Neurology. Intravenous Immunoglobulin (IVIg) is a plasma derived blood product which offers significant benefit for substantial numbers of people. It is also expensive, costing up to $78 per gram. In 2010/11 a total of $258m was spent on IVIg representing approximately 20% of total spend on blood products. Australia as a nation is one of the highest users of IVIg per head of population.

In common with many other examples of high cost interventions, there has been significant focus to ensure that eligibility for access to IVIg funded under the Nation al Blood Arrangements is appropriate. Criteria for Use have been developed that are evidence based. They have been strengthened and reviewed periodically and further checks and balances are in place with ordering through the Blood Service providing an additional gatekeeper step to confirm that requests are appropriate.

However, clinicians involved in the use of IVIg have also told us that there is still plenty of room for improvement and that there is an opportunity to make a step change in the Authorisation and Clinical Governance arrangements, building on the progress that has already been made.

In formulating our recommendations on what might change we have found that one of the greatest obstacles has been the lack of good quality, useable data about costs, activity and performance. Accordingly, our main recommendation is around the establishment of an Ordering and Outcomes database that will obtain the information required to establish an informed and ongoing review as to the future organisation and management of IVIg.

We have been encouraged by the positive engagement and enthusiasm shown by all parties involved in this review. There appears to be a widespread willingness to embrace change and seek further improvement on existing arrangements. To do so, will enable even greater clinical benefit for patients through the use of IVIg with the application of best practice supported by a robust evidence base founded on outcomes and cost effectiveness.

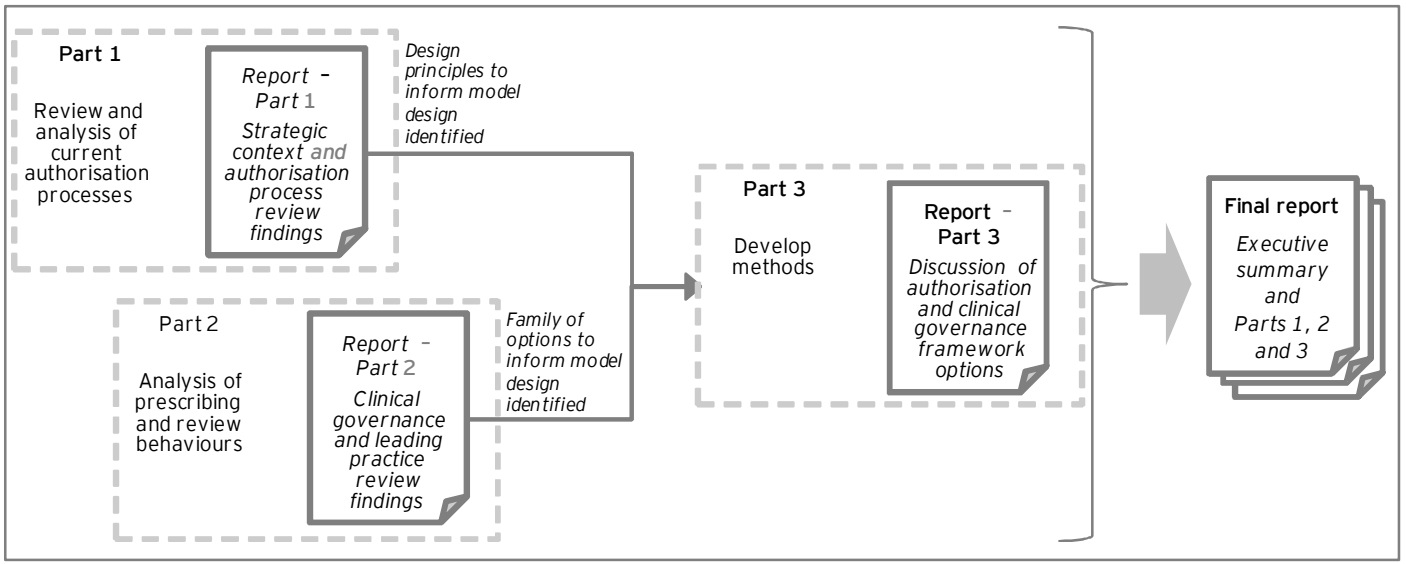
Purpose and overview of the executive summary

The National Blood Authority (NBA) on behalf of the Clinical, Technical and Ethical Principal Committee (CTEPC) of the Commonwealth of Australia has coordinated a review of the adequacy of current intravenous immunoglobulin (IVIg) authorisation and clinical governance arrangements. Ernst & Young was engaged by the NBA to undertake this Review.

This document is an Executive Summary covering a series of three reports, which together form the review of the clinical governance and authorisation process for intravenous immunoglobulin (the Review). It provides a summary of:

- An assessment of the adequacy of the current IVIg authorisation and clinical governance arrangements
- Recommendations on opportunities for improvement

Figure 1 Reporting structure for the Review



Contents

Section 1 – Summary

This section provides an overall summary of the review of the clinical governance and authorisation process for intravenous immunoglobulin. It presents an overview of the case for change and the recommended model for improvement.

Introduction

1. IVIg is an expensive blood plasma product that offers life saving therapy and significant quality of life improvements for thousands of Australians, many of whom have chronic conditions and will require the use of IVIg for the rest of their lives. It is used to treat a broad range of conditions, including applications in immunoglobulin replacement and immune modulation therapy.
2. Stewardship of blood and blood products requires careful management of a unique resource from across the health system in order to meet a growing health need at an affordable cost. This resonates with the governments' objectives for the management of IVIg which seeks to support clinical practice and outcomes data with a necessary focus on cost-effectiveness and equity. Health outcomes and best use of a scarce resource have, therefore, been central themes in this work.
3. This Review has examined the existing arrangements for IVIg and has sought to systematically identify and then address the opportunities to improve through an inclusive dialogue with the sector. Strong work has been completed in the past and there is goodwill toward building upon this in the future.
4. Such is the benefit of IVIg that demand for the product continues to rise steadily at double digit rates. Australian use of the product is acknowledged to be amongst the highest when international comparisons are made. This may well be entirely appropriate; however, work undertaken during this review has also highlighted significant variation in prescribing and dosing practice as well as inconsistencies across jurisdictions in relation to approval and review processes. Whilst reducing the use of IVIg to the levels of other countries may not be a desirable aim, our work would suggest that there is still room for improvement on the existing arrangements for access.
5. The triple interaction between cost, demand and dosage variation presents significant strategic and policy difficulties for Government in ensuring funded IVIg use reflects best clinical practice and is cost effective. In developing the recommendations and the approach to their implementation we have been cognisant of these factors and also the following:

   - **Clinical decision making** - the need for clinicians to be able to make informed clinical choices for patients based upon demonstrated patient outcomes, compliance with the criteria and cost effectiveness.
   - **Access to, and quality of data** – The lack of integrated information systems regarding patient outcomes means that there is limited evidence base to inform future best practice in IVIg use and validate clinical effectiveness.
   - **Structural disconnects between cost and prescription** – In practice there is little transparency of pricing, with clinicians not equipped or incentivised to discern between cost and benefits of alternate treatments.
   - **Complexity of stakeholder interplays** – Responsibilities are split between State and Federal governments each with different structures and clinical governance approaches.

