



Immunoglobulin (Ig) Governance and Ig System – BloodSTAR Privacy Impact Assessment Report

Version 2.0

Authorisation

This document is a document of the National Blood Authority (NBA). It is electronically controlled.

Document Control		
File Location at NBA	E13/668-15	
Date Created	9 February 2015	
Version Control		
Version	Revision Date	Revision Description
0.1	9-25/02/2015	Draft content – Ig Governance team
0.2	26/02/2015	Review and edits – Ig System team
0.3	2/03/2015	Review and privacy impact analysis drafted jointly by Ig Governance and Ig System teams.
0.4	10/03/2015	Internal legal review, addition of privacy survey summary and security matrix
0.5	14/04/2015	Review and edits – Ig System team post review of V0.4 and initial assessment on jurisdictional feedback.
0.6	17/04/2015	Amendments - Ig Governance team following assessment of jurisdictional feedback
0.7	7/05/2015	Amendments and additions – jurisdictional feedback incorporated and internal review
1.0	8/05/2015	Final
1.1	11/08/2015	<ul style="list-style-type: none"> ○ Addition of new section View Patient Records, ○ Amendments to privacy collection and notice - renamed Privacy Statement and Notice and content revised to be more user friendly. ○ Amendments to the Patient Record Security Matrix, including removal of Jurisdictional Authoriser
1.2		<ul style="list-style-type: none"> ○ Amendments to Patient Record Data Dictionary to clarify which stakeholders will have visibility of each of the data elements. ○ Removal of reference to Entities in section 8.4.2 as this title has been removed from the table. ○ Correction to word disaggregation – aggregation throughout.
2.0	08/10/2015	<ul style="list-style-type: none"> ○ Upgrade to version 2.0
References		
The following documents are referenced in this document:		
<ul style="list-style-type: none"> • NBA Privacy Policy • NBA IVIg Annual Report 2013-14 • Criteria for the clinical use of intravenous immunoglobulin in Australia, Second Edition July 2012 • Ernst & Young Review of the clinical governance and authorisation process for Intravenous immunoglobulin 2012 • Business Case: Integrated National Framework for the management of immunoglobulin (2013) • Business Case: Ig Ordering and Outcomes Database (2013) • Ig System High Level Design • Ig System Functional Specifications • Ig System Data Dictionary 		

- National Policy: Access to government funded immunoglobulin products in Australia (November 2014)
- Immunoglobulin Governance and Ig System Development Risk Management Plan
- Ig Governance and Ig System Communications Strategy
- NBA Data and Information Governance Framework

Contents

1	Purpose	5
1.1	Sensitive information	5
2	Project background	7
2.2	Ig Demand and Budget Impact	8
2.3	Review of the clinical governance and authorisation of IVIg.....	8
2.4	The program of measures to strengthen immunoglobulin authorisation and management and identification of where privacy implications may arise	10
3	Project Scope - BloodSTAR.....	14
4	Methodology.....	16
5	Mapping information flows and privacy framework	17
5.1	Data flow diagram.....	17
5.2	Collection of personal and sensitive information	17
5.3	Disclosure of personal and sensitive information	25
5.4	Correction of personal information	28
5.5	Security	28
5.6	Data Quality	29
5.7	Data Retention.....	30
5.8	Identity Management	30
5.9	Privacy Survey	32
6	Privacy Impact analysis	49
7	Privacy Management	60
7.1	Recommendations	60
8	Attachments.....	62
8.1	Attachment A – Privacy Statement and Notice	62
8.2	Attachment B – BloodSTAR Privacy Consent Form.....	65
8.3	Attachment C – User Terms and Conditions.....	67
8.4	Attachment D – Patient Record Data Dictionary	69
8.5	Attachment E– Patient Record Security Matrix	104

1 Purpose

Privacy Impact Assessments (PIAs) against the Australian Privacy Principles (APPs)¹ are a way of measuring the privacy impacts posed by a new project, whether it is a legislative, policy or technological initiative. PIAs are usually undertaken as part of a sound risk management strategy, to assess whether it is safe to proceed to the implementation phase of the project. A failure to properly embed appropriate privacy protection measures may result in a breach of privacy laws, a lack of community acceptance, or prohibitive costs in retro-fitting a system to ensure legal compliance or address community concerns about privacy.

In this report, 'privacy' encompasses personal health information privacy. Privacy impacts arising from an initiative may be negative (privacy-invasive) and/or positive (privacy-enhancing). However as privacy is a human right, privacy impacts only relate to impacts on individuals, not organisations.

This PIA Report aims to describe and analyse the privacy issues related to the Immunoglobulin Governance National Policy and the technical capability required to support it; BloodSTAR: the National **Blood** Authority's **S**ystem for **T**racking **A**uthorisations and **R**eviews. Early project documentation relating to the system development project refers to Ig System, which is the title given to the system prior to the name being decided.

Further aims are to identify and analyse the privacy implications, make recommendations for minimising privacy intrusion, and maximising privacy protection and confidentiality in relation to patient identifying information consequent to Commonwealth and state/territory legislation – while ensuring the policy's objectives are met.

This privacy impact assessment report, approved by the National Blood Authority (NBA) General Manager provides the detail on governance, management, security and technical governance measures in place for the immunoglobulin governance program and, in particular, the immunoglobulin system development to support it.

1.1 Sensitive information

Sensitive information is defined in the Privacy Act 1988 (Cth) (the Privacy Act) and relevant state/territory legislation to include health information about an individual. The National Blood Authority (NBA) is concerned with protecting sensitive information it collects and will take all reasonable steps to protect sensitive information held from misuse, interference and loss, and from unauthorised access, modification or disclosure. Sensitive information will only be stored on a password protected ICT system which complies with the Australian Government Protective Security Policy Framework and will have tightly restricted access controls placed on it under strict governance requirements. This includes ensuring that information stored is only accessed by those that are authorised and require access to undertake their identified functions and roles. In addition to password protection for access, a level of 256bit encryption will be applied for all data stored in accessible environments. Data is encrypted, both in transit and at rest. Data is physically held on hardware owned and operated by the NBA. The NBA's IT infrastructure specifically excludes the use

¹ Australian Privacy Principles (APPs), schedule 1 *Privacy Act 1988* (the Privacy Act).
<http://www.oaic.gov.au/privacy/privacy-act/australian-privacy-principles>

of Cloud computing technologies. These security measures also safeguard the accuracy and completeness of information provided.

At the conclusion of this PIA Report are findings and recommendations with respect to the privacy impacts of this program of work.

2 Project background

The key role of the national blood arrangements² administered by the National Blood Authority (NBA) is to:

- provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services.
- promote safe, high quality management and use of blood products, blood related products and blood related services in Australia.

Section 8 of the National Blood Authority Act 2003 (Cth) sets out the various functions of the NBA³. The National Blood Authority (NBA) is a statutory agency within the Australian Government Health portfolio that manages and coordinates arrangements for the supply of blood and blood products and services on behalf of the Australian Government and State and Territory governments. Several of the agreed roles of the NBA require the NBA to liaise with and continuously gather blood sector data. The NBA:

- 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
- 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
- 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
- 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
- provides secretariat support to the [Jurisdictional Blood Committee \(JBC\)](#).

At times the NBA needs to collect and use personal information to undertake specific functions and activities. For example personal information is only collected where it is reasonably necessary for, or directly related to, one or more of the NBA functions or activities. Where sensitive personal information is concerned, it will be only collected where consent has been provided to that collection and the purpose and necessity test is satisfied or where a legal exception under the Privacy Act 1988 (Cth) or other state/territory legislation arises. Where consent is provided, it needs to be valid consent in accordance with common law requirements, the Privacy Act 1988 (Cth) and state/territory legislation.

² [National Blood Authority Act 2003 \(Cth\)](#) and [National Blood Agreement](#)

³ [National Blood Agreement](#)

Immunoglobulin (Ig), human plasma derived product, offers lifesaving therapy and significant quality of life improvements for thousands of Australians, many of whom have chronic conditions for which there is no alternative treatment. Many people require therapeutic treatment with immunoglobulin for their entire lifetime. A rising demand and cost to provide Ig that is disproportionate to wider health costs, presents governments with a significant budget challenge that requires an improved management framework. As Ig is a precious and high cost resource, governments have determined the Criteria for the clinical use of intravenous immunoglobulin in Australia 2nd Edition (Criteria), first developed in 2007 and updated in 2012, developed from a systematic review of published evidence where available, or otherwise on consensus of informed specialist opinion. The purpose of the Criteria is to ensure that publicly funded immunoglobulin is directed to patients who are most likely to benefit based on reliable evidence and for whom there are no alternative safe and effective treatments. Access to Ig under nationally funded arrangements requires specific case by case authorisation.

2.2 Ig Demand and Budget Impact

There has been a steady increase in demand for Ig provided under the national blood arrangements over the last ten years, with increases of 10-12% per annum for the last five years. While a small proportion of this increase may be attributable to population increases, there has also been a steady increase of 8-10% per annum in the use of Ig per capita since the introduction of the Criteria in 2008. The increase in demand for Ig places a financial burden on the Australian health system. In Australia, the total cost of domestic Ig supply comprises the cost of the plasma collected by the Blood Service, plus the cost of purchase of the finished Ig product from the supplier (CSL Behring). Imported Ig is purchased at a total product cost only.

Total expenditure on Ig in 2013-14 was \$244.4 million, an increase of \$24.3 million (11.1%) over 2012-13. The increased expenditure predominately represents increases in demand. There has also been an increase in the price of plasma for fractionation due to the increased ratio of apheresis to whole blood plasma for fractionation being supplied, resulting in an increase in the cost of domestic Ig. Combined with expenditure for plasma for fractionation, Ig accounts for a total expenditure of \$427.1 million (excluding hyperimmunes).

A total of 13,981 patients were issued Ig under national blood arrangements during 2013-14 for 122,791 treatment episodes. This represents a 6.7% increase in the number of patients since 2012-13 (with 5,968 new patients). Demand for Ig continues to rise steadily, and Australian per capita use of this product is one of the highest among western countries when compared to international use on a per capita basis.

2.3 Review of the clinical governance and authorisation of IVIg

In 2012, governments commissioned a review of the clinical governance and authorisation of IVIg. The purpose of the review was to determine the adequacy of the current IVIg authorisation and clinical governance arrangements, and to recommend options for improvement against the following goals:

- ensure that funded IVIg 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 that will be determined from time to time by governments
- improve the capture of information on the need for, use and outcomes of treatment with IVIg and to improve the evidence base that will inform future changes as to what is regarded as best practice in IVIg use and prescribing
- improve government understanding of the issues, benefits and risks of including Normal Human Immunoglobulin (NHlg) and Subcutaneous Immunoglobulin (SClg) in the improved IVIg management framework.

The review found there were deficiencies that could be addressed to improve efficiency and patient outcomes. The review concluded that there were significant variations in Intravenous Immunoglobulin (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 and implications and no accountability for cost with the prescriber.

The implications of doing nothing to improve the current governance and management of IVIg include:

- continued variation in prescribing practice nationally
- continuation of cost increases
- increasing likelihood of periods of short supply
- a lost opportunity to take a consistent national approach to meet new requirements (National Safety and Quality Health Service Standards NSQHSS –Standard 7 Blood and Blood Products)
- a system unprepared for national health reforms
- a system unprepared for new products, and
- continuation of limited knowledge development

The review considered three families of options and recommended the implementation of a new management model for immunoglobulin intended to strengthen existing arrangements for the management of IVIg through the development of an evidence base for immunoglobulin therapy which is supported by clinical best practice, cost effectiveness and transparency. The review and development of recommendations was informed by an advisory group with wide jurisdictional and stakeholder representation. The process of the review included significant consultation with clinical and other stakeholders, through interviews, group discussions and a widely subscribed survey. While this business case draws on the findings and recommendations of the review of clinical governance and authorisation of IVIg, significant earlier NBA and jurisdictional work including the 2004 Cost Effectiveness Review have all drawn comparable conclusions towards a constructive management regime that would increase the expertise and knowledge on the use of the product to build comparative, measurable metrics. Subsequently, this would encourage consistency in assessing requests for initial and ongoing supply, including for very rare conditions, ensuring equity of access nationally.

2.4 The program of measures to strengthen immunoglobulin authorisation and management and identification of where privacy implications may arise

The measures under the Ig Governance program, endorsed by the Jurisdictional Blood Committee (JBC) following the Review are detailed below. The development of the system BloodSTAR is an integral part of these measures.

IMMUNOGLOBULIN GOVERNANCE MEASURES	DESCRIPTION	Is personal and/or sensitive information likely to be collected and used or disclosed to achieve these measures? If so, appropriate privacy consent needs to be applied.	
		PERSONAL	SENSITIVE
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.	NO	YES. Only summary level data may be used to inform policy decisions. This information will not identify individuals.
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.	NO	YES. Only summary level data may be used to inform policy decisions. This information will not identify individuals.
Evolving the criteria for access	The <i>Criteria for the clinical use of intravenous immunoglobulin in Australia (Criteria)</i> were issued in 2008 and updated in 2012, and have been successful in defining the eligibility for access to product funded under the national blood	NO	YES. Only summary level data may be used to inform policy decisions.

IMMUNOGLOBULIN GOVERNANCE MEASURES	DESCRIPTION	Is personal and/or sensitive information likely to be collected and used or disclosed to achieve these measures? If so, appropriate privacy consent needs to be applied.	
		PERSONAL	SENSITIVE
	arrangements. The <i>Criteria</i> will be further evolved 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 <i>Criteria</i> will include appropriate clinical practice, alternative therapies and health economic aspects.		This information will not identify individuals.
Development and implementation of a national ordering and outcomes database (BloodSTAR)	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 <i>Criteria</i> , 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 <i>Criteria</i> , and provide an improved evidence base for practice improvement and research.	YES	YES
Development and implementation of a performance improvement program	It is envisaged that under the guidance of the national committee network, and utilising the <i>Criteria</i> and governance policies, 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	NO	YES

IMMUNOGLOBULIN GOVERNANCE MEASURES	DESCRIPTION	Is personal and/or sensitive information likely to be collected and used or disclosed to achieve these measures? If so, appropriate privacy consent needs to be applied.	
		PERSONAL	SENSITIVE
	processes, and an appropriate framework for auditing.		
Development and implementation of 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.	NO	YES
Potential efficiency improvements (where identified and endorsed)	In light of the other elements of the improved governance and management framework, consideration will be given to: <ul style="list-style-type: none"> • automated authorisation of access to products through the BloodSTAR, 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, ie. home based delivery. 	YES	YES

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.

3 Project Scope - BloodSTAR

The purpose of the BloodSTAR development project is to:

- develop a system that enables government policy by delivering efficient, streamlined immunoglobulin product access and use capability across a number of key areas;
- integrate the BloodSTAR with NBAs existing blood sector systems;
- develop an elegant solution that minimises the need for data management at relevant collection points so the system is stable, effective and relevant to users and produces high quality data; and
- anticipate that future work on NBAs related projects will provide opportunities for further efficiencies in the management of Ig products.

BloodSTAR is an integrated solution designed to serve the needs of 11 key stakeholder groups, and will replace the current manual, largely paper based processes. There are anticipated to be 1500 national users of the system covering the areas of administration and management, prescribing, authorising, treating, nursing and the dispensing of immunoglobulin products. The key user groups include:

- A. Program Governance
 - i. Criteria Management (NBA)
 - ii. System Administrator (NBA)
 - iii. Data team (NBA)
- B. Hospital Governance
 - i. Facility Manager
- C. Prescribers (Consultants, Treating Specialists, Medical Officers, Health Professionals , Nurse Practitioners and Midwife Practitioners)
- D. Authorisers (Blood Service)
- E. Nurses and Midwives (Transfusion Nurses, Registered Nurses, Registered Midwives)
- F. Dispensers (Transfusion Scientists, Blood Bank Laboratory staff)
- G. Patients (General Population)

The key user groups identified in points C-G above will collect information in BloodSTAR, in order to perform their roles for access to the supply of product funded under the national blood arrangements.

BloodSTAR will be integrated with BloodNet, the NBAs blood product ordering and receipting system which is interfaced (where available) with Laboratory Information Systems (LIS), where data matching will enable the recording and automated reconciliation of product dispensing events. BloodNet is integrated with BloodSTAR to manage supply of Ig product to authorised patients.

Data from BloodSTAR will be aggregated to report on the use⁴ of immunoglobulin under the national blood arrangements. Summary level data will be analysed to set and monitor policy parameters for contracting the supply and distribution of products. Summary level data will also inform benchmarking for clinical best practice to improve treatment and care for people with medical

⁴ Historically the Blood Service reports on product issues; however when BloodSTAR is implemented, reporting capability will be available across the roles involved in the management of authorised patients, including Authorisation, Dispense Requests, Orders, Dispense Events and Infusions.

conditions that require the use of Ig products. Any reports that are published from BloodSTAR will only contain statistics and/or summaries that do not identify individuals. Any additional research using information from BloodSTAR will only be undertaken in accordance with the requirements of the Privacy Act 1988 (Cth) and relevant state/territory legislation. The data may only be provided for research if the research program has approval from a properly constituted Human Research Ethics Committee (HREC) where a data request is submitted to the National Blood Authority and approved under the Data and Information Governance Framework; all identifiable personal data is removed when these requests are fulfilled.

4 Methodology

The Privacy Act has changed and new obligations came into effect in March 2014. The Office of the Australian Information Commissioner (OAIC) has issued guidance to Australian Government Agencies and Private Organisations in order to achieve compliance. NBAs legal team has undertaken significant work on analysing the impact of these changes, where much of NBAs existing privacy framework governing systems and processes has been modified to comply, and is therefore well placed to instruct the project team.

A privacy survey was circulated to more than 1200 stakeholders to gain an understanding of the views of stakeholders to inform user expectations on capability and design of BloodSTAR, with particular focus on patient search features. 204 responses were received; the results are discussed in Section 5.9 of this document.

The project documentation upon which this Privacy Impact Assessment report has been based includes:

- Ig System High Level Design
- User Terms and Conditions
- Privacy Collection Notice
- Privacy Consent Form
- Ig System Data Dictionary
- Patient Registry Security Matrix
- User Registration Specification
- Audit logging of transactions and views requirements, and
- Ig System Privacy survey summary.