6. We believe the recommendations made in this review represent a comprehensive and practical program of work that sees the good work of the past taken onto the next stage of evolution. In doing so it will better enable achievement of the governments' objectives for IVIg and importantly, will also take large steps forward in preparations that may ultimately be required as the Blood Sector responds to National Health Reform. This includes gathering cost related data, and building capability at the jurisdictional levels which will support local budget management and decision making in the future.

Overview of the case for change

7. IVIg is a high cost product representing 20% of the overall government spend on blood products. Demand is growing at a rate of 11% per annum for established indications. It is seen as a benevolent product with relatively few side effects and an ease of access when compared to alternatives. New uses are likely to add to future demand, as the population ages and further indications for the treatment are found. This increase in demand is set against a context of limited supply, with Australia already dependant, in part, on imported product.
8. The Review has found that there are significant variations 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 price implications and no accountability for cost with the prescriber.
9. Maintaining the status quo runs the risk of growth in demand continuing at the same rate and a reliance on imported products, meaning the potential of patients who may benefit from IVIg not being able to access the therapy in periods of short supply.
10. Clinicians have expressed an appetite for change and there was strong engagement in the areas where the improvement could be made and benefits realised across the system.

The recommendations

11. The proposed changes strengthen existing arrangements for the management of IVIg through the development of an evidence base for Immunoglobulin (Ig) therapy which is supported by clinical best practice, cost effectiveness and transparency. Key elements to deliver this are:

    - To develop an Ordering and Clinical Outcomes Ig Database
    - To establish a standing National Ig Review Committee
    - To establish the next generation of Criteria for Use
    - To provide more transparency of cost and price across the system

12. Twelve projects (which are represented in Figure 2) will deliver the sustained change and have been proposed under three Work Programs which are:

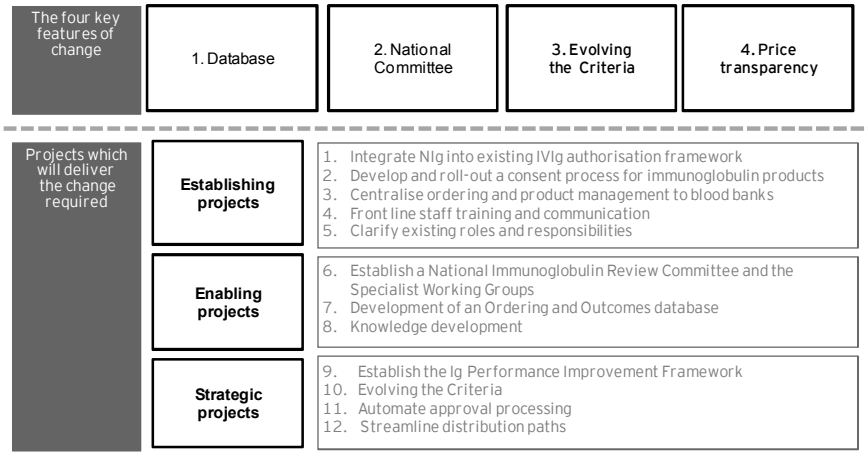
    Work program 1 – Establishment projects

    Work program 1 involves a set of foundation projects that can start immediately and be progressed reasonably quickly. These projects offer the opportunity of early benefits and increasing the knowledge and education of stakeholders ahead of the larger scale improvement projects.

    Work program 2 – Enabling projects

    Work program 2 involves undertaking three longer term enabling projects. These projects are anticipated to be completed over 18 months or so and will significantly enhance the information and database from which to build knowledge on IVIg and improve an informed decision making process. It is recommended these projects are commenced as an early priority in order to allow sufficient time for data and information sources to mature.

Figure 2 The mechanisms required to deliver the desired change



Work program 3 – Strategic projects

Work program 3 involves a series of strategic projects targeted at transitioning existing arrangements to a more integrated authorisation and clinical governance model capable of supporting the governments' strategic objectives in the medium and long-term.

13. It is envisaged that many of the smaller benefits can be realised almost immediately, however the full change will take at least 18 months to implement due to the size and complexity of some of the proposed projects.

14. The recommendations propose changes to the areas of focus and relationships for key entities within the IVIg management system. These changes are intended to provide greater emphasis on clinical governance and performance improvement of the system. They also respond to identified inefficiencies in approval processes through better streamlining flows of data, funding and product throughout the system.

15. The recommended improvement to IVIg management will deliver improved and more cost effective prescribing practices through:

    - Revising the Criteria to reduce variability in prescribing, establishing consistent qualification and patient review processes with agreed clinical outcomes for continuing therapy
    - Improving transparency of price
    - Building the evidence base for a self learning system
    - Introducing a performance management function
    - Requiring cost effectiveness to be considered alongside clinical governance

16. It also delivers efficiency and effectiveness gains through:

    - Prioritising eligibility during times of shortage
    - Providing transparency in order and approval status
    - Automating approval for a significant proportion of conditions
    - Requiring evidence submission only for complex cases
    - Engaging specialist societies and jurisdictional representatives
    - Delivering a program of clinical audits as part of performance management

Section 2 – The case for change

This section presents the reasons why there is an imperative for changes to the management of IVIg in Australia. It describes the drivers for change identified through the analysis of processes, prescribing and patient review practices.

17. Stewardship of blood and blood products requires careful management of a unique resource in order to meet growing health needs at an affordable cost. This resonates with the governments' objectives for the management of IVIg which seek to support clinical best practice and the generation of outcomes data with a necessary focus on cost-effectiveness. Health outcomes and best use of a scare resource have, therefore, been central themes in this work.

The imperatives for change

18. Excluding the costs of plasma collection, IVIg costs governments between $54-$77 per gram, resulting in FY 2010/11 total cost of $258 million. This represents 20% of the national spend on blood and blood products and internationally presents Australia as among the top per capita users.

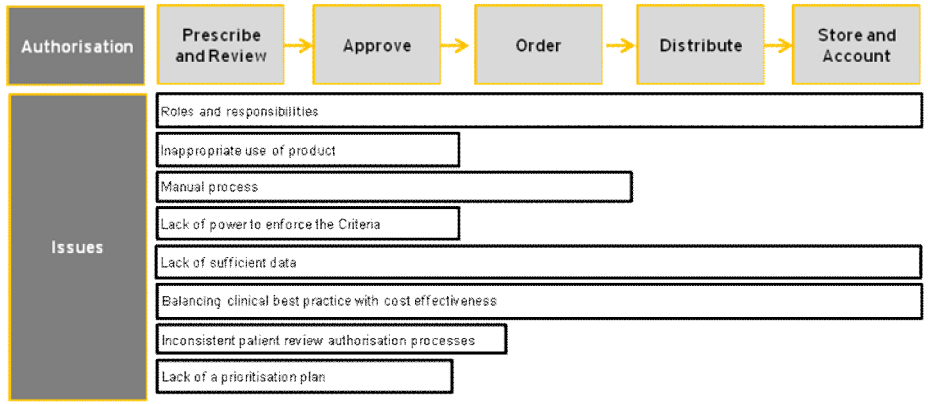
19. Demand for IVIg has been growing at double-digit rates for the last decade. An ageing population and the emergence of new uses suggest that this growth rate is set to continue if left unchecked.

Case for change highlights

- Australia spent $258 million in FY 2010/11 on IVIg, representing 20% of the national spend on blood and blood products
- Australia is among the top per capita users internationally
- Demand has been increasing annually at 11% pa and is forecast to continue due to an ageing population and continuing emergence of new indications for use

Current arrangements include:

- A large number of manual processes
- Limited availability of national and local data sets
- A variation in IVIg use by diagnoses between jurisdictions
- No requirements to demonstrate efficacy or trial breaks in therapy



20. Despite the establishment of national objectives for the management of IVIg, issuance data for IVIg continues to indicate significant variation in per capita use nationally. Moreover, the current practices surrounding IVIg do not always meet the Australian Health Ministers' stewardship expectations[1]. A number of key principles of these statements are not being met by the current system. Examples include the requirements for patient consent, processes to minimise waste and the availability of data to assist supply and demand planning.

21. While it is not yet confirmed precisely how blood products will be treated under the National Health Reforms, these changes will undoubtedly have a significant effect on IVIg use and management. What is clear is that the Reforms will require the IVIg framework to respond to a number of areas of change, including:

    - A greater focus on community care and the associated implications for equity of access
    - Changes in funding such as the potential incorporation of blood products into the national efficient price (NEP) – noting that IVIg by its nature is a product often used in a community setting and the NEP may not be the most appropriate funding vehicle
    - The requirements of the National Safety and Quality Healthcare Standard, which will apply from January 2013, particularly regarding consent, traceability and managing blood products

[1] *Australian Health Ministers' Conference Statement on National Stewardship Expectations for the Supply of Blood and Blood Products*

The drivers for change

The Foundation

22. Excellent work has been undertaken over many years and there is a high commitment and engagement across the sector toward the use of IVIg. The Criteria has been updated during the course of this Review. This has strengthened further, the focus for use of the product and gives a strong platform upon which to build. However, there is still further opportunity for improvement and more cost effective health outcomes can be achieved through an improved knowledge base regarding the efficacy of treatment, access to alternative therapies where appropriate, and by ensuring that IVIg is efficacious for all patients receiving treatment.

The Review

23. The purpose of this Review was to assess the adequacy of the current IVIg authorisation and clinical governance arrangements and recommend options for improvements in the delivery of governments' goals for the management of IVIg.

24. The Review has been considered in three parts which are summarised below :

25. **Part 1** - Review and analysis of current IVIg and NIg authorisation processes.

    This work culminated in:

    - The identification of the major strengths and weaknesses of different models and overall views on the effectiveness of the current authorisation framework
    - A description of the current state of the IVIg authorisation framework in Australia, including the processes, people and systems that support these arrangements

- Identification of design principles to inform the development of future models for a comprehensive and integrated clinical governance and authorisation framework for IVIg and NIg

26. **Part 2** - Analysis of clinicians' IVIg and NIg prescribing and patient review practices.

    This work culminated in:

    - An understanding of stakeholder perspectives on current authorisation processes as well as their knowledge relating to the prescribing of IVIg and NIg and patient review practices
    - An understanding of how clinical and management messages are received by stakeholders
    - A view as to the extent to which variations in perspectives and knowledge affect overall volumes and patterns of use
    - Insight into industry practice with respect to other high cost medications and IVIg management in other relevant jurisdictions

27. **Part 3** - Development of models for an improved authorisation and clinical governance framework.

    This work culminated in:

    - Presentation of options to improve IVIg management including an analysis of each option against the governments' objectives and a set of appraisal criteria
    - Detailed definition of the preferred option
    - An estimate of the investment required to implement and operate the recommendations as well as an estimate of potential savings
    - A detailed description of an approach to implementation including road maps for three programs of work and views on an approach to project management

The findings:

28. **Part 1 of the Review** found significant variation in the implementation of IVIg management processes nationally, at times a lack of clarity regarding roles and responsibilities, relative ease of access to product with no requirement for evidence, and some inequity of access through the direct order process.

    Inefficiency was found in processes undertaken across the system, with an under investment in integrated systems leading to a lack of national and local data sets.

29. **Part 2 of the Review** found variation in IVIg use by diagnoses between jurisdictions driven by different prescribing practices, high prescription rates in some conditions compared to international rates of use.

    Issues relating to Patient Education and Consent were identified. There was no price transparency or accountability for cost with the prescriber.

30. Parts 1 and 2 presented the drivers to improve IVIg management, which then became the focus areas for recommendations to improve.

    Section 3 of this report presents the recommended changes that were developed during **Part 3 of the Review**.

Section 3 – The recommended change

This section provides highlights of the proposed model for IVIg management. It proposes a range of initiatives to strengthen authorisation and clinical governance supported by the development of an evidence base to ensure that clinical best practice alongside principles of cost effectiveness and transparency are applied.

Introduction

31. Three options were identified during the Review. They were developed to offer different approaches to IVIg management and their strengths and weaknesses were appraised. At a high level they were:

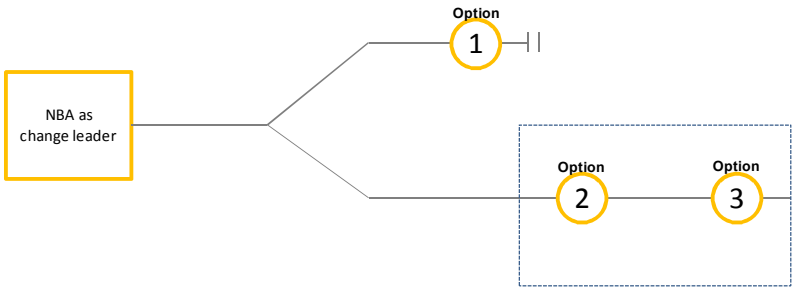
    Option One - Minimal change to current systems
    The development of an option that kept current roles and responsibilities in line with existing practice but formalised these and improved the coordination of some key functions.