5 Mapping information flows and privacy framework

5.1 Data flow diagram

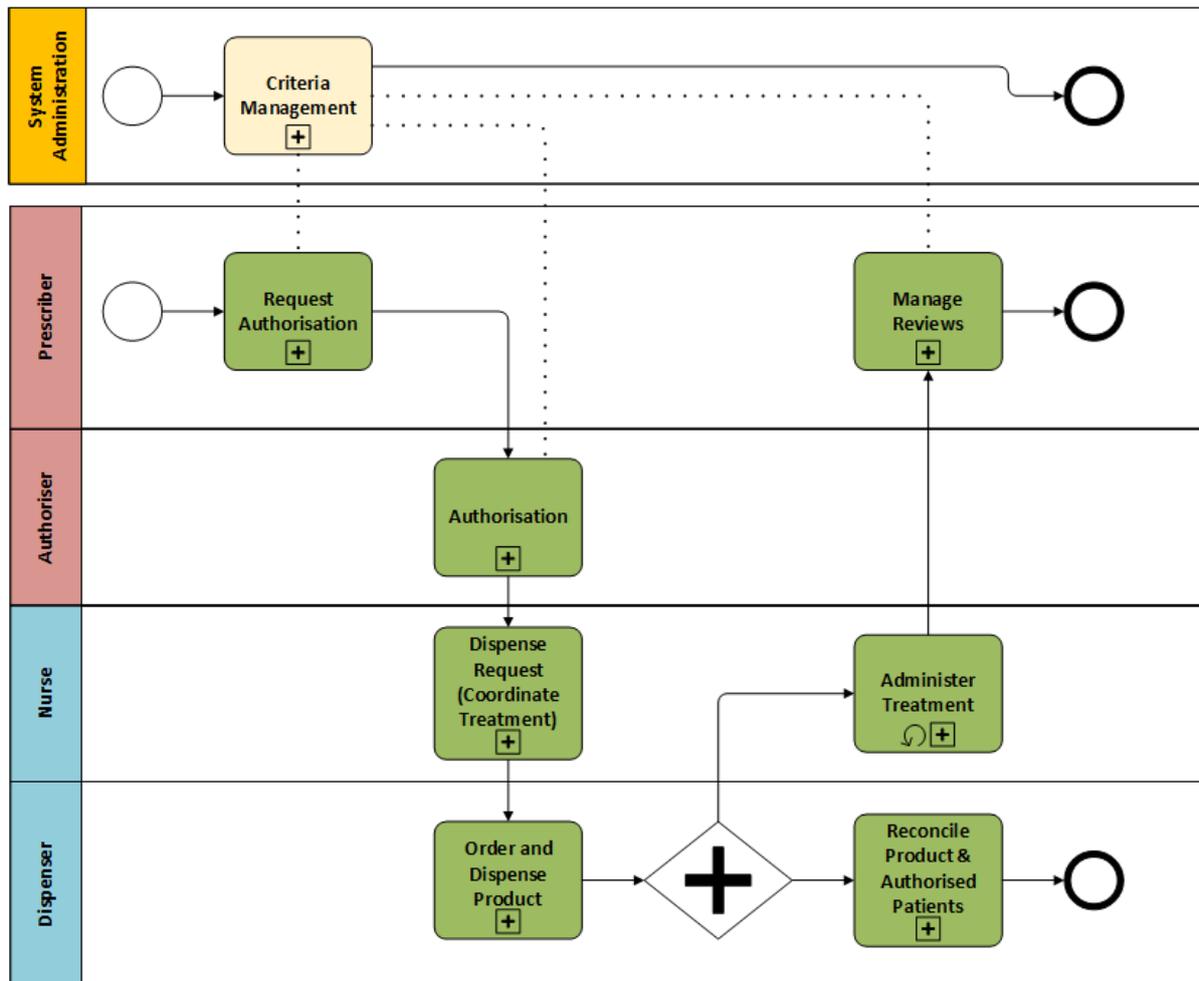


Figure 1 BloodSTAR end to end process

5.2 Collection of personal and sensitive information

A patient will become of interest to BloodSTAR once they are the subject of an authorisation request, for access to government funded immunoglobulin products under the national blood arrangements for the treatment of a condition specified in the Criteria. A patient may or may not be successful in obtaining authorisation for government funded immunoglobulin therapy. Sensitive information about a patient will be collected by a clinician (prescriber, nurse or dispenser) in the course of providing care to their patient. The information about a patient will be obtained from the patient and the patient’s hospital medical records by clinicians managing patient care. Clinicians are entities under the Privacy Act and are required to comply with the provisions of the Act as well as any state/territory laws.

The collection of sensitive information occurs at six points, as follows:

1. **Prescribers** – In the course of managing patient treatment, at the point of requesting authorisation for access to government funded product for the treatment of a patient’s medical condition;
2. **Authorisers** – Specified staff of the Australian Red Cross Blood Service, NBAs contracted service provider, are responsible for authorising initial and continuing access to government funded Ig products against government stated policy;
3. **Nurses** – In the course of managing patient treatment, to confirm patient’s authorisation status, request the dispense of product and coordinate with patient’s infusion appointments to ensure the correct product is dispensed;
4. **Dispensers** – In the course of managing inventory, ordering and dispensing the correct product to authorised patients;
5. **Patients** – In the course of recording infusion events, where they are self-managing subcutaneous treatment outside of the hospital setting; and
6. **NBA** – Specified staff that provide technical and user support for BloodSTAR and its patient portal, to assist in managing the integrity of the data entered into BloodSTAR and its patient portal, and to extract information for approved reports and supply planning.

Critical identification data is required to uniquely identify patients to enable assessment of an authorisation request and to ensure the appropriate supply of product in accordance with the prescribed therapy and current authorisation for access to product for treatment.

Critical health data is required to enable the assessment by the Authoriser of the patient’s medical condition against the qualifying criteria and review criteria as specified in the Criteria. This includes the provision of medical test results and reports uploaded to BloodSTAR, and discretionary information provided to substantiate a claim against the Criteria.

Information contained in medical test reports may be beyond the information required to support a claim, for example a haemoglobin level would be obtained from a full blood count (FBC) which may also contain information about the overall patient’s physiology. Many illnesses, diseases or infections can be indicated from abnormal FBC result.

Information relating to immunoglobulin product dispense events must be reconciled against authorised patients and will be collected via an interface with hospital laboratory information system (LIS), where available. Where an interface is not available, this reconciliation information will be entered into BloodSTAR manually by Dispensers.

5.2.1 Privacy consent

Confirmation that an individual has provided their explicit (written or verbal) consent to the collection, use and disclosure of their personal sensitive data is a requirement under APP 3, in the Privacy Act 1988 (Cth). Under the Act, individuals must provide their consent for the collection of

their personal and sensitive information, be informed about what their information is being used for and understand the usual disclosures⁵. A patient (or their parent/carer/guardian) who is the subject of an authorisation request will therefore be required to provide explicit consent (written or verbal) for the collection, use and disclosure of their personal and sensitive information. BloodSTAR users entering information into BloodSTAR about a patient will be required to ensure and confirm that consent has been obtained. Consent must be given by the person with legal “capacity” to do so, and be voluntary. The person consenting must also understand, in general terms, the risks of doing/not doing so; and that consent will remain current until it is withdrawn.

Reasonable steps will be taken to inform the patient of the reasons for the collection and what usual uses and disclosures may occur. This will be achieved through the provision of a Privacy Statement and Notice (Notice) written in plain English which will be made available within BloodSTAR for downloading and printing for the information of individuals. The Notice will describe what information is being collected, the purpose of the collection, and how information will be used and disclosed. The Notice will also describe the consequences of not providing explicit consent. A patient consent form will be made available within BloodSTAR for downloading, printing, signing and uploading to facilitate thorough record keeping practices. While verbal consent may also be obtained by the person collecting information from the individual, and confirmation of this can also be recorded in BloodSTAR by the person entering the information, a file note should be written and uploaded to BloodSTAR for the completeness of record keeping purposes. Record keeping purposes relate to the NBA’s obligations under the Commonwealth Archives Act 1983. Under the *NBA Records Authority, August 2007 class number 13116 – Supply Planning and Management – Authorisation* (issued by the National Archives of Australia) all data must be retained for a minimum of 10 years following the last completed action. To meet National Pathology Accreditation Advisory Council (NPACC) requirements (laboratory accreditation) data must be retained for 20 years. On this basis, the NBA will retain data in a usable form for at least 20 years following completion of the last action relating to an individual patient or unit of product.

Where a patient (or parent/carer/guardian) does not consent to their personal sensitive information being collected in BloodSTAR, it will not be possible for an assessment to be made on their eligibility for the supply of government funded immunoglobulin products under the national blood arrangements. The primary purpose of collection of this information is to uniquely identify individuals for assessment of authorisation for initial access and continuing access (where relevant) to ensure the safe and appropriate supply of product to that individual for the treatment of their medical condition.

Patients (or their parents/carers/guardians) who choose not to consent may access immunoglobulin products either as a Jurisdictional Direct Order (JDO) or Private Order, made directly with the imported immunoglobulin suppliers. A JDO and Private Order fact sheet is available on the NBA website a <http://www.blood.gov.au/ig-publications>.

Consent will remain valid up until and unless it has been withdrawn. The patient consent status will be recorded in the patient record.

⁵ Generally, 'disclosure' means releasing the personal information you have collected to another agency, body or organisation (this does not include the individual the information is about). However in the context of BloodSTAR, personal and sensitive information is not disclosed beyond the users of the system.

5.2.2 Withdrawal of privacy consent

A patient may withdraw their consent to the collection, use and disclosure of their personal and sensitive information at any time. Where a patient withdraws their consent, no more information about that individual will be collected in BloodSTAR. Information that had already been collected about that individual will not be deleted from BloodSTAR. An authorisation will become inactive and the patient will no longer be supplied immunoglobulin products under the national blood arrangements.

A patient who has withdrawn consent can later consent to re-activate their existing record. Therefore, their details will be returned in search results where there is a match on details entered.

The patient consent status will be stored against the patient record.

5.2.3 Collection of personal and sensitive information

The personal and sensitive information collected about an individual relating to an authorisation for initial and continuing access to treatment and supply of product is outlined in the following table. The primary purpose of collection and the consequences to the individual if it is not collected are also described.

Table 1 Summary of personal and sensitive information in BloodSTAR

Data element	Primary purpose of collection	Consequence to the individual if not collected
Personal Identifying information (patient)		
Family name	<ul style="list-style-type: none"> • Critical identification element used with other identifiers to uniquely identify individuals to ensure appropriate authorisation and supply of product. • Mitigate duplicate records. 	<ul style="list-style-type: none"> • Patient safety risk if not easily identifiable to clinicians involved in their care. • Ensures appropriate dispense of product for treatment.
Given name	<ul style="list-style-type: none"> • Critical identification element used with other identifiers to uniquely identify individuals to ensure appropriate authorisation and supply of product. • Mitigate duplicate records. 	<ul style="list-style-type: none"> • Patient safety risk if not easily identifiable to clinicians involved in their care. • Ensures appropriate dispense of product for treatment.
Date of birth	<ul style="list-style-type: none"> • Critical identification element used with other identifiers to uniquely identify individuals to ensure appropriate authorisation and supply of product. • Mitigate duplicate records. 	<ul style="list-style-type: none"> • Patient safety risk if not easily identifiable to clinicians involved in their care. • Ensures appropriate dispense of product for

Data element	Primary purpose of collection	Consequence to the individual if not collected
		treatment.
Sex	<ul style="list-style-type: none"> • Critical identification element used with other identifiers to uniquely identify individuals to ensure appropriate authorisation and supply of product. • Mitigate duplicate records. • Required for ideal body weight adjusted dosing measures. 	<ul style="list-style-type: none"> • Patient safety risk if Ideal Body Weight adjusted dosing is selected for the patient, gender is a key element to determining appropriate dosing.
Hospital identifiers: Such as but not limited to Medical Record Number (MRN); Unique Record Number (URN)	<ul style="list-style-type: none"> • Critical identification element used with other identifiers to uniquely identify individuals to ensure appropriate authorisation and supply of product. Mitigate duplicate records. • Enable automated reconciliation of dispensed product to authorised patients and data sharing where hospital laboratory information systems are interfaced. • Maintain established patient identification practice, specified in the National Safety and Quality Health Service Standards – Standard 5. Approved patient identifiers must be three of; patient name (family and given names), date of birth, gender, address, medical record number and/or Individual Healthcare Identifier. 	<ul style="list-style-type: none"> • Patient safety risk if not easily identifiable to clinicians involved in their care. Ensures appropriate dispense of product for authorised treatment.
Individual Health Identifier (IHI)	<ul style="list-style-type: none"> • Critical identification element used with other identifiers to uniquely identify individuals to ensure appropriate authorisation and supply of product. • Mitigate duplicate records. • Enable broader sharing of patient information where the patient actively participates in the use of personally controlled electronic health records to manage their health needs. 	
Authorisation elements (patient)		
Medical condition and indication for product use <ul style="list-style-type: none"> • Supporting evidence including medical test 	<ul style="list-style-type: none"> • To inform the assessment of the authorisation request. • To measure efficacy of therapy. 	<ul style="list-style-type: none"> • Inability of the Authoriser to assess the authorisation request against the Criteria and therefore approve the

Data element	Primary purpose of collection	Consequence to the individual if not collected
<p>results and measures plus the upload of these documents.</p> <ul style="list-style-type: none"> Free text fields for discretionary information. 		<p>request.</p> <ul style="list-style-type: none"> An inability to build the evidence base to evolve the Criteria to ensure that patients with medical conditions with proven efficacy receive appropriate therapy.
<p>Previous treatment with immunoglobulin (if any) including response</p>	<ul style="list-style-type: none"> Provides information regarding existing treatment that may not be recorded in BloodSTAR. May substantiate clinical benefit. To inform the authorisation request assessment and appropriate allocation of product for therapy. 	<ul style="list-style-type: none"> Patient safety risk if a previous treatment had resulted in a reaction to a particular product.
<p>Requesting Medical Officer</p>	<ul style="list-style-type: none"> To enable notification of authorisation to the appropriate medical officer responsible for patient care. 	<ul style="list-style-type: none"> Patient safety risk if notifications are not provided to the appropriate clinicians responsible for patient care.
<p>Treating Medical Specialist</p>	<ul style="list-style-type: none"> Critical identification for compliance with Criteria for diagnosis and review requirements. To enable notification of initial authorisation and review requirements for continuing authorisation to the appropriate medical specialist responsible for patient care. 	<ul style="list-style-type: none"> Patient safety risk if notifications are not provided to the appropriate clinicians responsible for patient care.
<p>Treatment arrangements:</p> <ul style="list-style-type: none"> Infusion method (intravenous or subcutaneous) Treating facility Administering facility Dispensing facility Product brand Patient weight & height Dose amount Dose frequency Date required Treatment plan Review date 	<ul style="list-style-type: none"> To inform the authorisation assessment. To ensure appropriate dispense of product for the treatment of authorised patients. To enable notification of initial and continuing authorisation to the appropriate dispenser, and where necessary the administering facility. To enable supply planning. 	<ul style="list-style-type: none"> Patient safety risk if information is not provided which informs the administration, product and dosage to treat the patient in accordance with prescribed therapy.

Data element	Primary purpose of collection	Consequence to the individual if not collected
Clinical outcomes (patient)		
<p>Medical condition and indication for use</p>	<ul style="list-style-type: none"> Build the evidence base for demand management modelling and future iterations for the criteria for access. 	<ul style="list-style-type: none"> An inability to build the evidence base to evolve the Criteria to ensure that patients with medical conditions with proven efficacy receive appropriate therapy.
<p>Evidence of clinical benefit or no clinical benefit:</p> <ul style="list-style-type: none"> Supporting evidence including medical test results and measures plus the upload of these documents. Free text fields for discretionary information. 	<ul style="list-style-type: none"> Build the evidence base for demand management modelling and future iterations of the criteria for access. 	<ul style="list-style-type: none"> An inability to build the evidence base to evolve the Criteria to ensure that patients with medical conditions with proven efficacy receive appropriate therapy.
Personal identifying information (requesting medical officer)		
<p>Family name</p>	<ul style="list-style-type: none"> Critical identification element used with other identifiers to uniquely identify individuals involved in patient care. To enable notification of initial and continuing authorisation approval to the appropriate clinicians involved in patient care. 	<ul style="list-style-type: none"> Patient safety risk if notifications are not provided to the appropriate clinicians involved in patient care.
<p>Given name</p>	<ul style="list-style-type: none"> Critical identification element used with other identifiers to uniquely identify individuals involved in patient care. To enable notification (where registered BloodSTAR user) of initial and continuing authorisation approval to the appropriate clinicians involved in patient care. To enable notification (where registered BloodSTAR user) of patient treatment review to the appropriate clinicians involved in patient care. 	<ul style="list-style-type: none"> Patient safety risk if notifications are not provided to the appropriate clinicians involved in patient care.
<p>Facility</p>	<ul style="list-style-type: none"> To ensure appropriate disclosure of patient information to relevant clinicians at a 	<ul style="list-style-type: none"> Patient safety risk if notifications are not provided to the

Data element	Primary purpose of collection	Consequence to the individual if not collected
	facility involved in patient care. <ul style="list-style-type: none"> To enable notification of initial and continuing authorisation approval to the appropriate clinicians involved in patient care. 	appropriate clinicians involved in patient care.
Contact details (phone/page)	<ul style="list-style-type: none"> To enable communication with appropriate clinician involved in patient care (only displayed to Authoriser, NBA). 	<ul style="list-style-type: none"> Patient safety risk if notifications are not provided to the appropriate clinicians involved in patient care.
Personal identifying information (treating medical specialist)		
Family name	<ul style="list-style-type: none"> Critical identification element used with other identifiers to uniquely identify clinicians involved in patient care. To enable notification of initial and continuing authorisation approval to the appropriate clinicians involved in patient care. 	<ul style="list-style-type: none"> Patient safety risk if notifications are not provided to the appropriate clinicians involved in patient care.
Given name	<ul style="list-style-type: none"> Critical identification element used with other identifiers to uniquely identify individuals involved in patient care. 	<ul style="list-style-type: none"> Patient safety risk if notifications are not provided to the appropriate clinicians involved in patient care.
Facility	<ul style="list-style-type: none"> To ensure appropriate disclosure of patient information to relevant clinicians at a facility involved in patient care. To enable notification of initial and continuing authorisation approval to the appropriate clinicians involved in patient care. 	<ul style="list-style-type: none"> Patient safety risk if notifications are not provided to the appropriate clinicians involved in patient care.
Contact details (phone/page)	<ul style="list-style-type: none"> To enable communication with appropriate individual involved in patient care (only displayed to Authoriser, NBA). 	<ul style="list-style-type: none"> Patient safety risk if notifications are not provided to the appropriate clinicians involved in patient care.

A detailed table of all data elements in BloodSTAR is provided at Attachment D – Patient Record Data Dictionary.

BloodSTAR initial and continuing authorisation request forms also contain free text fields, which will allow clinicians to include additional information in order to substantiate a claim against either a qualifying criteria or review criteria concerning a patient's medical condition and their eligibility to access product under the Criteria. These fields may present a risk to the collection of unsolicited third party information. To minimise the collection of unsolicited third party information, guidance will be provided to end users. Additionally, regular auditing of these fields will be undertaken on a weekly basis by NBA support staff, in accordance with Australian Government Protective Security Policy Framework to identify and remove content that does not meet the necessity test. Audit logging transactions will be retained in accordance with the Commonwealth Archives Act 1983 and relevant state/territory legislation.

5.3 Disclosure of personal and sensitive information

The National Blood Authority will manage the security of BloodSTAR so that only authorised users will be able to access data via a secure log in process for the purpose of undertaking their role in the management of authorised patients.

Clinicians will be required to have a unique username and password, approved by a facility administrator who can attest to their employment in their facility, to access BloodSTAR. This will enable users to complete and submit an initial or continuing authorisation request form resulting from the clinical assessment and patient treatment review processes.

5.3.1 Patient Search Scope Features

Patient search features include the default search scope specific to each user profile. The search scope aims to limit the patients available to a user based on the strength of the relationship that can be established from the patient's treatment arrangements and the users approved access at the facilities where the treatment is to be provided. The default search scope is set when the search features are initiated and apply the following rules:

My Patients

- where the user is recorded as the Treating Medical Specialist or Registered Medical Officer in an authorisation or authorisation request.

My Hospital/Facility

- where the user is approved to access patient records at the facility they are logged on at. If the user has access to more than one facility, they must select the facility they are working from in the logon process.

State/territory

- defaults to the state/territory nominated by the user when registering to access the system.
- the user must record a reason to search beyond their Hospital/Facility before results are presented.

National

- All patients.
- the user must record a reason to search beyond their state/territory before results are presented.

Application of the search scope rules by User Profile are described below.

Medical Officer

1. My Patients
2. My Hospital
3. State/territory
4. National

Nurse / Midwife

1. My Hospital
2. State/territory
3. National

Dispenser

Important note: dispensers will have visibility of Patient information via features that will be integrated with BloodNet and therefore will not be expressly acknowledged as users of BloodSTAR. Existing BloodNet processes conform to the security and access controls described in this document in relation to BloodSTAR.

1. My Hospital
2. State/territory
3. National

Authoriser

Patient details will be summarised to age and gender for the information of the Authoriser. Where more information about the patient is required, the Authoriser will take a discreet action to reveal patient name and date of birth. This feature will not be applied during the transition phase.

1. State/territory – Authorisation Jurisdiction
2. National

Patient searches can be initiated from a user's Home Page constrained by the Search Scope for each user profile. Additionally, patient searches can be executed from the Patient selector in an initial authorisation request. To minimise the possibility of creating duplicate patient records, the search scope for the patient selector will be broadened to be a national search, however at least two points of identification will be required to undertake a national search, to maximise result matches and minimise the number of returned results.

5.3.2 View Patient Record Permissions

The view patient record permissions are specific for each user profile. A user is permitted to view patient records as described below:

- Medical Officer –
 - where they are the Treating Medical Specialist or Requesting Medical Officer named in the authorisation request and the relationship is current
 - where the patient has an authorisation** with either the Treating or Administering Facility matching any of the facilities for which the user holds a Medical Officer Role and the relationship is current
 - where the user is required to record a reason, to view the record of a patient beyond their facility or where a relationship is not current in their facility, before the patient record can be viewed.*

- Nurse / Midwife –
 - where the patient has an authorisation** with either the Treating or Administering facility matching the facility at which the user is logged in and the relationship is current.
 - where the user is required to record a reason, to view the record of a patient beyond their facility or where a relationship is not current in their facility, before the record can be viewed.*

- Dispenser –
 - where the patient has an authorisation ** with either the Treating or Administering facility matching the facility at which the user is logged in and the relationship is current.
 - where the user is required to record a reason, to view a patient record of a patient beyond their facility or where a relationship is not current in their facility, before the record can be viewed.*

- System Administrator – a qualification reason will be required in all circumstances.

- Authoriser –
 - where the patient has an authorisation request in the state of the authorisers facility and the relationship is current.
 - the user will not be able to view patient identifying details once STARS has been decommissioned without recording a qualification reason. *
 - where the user is required to record a reason, to view a patient record of a patient beyond their facility or where a relationship is not current in their facility, before the record can be viewed.*
 - Authorisers will not be required to provide a qualification reason to view patient identifying information in the state of their facility during the period of transition from STARS to BloodSTAR, nominally defined as the 2016 calendar year.

* A user is permitted to view patient identifying information and patient records up to 7* days after providing a qualification reason for viewing the record.

** An authorisation request status will be displayed so that the user is aware of its existence, but the content of the authorisation request will not be displayed.

The Patient Record Security Matrix at Section 8.5 illustrates user permissions to view patient records.

5.4 Correction of personal information

Authorised users will have permission to access and edit patient records to correct personal identifying information, such as misspelt names, date of birth errors, or amendment/addition of hospital identifiers.

Patients will have the right to access and seek correction of their personal information held in BloodSTAR, in accordance with privacy laws. In order to access and correct information about themselves, they will need to contact their regular place of treatment to assess information held about them and seek changes as required.

A BloodSTAR user will be able to provide patients with information, limited to their user permissions. If a patient is unhappy with the response they receive, individuals will be able to contact the privacy commissioner in their state/territory. They may also contact the NBA at privacy@blood.gov.au.

5.5 Security

BloodSTAR management and operation will be tightly controlled. The NBA has implemented the highest levels of security available in Australia for its systems, housed in a highly secure data centre in Canberra. Stringent security protocols will be built into the system to control access to personal information. All reasonable steps will be taken to protect personal information from misuse, interference and loss, and from unauthorised access, modification or disclosure. Personal and sensitive information will only be stored on a password protected ICT system which complies with the Australian Government Protective Security Policy Framework. This includes ensuring that information is only accessed by authorised users that require access to undertake their official functions and roles.

Users of BloodSTAR will therefore be required to use unique user credentials for logging in to the system. The NBA combines the use of a unique user name and password as a means of identifying and authenticating users. Authorised users will be authenticated at the location at which they carry out their usual responsibilities. An audit log will be monitored to ensure the appropriate use of BloodSTAR and so that the NBA can identify unauthorised behaviour. BloodSTAR will be physically located in a secure data centre in Australia. The NBA will not pass on personal information to anyone without consent, unless the law permits or requires it to do so. These procedures protect information from unauthorised access, interference, alteration, or loss or disclosure, or misuse.

Consistent with Information Security Manual (ISM) requirements the NBA applies password selection and management mechanisms, such as using change cycles and prescribing password length and complexity. Password changes will be enforced every 180 days. Password length must be a minimum of nine (9) characters, consisting of at least one (1) character from at least three (3) of the following character sets:

1. lower case characters (a-z).
2. uppercase characters (A-Z).
3. digits (0-9).
4. punctuation and special characters (e.g. ! @ # \$ % ^ & *).

Personal and sensitive information will only be stored within Australia and will not be stored in a Cloud. Weekly back-ups of data will be encrypted and held off-site by a provider that is endorsed by the Australian Signals Directorate. All technical support staff approved to have access to the system will be security cleared by the government agency that provides security clearances for the Department of Defence and will undergo formal Privacy Training.

The ICT production environment for the system is hosted by the NBA in a highly secure data centre in Canberra which has been certified by both the Defence Signals Directorate (who provide ICT security services for the Australian Government) and the Australian Security Intelligence Organisation (ASIO, T4 Branch). The same data centre hosts a range of other government agencies including the Australian Federal Police and the Department of Human Services (i.e. Medicare, Centrelink, Family Assistance Office etc).

The ICT development environment and online replica of all database data is hosted in the NBA's secure offices inside a triple-layer access controlled area which exceeds the relevant ASIO T4 branch requirements. Off-site back-ups of the system on magnetic tape are produced weekly and held off-site by an ASIO T4 endorsed provider with all tape contents encrypted at 256 bits.

The National Blood Authority's ICT systems, including the arrangements for the registry, meet or exceed the mandatory requirements for an UNCLASSIFIED (G) system in the Australian Signals Directorate's Information Security Manual (ISM).

All NBA users with privileged access (ie system administrators, ICT support staff and software developers) have security clearances at or above 'Negative Vetting, Level 1' issued by the Australian Government Security Vetting Agency.

A series of firewalls and associated security devices protect the data and the primary firewalls are monitored 24/7 real-time by the Defence Signals Directorate's Cyber Security Operations Centre (CSOC). The database and reporting servers sit behind the primary and secondary fire-walls and so the likelihood of an intruder to compromise the system and reporting servers is very low.

Information identifying patients in alerts to clinicians can only be sent as an encrypted message external to the system's firewalls where decryption by the recipient is possible. The NBA will leverage Opportunistic TLS capability to improve the dissemination of information to clinicians into the future.

If there is a security breach, the NBA will respond in accordance with the NBA's Data and Information Governance Framework. Investigation of a suspected security breach will be initiated as close as possible to the time that the suspected security breach was discovered.

The retention of data in BloodSTAR will be determined in accordance with the requirements of the *Archives Act 1983* which applies to the NBA as a Commonwealth government agency.

5.6 Data Quality

Information collected about a patient at the point of the initial authorisation request may be updated at the point of a continuing authorisation request. Importantly, the patient weight may be

updated to ensure the appropriate dose is prescribed for the patient. The onus will be on the clinicians to ensure the currency of information held about a patient to enable the assessment of their eligibility for access to product for their treatment. The interface between the hospital laboratory information system (LIS) and BloodSTAR via integration with BloodNet will ensure the currency of product dispense events and automate the reconciliation for authorised patients. The patient's hospital identifier (e.g. Medical Record Number) will need to be correctly recorded to enable this exchange of information.

The risks to patient safety are increased if the information is not accurate or up to date.

Where a patient record has been updated at any point in time, the information will be made available for the information of those with a role in the management of an authorised patient's treatment. Changes to a patient record will not initiate any alert or notification to any person that has previously accessed the patient's record for the purposes of carrying out their role in the management of authorised patients.

5.7 Data Retention

BloodSTAR patient records will be retained for a period of 20 years in accordance with the Commonwealth Archives Act 1983 and National Pathology Accredited Advisory Council (NPAAC) requirements.

Patient records which are inactive as a result of withdrawn consent will be kept for a period of 20 years to enable a record to be re-activated if the individual chooses to provide consent at a later date.

Audit logging transactions will be retained for seven years in accordance with minimum retention periods for Commonwealth records defined by the National Archives of Australia's Administrative Functions Disposal Authority.⁶

5.8 Identity Management

According to The National Safety and Quality Health Service Standards (NSQHS), Standard 5 Patient Identification and Procedure Matching, at least three approved patient identifiers are used when providing care, therapy or services in the hospital setting. These may include:

- Name;
- Date of birth;
- Sex;
- Address;
- Hospital Identifiers (Medical record number); and
- Individual Healthcare identifier (IHI).

⁶ [National Archives of Australia Administrative Functions Disposal Authority www.naa.gov.au/records-management/agency/keep-destroy-transfer/agency-ra/index.aspx](http://www.naa.gov.au/records-management/agency/keep-destroy-transfer/agency-ra/index.aspx).

All of the above personal identifiers, other than address, are collected in BloodSTAR to facilitate patient identification and procedure matching, the limitations are IHI is optional and in some circumstances, such as the private setting, hospital identifiers may not be used. Phase 1 implementation of the system will not include collecting the address of the patient as it is not required due to therapy being administered either within the hospital setting or product being dispensed at the hospital for home treatment.

The minimum amount of identifiable information is being collected to ensure that an individual can be verified by the end user. Verification of identification is achieved by a combination of the search terms when accessing BloodSTAR for the purpose of creating a new patient record in an initial authorisation request, continuing authorisation request, ceasing treatment, or recording clinical outcomes. This is to ensure the appropriate dispense of product to patients based on the prescribed and authorised treatment.

The patient search scope is detailed in section 5.3.1.

BloodSTAR will generate a unique identifier in the registry, however this identifier is not used or displayed to system users.

5.8.1 Pseudonymity and anonymous options

Under APP 2 an individual must have the option of dealing with the NBA anonymously or by pseudonym as a default starting point. However, the NBA is not required to provide those options where the entity is required or authorised by law to deal with identified individuals or it is impracticable for the entity to deal with individuals that have not identified themselves. A patient may receive Ig product authorisation for treatment for a number of different conditions over time, via different hospitals, in different locations with different record management capabilities. Patients may have authorisation for the treatment of concurrent conditions. Given the importance of identifying patients and understanding their past treatments it may be a patient safety risk and impracticable to link pseudonymity and anonymous records with the actual patient record. A patient's response to previous treatments including reactions to some products will impact on the decisions made by clinicians and authorisers, for continuing treatment for patients.

When BloodSTAR is introduced, it is expected that home delivery of product will become available. However, it is also impracticable to provide pseudonymity and anonymous options to patients who in the future may receive product by home delivery as a name and address is required to deliver the product to the authorised individual.

The use of pseudonym and anonymous names would be ineffective where other elements contained within the record could re-identify the individual. For example, the patient Medical Record Number is an identifiable element of the patient record, used as a critical personal identifier and to facilitate the exchange of data between the hospital laboratory information system and BloodNet. Where we are unable to make any guarantee of not being able to re-identify an individual, a privacy consent form would still need to be provided by the patient. The use of hospital identifiers without other identification elements, such as name and date of birth would present a patient safety risk for patient identification and matching appropriate treatment.

5.8.2 Removal of name and use of hospital identifier for patient records

Western Australia Department of Health has suggested using the hospital identifier in the place of the patient name. In WA, a hospital identifier is unique to the patient and is transportable across hospitals. This is not the case in other states/territories where a single patient may have many hospital identifiers, including multiple hospital identifiers which relate to the same hospital. The private setting also presents a challenge, as hospital identifiers may not exist and would not be transferrable.

The risk of utilising a hospital identifier as a point of identification is the lack of confidence in establishing the identity of a patient on an identifier alone, particularly if the patient travels interstate and requires treatment with authorised product. There is current expectation that a patient can receive one or more infusions under a current authorisation in any facility Australia-wide.

5.9 Privacy Survey

5.9.1 Introduction

The National Blood Authority (NBA) conducted an Immunoglobulin (Ig) System Privacy Survey as part of the Ig Governance and System Development Projects. The survey's aim was to gain more detailed insight into users expectations on levels of access versus privacy constraints in system design and capability. While the system has been named BloodSTAR, Ig System has been retained in this section to maintain consistency with the terminology at the time the survey was circulated.

Initial circulation of the survey went to 66 participants who were members of the Ig System User Reference Groups. Subsequently, the Blood Service, on behalf of the NBA, circulated the survey to an additional 1236 stakeholders.

The survey consisted of 25 questions, and included:

- descriptions of Survey Purpose (the Preamble);
- make-up of the patient record held in the patient registry;
- a range of assumptions; and
- 19 questions describing scenarios in which a system user would need to search for patient records and the level of patient information available to them. The scenarios were specific to individual roles within the system;
 - Prescriber (8);
 - Authoriser (5);
 - Nurse (3); and
 - Dispenser (3).

5.9.2 Analysis on Survey Results

The survey closed on 28 February 2015 with 204 respondents across the states and territories and five key stakeholder (role) groups, a breakdown of survey respondents is listed in Table 2. The number of Ig System users performing one of the five roles, as listed in Table 2, is anticipated to be 1500; the number of respondents represents 14% of the cohort.

Table 2: Survey Respondents by State and Role (Q1 & Q2)

Role	State								Total
	ACT	NSW	NT	QLD	SA	TAS	VIC	WA	
Authoriser		5		5	2		7	1	20
Dispenser	1	18	2	12	3	3	25		64
Governance	4	4		2	5		5		20
Nurse	1	9	1	13	3	1	20	2	50
Prescriber		13		10	3	3	16	5	50
Total	6	49	3	42	16	7	73	8	204

5.9.3 Comments

A total of 1229 comments were made by survey respondents across the range of questions and scenarios. These comments provide insight into current clinical practice, justification for users to access patient records held in the Ig System, propose new system requirements and raise a number of concerns for the project team to consider. In addition the comments indicate a strong desire for the system to provide an electronic, paperless business process that facilitates the delivery of care to patients across the treatment spectrum.

Overall respondents see the Ig System as a mechanism to improve and manage patient safety while delivering health services but they expect to see access to patient records reserved for those system users that have a genuine need. In an environment where the patient-facility-clinician-relationship is ever changing this is a significant technical challenge that carries facility administrator overheads. However, the patient search scope has been designed to leverage known relationships. The patient search scope is described in Section 5.3.1.

Generally the results of the survey support the assumptions made in system design further supported by analysis on the measures described in this PIA to treat risks associated to patient privacy. The greatest challenge is the management of traveling patients by nurses.

5.9.4 Survey Questions and Responses

Preamble

The primary objective of the Immunoglobulin (Ig) System is delivering core capability to meet the requirements of the “Immunoglobulin (Ig) Governance: National Policy: Access to government funded Ig products”. This includes assisting stakeholders to meet the key areas of accountability under the policy including establishing the IVIg / SCIg authorisation arrangements, promoting appropriate practice and quality health outcomes, maintaining and monitoring data information management for the authorisation process, performance improvement and knowledge development to support better clinical practice. To deliver this, supplementary capability in the Ig System including, but not limited to, a patient registry, Prescriber registry, user profile management and search features are required.

While protecting the privacy of Patient and Prescriber details is paramount, the Ig System Project Team is challenged with balancing system utility with privacy obligations. One of the key aspects of the Australian Privacy Principles (Commonwealth Legislation) is a requirement to demonstrate that there is a necessity to capture personal information considering the functions and activities of the agency or organisation concerned. An individual that provides a health service and holds any health

information is required to meet the Australian Privacy Principles including the requirement to demonstrate this necessity for the collection of personal information. The proposed uses and disclosures of personal information inform the necessity of that collection.

This survey is designed to gain your insight on how personal information that may be collected in the Ig System should be accessed, used and disclosed in different clinical scenarios. Your insight will help formulate the arguments for data capture by feeding into the privacy assessment. It will also assist to determine system features to facilitate required access, use and disclosure of that information.

The Ig Governance Team may use results of this survey and any specific comments you make to assist in the privacy assessment process and for other purposes. Your participation, results and comments will remain anonymous unless you expressly agree otherwise on completion of the survey.

The scenarios are not intended to be exhaustive; rather they represent some common circumstances occurring in hospitals today based on the Ig System Project Teams' current understanding – we would love to know more!!

Question	Question / Scenario														
1	Role <ul style="list-style-type: none"> • Authoriser • Dispenser • Governance • Nurse • Prescriber 														
Response	<table border="1"> <thead> <tr> <th>Role</th> <th>Respondents</th> </tr> </thead> <tbody> <tr> <td>Authoriser</td> <td>20</td> </tr> <tr> <td>Dispenser</td> <td>64</td> </tr> <tr> <td>Governance</td> <td>20</td> </tr> <tr> <td>Nurse</td> <td>50</td> </tr> <tr> <td>Prescriber</td> <td>50</td> </tr> <tr> <td>Total</td> <td>204</td> </tr> </tbody> </table>	Role	Respondents	Authoriser	20	Dispenser	64	Governance	20	Nurse	50	Prescriber	50	Total	204
Role	Respondents														
Authoriser	20														
Dispenser	64														
Governance	20														
Nurse	50														
Prescriber	50														
Total	204														
2	State <ul style="list-style-type: none"> • ACT • NSW • NT • QLD • SA • TAS • VIC • WA 														
Response	<table border="1"> <thead> <tr> <th>State</th> <th>Respondents</th> </tr> </thead> <tbody> <tr> <td>ACT</td> <td>6</td> </tr> <tr> <td>NSW</td> <td>49</td> </tr> <tr> <td>NT</td> <td>3</td> </tr> </tbody> </table>	State	Respondents	ACT	6	NSW	49	NT	3						
State	Respondents														
ACT	6														
NSW	49														
NT	3														

Question	Question / Scenario	
	QLD	42
	SA	16
	TAS	7
	VIC	73
	WA	8
	Total	204
	<p>Remarks</p> <p>In all states and territories the percentage of survey respondents is equivalent within 1%-2% of the population and anticipated number of users (1500). The exception is in NSW where survey respondents were down 8% on the anticipated number of users in that state, and WA where survey respondents were down 11% on the anticipated number of users, due to WA Health concerns with implementing the National Policy and associated System.</p>	
3	<p>The questions in this survey are separated into scenarios for Prescribers (Doctor/Medical Officer), Authorisers, Nurses and Dispensers. Please respond to each question regardless of your role; your expectation on the role of others involved in the delivery of health care services to patients is integral to Ig System design.</p> <p>Assumptions that apply to all of the scenarios in this survey are:</p> <ul style="list-style-type: none"> I. the Prescriber, Authoriser, Nurse or Dispenser is a registered user of the Ig System, and has agreed to the terms and conditions of use (to be defined); <p>AND</p> <ul style="list-style-type: none"> II. all patients have expressly consented to having their health information recorded in the Ig System for the purpose of managing their access to government funded immunoglobulin products and directly related purposes, including to optimise patient safety and improve clinical practice; <p>AND</p> <ul style="list-style-type: none"> III. all patients will have been the subject of an IVIg/SCIg authorisation request (in the Ig System, not any other system), irrespective of its current status; <p>AND</p> <ul style="list-style-type: none"> IV. the hospital/facility from where the Ig System search is being conducted is the location where Treatment for the particular patient is prescribed, treatment is Administered (may be different to the hospital where the treatment is prescribed) or where arrangements are made for product Dispensing (e.g. SCIg Home Therapy). Refer to definitions below for additional detail. <p>AND</p> <ul style="list-style-type: none"> V. all page views, searches and updates performed by registered system users are recorded in an audit log and are used for reporting and to detect 	

Question	Question / Scenario																			
	<p>privacy breaches.</p> <p>Definitions for hospitals and facilities involved in delivering health services</p> <p>Treatment Hospital/ Facility: The hospital that is responsible for the management of a patient’s diagnosed medical condition.</p> <p>Administering Hospital/Facility The hospital at which a patient has immunoglobulin treatment administered. This may differ from the hospital that is responsible for the management of the medical condition. For example a patient may be managed at a city hospital but may present at a regional hospital for the purpose of having an infusion.</p> <p>Dispensing Hospital/Facility The lab or pharmacy at which a product dispensing arrangement is made for a patient’s treatment. This may be different from the Treatment hospital and or Administering hospital. A dispensing facility is generally relevant in SCIg scenarios where a patient collects product from a hospital that is different to where their treatment is managed.</p> <p>Do you have any comments to make on these assumptions?</p>																			
Response	<table border="1"> <thead> <tr> <th></th> <th style="background-color: #FFD700;">Skipped</th> <th style="background-color: #FFD700;">Answered</th> <th style="background-color: #FFD700;">Yes</th> <th style="background-color: #FFD700;">No</th> </tr> </thead> <tbody> <tr> <td style="background-color: #FFD700;">Count</td> <td>26</td> <td>178</td> <td>36</td> <td>142</td> </tr> <tr> <td style="background-color: #FFD700;">%</td> <td>13%</td> <td>87%</td> <td>20%</td> <td>80%</td> </tr> </tbody> </table> <p>Remarks</p> <p>A high response to ‘No’ in this question indicates that respondents do not have any concerns with the assumptions.</p> <p>Of the ‘Yes’ responders, 27 provided comments which indicate they were seeking further clarification on the assumptions including the definitions on facility types and therefore do not indicate significant concern with the assumptions.</p> <p>Further comments raise concern around the logistics of gaining consent and registering to access the Ig System in order to prescribe.</p>						Skipped	Answered	Yes	No	Count	26	178	36	142	%	13%	87%	20%	80%
	Skipped	Answered	Yes	No																
Count	26	178	36	142																
%	13%	87%	20%	80%																
4	<p>For the purposes of this survey the “Ig System record” for the patient is made up of identifying information including:</p> <ul style="list-style-type: none"> • name, sex and date of birth; • past and present IVIg/SCIg authorisation requests; • previous treatments relevant to an authorisation; • treatment duration and review; • treating medical specialist details; 																			