    Option Two – A centralised approach to demand management
    An option that sought to both formalise and centralise clinical governance at a national level in order to gain efficiencies and ensure equity of product use across Australia.

    Option Three – A decentralised approach to IVIg management
    An option that sought to devolve key elements of decision making and prioritisation to a more local level, aligned with the intent of National Health Reforms.

The Recommended Model

32. Option Two (the recommended model) was viewed as the most practical solution which strengthened many areas of IVIg management and had the added benefit of also being a foundation and potential transition toward the longer term direction of travel which was described in Option Three.



33. Option Two was been designed to:

- Deliver an evidence base to support best clinical practice, and to improve cost effectiveness and demand management through the prioritisation of eligibility
- Deliver consistency and equity by establishing a national focus on key areas within the IVIg system such as the approval function and performance improvement
- Provide a framework upon which capability and knowledge development can be built to facilitate a smooth and effective transition to localised decision making. This provides a strong position from which to consider Option Three when the funding of blood products under the National Health Reforms is determined.

Overview of the Recommended Model

34. In summary, the key elements of our recommendations are:

I. The development of a national ordering and clinical outcomes Ig database

II. The establishment of a standing national governance committee (with both government and clinical expert representatives) supported by specialist working groups

III. Further development of the Criteria to ensure cost effective prescribing

IV. Providing more transparency of cost and price across the system

i. <u>The development of a national ordering and clinical outcomes database</u>

An ordering and outcomes database will be critical to delivering transparency of prescribing practices, building the evidence base to help determine clinical best practice and for driving continuous improvement of prescribing behaviour. It is proposed that it should include a decision support tool for prescribers that will guide prescribing practice specific to the indication and replace the current request form and phone call approval processes. The database should be designed with the capacity to evolve into a clinical quality register.

ii. <u>The establishment of a standing national governance committee (with both government and clinical expert representatives) supported by specialist working groups</u>

It is proposed a committee be established to provide governance for the revised framework and oversight of the change program as well as having an ongoing performance management and leadership role. Administered by the NBA, the Committee should be a subcommittee of the JBC or be sufficiently authorised with the required decision making power to determine eligibility for access in line with government objectives. It should drive the performance management and improvement agendas, inform education and training strategies and support development of the evidence base to support more cost effective prescribing.

It is also proposed that the Committee has sufficient authority to be able to approve legitimate requests for access to funded IVIg not currently listed in the Criteria where evidence supports benefit. This would remove these requests from the direct order process and improve equity of access. Self funded direct orders would still be available and a process for accessing product in an urgent or emergency situation would need to be developed.

iii. Strengthening of the Criteria to ensure cost effective prescribing

The Criteria, which define eligibility for access to IVIg under the National Blood Arrangements, should be further developed to describe initial patient qualification and then review requirements for continuing therapy in a more consistent and detailed way across all conditions.

It must become more than just an evidence base for IVIg by including consideration of cost and all alternative therapies. The application of defined periods of trial therapy within appropriate conditions should be required.

Most importantly, demonstration of efficacy should be a key principle through the definition of outcomes for each indication as part of the patient review. Data from the recommended ordering and outcomes database would serve to strengthen the evidence base upon which the Criteria can continue to be reviewed. Where evidence suggests benefit and practice has unexplained variation, clinical practice guidelines or consensus statements should be commissioned or investment made in clinical research trials and studies.

In addition, access should be provided to clinical pharmacologists, epidemiologists and health economists to ensure cost effective treatment options are effectively explored. A revision is also proposed to include prioritisation of eligibility within approved conditions, to be used to support a demand management plan as needed during times of shortage.

iv. Providing transparency of price

The introduction of shadow budgets and pricing is proposed in order to provide greater visibility of price and cost to prescribers and managers. Prescribers can use this information when planning their patients' care including during the informed consent process. It is also an important precursor should blood products become incorporated into the National Efficient Price in the future.

The future funding model for IVIg and indeed blood products per se is a topic which requires further consideration. We understand that introductory discussions have commenced with the Independent Hospital Pricing Authority in relation to this. The chronic nature of many IVIg conditions lend themselves to more community care type conditions and so alternative models may also be appropriate. This would include the potential for the product to be funded as a pharmaceutical.

Twelve projects to deliver change

35. Twelve change projects have been recommended grouped under three work programs. Each is presented in further detail overleaf.

Work program 1 - Establishment projects	
1. Integrate NIg into existing IVIg authorisation frameworks	NIg is not subject to the same eligibility and approval rigour as IVIg and data. Including NIg into the IVIg framework will allow accurate forecasting of demand, which is critical considering its increasing use and the possible introduction of a subcutaneous product (ScIg), for which it is currently used as a substitute.
2. Develop and roll-out a consent process for immunoglobulin products	Business processes will be strengthened and standardised through introducing patient and clinician consent forms. It is a requirement of both the National Safety and Quality Health Service Standards[2] and the Australian Health Ministers' stewardship expectations that patients undergo an informed consent process prior to treatment with blood products.
3. Centralise ordering and product management to relevant blood banks and pharmacies	Emergency stocks and centralising the ordering to achieve transparency and accountability within each Approved Health Provider (AHP). This will promote appropriate tracking, storage of IVIg and collection of unused product within the identified AHPs.
4. Clarify existing roles and responsibilities	Governments should clarify, define and document nationally consistent roles and responsibilities of key stakeholders to improve the effectiveness of the current framework. This includes the introduction of nationally consistent approval and patient review processes as an interim requirement.
5. Implement a national front-line staff training and communication program	This will reduce the current levels of inefficiency; ordering problems; and confusion regarding infusion protocols, management and reporting of adverse events. It will also support improved awareness and education in patients.

Work program 2 – Enabling projects	
6. The National Immunoglobulin Review Committee (the Committee) and Specialist Working Groups	The Committee is proposed to be a subcommittee of the JBC or be sufficiently authorised with the required decision making power to determine eligibility for access in line with government objectives. It will be administered by the NBA and should comprise NBA, government, clinician and technical health expert representation. Its main purpose is to coordinate the delivery of eligibility recommendations, using the clinical expertise within the Working Groups. Eligibility recommendations include revisions to the Criteria and consideration of cases where evidence exists but that are not currently covered under the Criteria. It should be supported in its role through the provision of performance management information and health economic data with the periodic review of datasets, performance of clinical audits and review of adverse events. The Committee should oversee Specialist Working Groups and be supported by jurisdictional Ig Advisory groups, both of which will form the basis of clinical expert networks.
7. Develop an Ordering And Outcomes Database	The database will deliver whole of system performance data to inform continuous improvement and drive the accuracy and efficiency of the access and authorisation processes. It is a critical component of the proposed change and is the foundation of future knowledge development. The NBA can draw on its previous system development experience and its current capability to work closely with clinicians to develop this database including a clinical support system. A user view could be developed consistent with the clinician's path through prescribing and review processes including screens which guide the user through an approval. It should deliver a number of notifications such as approval decisions and reminders for patient reviews. It should house patient information material and documentation such as consent forms, patient information and generate reports which help the clinicians review their own practice.