Question	Question / Scenario															
	<ul style="list-style-type: none"> • medical condition and indication; • patient characteristics (weight); • dosage, product and reason for product choice as well as do not prescribe advisories. <p>It may also include:</p> <ul style="list-style-type: none"> • particular infusions and reactions to those infusions. <p>Additionally, the outcomes of Immunoglobulin Therapy will be captured at each review for the purpose of assessing efficacy and continuing access to Immunoglobulin Therapy.</p> <p>IMPORTANT NOTE: the Ig System <i>record</i> is not a copy of the patient’s medical record nor is it a clinical registry. It is therefore important to understand that in many scenarios the Ig System is unlikely contain more detailed information about the patient than the patient record at the hospital/facility at which they're receiving treatment.</p> <p>Do you have any comments to make on the proposed make-up of the 'Ig System record'?</p>															
Response	<table border="1"> <thead> <tr> <th style="background-color: #FFD700;"></th> <th style="background-color: #FFD700;">Skipped</th> <th style="background-color: #FFD700;">Answered</th> <th style="background-color: #FFD700;">Yes</th> <th style="background-color: #FFD700;">No</th> </tr> </thead> <tbody> <tr> <td style="background-color: #FFD700;">Count</td> <td>33</td> <td>171</td> <td>39</td> <td>132</td> </tr> <tr> <td style="background-color: #FFD700;">%</td> <td>16%</td> <td>84%</td> <td>23%</td> <td>77%</td> </tr> </tbody> </table> <p>Remarks</p> <p>A high response to ‘No’ in these questions indicates that respondents do not have any concerns with the make-up of the Ig System patient record.</p> <p>Of the ‘Yes’ responders, 33 provided comments which indicates support for the decision to replace the current process to fax forms with an electronic system. Comments also indicate an understanding around the difficulties of uniquely identifying patients and suggesting additional information that could be useful if captured.</p> <p>In addition a number of comments raise an interest in research and the value of the system for this purpose. It was evident that there was a level of confusion between the consent for treatment of biological product and separate consent to record personal and sensitive patient data in system.</p> <p>And further there is concern around the system increasing workload and an interest in defining relationships between groups of doctors and a single patient.</p>		Skipped	Answered	Yes	No	Count	33	171	39	132	%	16%	84%	23%	77%
	Skipped	Answered	Yes	No												
Count	33	171	39	132												
%	16%	84%	23%	77%												
5	<p>Searching for a patient – Prescriber</p> <p>The Prescribers default search is all patients that the Prescriber already has, or could reasonably be assumed to have, a relationship with.</p> <p>We believe the following Scenario represents the minimum requirement for</p>															

Question	Question / Scenario																		
	<p>system capability when a Prescriber is searching for patient details.</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – patient returns for a consultation with the same prescriber at the same hospital.</p> <p>The Prescriber searches for the patient and the patient's Ig System record can be seen. This also applies to any patients of the Prescriber who may have previously received IVIg/SCIg treatment.</p> <p>Do you agree?</p>																		
Response	<table border="1"> <thead> <tr> <th></th> <th>Skipped</th> <th>Answered</th> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>Count</td> <td>56</td> <td>148</td> <td>132</td> <td>16</td> </tr> <tr> <td>%</td> <td>27%</td> <td>73%</td> <td>89%</td> <td>11%</td> </tr> </tbody> </table> <p>Remarks</p> <p>A high response to 'Yes' in this question indicates that, in principle, respondents agree that where the patient is being treated by the nominated prescriber a prescriber in their hospital, or there is shared care of a patient, the patients record should be available.</p> <p>Of the 'No' responders, 16 made comments some of which indicate an understanding of the tenuous relationship between doctor and patient and the need to search for patients when the care of the patient changes hands.</p>					Skipped	Answered	Yes	No	Count	56	148	132	16	%	27%	73%	89%	11%
	Skipped	Answered	Yes	No															
Count	56	148	132	16															
%	27%	73%	89%	11%															
6	<p>Searching for a patient – Prescriber</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – Different Prescriber – Same Hospital</p> <p>A patient presents at hospital for a consultation, the Prescriber they usually see at the hospital is not available so they are seen by a different Prescriber who searches for the patient.</p> <p>When searching, should the different Prescriber be able to see the patient's 'Ig System record'?</p>																		
Response	<table border="1"> <thead> <tr> <th></th> <th>Skipped</th> <th>Answered</th> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>Count</td> <td>57</td> <td>147</td> <td>143</td> <td>4</td> </tr> <tr> <td>%</td> <td>28%</td> <td>72%</td> <td>97%</td> <td>3%</td> </tr> </tbody> </table> <p>Remarks</p> <p>A high response to 'Yes' in this question indicates that, in principle, respondents agree that where the patient is being treated by the nominated prescriber a prescriber in their hospital, or there is shared care of a patient, the patients record should be available.</p> <p>All four of the 'No' responders made comments indicating:</p> <ul style="list-style-type: none"> • that it would only be appropriate to do so if the doctor and or patient consented; or • suggesting that the information should be available in the Medical Record. 					Skipped	Answered	Yes	No	Count	57	147	143	4	%	28%	72%	97%	3%
	Skipped	Answered	Yes	No															
Count	57	147	143	4															
%	28%	72%	97%	3%															

Question	Question / Scenario															
	<p>These comments suggest there is some misunderstanding of the purpose of the Ig System, it is to provide information on a patients authorisation status to access funded immunoglobulin products, not provide a detailed medical record.</p>															
7	<p>Searching for a patient – Prescriber</p> <p>SCENARIO: Patient previously (but no longer) on IVIg/SCIg – Different Prescriber – Same Hospital</p> <p>The patient presents to a Prescriber at the hospital and advises that they previously had IVIg/SCIg under the care of a different Prescriber at that hospital.</p> <p>When searching, should the new Prescriber be able to see the patient's 'Ig System record'?</p>															
Response	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #FFD700;"></th> <th style="background-color: #FFD700;">Skipped</th> <th style="background-color: #FFD700;">Answered</th> <th style="background-color: #FFD700;">Yes</th> <th style="background-color: #FFD700;">No</th> </tr> </thead> <tbody> <tr> <td style="background-color: #FFD700;">Count</td> <td style="text-align: center;">60</td> <td style="text-align: center;">144</td> <td style="text-align: center;">139</td> <td style="text-align: center;">5</td> </tr> <tr> <td style="background-color: #FFD700;">%</td> <td style="text-align: center;">29%</td> <td style="text-align: center;">71%</td> <td style="text-align: center;">97%</td> <td style="text-align: center;">3%</td> </tr> </tbody> </table> <p>Remarks</p> <p>A high response to ‘Yes’ in this question indicates that, in principle, respondents agree that where the patient is being treated by the nominated prescriber a prescriber in their hospital, or there is shared care of a patient, the patients record should be available.</p> <p>All five of the ‘No’ responders made the same comments as Question 6 with the additional clarification that patient information should only be available where the authorisation for the patient is current.</p>		Skipped	Answered	Yes	No	Count	60	144	139	5	%	29%	71%	97%	3%
	Skipped	Answered	Yes	No												
Count	60	144	139	5												
%	29%	71%	97%	3%												
8	<p>Searching for a patient – Prescriber</p> <p>SCENARIO: Patient previously (but no longer) on IVIg/SCIg – Different Prescriber – Different Hospital – Same State</p> <p>A patient presents to a Prescriber in a hospital and advises that they previously had IVIg/SCIg under the care of a different Prescriber at a different hospital.</p> <p>When searching, should the Prescriber be able to see the patient's 'Ig System record'?</p>															
Response	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #FFD700;"></th> <th style="background-color: #FFD700;">Skipped</th> <th style="background-color: #FFD700;">Answered</th> <th style="background-color: #FFD700;">Yes</th> <th style="background-color: #FFD700;">No</th> </tr> </thead> <tbody> <tr> <td style="background-color: #FFD700;">Count</td> <td style="text-align: center;">63</td> <td style="text-align: center;">141</td> <td style="text-align: center;">121</td> <td style="text-align: center;">20</td> </tr> <tr> <td style="background-color: #FFD700;">%</td> <td style="text-align: center;">31%</td> <td style="text-align: center;">69%</td> <td style="text-align: center;">86%</td> <td style="text-align: center;">14%</td> </tr> </tbody> </table> <p>Remarks</p> <p>While there is still a high ‘Yes’ response it has decreased with a higher proportion of respondents answering ‘No’. Overall there is still a consensus that the patient’s record should be available in this scenario.</p> <p>‘Yes’ responders agree based on patient consent and cite problems with patients not always being able to provide good past history of treatment regimens.</p>		Skipped	Answered	Yes	No	Count	63	141	121	20	%	31%	69%	86%	14%
	Skipped	Answered	Yes	No												
Count	63	141	121	20												
%	31%	69%	86%	14%												

Question	Question / Scenario				
	<p>Currently prescribers rely on the ARCBS for current information on a patient's authorisation status which is helpful in those circumstances where the medical records are not up to date.</p> <p>18 of the 'No' responders provided a justification for their answer suggesting that the transfer of information should occur between prescribers or from the medical records at the original hospital.</p>				
9	<p>Searching for a patient – Prescriber</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – After Hours On-Call Prescriber – Different Hospital – Same State</p> <p>A patient presents to the emergency department in a regional hospital (e.g.: Orange, NSW) and advises they are currently receiving IVIg/SCIg at the Outpatient Clinic but their regular Prescriber is at a different hospital (e.g.: Westmead, NSW)</p> <p>When searching, should the Prescriber in Orange be able to see the patient's 'Ig System record'?</p>				
Response		Skipped	Answered	Yes	No
	Count	67	137	118	19
	%	33%	67%	86%	14%
	<p>Remarks</p> <p>While there is still a high 'Yes' response, 33% of respondents skipped the question. Overall the consensus remains that the patient's record should be available in this scenario.</p> <p>'Yes' responders are cognisant of the potential to duplicate records which flows on to inefficiencies when product orders are also duplicated leading to poor inventory management practices.</p> <p>16 'No' responders commented with the sentiments largely consistent with question 8.</p>				
10	<p>Searching for a patient – Prescriber</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg - After Hours On Call Prescriber - Different Hospital - Different State</p> <p>A patient presents to the emergency department in a regional hospital (e.g.: Byron Bay, NSW) and advises that they are currently receiving IVIg/SCIg at the Outpatient Clinic but their regular Prescriber is at a different hospital in a different state (e.g.: Royal Brisbane and Women's Hospital, Qld)</p> <p>When searching, should the Prescriber in Byron Bay be able to see the patient's 'Ig System record' that was created at the Royal Brisbane and Women's Hospital?</p>				
Response		Skipped	Answered	Yes	No
	Count	69	135	115	20
	%	34%	66%	85%	15%

Question	Question / Scenario				
	<p>Remarks</p> <p>The 'Yes' response rate is still high, however there is an increase in both the rate of respondents answering 'No' and skipping the question.</p> <p>The sentiments of the 15 'No' responders who commented are consistent with Question 8.</p> <p>The majority of 'Yes' responders who commented feel that access to this information improves the quality of care to the patient and minimises patient safety risks.</p>				
11	<p>Searching for a patient – Prescriber</p> <p>SCENARIO: Same Scenario as described in the previous Question (10) except on this occasion it is not an after-hours emergency.</p> <p>When searching, should the Prescriber be able to see the patient's 'Ig System record'?</p>				
Response		Skipped	Answered	Yes	No
	Count	69	135	110	25
	%	34%	66%	81%	19%
	<p>Remarks</p> <p>Comments on this question indicate that the changing scenarios may not have been understood. However, while the 'Yes' response rate is still there is a further increase in skipped questions to 34%, only 19% of the respondents answering the question have said 'No'.</p> <p>Many of the comments refer to those made on previous questions, as per Questions 8 – 10.</p> <p>Similarly, with comments made by the 'Yes responders are consistent with those recorded in remarks for Question 10.</p>				
12	<p>Searching for a patient – Prescriber</p> <p>SCENARIO: Many patients currently receiving IVIg/SCIg – Same Prescriber – Treats patients at many locations</p> <p>While logged on at a Hospital (Location A), the Prescriber requires information about a patient that he treats at a different Hospital or Private Medical Centre (Location B).</p> <p>When searching, should the Prescriber be able to see the patient's 'Ig System record' from Location B when logged on at Location A?</p>				
Response		Skipped	Answered	Yes	No
	Count	73	131	123	8
	%	36%	64%	94%	6%
	<p>Remarks</p> <p>A 94% response to 'Yes' form respondents answering this question indicates, in</p>				

Question	Question / Scenario															
	<p>principle, respondents agree that where a prescriber is managing many patients across a number of locations, the patients record should be available in a way that provides efficiencies to the prescriber.</p> <p>36% of respondents skipped the question . One of the three respondents who left comments indicated the logistics of connecting information is likely to be problematic.</p>															
13	<p>Searching for a patient – Authoriser</p> <p>As an Authoriser the default search is all patients in their State or area of Authorisation (e.g. NSW / ACT).</p> <p><i>Note: The Australian Red Cross Blood Service, Blood Service, is the contracted service provider for assessing authorisation requests, other than in South Australia where this is also done at some hospitals.</i></p> <p>Do you agree with this default position?</p>															
Response	<table border="1"> <thead> <tr> <th></th> <th>Skipped</th> <th>Answered</th> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>Count</td> <td>72</td> <td>132</td> <td>97</td> <td>35</td> </tr> <tr> <td>%</td> <td>35%</td> <td>65%</td> <td>73%</td> <td>27%</td> </tr> </tbody> </table> <p>Remarks</p> <p>97% of respondents answering the question responded ‘Yes’ with 35% of respondents skipping the question. There are a range of comments indicating that responsibility should rest with the Blood Service and others that suggest removing access to patient details from them.</p> <p>The broad sentiment indicates a dependency on the Blood Service to facilitate the flow of information to meet the rules set out in the <i>Criteria</i>. Standardisation across the states and territories features in the comments.</p>		Skipped	Answered	Yes	No	Count	72	132	97	35	%	35%	65%	73%	27%
	Skipped	Answered	Yes	No												
Count	72	132	97	35												
%	35%	65%	73%	27%												
14	<p>Searching for a patient – Authoriser</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – Same State as Authoriser</p> <p>A patient presents to their regular Prescriber for a routine clinic, the Prescriber calls the Blood Service for background details on current authorisation.</p> <p>When searching, should the Blood Service staff member be able to see the patient's 'Ig System record' to assist the Prescriber?</p>															
Response	<table border="1"> <thead> <tr> <th></th> <th>Skipped</th> <th>Answered</th> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>Count</td> <td>75</td> <td>129</td> <td>120</td> <td>9</td> </tr> <tr> <td>%</td> <td>37%</td> <td>63%</td> <td>93%</td> <td>7%</td> </tr> </tbody> </table> <p>Remarks</p> <p>93% of respondents answering the question responded ‘Yes’ and 35% of respondents skipped the question. This indicates a strong sentiment for the Blood Service to remain active in managing information associated to patients.</p>		Skipped	Answered	Yes	No	Count	75	129	120	9	%	37%	63%	93%	7%
	Skipped	Answered	Yes	No												
Count	75	129	120	9												
%	37%	63%	93%	7%												

Question	Question / Scenario				
15	<p>Searching for a patient – Authoriser</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – After Hours On-Call Prescriber – Same State</p> <p>A patient presents to the emergency department in a regional hospital (e.g.: Orange, NSW) and advises they are currently receiving IVIg/SCIg at the Outpatient Clinic but their regular Prescriber is at a different hospital (e.g.: Westmead, NSW).</p> <p>The On-Call Prescriber calls the Blood Service for advice on the patient’s authorisation.</p> <p>When searching, should the Blood Service staff member be able to see the patient's 'Ig System record' to assist the Prescriber?</p>				
Response		Skipped	Answered	Yes	No
	Count	79	125	117	8
	%	39%	61%	94%	6%
	<p>Remarks</p> <p>94% of respondents answering the question responded ‘Yes’ and 39% of respondents skipped the question. While respondents in principle agree the Blood Service should have access to the patient record, there is also a sentiment for the information to be communicated from prescriber to prescriber.</p>				
16	<p>Searching for a patient – Authoriser</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – Different State or area of Authorisation to the Authoriser</p> <p>A patient on holidays interstate presents at a Hospital for treatment, the Prescriber calls the Blood Service for advice on the patient’s current authorisation.</p> <p>When searching, should the Blood Service staff member be able to see the patient's 'Ig System record' to assist the Prescriber?</p>				
Response		Skipped	Answered	Yes	No
	Count	80	124	111	13
	%	39%	61%	90%	10%
	<p>Remarks</p> <p>90% of respondents answering the quested responded ‘Yes’ and 39% of respondents skipped the question. While respondents in principle agree the Blood Service should have access to the patient record, there is also a sentiment for the information to be communicated from prescriber to prescriber via letter arranged by the patient before travelling.</p> <p>Continuity of treatment to the patient is cited as reason to provide the Authoriser with access to the patient records.</p>				

Question	Question / Scenario				
17	<p>Searching for a patient – Authoriser</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – After Hours On-Call Prescriber – Different State</p> <p>A patient presents to the emergency department in a regional hospital (e.g.: Byron Bay, NSW) and advises that they are currently receiving IVIg/SCIg at the Outpatient Clinic but their regular Prescriber is at a different hospital (e.g.: Royal Brisbane and Women’s Hospital, Qld).</p> <p>The On-Call Prescriber calls the Blood Service for advice on the patient’s authorisation.</p> <p>When searching, should the Blood Service staff member be able to see the patient's 'Ig System record' outside of their State or area of authorisation to assist the Prescriber?</p>				
Response		Skipped	Answered	Yes	No
	Count	79	125	107	18
	%	39%	61%	86%	14%
	<p>Remarks</p> <p>86% of respondents answering the question responded ‘Yes’ and 39% of respondents skipped the question. While respondents in principle agree the Blood Service should have access to the patient record, there is also a sentiment for the information to be communicated from prescriber.</p> <p>The importance of accessing a patient’s record to assess a request for expensive product based on previous periods of authorisation is seen to be critical.</p>				
18	<p>Searching for a patient – Nurse</p> <p>As a Nurse the default search is all patients that have a relationship with the hospital or hospitals where the Nurse works.</p> <p>We believe the following scenario is the minimum requirements for system capability when a Nurse is searching for patient details:</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – Nurse – Same Hospital</p> <p>A patient presents for treatment where the Treating or Administering hospital or the Dispensing Facility is the same as the hospital where the Nurse is logged on to the Ig System.</p> <p>The Nurse searches for the patient and can see their Ig System record.</p> <p>Do you agree?</p>				
Response		Skipped	Answered	Yes	No
	Count	80	124	112	12
	%	39%	61%	90%	10%

Question	Question / Scenario																			
	<p>Remarks 90% of respondents answering the question answered 'yes', while 39% skipped the question. Continuity of care and an understanding of a patient's authorisation status is critical as the nurse is part of the treating team. The 10% of respondents answering No indicates that medical records should be relied on for this purpose.</p>																			
19	<p>Searching for a patient – Nurse</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – Nurse – Different Hospital – Same State</p> <p>A patient presents for treatment where the Treating or Administering hospital or the Dispensing Facility is NOT the same as the hospital where the Nurse is logged on to the Ig System at but it is in the same State.</p> <p>When searching, should the Nurse be able to see the patient's 'Ig System record'?</p>																			
Response	<table border="1"> <thead> <tr> <th style="background-color: #FFD700;"></th> <th style="background-color: #FFD700;">Skipped</th> <th style="background-color: #FFD700;">Answered</th> <th style="background-color: #FFD700;">Yes</th> <th style="background-color: #FFD700;">No</th> </tr> </thead> <tbody> <tr> <td style="background-color: #FFD700;">Count</td> <td>80</td> <td>124</td> <td>81</td> <td>43</td> </tr> <tr> <td style="background-color: #FFD700;">%</td> <td>39%</td> <td>61%</td> <td>65%</td> <td>35%</td> </tr> </tbody> </table> <p>Remarks 65% of respondents answering the requested responded yes and 39% skipped the question.</p> <p>The lower percentage of Yes responses, compared to previous questions, indicates there is a shift in the need for a nurse to access patient records. The Yes responses indicate that the success in delivery of care to patients rests with the nursing staff.</p>						Skipped	Answered	Yes	No	Count	80	124	81	43	%	39%	61%	65%	35%
	Skipped	Answered	Yes	No																
Count	80	124	81	43																
%	39%	61%	65%	35%																
20	<p>Searching for a patient – Nurse</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – Nurse – Different Hospital – Different State</p> <p>A patient presents for treatment where the Treating or Administering hospital or the Dispensing Facility is NOT the same as the hospital or the State where the Nurse is logged onto the Ig System (Grey Nomad Scenario).</p> <p>When searching, should the Nurse be able to see the patient's 'Ig System record'?</p>																			
Response	<table border="1"> <thead> <tr> <th style="background-color: #FFD700;"></th> <th style="background-color: #FFD700;">Skipped</th> <th style="background-color: #FFD700;">Answered</th> <th style="background-color: #FFD700;">Yes</th> <th style="background-color: #FFD700;">No</th> </tr> </thead> <tbody> <tr> <td style="background-color: #FFD700;">Count</td> <td>80</td> <td>124</td> <td>81</td> <td>43</td> </tr> <tr> <td style="background-color: #FFD700;">%</td> <td>39%</td> <td>61%</td> <td>65%</td> <td>35%</td> </tr> </tbody> </table> <p>Remarks The trend in responses on the Nursing scenarios is consistent, with fewer respondents answering Yes than those scenarios cited for Prescribers and Authorisers.</p> <p>Comments provided on this question are consistent with Questions 18 and 19.</p>						Skipped	Answered	Yes	No	Count	80	124	81	43	%	39%	61%	65%	35%
	Skipped	Answered	Yes	No																
Count	80	124	81	43																
%	39%	61%	65%	35%																

Question	Question / Scenario				
21	<p>Searching for a patient – Dispenser</p> <p>As a Dispenser the default search is all patients that have a relationship with the hospital or hospitals where the Dispenser is logged on to BloodNet. BloodNet is the NBAs electronic blood and blood products ordering system allowing hospitals to communicate directly with the Blood Service. All Ig System capability developed for Dispensers will be delivered within BloodNet.</p> <p>We believe the following scenario is the minimum requirement for Ig System capability when a Dispenser is searching for patient details.</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – Dispenser – Same Hospital – Same State</p> <p>A patient presents for treatment and the Dispenser is logged onto BloodNet at the Treating or Administering hospital or Dispensing Facility for the patient.</p> <p>The Dispenser searches for the patient. As the patient’s authorisation has the same hospital recorded as either the Treating or Administering hospital or the Dispensing Facility as the Dispenser’s, the Ig System record can be seen.</p> <p>Do you agree?</p>				
Response		Skipped	Answered	Yes	No
	Count	86	118	111	7
	%	42%	58%	94%	6%
	<p>Remarks</p> <p>94% of respondents answering the question responded ‘Yes’, however the high proportion of skipped responses indicates that those who responded agreed that Dispensers must have access to the patient record.</p>				
22	<p>Searching for a patient – Dispenser</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – Dispenser – Different Hospital – Same State</p> <p>A patient presents for treatment where the Treating or Administering hospital or the Dispensing Facility is NOT the same as the hospital/facility where the Dispenser is logged on at but is in the same State.</p> <p>When searching, should the Dispenser be able to see the patient's 'Ig System record'?</p>				
Response		Skipped	Answered	Yes	No
	Count	87	117	91	26
	%	43%	57%	78%	22%
	<p>Remarks</p> <p>98% of respondents answering the question responded ‘Yes’, however the high proportion of skipped responses indicates that those who responded agreed that Dispensers must have access to the patient record.</p>				

Question	Question / Scenario															
23	<p>Searching for a patient – Dispenser</p> <p>SCENARIO: Patient currently receiving IVIg/SCIg – Dispenser – Different Hospital – Different State</p> <p>A patient presents for treatment where the Treating or Administering hospital or the Dispensing Facility is NOT the same as the hospital/facility where the Dispenser is logged on at and NOT in the same State (Grey Nomad Scenario).</p> <p>When searching, should the Dispenser be able to see the patient's 'Ig System record'?</p>															
Response	<table border="1"> <thead> <tr> <th></th> <th>Skipped</th> <th>Answered</th> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>Count</td> <td>90</td> <td>114</td> <td>80</td> <td>34</td> </tr> <tr> <td>%</td> <td>44%</td> <td>56%</td> <td>70%</td> <td>30%</td> </tr> </tbody> </table> <p>Remarks Then number of respondents answering ‘Yes’ dropped to 70%, however the high proportion of skipped responses indicates that those who responded agreed that Dispensers must have access to the patient record in order to ensure that the correct dose and product is dispensed. As with other scenarios where patients are travelling, comments indicate that patients are likely to experience delays in receiving treatment if dispensers don’t have access to the information.</p>		Skipped	Answered	Yes	No	Count	90	114	80	34	%	44%	56%	70%	30%
	Skipped	Answered	Yes	No												
Count	90	114	80	34												
%	44%	56%	70%	30%												
24	<p>Do you have any other scenarios, privacy (confidentiality or other) or legal concerns that are not covered in the survey that you would like considered in Ig System design?</p> <p>If so, please provide details:</p>															
Response	<table border="1"> <thead> <tr> <th></th> <th>Skipped</th> <th>Answered</th> <th>Yes</th> <th>No</th> </tr> </thead> <tbody> <tr> <td>Count</td> <td>172</td> <td>32</td> <td>32</td> <td>0</td> </tr> <tr> <td>%</td> <td>84%</td> <td>16%</td> <td>100%</td> <td>0%</td> </tr> </tbody> </table> <p>Remarks When asked whether any other scenarios or topics not covered in the survey should be considered system design only 13% of respondents made a comment.</p> <p>The themes raised in the comments are related to a patient’s access to IVIg including alternative avenues, privacy, ethics and legal aspects. The content of the Privacy Impact Assessment Report addresses the legal aspects of these concerns by detailing the content of the privacy collection notice, consent declarations and user terms and conditions. Had these documents been available to survey respondents it is likely their concerns would have been alleviated.</p>		Skipped	Answered	Yes	No	Count	172	32	32	0	%	84%	16%	100%	0%
	Skipped	Answered	Yes	No												
Count	172	32	32	0												
%	84%	16%	100%	0%												
25	<p>Your participation in this survey is anonymous however, if you’d prefer to be contacted to provide further comment on this survey or you would be comfortable with the NBA’s Ig System Development Project Team contacting you to discuss your response, please provide your name and best contact details.</p> <ul style="list-style-type: none"> Name 															

Question	Question / Scenario				
	<ul style="list-style-type: none"> • Mobile/Phone • Email • Specific comment/requirement 				
Response		Skipped	Answered	Yes	No
	Count	163	41	41	0
	%	80%	20%	100%	0%
	<p>Remarks 20% of respondents chose to leave their contact details to be more involved in the Ig System Development Project; 17 were already known to the project team and the remaining 25 were added to the Ig System User Reference Group (ISURG) contact list. These respondents will be contacted by the project team.</p>				

6 Privacy Impact analysis

The following table provides an analysis of the functions and processes of BloodSTAR against the requirements set out in the Australian Privacy Principles (APPs).

Australian Privacy Principle	Consideration	Y/N	Response	Action required to address APPs	Gap or compliance evidence
APP 1 — open and transparent management of personal information	A. Will personal information or sensitive information be handled?	Yes	Personal and sensitive information will be collected and used for the purposes of assessing patient eligibility against the qualifying and review criteria specified in the <i>Criteria for the clinical use of intravenous immunoglobulin in Australia</i> . Consent to the collection, use and usual disclosures of personal sensitive information will be sought and recorded in BloodSTAR.	1. Provide Privacy Statement and Notice for the information of individuals of interest to BloodSTAR.	1. Privacy Statement and Notice will be made available in BloodSTAR. Compliant
	B. Will reasonable steps be taken to tell the individual about the purpose of the collection and usual disclosures?	Yes	A Privacy Statement and Notice will be provided for the information of individuals who become of interest to BloodSTAR. The notice will detail the purpose for the collection of sensitive information, its use, usual disclosures and consent. The notice will also explain the consequences of not providing consent.	2. Obtain consent from the individuals of interest to BloodSTAR, and record their consent status in the system.	2. Consent form will be made available in BloodSTAR. The consent form will record explicit written or oral consent and can be uploaded to BloodSTAR for record keeping purposes. Compliant

Australian Privacy Principle	Consideration	Y/N	Response	Action required to address APPs	Gap or compliance evidence
	C. Will the agency's privacy policy be available for the information of individuals?	Yes	The NBA Privacy Policy is available and published on the NBA website at http://www.blood.gov.au/system/files/documents/nba-privacy-policy_0.pdf . The NBA privacy policy describes the processes for handling privacy enquiries and complaints.	3. Develop and publish NBA Privacy Policy	3. NBA Privacy Policy is published on the NBA website. Compliant
APP 2 — anonymity and pseudonymity	D. Will individuals have the option of not identifying themselves?	No	Pseudonymity and anonymous options are impracticable. The primary purpose of collection of personal and sensitive information is to uniquely identify individuals for assessment of authorisation for initial access and continuing access (where relevant) against the <i>Criteria for the clinical use of intravenous immunoglobulin in Australia</i> , to ensure the appropriate supply of product to that individual for the treatment of their specific medical condition. The use of multiple hospital identifiers, across and within hospitals, will not enable accurate data matching to minimise the patient risk of receiving treatment for different medical conditions in different hospitals.	4. Develop information for patients to explain why pseudonymity and anonymous options are impracticable.	4. The Privacy Statement and Notice will include information for patients about the impracticability of pseudonymity and anonymous options. Compliant
APP 3 - collection of solicited personal information and	E. Is personal information collected for a lawful purpose directly related to a	Yes	The key role of the NBA is to: <ul style="list-style-type: none"> provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services, and 	5. None	5. Compliant

Australian Privacy Principle	Consideration	Y/N	Response	Action required to address APPs	Gap or compliance evidence
APP 5 – Notification of collection	function or activity of the agency?		<ul style="list-style-type: none"> • promote safe, high quality management and use of blood products, blood related products and blood related services in Australia. • Section 8 of the <i>National Blood Authority Act 2003</i> (Cth) sets out the various functions of the NBA. • Several of the agreed roles of the NBA require the NBA to liaise with and continuously gather blood sector data in order to: <ul style="list-style-type: none"> ○ monitor the demand for blood and blood products; ○ undertake annual supply and production planning and budgeting; ○ undertake or facilitate national information management, benchmarking and cost and performance evaluation for the national blood supply. 		
	F. Will the agency ensure that information is collected in accordance with the higher protections in APP3.3?	Yes	The protections for sensitive information will be adhered to, in that personal and sensitive information is reasonably necessary for or directly related to one or more of the NBA’s functions. Consent to that collection will be obtained.	6. Provide Privacy Statement and Notice for the information of individuals of interest to BloodSTAR. 7. Develop a privacy consent form for	6. The Privacy Statement and Notice will include information for patients about the requirement to provide consent. Compliant

Australian Privacy Principle	Consideration	Y/N	Response	Action required to address APPs	Gap or compliance evidence
				recording explicit written or oral	7. The Consent form will include both written and oral consent. This document will be uploaded to BloodSTAR for record keeping purposes. Compliant
	G. Is express consent sought and recorded for the collection of personal or sensitive information? How is it collected (written or oral)?	Yes	A patient consent form will be made available in BloodSTAR for recording written consent. Verbal consent can also be recorded in the consent form by the clinician whom has obtained verbal consent from the individual. The consent form can be uploaded to BloodSTAR and retained as an attachment to the patient record.	8. Provide Privacy Statement and Notice for the information of individuals of interest to BloodSTAR. 9. Develop a privacy consent form for recording explicit written or verbal consent and make available to the	8. The Privacy Statement and Notice will include information for patients about the requirement to provide consent. Compliant 9. The Consent form will allow for both written and verbal

Australian Privacy Principle	Consideration	Y/N	Response	Action required to address APPs	Gap or compliance evidence
				general public on NBAs website.	consent to be recorded. This document will be uploaded to BloodSTAR for record keeping purposes. Compliant
APP 4 – Dealing with unsolicited personal information	H. Will the agency receive unsolicited personal information?	Yes	It is a probability that unsolicited information may be obtained from clinicians where they are providing additional information to substantiate a claim under the access criteria for access to government funded immunoglobulin products. This may be information written by clinicians in the free text fields or additional information contained in documents uploaded to BloodSTAR. Information may be about a next of kin or relative, or a medical test report which contains more information about an individual than is required for the assessment of their eligibility against the access criteria.	10. Provide guidance for clinicians and Authorisers to minimise the risk of obtaining unsolicited information.	10. Guidance will be developed and made available for the information of clinicians. The opportunity to collect unsolicited information will be minimised and where the risk exists, the content of collection will be monitored and removed.

Australian Privacy Principle	Consideration	Y/N	Response	Action required to address APPs	Gap or compliance evidence
	I. Will the agency have practices, procedures and systems for dealing with unsolicited information?	Yes	Guidance will be provided to clinicians and Authorisers to minimise the risk of obtaining unsolicited information. Monitoring procedures will be put in place to manage removing or archiving unsolicited information.	11. Develop guidance to clinicians and Authorisers to reduce the risk of collecting unsolicited personal or sensitive information.	<p>Compliant.</p> <p>11. Guidance will be developed and made available for the information of clinicians. The opportunity to collect unsolicited information will be minimised and where the risk exists, the content of collection will be monitored and removed.</p> <p>Compliant</p>
APP 6 – Use or disclosure	J. For what purposes will the agency use and disclose personal information and sensitive information?		Personal and sensitive information is used to enable assessment of authorisation for initial and continuing access to government funded immunoglobulin products against policy parameters set by Health Ministers. Only authorised users will be able to access data via a secure log in process for the purpose of undertaking their role in patient care and manage the appropriate treatment of the patient’s medical condition.	12. None	12. Reporting capability will use summary information that does not include personal and sensitive

Australian Privacy Principle	Consideration	Y/N	Response	Action required to address APPs	Gap or compliance evidence
			<p>'Disclosure' means releasing the personal information you have collected to another agency, body or organisation (this does not include the individual the information is about). However in the context of BloodSTAR, personal and sensitive information is not disclosed beyond the users of the system.</p>		<p>information that can identify individuals.</p> <p>Compliant</p>
APP 7 – Direct marketing	K. Will personal information be used for direct marketing?	No	This APP does not apply; no direct marketing will be undertaken.	13. None	13. N/A
APP 8 – Cross border disclosure	L. Will personal or sensitive information be sent overseas?	No	Data will not be sent overseas.	14. None	14. N/A
APP 9 - Adoption, use or disclosure of government related identifiers	<p>M. Will government related identifiers be adopted as the agency's own identifier? (APP9.1)</p> <p>N. Will government related identifiers be used or disclosed?</p>	<p>No</p> <p>Yes</p>	<p>A collection of government identifiers will be used to assist with uniquely identifying individuals together with a BloodSTAR patient identifier. These may include:</p>	15. Provide Privacy Statement and Notice for the information of individuals of interest to BloodSTAR which describes the purpose for using hospital and	<p>15. The Privacy Statement and Notice will include information for patients about the use of hospital and health identifiers.</p> <p>Compliant</p>

Australian Privacy Principle	Consideration	Y/N	Response	Action required to address APPs	Gap or compliance evidence
	(APP9.2)		<ul style="list-style-type: none"> • Medical Record Numbers or hospital identifiers in one or more hospitals/treatment facilities; • Individual Health Identifier (IHI). 	health identifiers.	
APP 10 – Quality	O. Will reasonable steps be taken to ensure that the personal information collected, used or disclosed is up to date, complete and accurate and relevant for the purpose of the use or disclosure?	Yes	<p>BloodSTAR users will be required to collect and manage information relating to a patient in order to ensure that each entity involved in patient care has the information it needs to fulfil its role. Where errors are detected, users will be empowered to correct errors to ensure that information is as accurate as possible.</p> <p>When requested, BloodSTAR users must provide information to patients about information stored about them, and have the opportunity to identify and correct errors.</p>	<p>16. User terms and conditions will require users to correct errors and maintain accuracy of records.</p> <p>17. Users in the hospital setting will have access to system functions to correct records when errors are detected.</p> <p>18. Patients will be advised through the Privacy Statement and Notice of their right to access</p>	<p>16. User terms and conditions will include this provision.</p> <p>17. User terms and conditions will include this provision.</p> <p>18. Privacy Statement and Notice will include this provision.</p> <p>Compliant</p>

Australian Privacy Principle	Consideration	Y/N	Response	Action required to address APPs	Gap or compliance evidence
				and correct details about them.	
APP 11 – Security	P. Is the agency taking reasonable steps to ensure that the personal information it collects is protected from misuse, interference, loss and from unauthorised access, modification or disclosure?	Yes	BloodSTAR, its management and operation will be tightly controlled. NBA systems have one of the highest levels of security available in Australia, housed in a highly secure data centre in Canberra. Stringent security protocols will be built into the system to control access to personal information. All reasonable steps will be taken to protect personal information from misuse, interference and loss, and from unauthorised access, modification or disclosure. Personal and sensitive information will only be stored on a password protected ICT system which complies with the Australian Government Protective Security Policy Framework. This includes ensuring that information is only accessed by authorised users that require access to undertake their official functions and roles.	19. Controls must be in place to authenticate users using unique user names and passwords for roles appropriate to roles supporting patient care.	19. All users established in the system will be authenticated before access is granted. Compliant
	Q. Will reasonable steps be taken to ensure personal information is destroyed or de-identified when it is no longer needed for	N/A	Information held within BloodSTAR will have a historical purpose required for evolving the Criteria and look back purposes. There is an on-going concern to maintain patient uniqueness as patients may require treatment over extended periods and intermittent episodes.	20. None	20. N/A

Australian Privacy Principle	Consideration	Y/N	Response	Action required to address APPs	Gap or compliance evidence
	any authorised purpose? Do any exceptions apply to the information the agency will hold?				
APP 12 – Access APP 13 – Correction	R. Will processes be in place for responding to requests from individuals for request for access to and correction of personal information?	Yes	When requested, BloodSTAR users must provide information to patients about information stored about them, and have the opportunity to identify and correct errors.	21. Patients will be advised through the Privacy Statement and Notice of their right to access and correct details about them.	21. Privacy Statement and Notice will include this provision. Compliant
	S. What processes will be in place for identifying and correcting personal information that is inaccurate, out of date, incomplete, irrelevant or	N/A	BloodSTAR users will be required to collect and manage information relating to a patient in order to ensure that each entity involved in patient care has the information it needs to fulfil its role. Where errors are detected, users will be empowered to correct errors to ensure that information is as accurate as possible. When requested, BloodSTAR users must provide information to patients about information stored about them, and have	22. Terms and conditions for users should include the responsibility to identify and correct	22. Terms and conditions will include this provision. Compliant

Australian Privacy Principle	Consideration	Y/N	Response	Action required to address APPs	Gap or compliance evidence
	misleading?		the opportunity to identify and correct errors.	information.	