[2] Australian Commission on Safety and Quality in Health Care, June 2011, *National Safety and Quality Health Service Standards*,

8. Facilitate knowledge development	Feedback from across the system and analysis of the outcomes database will identify areas for possible clinical trials and the development of clinical guidelines. The output from these research initiatives will support the evidence base on which the Criteria & associated decision making across the system is based.
Work program 3 – Strategic projects	
9. Performance Improvement Program	IVIg should be managed through an incorporated performance management capability within the NBA, which will monitor prescribing practices and commission periodic compliance audits. Prescribers should be supported by a national approach to training & communication and have access to prescriber data benchmarking against other jurisdictions, AHPs and peers.
10. Evolving the Criteria	Development of the next generation of the criteria to apply more consistent qualifying and review criteria across conditions, including the use of alternate therapies, and the use of cost effective treatment algorithms where appropriate, supported by health economic data. Prioritisation of eligibility within approved conditions should also be a key component, to be used as a demand management plan during times of shortage.
11. Automated approval processing	Use of an automated approval process supported by the outcomes database. Where the Criteria is clear in its requirements, these conditions would logically suit automated approval as the requesting clinician can answer a set of questions to determine eligibility and transparency of prescribing will allow benchmarking of practice. Automated approval will apply for a timeframe as defined in the Criteria with patients still requiring formal review in due course. Removal of significant effort regarding the approval role should be achieved through the introduction of automated approval within the new outcomes database. The remaining requests then being approved by the Specialist Working Groups and expert networks via an escalation process.
12. Streamline distribution paths	Streamlining the supply and distribution path for IVIg and NIg products has the potential to enhance the efficiency of product supply. At a logical point in time, once automation of approval has bedded down, and with appropriate safeguards in place, this could include the opportunity of transferring the responsibility for distribution from the Blood Service to the Manufacturer. If ScIg becomes available it is also recommended to align with this distribution path. Scenarios should be developed and tested to ensure all risks and benefits are understood.

Section 4 – Impact on the NBA

The Recommended Model represents a significant change to the IVIg system, requiring the establishment of new areas of focus and the implementation of a number of supporting projects. It is, therefore, imperative that the approach taken toward implementation considers the whole system and is founded on strong stakeholder engagement and communication.

Implementation

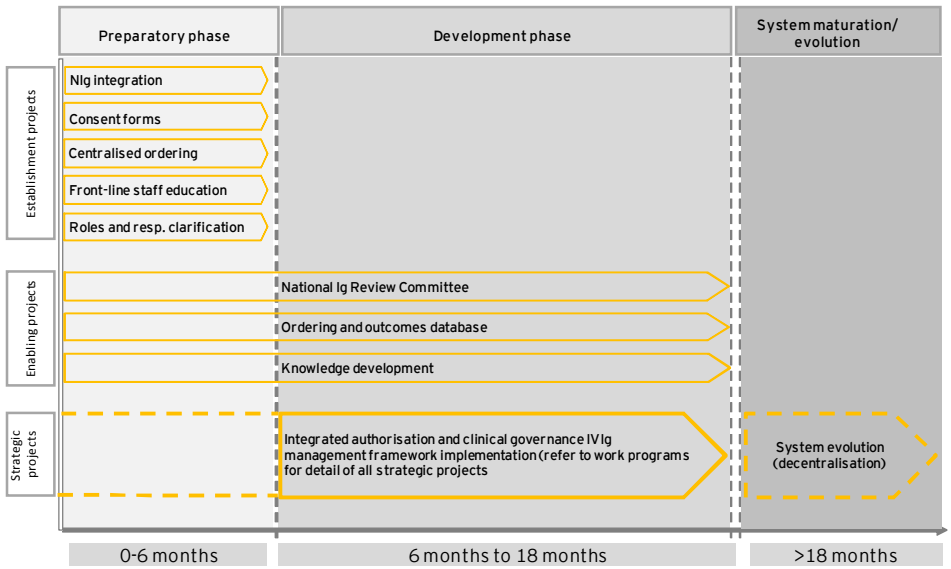
36. To implement the Recommended Model, the twelve supporting projects have been identified and allocated to their relevant Work Programs as described in Section 3:

    Work Program 1 – Establishment projects
    Work Program 2 – Enabling projects
    Work Program 3 – Strategic projects

37. The Work Programs are presented in Figure 3. It is envisaged that many small benefits can be realised almost immediately, however the full change will take up to 18 months to implement due to the size and complexity of some of the proposed projects. Implementation will, therefore, require the NBA to commit resources and time to the project that are consistent with the effort required to achieve sustained change.

38. In addition to the Work Programs, an approach to program management has been proposed to oversee and govern the implementation of change and transition to business as usual.

Figure 3 Phased implementation of the Work Programs

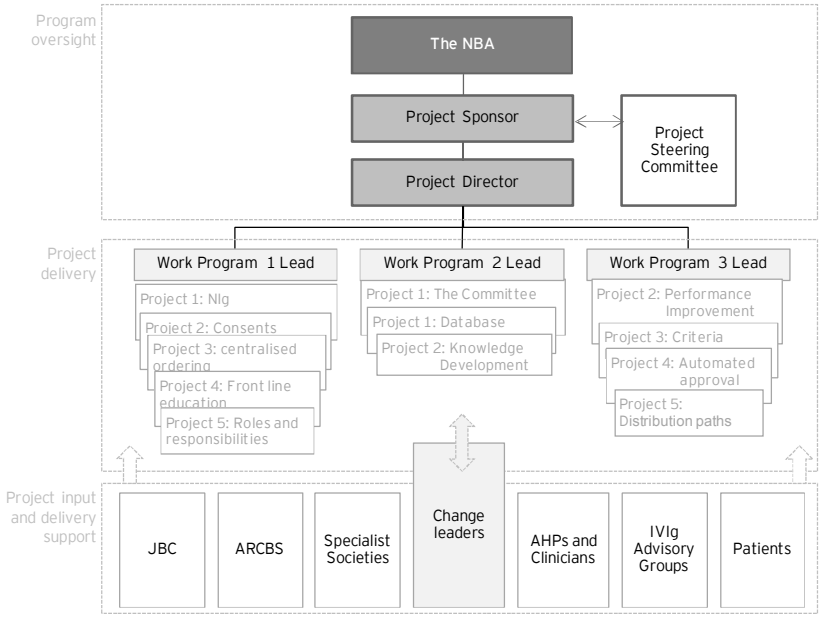


NBA implementing the change

39. The program management component of implementation will be crucial given the stakeholder environment and the effect that these recommendations will have on the whole system. Given this, the NBA will need to establish an effective project governance structure to oversee the change. A steering committee should include representation from key stakeholders across the system in order to engage the support required to drive sustained success. The project team should be resourced by people with experience in working with stakeholders to achieve sustained change.

    A proposition for project governance is represented in Figure 4 below.

Figure 4 Project Governance Structure



NBA's investment

40. The investment required to implement the proposed changes has been estimated for:
    - Initial set up costs
    - Ongoing operating costs
    - Those costs with an investment impact for the NBA. There will be additional cost implications for some stakeholders who will deliver components of the change or are impacted by it. These are not included in this estimation.
41. It has been estimated that a centralised investment of around $3.5 million would be required to support establishment of the recommendations contained within this report. A significant proportion of this relates to the Ordering and Outcomes Database ($2.2 million).
42. It is also estimated that there would be ongoing operating costs in the region of $1.5 million per annum.
43. A summary of these costs is presented in Figure 5.
44. Other costs will need to be finalised once the detailed plans, complexity and risk are confirmed. These include a project contingency and costs associated with the business requirements of the ordering and outcomes database, such as software licences and system integration costs.

Figure 5 Summary of the estimated cost to implement and operate the recommendations

	FTE	Project costs		TOTAL
Project governance management	$270,000	-	-	$270,000
Work Program 1 Establishment project	$103,700	$165,000	-	$268,700
Work Program 2 Enabling projects	$94,300	$2,294,000	-	$2,388,300
Work Program 3 Strategic projects	$486,000	$50,000	-	$536,000
TOTAL IMPLEMENTATION COSTS	**$954,000**	**$2,509,000**		**$3,463,000**

	FTE pa		Operating Costs pa	TOTAL
Projects to transition to business as usual	$620.000	-	$850,000	$1,470,000
TOTAL OPERATING COSTS				$1,470,000

Potential Savings

45. Whilst it is difficult to accurately predict the precise effect of recommendations on overall usage it is reasonable to expect that implementation of the recommendations contained in this report would lead to a reduction in overall usage over time. In prescribing practice, there are a number of examples such as the tightening of eligibility criteria to reduce the number of future patients, enforcing trials of therapy and the application of consistent patient review practices, requiring the use of alternative therapies and establishing minimum effective dosing. It is acknowledged that until transparency of actual prescribing data is available, it is difficult to analyse the potential impact of such changes.

46. However, in order to illustrate potential savings, a number of different scenarios have been modelled using an analysis of the impact on individual jurisdictional prescribing rates applying conservative assumptions.

47. Individually indicative savings for each of the scenarios range from $400,000 (for scenario 4 in Figure 6) to $11 million (for scenario 2 in Figure 6) per annum based on 2010-11 product expenditure data. If all of the scenarios were realised, in 2010-11 a total of around $21million may have been saved representing 8% of that year's expenditure.
The scenarios are summarised in Figure 6.

Figure 6 The potential savings for each of these six scenarios

Scenario	Context	The Scenario	Illustrative savings
1 Idiopathic thrombocytopenic purpure (ITP)	5% of total usage in 10-11 (163,905 grams). There is wide variation in dosing and alternative therapies (steroids) may not always be used as recommended.	The IVIg grams used per 1000 pop is reduced to 6 g for those states with higher rates of prescription - NSW, NT, QLD, SA	$2.5m
2 Acquired hypogamma-globulinaemia secondary to haematological malignancies	21% of total usage (631,689 grams)	The average IVIg grams used is reduced to 20 grams per 1000 population for the higher states - NSW, QLD, Tasmania and Victoria	$13.8m
	***Alternatively**, this can be examined at a diagnosis level*	***CLL** - reduce high states to average use of 9 grams per 1000 population*	*$2.6m*
		***Multiple Myeloma** - reduce high states to an average use of 5 grams per 1000 population*	*$5.0m*
		***NHL** - reduce high states to average use of 5 grams per 1000 pop*	*$3.1m*
3 Common Variable Immunodeficiency	13% of total usage (388,711.5 grams (CVID only))	The average IVIg grams used is reduced to 20 grams for NSW. All other states (except ACT) had an average lower than 18 grams.	$1.9m
4 Inflammatory myopathies: polymyositis (PM), dermatomyositis (DM) and inclusion body myositis	5% of total usage (139,194.5 grams)	The average IVIg grams used is reduced to 8g per 1000 population for NSW and Tasmania. All other states had an average lower than 5.31 grams.	$385k
5 Chronic inflammatory demyelinating polyneuropathy	20% of total usage (599,181gms)	Of the 20% of CIDP patients who are on long term therapy, 20% who are trialled are assumed to remain off therapy and symptom free.	$1.5m
6. Guillain–Barré Syndrome (GBS)	3% of total usage (101,013.5 grams)	Reduce the average use in NSW and Victoria to 4 grams per 1000 population.	$884k

The assumptions underpinning this analysis include:
1. 2010/11 data
2. Costs calculated at $65/g of product
3. Implementation of recommendations contained in the report enable delivery of the scenarios described above

Section 5 – The impact on stakeholders

This Review has taken a system wide perspective of IVIg management and, as a result, the recommendations outlined will have an effect on a range of stakeholders. The key groups impacted are outlined below.

The Patients

The change

48. Patients will benefit from their clinical teams being supported by a continuous improvement program and enhanced knowledge base. At an individual level, treatment with IVIg should be proven to be efficacious through the patient review process with the intent of leading to improved clinical outcomes.

49. Patients should be more informed about their IVIg treatment program through the introduction of the patient consent process. This will inform them of the requirements for IVIg treatment, risks and costs, allowing them to make more decisions around their treatment and prepare them for any potential future changes to their access to IVIg such as treatment cessation or change of product.

50. It is always a possibility that any revision of the Criteria may result in patients who are currently receiving IVIg no longer being funded. This may also be the case for patients on IVIg in periods of short supply.

51. In the future there is a potential for patients to have portal access to the outcomes database to enter their treatment data. This will facilitate the continued introduction of home-based therapy and support for remote patient management by allowing easier monitoring of these patients.