7 Privacy Management

In order to minimise the privacy concerns and risks to individuals, BloodSTAR will include the following processes and functions.

- User terms and conditions
- User authentication
- Activity logging and auditing at the user level, including searches and views
- Privacy Statement and Notice
- Patient consent to the collection, use and disclosure of their personal and sensitive information.

The NBA's expectation is that the provision of personal and sensitive information in order to obtain access to a high cost publically funded biopharmaceutical product will be regarded as unremarkable by the vast majority of patients. This type of requirement is commonplace for access to many high cost medications and medical services, whether funded publically or by private health insurance, in Australia and in most comparable countries globally.

Access to immunoglobulin is available under multiple funding and supply pathways in Australia. While a decision making process may be involved in each case, these alternatives do provide an avenue for the health system to meet the needs of a patient who may be concerned about the provision of personal and sensitive information.

7.1 Recommendations

	Recommendation	Cross reference to relevant document
A.	Provide Privacy Statement and Notice for the information of individuals of interest to BloodSTAR and make it available to the general public on NBAs website.	Attachment A – Privacy Statement and Notice
B.	Develop a privacy consent form for recording explicit written or oral consent and make available to the general public on NBAs website.	Attachment B – Privacy consent form
C.	Ensure consent is obtained from the individuals of interest to BloodSTAR, and record their consent status in the system.	System control.
D.	Develop and publish NBA Privacy Policy.	http://www.blood.gov.au/system/files/documents/nba-privacy-policy_0.pdf
E.	Develop information for patients to explain why pseudonymous and anonymous options are impracticable.	Attachment A – Privacy Statement and Notice
F.	The search requirements when searching nationally or beyond a user's usual search scope will include at	System control.

Recommendation		Cross reference to relevant document
	least two points of identification for an individual i.e. name and date of birth or hospital identifier, to reduce the return results for a national search and minimise the privacy impact on individuals.	
G.	Develop guidance to clinicians and Authorisers to reduce the risk of collecting unsolicited personal or sensitive information.	Will be provided as part of the training material and user manual.
H.	User terms and conditions must require users to correct errors and maintain accuracy of records.	Attachment C - User Terms and Conditions
I.	Users in the hospital setting must have access to system functions to correct records when errors are detected.	System control.
J.	Patients must be advised through the Privacy Statement and Notice of their right to access and correct details about them.	Attachment A – Privacy Statement and Notice
K.	Controls must be in place to authenticate users using unique user names and passwords for appropriate roles in the treatment of patients.	System control.

8 Attachments

8.1 Attachment A – Privacy Statement and Notice

BloodSTAR Privacy Statement and Notice

This statement explains how the National Blood Authority (NBA) manages personal and sensitive information that it collects about you. The NBA is the Commonwealth Government agency responsible for the supply of blood and blood products in Australia, including immunoglobulin (Ig) products derived from human blood plasma.

The NBA is currently developing BloodSTAR (System for Tracking Authorisations and Reviews) to support the “[Immunoglobulin Governance National Policy: Access to Government Funded Immunoglobulin Products in Australia](#).”⁷ BloodSTAR will replace the current paper based processes and the Blood Service’s information management system, and will be rolled out in early 2016. Information about patients approved to receive government funded immunoglobulin products that is expected to extend beyond 2015 will need to be recorded in BloodSTAR and cannot be stored without your explicit consent.

How the NBA collects information

The NBA collects your personal and sensitive information from organisations or persons who provide healthcare products or services such as doctors, nurses, hospitals and pathology laboratories.

What information will be collected?

The information collected about you will include identification details such as your name, date of birth, sex and may include your individual health identifier (IHI), hospital identifiers and sensitive health information.

Purpose of collection:

Why is my personal and sensitive information collected?

Immunoglobulin products are a precious and high cost resource. Government policy requires that government funded Ig products can only be approved for specific medical conditions. Accordingly, the primary purpose for collecting your information is to correctly identify you and to assess your eligibility to receive these products. It will also help your doctor or nurse to quickly access reliable information about your continuing eligibility.

As a secondary purpose, summary level grouped information, which does not identify you, is also important for:

- identifying priorities for research
- prescriber education and training

⁷ National Blood Authority, [Immunoglobulin Governance National Policy: Access to Government Funded Immunoglobulin Products in Australia, November 2014, \(www.blood.gov.au/ig-program\)](#)

- performance evaluation and improvement of the supply, authorisation and use of immunoglobulin products
- further developing the Criteria upon which government policy is based
- supply planning so the NBA can make sure enough Ig products are available to meet patients' needs.

Any additional research will only be undertaken in line with the requirements of the Privacy Act 1988 (Cth) and any relevant laws. The data may only be made available for research if it has a properly constituted human research ethics committee (HREC) approval.

How long will my information be kept for?

Patient records will be retained for a minimum period of 20 years, in line with the requirements of the *Archives Act 1983* (Cth) and the National Pathology Accreditation Advisory Council (NPAAC) requirements (laboratory accreditation).

Can I choose not to provide consent or be included in BloodSTAR?

Yes. However, your doctor will not be able to submit your personal information to enable assessment of your eligibility and you will therefore not be able to receive government funded Ig products. Alternative arrangements are available, including Jurisdictional Direct Order or Private Order and should be discussed with your doctor. For more information visit: <http://www.blood.gov.au/Ig-publications>

Who will access my personal information?

Only authorised users involved directly or indirectly in your treatment via a secure log in. These include: your doctor, nurse, laboratory staff, pharmacy staff, Authorisers (specified staff at the Blood Service) and NBA staff that provide technical and user support.

How can I be confident that my personal information is protected?

The NBA uses a security protected system with strict rules around access. We will also not pass on your personal information to anyone without your consent, unless the law requires us to do so. These procedures protect your information from unauthorised access, interference, alteration, disclosure, loss or misuse.

Do I have to use my name in BloodSTAR?

Yes. Your name and personal details are used to uniquely identify you to ensure that you receive the appropriate treatment. Pseudonym and anonymity will not be possible as these cannot be reliably cross checked with hospital processes and may potentially put you or other patients at risk of not receiving appropriate treatment.

Can I access and correct my personal information?

Yes, you can do this in line with privacy laws. Contact your doctor in the first instance. If you are unhappy with the response you receive, you can contact the NBA at privacy@blood.gov.au, the privacy commissioner or equivalent in your State or Territory, or the Australian Privacy Commissioner.

How long is my consent to collection of my information valid for?

Your initial consent to the collection, use and disclosure of your personal information will remain valid unless you withdraw it. This applies whether such information is used for the primary purpose or for the secondary purpose.

If I have changed my mind, how do I opt out of BloodSTAR?

You can withdraw your consent by contacting your doctor. From that point on, no further details about you will be collected. Information already recorded in your individual patient record will not be deleted but will be retained for historical reporting purposes. However ongoing access to government funded Ig products will cease. Alternative arrangements are available, including Jurisdictional Direct Order or Private Order and should be discussed with your doctor. For more information visit: <http://www.blood.gov.au/Ig-publications>

If I have withdrawn my consent can I change my mind and opt back in to BloodSTAR?

If you withdraw your consent to BloodSTAR, you may at a later date choose to reactivate your patient record by providing consent again.

NBA Privacy Policy

The privacy policy gives more details on how the NBA manages personal information generally and how you can make a privacy complaint to the NBA. A copy of the policy can be found at <http://www.blood.gov.au/privacy>

Contact us

If you have any questions in relation to this information or require more information, please contact the NBA Support Team on 13 000 BLOOD (25663) or email support@blood.gov.au

8.2 Attachment B – BloodSTAR Privacy Consent Form

BLOODSTAR – RECORD OF PRIVACY CONSENT:

The nature of BloodSTAR has been fully explained to me. I understand the BloodSTAR Privacy Statement and Notice and Patient Information Brochure and I have received a copy to take away with me. I have had the chance to ask questions, and all my questions have been answered to my satisfaction. I consent to:

- the recording of personal information (including sensitive health information) about me/my child/the person I care for or represent in BloodSTAR,
- the use of this information to submit a request for, and for the assessment of, initial or ongoing authorisation for access to publicly funded immunoglobulin products, against the criteria determined by Australian governments for this purpose,
- the use of limited identifying details within BloodSTAR search functions to ensure that patients are correctly identified,
- the use of this information by clinicians in Australian treatment facilities that I attend for health care, in order to deliver health services according to the purposes for which authorisation has been given, and
- the use of this information in a manner which will not readily identify me (such as through the removal of directly identifying personal information, or use of summary level grouped data) for the purposes of: identifying priorities for research, education and training; performance evaluation and improvement of the supply, authorisation and use of immunoglobulin products; further developing the criteria upon which Government policy is based; supply planning so the National Blood Authority can make sure enough Ig products are available to meet patients' needs; and enabling reporting on the program for supply, authorisation and use of publicly funded immunoglobulin products.

I understand that any additional use of information in BloodSTAR will only be undertaken in accordance with the requirements of the *Privacy Act 1988* (Cth) and any relevant state/territory laws, and that the information may only be made available for medical or public health research only with approval of properly constituted human research ethics committee (HREC).

Signature of patient:

Date

Signature of parent/carer/guardian:

Date

(Required if the patient is a minor and unable to consent to medical treatment or otherwise lacks the capacity to consent).

BLOODSTAR – RECORD OF VERBAL/TELEPHONE PRIVACY CONSENT:

Declaration: I have supplied a BloodSTAR Privacy Statement and Notice and Patient Information Brochure to the patient (or parent/carer/guardian of the patient if the patient is a minor and unable to consent to medical treatment or otherwise lacks the capacity to consent).

I believe that the patient (or parent/carer/guardian) understands the purpose, extent and possible consequences of giving consent to the collection of their personal and sensitive health information. They are aware of the purpose of the collection of their personal and sensitive health information and all usual uses and disclosures of that information.

I confirm that the patient (or parent/carer/guardian) has voluntarily provided express consent to the collection of their personal and sensitive health information into BloodSTAR and to the usual uses and disclosures as set out in the Privacy Statement and Notice.

Name and position of clinician obtaining consent:

Signature of clinician obtaining consent:

Date:

Time:

8.3 Attachment C – User Terms and Conditions

BloodSTAR User Terms and Conditions

1. These user terms and conditions are directed at ensuring user validity, access security, data reliability and proper use. Compliance with these the terms and conditions is essential to maintaining the integrity and utility of BloodSTAR and the privacy of patients and other individuals whose information is stored in that system.
2. These terms and conditions also provide you with information about how the National Blood Authority (NBA) will manage your personal information stored in this system. The full NBA privacy policy can be located at www.blood.gov.au/privacy. This includes information on how you can complain about the NBA’s management of your personal information. For specific privacy questions email privacy@blood.gov.au.
3. BloodSTAR Access Request Form requires you to specify one or more roles, which define your BloodSTAR user category. You must promptly notify the NBA (by email to support@blood.gov.au) of any changes to the roles you have specified on that form.
4. As a BloodSTAR user you will be allocated with a unique username and password to log on to the system. You must keep these logon details secure and not disclose them to any other person (other than to authorised BloodSTAR support personnel for proper system or user administration purposes) at any time.
5. Each category of BloodSTAR user is authorised to access and use BloodSTAR for certain specified purposes only. You must not access or use BloodSTAR data for any purpose except the purposes to which you are authorised and which are required by your job.
6. As a BloodSTAR user, you are required to comply with these terms and conditions, any instructions issued for the proper use of BloodSTAR, procedures associated with the use of BloodSTAR, and any protocols relating to the collection, use, disclosure and protection of patient personal information notified to you by the NBA at any time. In particular, you must comply with requirements (as applicable) to:
 - correct entry of data;
 - take all reasonable steps to ensure that a patient record is not duplicated where a record already exists about that individual;
 - notification of apparent BloodSTAR problems to support@blood.gov.au;
 - auditing of the collection, use or disclosure of information collected in BloodSTAR, conducted by or on behalf of the NBA; and
 - ensuring data security when providing patients with access, upon request, to their personal information for data correction purposes.
7. If you fail to comply then your access to BloodSTAR may be revoked and your supervisor will be notified.
8. The personal information you are required to complete on BloodSTAR User Access Request Form is collected by the NBA for the purpose of assessing and approving your user status and ongoing management of your BloodSTAR user account. As a user of BloodSTAR you will receive regular updates about BloodSTAR to ensure you are kept up to date on the correct operation of the system, any changes or outages that may impact on your use of BloodSTAR. BloodSTAR includes an inbuilt audit log which records when a user logs on, and views or

changes to data. This assists validation of changes when accuracy is disputed and enables monitoring of appropriateness of access and use. As your personal information will be managed in accordance with the *Privacy Act 1988* it will not be provided to any other person or for any other purpose without your consent (unless authorised by that Act).

9. The information you provide in your BloodSTAR User Access Request Form, and any information you subsequently provide concerning your BloodSTAR User status, must be true and correct to the best of your knowledge at the time the information is provided. The giving of false and misleading information to a Commonwealth entity such as the NBA is a serious offence under Division 137.1 of the *Criminal Code 1995* (Cth).

8.4 Attachment D – Patient Record Data Dictionary

8.4.1 Purpose

The purpose of this document is to describe the minimum set of BloodSTAR data elements required to underpin the “*Immunoglobulin (Ig) Governance: National Policy: Access to government funded Ig products*”. It is designed to be read in conjunction with the [Ig System High Level Design](#) document, the original documentation developed to describe BloodSTAR capability, and functional specifications. It will evolve as the functional specifications are written for each area of capability that is in scope for BloodSTAR.

Note that where LOV appears in the ‘Type’ column of the following tables, it means ‘List of Values’, which are the values that will be displayed in drop down lists for the corresponding field name. Use of LOVs improves data integrity and provides a sound basis for analysis. In some circumstances data elements that have a type of ‘Text’ may be converted to LOVs where possible to improve the data analysis potential.

8.4.2 Privacy Assessment

In addition to informing development of BloodSTAR, this Data Dictionary will be used to aid in the assessment of BloodSTAR against the Australian Privacy Principles (APPs) in the *Privacy Act 1988* (Cth). Where relevant, the Data Dictionary may also assist in the consideration of other more stringent privacy or associated requirements that apply at a state or territory level. This may include any special regulations for cross border data flow and any particular issues raised by jurisdictions for consideration that are relevant but that may fall outside of general privacy laws (e.g.: doctor-patient confidentiality concerns). It is important to note that BloodSTAR is being approached on the basis that express consent of each individual patient will be needed before personal information is collected and included in the system.

In particular, the Data Dictionary will assist with assessing compliance against APP 1 (open and transparent management of personal information), APP 2 (anonymity and pseudonymity), APP 3 (collection of personal information), APP 5 (notification of collection), APP 6 (use or disclosure of personal information), APP 9 (adoption, use or disclosure of government related identifiers), APP 10 (quality of personal information). The user security matrix, the systems design itself, governance for the system, and physical security will aid in meeting the requirements of APP 11 (security of personal information), APP 12 (access for an individual to their personal information) and APP 13 (correction of personal information). Given the nature of BloodSTAR and its design there is very limited scope for obtaining unsolicited information from individuals. Therefore, although APP 4 (dealing with unsolicited information) will be considered it is unlikely to pose any specific risk for this project. APP 7 and APP 8 are not likely to be relevant to BloodSTAR.

The column headers shown in Blue in the following tables, “Primary Purpose for collection” and “Secondary purpose for collection” will be populated by the Ig Governance team. Once populated, NBA’s legal counsel will consider whether the collection of the proposed fields meets the legal requirement of “necessity” of collection at the Commonwealth level. Note that a collection will occur at the hospital level, by the NBA as custodian of the system, and by

other users of BloodSTAR that access and input personal information. The content of this document will also be used to write appropriately detailed privacy notification statements, to assess whether the approach to patient express consent will comply with privacy (and other relevant law) and to develop tools⁸ to implement that patient express consent process once finalised. This document will be circulated to relevant stakeholders at various stages including when the disclosure statements are written.

Where significant change occurs during the functional specification writing process, the privacy assessment will be revisited to ensure there is no material change to the disclosure statements, legal basis for collection or patient consent process.

NBA Necessity for Collection

The following key is provided to assist in understanding the columns headed “primary purpose of collection” and “secondary purpose of collection”. It sets out particular functions of the NBA that are relevant to some or all aspects of BloodSTAR, which are then referred to within those columns for each data field by the corresponding number.

1. The collection of this data is reasonably necessary for, or directly related to liaising with and gathering information from, governments, suppliers and others about matters relating to blood products and services (s 8(1)(a) *National Blood Authority Act 2003*);
2. The collection of this data is reasonably necessary for, or directly related to carrying out national blood arrangements to ensure that there is a sufficient supply of blood products and services in all the States and covered Territories (s 8(1)(c) *National Blood Authority Act 2003*);
3. The collection of this data is reasonably necessary for, or directly related to carrying out national blood arrangements relating to the funding of the supply of blood products and services (s 8(1)(d)(i) *National Blood Authority Act 2003*);
4. The collection of this data is reasonably necessary for, or directly related to entering into and managing contracts and arrangements for the collection, production and distribution of the blood products and services necessary to ensure a sufficient supply of blood products and services in all the States and covered Territories (s 8(1)(e) *National Blood Authority Act 2003*);
5. The collection of this data is reasonably necessary for, or directly related to carrying out national blood arrangements relating to safety measures, quality measures, contingency measures and risk mitigation measures for the supply of blood products and services (s 8(1)(f) *National Blood Authority Act 2003*);
6. The collection of this data is reasonably necessary for, or directly related to carrying out national blood arrangements relating to the facilitation and funding or research, policy development and other action about matters relating to blood products and services (s 8(1)(h) *National Blood Authority Act 2003*); and,

⁸ Note that this may include forms, communication aids, and implementation protocols for hospitals and associated governance materials.

7. The collection of this data is reasonably necessary for, or directly related to carrying out national blood arrangements relating to annual plans and budgets for the production and supply of blood products and services (s 8(1)(b) *National Blood Authority Act 2003*);

Overall, the NBA also considers that the collection of the entire data set is necessary to facilitate the provision of information which in turn directly assists the Agency to achieve the functions and activities noted above.

8.4.3 Patient

A patient is an individual that is of interest to BloodSTAR. An individual becomes of interest to the system once they become the subject of an Authorisation Request. A patient may or may not be successful in obtaining authorisation for immunoglobulin treatment.

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence for individual patient if not collected	Proposed Use and Disclosure
Patient ID		A unique identifier of the patient generated and used by the system.		Uniquely identifies patient record within the system. Lessens risk of duplicate record generation if original record not identified in search by user. Important especially where patients change hospitals or develop new (2 nd) condition for Ig treatment.	NBA - 1, 2 and 5	To ensure compliance with the Criteria the Authoriser must know with certainty the patient's identity. If patient identifying details are not captured then the patient cannot be authorised in the system to receive IVIg. Patient safety risk due to increased risk of prescriber linking condition to wrong record leading to incorrect prescription, dispense and infusion.	Use – Transparent to some users of system for particular purpose in accordance with defined role (see security matrix). Disclosure - Reported to level of individual patient record for prescribing practice performance review.