Implementation considerations

52. Patients representing both replacement and therapeutic IVIg use must be included in the implementation planning of the new system. This will be through patient representatives providing guidance to the project team in areas such as the development of the database, patient information and patient consent form design.

The Prescribers

The change

53. The recommendations set out in this report will have significant impact on prescribing clinicians. Many of the changes will benefit them through a more efficient automated approval process, deeper clinical knowledge base, and more informed support staff and patients.

54. Clinicians should be given much greater opportunity to input into the IVIg framework. This would be through participation in the Specialist Working Groups, local Ig Advisory Groups or in approving use as part of the clinical expert networks. Opportunity for undertaking research and trials will also be improved.

55. The introduction of the Ordering and Outcomes Database will improve the evidence base upon which treatment decisions are based, leading to improved treatment for many patients. It will also provide a communication system for important messages and notifications, guiding a clinician through the life cycle of IVIg treatment. However, the database needs to be built on clinical input and entry into this data base will take time.

56. There will be tighter Criteria, which will lead to reduced access to IVIg in certain circumstances. However, eligibility will be defined on the best outcomes for patients as well as the health system as a whole, given the high cost and limited supply of IVIg.

57. Tighter requirements around patient review will ensure that IVIg is being used only where it is demonstrated to be providing clinical benefit.

58. It is a requirement of the Standards that patients are able to make an informed consent decision prior to treatment with blood products and that ongoing therapy may be linked to clinical outcome. The introduction of clinician consent forms will require clinicians to provide this information, as well as adhere to the requirements of IVIg therapy.

59. As NIg will be included in the IVIg framework, clinicians who have been prescribing it may be required to alter their treatment practices, especially where this use is not within the requirements of the revised Criteria.

60. While the automated approval process will provide efficiency in the approval process for many conditions, it has limited control over compliance. For this reason, an audit program has been recommended which will include a focus on the information provided through automated approval. Prescribers would be expected to comply with the audit.

Implementation considerations

61. The Ordering and Outcomes database should include a decision support tool. It would support the clinician through the life cycle of IVIg treatment, for example through ease of access to the consent forms and supporting patient information, and reminder notifications which will be generated prior to the need for patient review.

62. Clinician feedback will be a crucial part of the success of any change to the IVIg framework. Therefore, clinicians must have the opportunity to provide feedback to the NBA through appropriate mechanisms. Feedback could also include nominating priority areas for clinical guidelines, clinical trials, and education and training.

The Jurisdictional Blood Committee (JBC)

The change

63. The proposed National Ig Review Committee should be formed as a subcommittee of the JBC (or similar arrangement to enable the recommendations to be implemented). There will be JBC representation on the Committee, as well as the local JBC representative sitting on the jurisdictional Ig Advisory Groups.

Implementation considerations

64. Due to its national approach, the JBC members should either lead the Ig Advisory Groups or each nominate independent Chairpersons to promote national consistency.

Australian Red Cross Blood Service

The change

65. As a consequence of automating many approvals and as a means of promoting national consistency and centralising knowledge, the role of 'approver' should be reviewed in order to ensure the most appropriate model is in place given the improvements to database, criteria and evolution of a self learning system.

66. Some of the expert resources may need to transfer if there is a shift in the approval role, thus continuing their role in approval based on the knowledge gained within the Blood Service.

67. Ultimately, as automated approval becomes established the responsibility for distribution may shift from the Blood Service to the Manufacturer to further enhance the efficiency of product supply.

Implementation considerations

68. The Blood Service should be engaged to provide support to the new system's implementation, especially though any transition period should approval and distributions roles change in the future. There may also be a transition of some expert resources dependent upon the models agreed.

69. Removal of the approval role may present a challenge for the Blood Service and sector as the function sits within roles with other responsibilities. Appropriate safeguards and time needs to be given prior to implementing this recommendation in order to understand its impact once the database and changes to approval mechanisms have bedded down.

70. The Blood Service's experience in IVIg management is highly valuable and should be used in planning the implementation of the Recommended Model and the supporting projects.

The AHP blood banks

The change

71. Centralising the ordering of IVIg for on-going patients to AHPs' blood banks and pharmacies will reduce inappropriate movement, storage and hording of product. The blood banks will need to collect and account for unused product and ensure transparency of order and product to a patient.

72. Blood banks will see the new database built to connect with BloodNet, providing greater clarity over the product life cycle, from ordering to infusion.

73. Blood banks/pharmacies will be subject to audit of their product management and traceability processes. This will ensure that standards are being met in all AHPs.

Implementation considerations

74. Blood banks must be consulted during the database's design phase to plan the opportunity to build on their existing IT capability and systems.

75. The levels of emergency stock will be agreed upon between the NBA and the AHP, in line with use with input from the Jurisdictional IVIg Advisory Committees.

Specialist societies

The change

76. The specialist societies will be a key component of the governance system required. This starts with representation on the Specialist Working Groups and includes a patient advocacy role.

77. Specialist societies can access their members to contribute to the new framework (including through expert networks). Any clinical guidelines should be developed and validated by the specialist societies and provided as draft to the NBA for endorsement. The specialist societies will need to be supported in this function by the NBA.

78. Specialist societies currently deliver training and education to their members through a number of mechanisms. There is an opportunity to build on this to develop and deliver initiatives specific to IVIg management.

79. Consideration should be given to Specialist societies being able to access the outcomes database to obtain IVIg information and standard reports.

Implementation considerations

80. Specialist societies should contribute to the design of the outcomes database. This would include aligning the design to the clinical requirements to optimise ease of use and promote compliance. They should also contribute to a range of datasets such as the outcomes required for diagnosis and condition.

81. NBA may need to provide support to the specialist societies to ensure that they are able to fill their critical role in delivering the recommendations.

IVIg Advisory Groups

The change

82. The role of local IVIg Advisory Groups should be nationally consistent and locally relevant. The group would consider direct order requests as required and would be involved in providing feedback to the Committee regarding eligibility. They would provide localised support to clinical governance and performance management through reviewing performance and prescribing data.

83. Members of these groups may become members of the Specialist Working Groups becoming state representatives in a key component to drive change at a national level. The experience and capability this group builds can assist states and territories in the future should the National Health Reforms require local decision making and budgets.

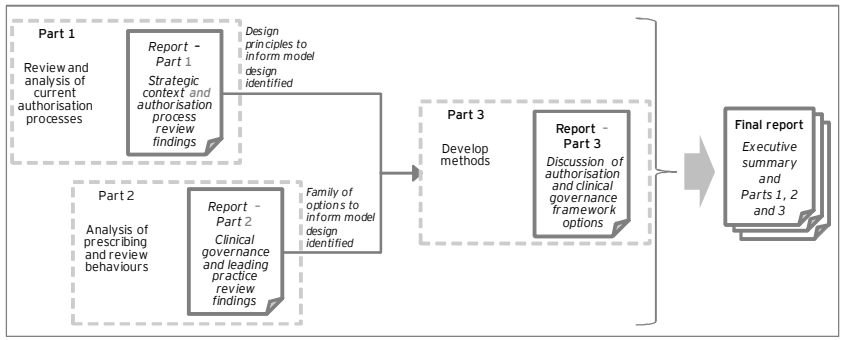
Implementation considerations

84. Representation across the jurisdictions through the Specialists Working Groups is a key component of local knowledge development in preparation for potential future localisation of control and decision making.

Section 6 – The approach to the Review and navigating the full reports

This review has been divided into three parts with an Executive Summary drawing together the reports from each part of the Review. This section helps the reader identify key areas of interest.

Figure 7 Reporting structure for the Review



Executive summary (this document)

85. The Executive Summary presents an overview of the report, with a particular emphasis on the recommended model. The high level implementation requirements for the NBA are outlined, as is the impact on key stakeholder groups.

Part 1 Report

86. Part 1 contains a description of the context for the Review and an assessment of the current authorisation processes across jurisdictions.

    The approach to Part 1 is described overleaf.

Part 2 Report

87. Part 2 outlines the major findings from the analysis of current clinical governance arrangements. It also presents the findings of research undertaken into international approaches to IVIg management and Australian approaches for other high cost medications. Appendices from Part 2 include IVIg use data analysis, research findings and survey results.

    The approach to Part 2 is described overleaf.

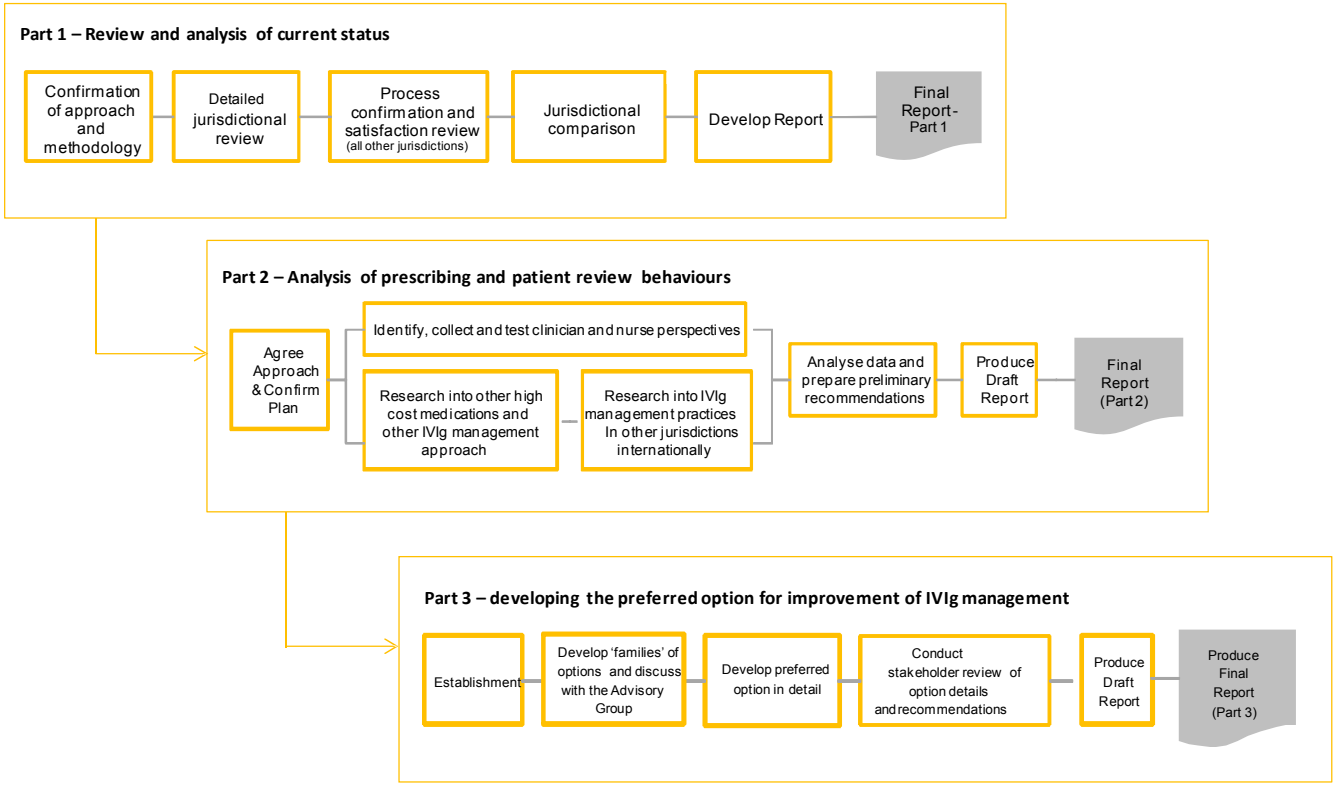
Part 3 Report

88. Part 3 outlines the recommendations for an integrated Authorisation and Clinical Governance model for IVIg. A high level implementation plan is outlined, with associated considerations and potential costs and potential gains.

    The approach to Part 3 is described overleaf.

The major steps undertaken in Parts 1, 2 and 3 of the Review are presented in Figure 8.

Figure 8 The approach to Parts 1, 2 and 3



Section 7 – Conclusion

89. This Review has examined the existing arrangements for IVIg authorisation and clinical governance and has identified a number of opportunities for improvement.

90. There has been strong engagement and commitment from across the sector over many years to seek ways of improving clinical best practice for IVIg, however, a number of challenges that have been well documented in this report have constrained full achievement of governments' objectives for IVIg.

91. The Review has sought to systematically identify and then address these challenges through an inclusive dialogue with the sector. A momentum for change has been built and a comprehensive program of work proposed that will span several years.

92. It will require investment in a range of areas such as the development of a National Ordering and Clinical Outcomes database but it also offers the potential of a sizable reduction in the use of IVIg in a way that will be based upon clinical best practice and cost effective prescribing practices.

93. International comparisons have shown Australia to be a high user of IVIg. An aging population, new indications for use and increasing dependency on imported product means high relative costs will prevail and shortages are likely to occur in the future if inadequacies in the current system are not addressed.

94. We believe the recommendations made represent a comprehensive and practical program of work that sees the good work of the past taken onto the next stage of evolution. In doing so it will better enable achievement of the Governments objectives for IVIg and importantly, will also take large steps forward in preparations that may ultimately be required as the Blood Sector responds to Nation Health Reform.

95. The next step is to develop a comprehensive business case to finalise the investment required and detail the impact on the key stakeholders.

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