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence for individual patient if not collected	Proposed Use and Disclosure
				NBA – 3		Greater compromise of patient privacy likely in reporting for prescribing practice.	
Family Name	Text	The surname of the patient.		<p>Critical identification parameter for maintaining patient record and data integrity -supports correct patient record creation, identification for product authorisation and access during system search by user.</p> <p>(Authoriser, Prescriber, Nurse, Dispenser)</p> <p>NBA – 3</p>	<p>To reduce likelihood of duplicate patient records being created when used with DOB and other patient names.</p> <p>NBA – 1,2 and 5</p>	<p>As above – if we cannot be satisfied of ID then no authorisation via the system or in fact manually since we need ID? Will it impact ability to get the product elsewhere – what is the cost?</p> <p>Patient safety risk due to increased risk of prescriber linking condition (qualifying and review criteria) to incorrect patient record leading to incorrect authorisation, prescription dose, product, dispense and/or infusion. – as above and throughout</p>	<p>Use – Transparent to some users of system for particular purpose in accordance with defined role (see security matrix).</p> <p>(see security matrix)</p> <p>Disclosure – not intended for release. What about Distributor for home delivery patients?</p>

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence for individual patient if not collected	Proposed Use and Disclosure
Given Name	Text	The first or given name of the patient		<p>Critical identification parameter for maintaining patient record and data integrity - supports correct patient record access and identification during system search by user.</p> <p>(Authoriser, Prescriber, Nurse, Dispenser)</p> <p>NBA – 3</p>	<p>Reduces likelihood of duplicate patient records being created when used with DOB and other patient names.</p> <p>NBA – 1,2 and 5</p>	<p>Patient safety risk due to increased risk of prescriber linking condition to wrong record leading to incorrect authorisation, prescription dose, product, dispense and infusion.</p>	<p>Use – Transparent to some users of system for particular purpose in accordance with defined role (see security matrix).</p> <p>Disclosure – not intended for release. What about Distributor for home delivery patients?</p>
Middle Name	Text	The middle given name of the patient		<p>Critical identification parameter for maintaining patient record and data integrity - supports correct patient record access and identification during system search by user.</p> <p>(Authoriser, Prescriber, Nurse, Dispenser)</p>	<p>Reduces likelihood of duplicate patient records being created when used with DOB and other patient names.</p> <p>NBA – 1,2 and 5</p>	<p>Patient safety risk due to increased risk of prescriber linking condition to wrong record leading to incorrect authorisation, prescription dose, product, dispense and infusion.</p>	<p>Use – Transparent to some users of system (see security matrix)</p> <p>Disclosure – not intended for release.</p>

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence for individual patient if not collected	Proposed Use and Disclosure
				NBA – 3			
Date of Birth	Date Time	The date of birth of the patient	Cannot be a future date	<p>Critical identification parameter for maintaining patient record and data integrity - supports correct patient record access and identification during system search by user.</p> <p>(Authoriser, Prescriber, Nurse, Dispenser)</p> <p>NBA -3</p>	<p>Supports demographic analysis to support short, medium and long term Ig demand forecasting to assure security of supply. Enables performance analysis of product and treatment protocol efficacy by age.</p> <p>NBA – 7</p>	<p>Failure to accurately forecast product demand and assess security of supply hence the patient may not always obtain the product that they need.</p> <p>Loss of evidence supporting product efficacy and optimising treatment protocols.</p>	<p>Use – Transparent to some users of system (see security matrix)</p> <p>Disclosure – not intended for release other than contained in aggregated data sets.</p>
Sex	LOV: Gender	The sex of the patient	<p>Valid Values:</p> <ul style="list-style-type: none"> ▪ Female ▪ Male ▪ Unknown 	<p>Critical identification parameter for maintaining patient record and data integrity</p> <p>(Authoriser, Prescriber, Nurse, Dispenser)</p> <p>NBA – 3</p>	<p>Reduces likelihood of duplicate patient records being created when used with DOB and other patient names.</p> <p>Supports demographic analysis of Ig use and demand forecasting.</p> <p>(NBA, Hospital,)</p>	<p>Patient safety risk due to increased risk of prescriber linking condition to wrong record leading to incorrect authorisation, prescription dose, product, dispense and infusion.</p>	<p>Use – Transparent to some users of system (see security matrix)</p> <p>Disclosure – not intended for release other than contained in aggregated data sets.</p>

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence for individual patient if not collected	Proposed Use and Disclosure
IHI	Text	The individual healthcare identifier of the patient.		Facilitates integration with the Personally Controlled Electronic Health Record (PCEHR).		No consequence for individual	Use – Transparent to some users of system (see security matrix) Disclosure - not intended for release
Home Therapy	True / False	Indicates whether the patient is registered for home therapy.		Provides system transparency of home therapy status – relevant to infusion recording. (NBA, Authoriser, Prescriber, Nurse, Dispenser)	Provision of access to additional functionality in patient record including delivery address to support product distribution and access for patient to record all infusions. (NBA, Prescriber, Nurse, Dispenser)	Failure to identify those patients on home therapy and lack of data being collected on infusions resulting in lack of accurate data for clinical review without patient attending hospital, standardised recording of treatment provision and relationship to clinical outcome.	Use – Transparent to some users of system (see security matrix) Disclosure – Record available for local hospital printing and inclusion in patient medical record. Distributor? Data not intended for release other than inclusion in aggregated data sets.

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence for individual patient if not collected	Proposed Use and Disclosure
Hospital Identifiers	Collection of Hospital Identifiers	A list of hospitals at which the patient has received treatment and the identifier of the patient in that hospital.		<p>Provides transparency of all hospital affiliations of patient - reduces the potential for multiple treatments being provided to the same patient</p> <p>And supports contact of correct treating specialist when patient treatment review for access to ongoing therapy is required.</p> <p>(NBA, Prescriber, Nurse, Dispenser)</p> <p>NBA – 3</p>	<p>Facilitates easy retrieval of patient record by hospital staff and confirmation that correct patient record has been identified.</p> <p>(Prescriber, Nurse, Dispenser)</p>	Risk of patients receiving multiple treatments at different hospitals Patient safety risk due to increased risk of user linking data (e.g. condition, authorisation, product or infusion) to wrong record leading to incorrect authorisation, prescription dose, product, dispense and infusion.	<p>Use – Transparent to some users of system (see security matrix)</p> <p>Disclosure - not intended for release.</p>
Authorisation Requests	Collection of Authorisation Requests	A list of authorisation requests that the patient has been the subject of.		<p>Provides transparency of all authorisation requests relevant to the patient (NBA, Authoriser, Prescriber, Nurse, Dispenser)</p> <p>Reduces the potential for multiple treatments</p>		[not individual consequence for patient but this section could serve a purpose beyond privacy]	<p>Use – Transparent to some users of system (see security matrix)</p> <p>Disclosure - not intended for release other than inclusion as part of</p>

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence for individual patient if not collected	Proposed Use and Disclosure
				being provided to the same patient. And/or for communication and planned treatment between clinicians for patients with 2 eligible conditions. (NBA, Authoriser, Hospital) NBA – 3			aggregated dataset for reporting..
Authorisations	Collection of Authorisations	A list of authorisations that have been approved for the patient.		Provides transparency of all authorisation requests relevant to the patient - reduces the potential for multiple treatments being provided to the same patient. And/or for communication and planned treatment between clinicians for patients with 2 eligible conditions. (NBA, Authoriser, Prescriber, Nurse, Dispenser) NBA – 3	Supports contact of correct treating specialist when patient treatment review for access to ongoing therapy is required. (NBA, Authoriser)	Risk of patients receiving multiple treatments for multiple conditions, and / or inappropriately attending multiple hospitals for treatment.	Use – Transparent to some users of system (see security matrix) Disclosure - not intended for release other than inclusion as part of aggregated dataset for reporting to....or for research in.....

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence for individual patient if not collected	Proposed Use and Disclosure
Do not prescribe Advisories	Collection of Do not prescribe advisories	A list of advisories to not prescribe a particular product to the patient.		Captures and provides transparency of reasons why a particular Ig Product should not be prescribed (Prescriber, Nurse, Authoriser, Dispenser, NBA)	Supports intelligence where advisory is patient preference rather than safety such that at times of preferred product shortage, patient may safely be prescribed non preferred product (as opposed to safety reason).	Risk to patient safety if Ig product is prescribed to which the patient has had previous adverse reaction.	Use – Transparent to some users of system (see security matrix) Disclosure - not intended for release other than inclusion as part of aggregated dataset for reporting to

8.4.4 Home Therapy Additional Details

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed Use and Disclosure
Device	LOV: Devices	The type of pump that the patient uses to infuse the product.		Provides transparency of the device pump type that is used by the patient to infuse Ig product at home so that consumables, device spare parts & servicing and training can be given		Potential for error in issuing consumables, planning maintenance or replacement pumps to patient in event of breakdown. Inconvenience to hospital staff to identify	Use – Transparent to some users of system (see security matrix) Disclosure – not intended for release other than ability for local hospital printing to include in patient

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed Use and Disclosure
				to patient. (Authoriser, Prescriber, Nurse, Dispenser)		which device (pump) is being used by the patient for infusions	medical record.
Home Therapy Contact	Text	The Name of a person that can act as the contact for the patient's home therapy deliveries.		Provides transparency of the name of responsible person to provide important information regarding deliveries of product. The contact person might be the Patient or may be another person if carer or patient is a child. (Authoriser, Prescriber, Nurse, Dispenser) ,)		Risk to patient safety and convenience as potential for inability to contact conveniently regarding issues related to delivery of product.	Use – Transparent to some users of system (see security matrix) Disclosure - No plans for disclosure other than ability for local hospital printing to include in patient medical record or as part of de-identified aggregated dataset. – as above
Home Therapy Contact	LOV: Relationships	The relationship to the		Provides transparency of the relationship of contact person to		Lack of validation and identification of contact person and relationship	Use – Transparent to some users of system

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed Use and Disclosure
Relationship		patient of the home therapy contact.		patient (NBA, Authoriser, Prescriber, Nurse, Dispenser)		to patient. Will this lead to no delivery?	(see security matrix) Disclosure - No plans for disclosure other than ability for local hospital printing to include in patient medical record.
Phone	Text	A phone number at the delivery address		Provides transparency of telephone contact at delivery address. (Prescriber, Nurse, Dispenser)	Supports telephone contact regarding product deliveries. (Hospital,)	Inability to readily contact patient regarding changes in product deliveries. Potential patient safety risk where product remains unrefrigerated for extended periods and/or product wastage.	Use – Transparent to some users of system (see security matrix) Disclosure - No plans for disclosure other than ability for local hospital printing to include in patient medical record.
Supply Arrangement	LOV: Home Therapy Supply Arrangements		Valid Values: <ul style="list-style-type: none">▪ Patient collects from dispenser▪ Delivery to Patient's address	Provides transparency of patient/hospital preference for product deliveries in order to distinguish those patients on home delivery of product from patients attending hospital to collect		Patient home deliveries could not be supported in future and/or increased cost to modify system at a later stage.	Use – Transparent to some users of system (see security matrix) Disclosure - No plans for disclosure other than ability for local hospital printing to include in patient

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed Use and Disclosure
				product. (Authoriser, Prescriber, Nurse, Dispenser, NBA)			medical record.
Delivery Address	Address	The address to which deliveries of product shall be sent	Required if Supply Arrangement = Delivery to Patient's Address	Provides transparency of the delivery address for product to be sent for infusion by patients. (Authoriser, Prescriber, Nurse, Dispenser, NBA)		Home delivery of product cannot be supported without identification of a delivery address.	Use – Transparent to some users of system (see security matrix). Information would be provided to distributor. Disclosure – (what about to the Distributor to deliver the product?) No plans for disclosure other than ability for local hospital printing to include in patient medical record.

8.4.5 Hospital Identifier

A hospital identifier represents the relationship between a patient and a hospital. A Hospital Identifier is created for each hospital at which the patient has an interaction (consultation or treatment).

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence if not collected	Proposed use and disclosure
Patient	Patient	The patient to which the hospital identifier pertains to.		Provides transparency and confirmation of access to the correct patient record to deliver the correct data relevant to the patient and treatment (Prescriber, Nurse, Dispenser, NBA)		Patient safety risk where user accesses incorrect patient record and enters data activating wrong treatment/product. Increased risk of duplicate patient record being created.	Use – Transparent to some users of system (see security matrix). Information would be provided to distributor. Disclosure - No plans for disclosure other than including data in aggregated dataset. – as above
Hospital	Site	The hospital (site) for which this identifier is defined where patients will attend to collect or attend for treatment and/or attend for consultation with doctors.	List will default to site for logged on user or selected from valid list generated from BloodNet	Links the patient to a hospital for treatment thereby enabling transparency of all hospital affiliations for a patient. (Prescriber, Nurse, Dispenser, NBA)	Reduces the potential for multiple treatments being provided to the same patient. And supports contact of correct treating specialist when patient treatment review for access to ongoing therapy is required.	Patient safety risk where user accesses incorrect patient record and enters data activating wrong treatment/product. Increased risk of duplicate patient record being created.	Use – Transparent to some users of system (see security matrix). Disclosure - No disclosure at record level other than local hospital printing of record for medical case notes.
Patient ID	Text	The identifier used by the hospital/site to		Supports patient search process and provides an additional check that	Ease of search by hospital staff where Patient ID is	Patient safety risk where user accesses incorrect patient record and	Use – Transparent to some users of system

Column	Type	Description	Validation	Primary Purpose for collection	Secondary purpose for collection	Consequence if not collected	Proposed use and disclosure
		uniquely identify the patient.		access has been gained to the correct patient record. (Prescriber, Nurse, Dispenser, NBA)	readily accessible. Used as a reference in email and Treating Specialist correspondence regarding identifying the correct patient for periodical treatment review prior to authorisation for ongoing therapy. (Hospital)	enters data activating wrong treatment/product. Increased risk of duplicate patient record being created.	(see security matrix). Disclosure - No disclosure at record level other than local hospital printing of record for medical case notes.

8.4.6 Authorisation Request

A formal request from a medical officer to treat a patient with immunoglobulin under one of the authorisation pathways. A request must be made for a specific patient having a condition set out in the Criteria for Use.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
Authorisation Request ID	Alphanumeric Characters	Unique identifier for the authorisation request generated by		Provides transparency of each authorisation request. (Authoriser, Prescriber, Nurse, Dispenser, NBA)	Supports reporting and analysis of system activity (NBA, Hospital)	[see above – for privacy consideration is consequence to the individual patient if not collected but may assist beyond this	Use – Transparent to some users of system (see security matrix). Disclosure - No disclosure other than at level of aggregated

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
		the system.				purpose to include this]	reports.
Authorisation Program	LOV: Authorisation program	The blood product program under which the authorisation request is made and will be assessed.	Valid Values: <ul style="list-style-type: none"> IVIg SCIg 	Provides transparency regarding the type of Blood product authorisation request being made e.g. IVIg, SCIg. (NBA, Authoriser, Hospital, Jurisdictional DoH)	Supports efficient reporting and data analysis by product type. (NBA, Hospital)	Risk of incorrect product being authorised, dispensed or delivered.	Use – Transparent to some users of system (see security matrix). Disclosure - No disclosure other than at level of de-identified aggregated reports.
Request Date	Date Time	The date that the request is being made	Must not be a past date	Provides transparency and accuracy regarding date of request for product. (NBA, Hospital, Authoriser, Dispenser,)	Supports performance analysis of time to respond along authorisation & treatment processes.	Risk of lack of timely management of request. Lack of trigger date for patient clinical review due date regarding ongoing access to treatment.	Use – Transparent to some users of system (see security matrix). Disclosure - No disclosure other than at level of de-identified aggregated reports.
Patient	Patient	The patient for which treatment is being requested.	Mandatory	Provides transparency regarding the patient relevant to the request. (NBA, Hospital, Authoriser)	Transparency supports confirmation that correct patient record has been accessed for data entry and review	Risk to patient safety if incorrect patient record has been accessed and/or inability to support verbal conversation	Use – Transparent to some users of system (see security matrix). Disclosure - No disclosure other than

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
				NBA - 3	of authorisation request. (Authoriser, NBA)	when required to confirm qualifying/ review criteria, regarding details of clinical condition/response, dose or product with prescriber.	at level of de-identified aggregated reports.
	Collection of Previous Treatments	A list of previous treatments that the medical officer deems important (or may be required) to disclose in the authorisation request.		Provides transparency of previous treatments that are relevant to ongoing patient management. Data supports planning of future authorisation requests, clinical review of current and future treatments, assessment of clinical outcome, timing of trial cessations of therapy and determining ongoing patient treatment needs. (NBA, Authoriser, Hospital)	Transparency also supports validation of future product selections and reduces likelihood of duplicate treatments being requested or authorised from different prescribers/hospitals. (Hospital, Authoriser, NBA)	Reduced rigor and quality of both authorisation requests and authorisation outcome. Increased risk of duplicate authorisation requests for same patient being authorised concurrently.	Use – Transparent to some users of system (see security matrix). Disclosure - No disclosure other than at level of de-identified aggregated reports.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
Treating Medical Specialist	Medical Officer	The Medical Officer who is responsible for the overall treatment of the patient's condition.	Mandatory Medical Officer must be permitted to be nominated as the Treating Medical Specialist	Critical identification parameter for compliance with Criteria for Use by ensuring that a Medical Specialist performs the patient review and provides evidence of clinical outcome. (NBA, Hospital, Authoriser)	Flag supports the identification and timely notification of appropriate Treating Medical Specialist in order to provide required patient clinical review prior to expiry of the previous request, where ongoing access to treatment is required for patient condition. (Authoriser, Hospital, NBA)	Potential for non-compliance with the requirements of Criteria for Use and non-expert clinical assessment of outcome/ request for continuing therapy. Lack of timely patient review, expiry of authorisation and cessation of treatment for patients due to not being able to contact correct specialist.	Use – Transparent to some users of system (see security matrix). Disclosure – Used to generate confidential patient review correspondence. No other disclosure except at level of de-identified aggregated reports for clinical governance and Ig governance purposes.
Consultant Confirming Diagnosis	Medical Officer	A medical officer that has confirmed the diagnosis of a condition.		Providing transparency that specialist made initial diagnosis and compliance with <i>the Criteria for Use</i> . (Authoriser, Hospital, NBA)	Provides transparency of specialist name (determining the diagnosis) – and documenting historic reference point should clarification or additional information be required in the	Failure to comply with the criteria - risk that diagnosis is not confirmed and Ig treatment is not indicated.	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
				NBA - 3	future. (NBA, Authoriser, Hospital)		
Requesting Medical Officer	Medical Officer	The Medical Officer who has completed the authorisation request form.		Capturing the name of the Medical Officer that completes the Authorisation request (which equates a prescription in content) will be important for performance review analysis to support the evaluation of compliance with the Criteria in prescribing behaviour. (NBA, Hospital) NBA - 3	The requesting medical officer will often be a junior doctor working under supervision. It is important to differentiate this person from the Responsible Specialist overall. (NBA, Hospital)	– as above not really patient consequence but may also assist for other purposes to record this.	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.
Condition	Condition	The Medical Condition for which treatment is being	Valid values – Conditions as defined in <i>the Criteria</i>	Providing transparency of condition requiring treatment is a critical element needed for accurate Authorisation of proposed patient	The linkage of clinical outcome data to condition and prescribed treatment is essential for ongoing evidence	Risk to assessing incorrect dose and infusion plan at authorisation resulting in potential ineffective clinical outcome,	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of de-

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
		requested.		<p>treatment as dose, frequency and treatment schedule is different for different conditions and indications.</p> <p>(NBA, Hospital, Authoriser,)</p> <p>NBA - 3</p>	base and determining the efficacy of Ig treatment. (NBA, Hospital)	inappropriate product and dose/schedule of treatment, determining efficacy of treatment and inability to demand forecast and secure sufficient product supply.	identified aggregated reports for clinical governance and Ig governance purposes.
Specific Condition	Specific Condition	The specific condition (as a subset of the Condition) for which treatment is being requested		<p>Providing transparency of condition requiring treatment is a critical element needed for accurate Authorisation of proposed patient treatment as dose, frequency and treatment schedule is different for different conditions and indications.</p> <p>(NBA, Hospital, Authoriser,)</p>	<p>The linkage of clinical outcome data to condition and prescribed treatment is essential for ongoing evidence base and determining the efficacy of Ig treatment.</p> <p>(NBA, Hospital)</p>	Risk to assessing incorrect dose and infusion plan at authorisation resulting in potential ineffective clinical outcome, inappropriate product and dose/schedule of treatment, determining efficacy of treatment and inability to demand forecast and secure sufficient product supply.	<p>Use – Transparent to some users of system (see security matrix).</p> <p>No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.</p>

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
				NBA - 3			
Indication	Indication	The indication for which treatment is being requested		<p>Providing transparency of the specific indication relating to the condition requiring treatment is a critical element needed for accurate Authorisation of proposed patient treatment (dose, frequency and treatment schedule). This is different for different conditions and indications.</p> <p>(NBA, Hospital, Authoriser,)</p> <p>NBA - 3</p>	<p>The linkage of specific indication and condition to clinical outcome data and prescribed treatment is essential for building the evidence base and determining the efficacy of Ig treatment.</p> <p>(NBA, Hospital)</p>	<p>Risk to assessing incorrect dose and infusion plan at authorisation resulting in potential ineffective clinical outcome, inappropriate product and dose/schedule of treatment, determining efficacy of treatment and inability to demand forecast and secure sufficient product supply.</p>	<p>Use – Transparent to some users of system (see security matrix).</p> <p>No disclosure other than at level of aggregated reports for clinical governance and Ig governance purposes.</p>
Selected Criteria	Collection of Criteria	The Qualifying or Review Criteria that the patient’s condition meets (as selected by the requesting		<p>Providing transparency of the qualifying or review criteria that define eligibility to funded Ig treatment is a critical element needed for accurate</p>	<p>The linkage of qualifying criteria to specific expected clinical outcome data and prescribed treatment is essential for building the</p>	<p>Risk of not providing transparency and accessible documentation of the qualifying and review criteria that define eligibility for each</p>	<p>Use – Transparent to some users of system (see security matrix).</p> <p>No disclosure other than at level of aggregated reports</p>

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
		medical officer)		Authorisation of proposed patient treatment as dose, frequency and treatment schedule is different for different conditions and indications. (NBA, Hospital, Authoriser,)	evidence base and determining the efficacy of Ig treatment. (NBA, Hospital)	patient to access to Ig funded under the national blood arrangements. Inability to undertake clinical governance activities and performance review of prescribing practice as no data would be available for reporting purposes.	for clinical governance and Ig governance purposes.
Evidence	Collection of Evidence Responses	Responses to evidence items to support selection of criteria.		The collection of evidence (where relevant) is required to provide proof that qualifying and/or review criteria have been met, and that patients are eligible for access to Ig funded under the national blood arrangements. This approach is consistent with approach used by the	The value of measured evidence will support the development of data for future analysis of minimum effective dose and efficacy of Ig treatment for some conditions. (NBA)	Risk of the ongoing potential for inappropriate prescribing practice and/or non-compliance with the <i>Criteria for Use</i> . Failure to build the evidence base to support future analysis of treatment effectiveness and dosing.	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of-aggregated reports for clinical governance and Ig governance purposes.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
				high cost drugs program. (NBA - 3)			
Selected Exclusion Criteria	Collection of Exclusion Criteria	The exclusion criteria that was selected by the user as applying to the patient's condition.		The collection of exclusion criteria is important to confirm that all patients are eligible for access to Ig under the national blood arrangements – that prescribing practice is compliant with the <i>Criteria for Use</i> . (NBA - 3)		Failure to collect exclusion criteria as part of the Authorisation request is likely to result in patients inappropriately receiving Ig treatment and non-compliance with the <i>Criteria for Use</i> . Exclusion criteria have been determined as ineffective and inappropriate use of Ig by using a clinical evidence base	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.
Proposed Dose	Collection of Proposed Doses	A specification of a dose that is being requested for treatment.		The proposed dose is assessed by the Authoriser and provided compliant with the dose range for each indication in <i>the</i>	Analysis of proposed dose by indication/condition is important as part of performance review and by linking to the	Failure to capture the proposed dose is likely to result in approval and supply of the maximum dose allowable in <i>the Criteria</i>	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of de-identified aggregated

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
				<p><i>Criteria for use</i>, will be approved. Given that a range is permissible, the clinical circumstance will determine the individual patient need.</p> <p>(Authoriser, NBA)</p>	<p>clinical outcome, will provide evidence of minimal effective dose in the future.</p> <p>(NBA)</p>	<p><i>for Use</i> in every instance, resulting in potential over prescription and not achieving cost effective treatment.</p>	<p>reports for clinical governance and Ig governance purposes.</p>
Dispensing Site	Distribution Site (BloodNet)	The site that will be responsible for dispensing immunoglobulin product to the patient.		<p>Capturing and providing transparency of the dispensing site is important to ensure that treatment is provided at the correct location for the patient. In some instances, the Treating Specialist (overall responsible for care) may be in a capital city; however, the majority of treatment is delivered in a regional or rural location or in some instances, home therapy.</p>		<p>Failure to capture and display the dispensing site is likely to result in errors in the availability of product and delays to access and treatment delivery.</p>	<p>Use – Transparent to some users of system (see security matrix).</p> <p>No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.</p>

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
				(Hospital, NBA)			
Authorisation Jurisdiction	LOV: Jurisdiction	The jurisdiction under which the authorisation request will be assessed.	Valid Values: <ul style="list-style-type: none"> ▪ ACT ▪ NSW ▪ NT ▪ QLD ▪ SA ▪ TAS ▪ VIC ▪ WA 	Capturing and providing transparency of the Authorisation jurisdiction ensures that there is transparency of location of the Authoriser to prescribers and other users to contact the Authoriser where necessary. (Hospital, NBA)	Review of Authoriser performance (e.g. to assess the level of comparable decision making nationally) is an important part of the ongoing governance of Ig management. (NBA)	Prescribers will be unable to easily follow-up and contact the relevant Authoriser in the event of clarification of problems with requests. Failure to collect the Authorisation site removes the ability to undertake appropriate performance analysis of this function.	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.
Is Retrospective	True / False	Indicates that the request is being made retrospectively (after treatment has begun)		In some instances, product is required to be dispensed without authorisation approval (e.g. in an emergency), and data entry is addressed after the fact. The system must be able to accommodate retrospective data	The frequency of such requests and other relevant process issues can be evaluated for improvement opportunities as part of performance review using this field.	Failure to allow flagging of retrospective requests in the system will result in incorrect treatment dates being recorded and lack of visibility of the practice of dispensing without authorisation approval.	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence to individual if not collected	Proposed use and disclosure
				entry of authorisation requests and track them. (Hospital, NBA)	(NBA)		
Is Emergency	True / False	Indicates that the request is being made in an emergency and that treatment is likely to be given before the assessment has been completed.		This field is important to distinguish emergency need from other reasons for dispensing without authorisation. While the system must be able to accommodate retrospective data entry of authorisation requests and track them, some emergencies will be able to receive authorisation approval. The flag can be used to more highly prioritise such requests for the Authoriser and the Dispenser (Hospital, NBA)	The frequency of the subset of emergency requests allows investigation of other reasons for retrospective data entry and monitoring of how many emergency requests there are. Process problems can be evaluated for improvement opportunities as part of performance review using this field together with the retrospective flag. (Hospital, NBA)	Failure to identify emergency requests denies the opportunity to fully evaluate the frequency of such instances and the degree to which they are able to be accommodated by the Ig management structures including by different Authorisation locations.	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.

8.4.7 Previous Treatment

A record of a previously administered course of immunoglobulin treatment.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence if not collected	Proposed use and Disclosure
Treatment Type	LOV: Ig product Types	The product types of the previous Immunoglobulin treatment.	Valid Values product brand names for each of : <ul style="list-style-type: none"> ▪ IVIg ▪ SCIg ▪ NHIg 	The collection of type of Ig Product that was used in previous treatments may support the allocation of the correct /best treatment type for current or future treatments. Product type (rather than brand) is specific for indication and condition however; it is preferable to retain patients on the same brand of product where supply constraints allow. (Prescriber, Nurse, Dispenser, Authoriser, NBA)	The evaluation of previous treatment types when linked with clinical response provides important intelligence to build the evidence base and potentially assess performance of different brands by condition. (NBA)	Failure to collect and display the previous treatment type may result in patients being allocated a different product at next infusion. Different brands have different infusion rates and may cause adverse reactions. Constraints exist in some jurisdictions regarding the number of product brands within hospitals which may be difficult to manage without this flag.	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.
Date	Date Time	The date of the previous	Must not be current or	The date of the most recent treatment is important to schedule	Display of previous treatment will avoid duplicate treatments	Failure to collect/display the date of previous treatment	Use – Transparent to some users of system

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence if not collected	Proposed use and Disclosure
		treatment	future date.	the next treatment. (Prescriber, Nurse, Dispenser, Authoriser, NBA)	being scheduled and given. Data analysis of treatment timings is an important indicator to support evaluation of treatment effectiveness and Ig performance management. (Hospital, NBA)	will result in paper records needing to be accessed and reduces the efficiency of the system to support Ig treatment. Risk of duplicate treatments at incorrect time intervals being given across different sites.	(see security matrix). No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.
Response	Text	A comment on the patient's response to the treatment.		The recording of the response patients have had to particular brands of Ig product ensures that allocation of the next treatment type is appropriate for patient safety. (Prescriber, Nurse, Dispenser, Authoriser, NBA)		Failure to collect and display the patient's response to a previous Ig treatment may result in patients receiving a brand of product to which they have had a reaction.	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.

8.4.8 Medical Officer

An individual with the qualifications and credentials to prescribe immunoglobulin treatment. The medical officer record may or may not be related to a user account.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence if not collected	Proposed use and disclosure
Medical Registration Number	Text	The registration number of the medical officer as assigned by relevant medical board.		The collection and display of medical registration number allows the verification of the medical officer against the AHPRA website and as such, as a valid prescriber of Ig products supporting approval for system access. (Prescriber, Nurse, Dispenser, Authoriser, NBA)	The registration number is a nationally unique identifier which supports the creation of a single medical officer record that can be transferred across different hospital institutions. In this way, an individual's prescribing practice can be assessed. (NBA)	Risk of BloodSTAR access being granted to non-medical staff as prescribers and duplication of multiple medical officer records for the same individual being created.	Use – Transparent to some users of system (see security matrix). No disclosure planned however this indicator will be used to evaluate individual prescribing practice and data inclusion in de-identified reports as part of performance review and management activities.
Given Name	Text	The Given name of the Medical Officer		Collection and display of given name will help distinguish medical officers with the same surname within the system. (Prescriber, Nurse, Dispenser, Authoriser,		Failure to display given name will lead to failure identify the relevant medical officer within the system for authorisers and other hospital staff.	Use – Transparent to some users of system (see security matrix). No disclosure planned other than in correspondence to the medical officer.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence if not collected	Proposed use and disclosure
				NBA)			
Family Name	Text	The Family Name of the Medical Officer		Collection and display of surname is important for identification of medical officers within the system (Prescriber, Nurse, Dispenser, Authoriser, NBA)		Failure to display surname will lead to failure identify the relevant medical officer within the system for authorisers and other hospital staff.	Use – Transparent to some users of system (see security matrix). No disclosure planned other than in correspondence to the medical officer.
Designation	LOV: Medical Officer Designation	The designation of the individual in their current role.	Valid Values: <ul style="list-style-type: none"> ▪ TBA 	Collection and display of medical officer designation supports the assessment of the authorisation request and indicates that additional advice may be required to modify the request where the designation is of junior staff. (Prescriber, Nurse, Dispenser, Authoriser, NBA)	The differentiation of medical officer type supports the analysis and determination of education and training needs to particular medical officer segments. (NBA)	Failure to differentiate levels of seniority and experience of medical staff is likely to result in authorisation requests for Ig to not be challenged by authorisers and difficulty in assessing and targeting education and training needs.	Use – Transparent to some users of system (see security matrix). No disclosure other than at level of de-identified aggregated reports for clinical governance and Ig governance purposes.
Mobile Phone	Text	The medical officer's mobile		The collection and display of medical staffs'		Failure to display the mobile telephone or	Use – Transparent to some users of system

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence if not collected	Proposed use and disclosure
/ Pager		phone number or pager number		mobile or pager numbers is required by authorisation staff to contact the medical officer for further information or discuss an authorisation request. (Authoriser, NBA)		pager details of requesting and treating medical staff is likely to result in delays in authorisation and therefore patient treatment and potentially higher doses and longer treatment periods because the prescribing or treating medical officer cannot be contacted easily.	(see security matrix). No disclosure planned.
Contact Details	Collection of Contact Details	A list of email address, phone and fax numbers at which the medical officer can be reached		The collection and display of contact details for medical staff is important for communication regarding Ig in particular, the preferred email address (Authoriser, NBA)	Communication regarding changes to the Ig Program, changes to eligibility criteria and access, product recalls and other relevant advice is needed to be provided to medical staff from time to time. (NBA)	Failure to collect and display contact details for medical staff will result in an inability to advise them in a timely manner regarding changes to the Ig Program, eligibility and access, product recalls and other relevant advice will not be able to be provided to medical staff as the	Use – Transparent to some users of system (see security matrix). No disclosure planned other using to contact the specific medical officer.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence if not collected	Proposed use and disclosure
						need arises.	
Primary Jurisdiction	LOV: Jurisdiction	The jurisdiction in which the medical officer primarily works.	Valid Values: <ul style="list-style-type: none"> ▪ ACT ▪ NSW ▪ NT ▪ QLD ▪ SA ▪ TAS ▪ VIC ▪ WA 	The collection and display of the main jurisdiction in which the medical officer works is important to segment the prescribing practice of medical staff on a jurisdictional basis, for reporting purposes. (NBA)		Failure to designate medical staff to primary jurisdictions may result in inaccurate analysis of prescribing practice for performance management purposes.	Use – Transparent to some users of system (see security matrix). No disclosure planned other than in de-identified aggregated reporting.
Postal Address	Address	The postal address to which formal correspondence can be sent to the medical officer.		Preferred postal address is required when formal correspondence (e.g. relating to patients) must be sent. Examples include that patient clinical review is becoming due. (Authoriser, NBA)		Risk of failure to send confidential correspondence regarding the timely notification for patient clinical review being due and need for assessment regarding ongoing Ig treatment, resulting in delays to authorisation and patients losing access to Ig treatment.	Use – Transparent to some users of system (see security matrix). No disclosure planned other using to contact the specific medical officer.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence if not collected	Proposed use and disclosure
Is a specialist	True / False	Indicates if the Medical Officer is authorised to be nominated as the Treating Medical Specialist on authorisation requests.		Flagging the medical officer as a Specialist is required to enable BloodSTAR to ensure compliance with <i>the Criteria for Use</i> – e.g. for some conditions a specialist medical staff must undertake the patient clinical review for ongoing access to Ig treatment. (NBA, Authoriser)		Failure to designate medical officers as specialists within BloodSTAR will result in failure to comply with <i>the Criteria for Use</i> at a system level.	Use – Transparent to some users of system (see security matrix). No disclosure planned other than in de-identified aggregated reporting.
Speciality Registrations	Collection of Specialties	A list of specialty areas for which the Medical Officer is registered.	mandatory where Is a Specialist = true	The capturing of the specific speciality for medical officers is required to support the medical staff verification and credentialing process to gain access to BloodSTAR. (Prescriber, Nurse, Dispenser, Authoriser, NBA)	The designation of speciality will support the analysis of prescribing practice for each speciality type and in turn help determine education and training needs.	Failure to collect the speciality to which the medical officer is credentialed will result in incomplete verification data and lack of analysis regarding specialities and inability to determine need and appropriately target education and training programs.	Use – Transparent to some users of system (see security matrix). No disclosure planned other than in de-identified aggregated reporting.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence if not collected	Proposed use and disclosure
Is Validated	True / False	Indicates whether the record was validated at the last validation challenge. Updated by system only. Not editable by user.		Each medical officer will undergo a verification process (to confirm their medical registration) prior to being provided access to BloodSTAR. This flag identifies that this external manual process has been successfully performed or not. (NBA, Authoriser)	This is a control mechanism within BloodSTAR to display that the Medical Officer has been validated supporting the principle that only AHPRA registered medical officers can prescribe Ig. – this seems to mirror primary purpose?	Failure to track attempts to gain access to BloodSTAR and success in the verification process will result in an inability to assure appropriate governance regarding prescribing practice.	Use – Transparent to some users of system (see security matrix). No disclosure planned.
Username	Text	The user name of the user account to which the medical officer is linked.		A Medical Officer must request access to BloodSTAR in order to view details related to their prescribing practice. When BloodSTAR access is approved the username is associated to their Medical Officer role/s to display authorisation details related to their patients.	Enable alerts to be circulated via secure methods external to BloodSTAR	Medical Officer cannot access BloodSTAR.	Use – Transparent to some users of system (see security matrix). No disclosure planned.

Column	Type	Description	Validation	Primary purpose for collection	Secondary purpose for collection	Consequence if not collected	Proposed use and disclosure
Authorisations	Collection of Authorisations	All authorisations for which the Medical Officer is nominated as the Treating Medical Specialist.		Manage aspects related to management the treatment Enables alerts to be sent to the Medical Officer when patient authorisation requests are approved due for review and other aspects of managing authorised patient treatment.		Unable to manage treatment needs for authorised patients.	Use – Transparent to some users of system (see security matrix). Disclosure will be used to assemble reports regarding prescribing practice for clinical governance purposes.

8.5 Attachment E– Patient Record Security Matrix

Component of Patient Record	Medical Officer	Authoriser	Nurse	Dispenser	System Admin
Patient Identifying Detail	Yes	Yes during the transition from STARS to BloodSTAR, and only on the provision of a reason once STARS has been decommissioned	Yes	Yes	Yes
- Condition		Patient identifying information is obscured (ie. Male, 52 years) but available on the provision of a reason.			
- Rationale	To ensure that data and authorisation requests are being entered under the correct patient record.	To assist in understanding the clinical need for access to immunoglobulin treatment.	To ensure that the information garnered from the system pertains to the correct patient.	To ensure that the record of dispensing in BloodNet Matches a patient in the facility or LIS.	
Facility Identifiers	Yes	No	Yes	Yes	Yes
- Condition					
- Rationale	To ensure that the correct patient record is used	This is not required	To ensure that the patient record matches the patient	To ensure that the patient record is the correct patient record.	
Do not prescribe advisories	Yes	Yes	Yes	Yes	Yes

Component of Patient Record	Medical Officer	Authoriser	Nurse	Dispenser	System Admin
- Condition					
- Rationale	To facilitate the selection of product for which the patient has not had a reaction to	To facilitate the selection of product for which the patient has not had a reaction to	To facilitate the selection of product for which the patient has not had a reaction to	To facilitate the selection of product for which the patient has not had a reaction to	
Current Authorisations	Yes	Yes	Yes	Yes	Yes
- Condition					
- Rationale	To provide knowledge of existing treatment being given to a patient to avoid prescribing a treatment that is already being undertaken. To provide data on the progress of treatments for a patient.	To provide knowledge of existing treatment being given to a patient to assist with assessment of continuing authorisation requests.	To ensure that treatment is administered within the authorised parameters for a patient.	To ensure that product is dispensed within the authorised parameters for a patient.	
Previous Authorisations	Yes	Yes	No	No	Yes
- Condition					
- Rationale	To provide knowledge of previous treatment given to a patient to avoid prescribing a treatment that has already being undertaken.	To provide knowledge of previous treatment given to a patient to assist in the assessment of authorisation.	A nurse does not need to know about previous authorisation in order to safely administer treatment.	A dispenser does not need to know about previous authorisation in order to safely dispense product for treatment.	
Authorisation	Yes	Yes	No	No	Yes

Component of Patient Record	Medical Officer	Authoriser	Nurse	Dispenser	System Admin
Requests					
- Condition	Can only see authorisation requests for which they are nominated as the Treating Medical Specialist or the Requesting Medical Officer	Only where the Status is not DRAFT			
- Rationale	These requests pertain specifically to a Medical Officer’s own patient. The medical officer cannot gather any more information from a request than they has entered themselves.	The authoriser needs to be able to see the request in order to assess it.	A nurse does not need to know anything about how an authorisation came to be.	A dispenser does not need to know anything about how an authorisation came to be.	
Consent Records	Yes	Yes	Yes	Yes	Yes
Review outcomes (identifiable)	Yes	Yes	No	No	Yes
- Condition	Can only see review outcomes for authorisations for which the Medical Officer is the Treating Medical Specialist				
- Rationale	The Medical Officer cannot gather any more information from review outcomes than that which they have entered themselves.	The authoriser must assess review outcomes to ascertain that there has been a clinical benefit before approving continuing access to	A nurse does not need to understand the clinical effectiveness of the treatment in order to safely administer treatment.	A dispenser does not need to understand the clinical effectiveness of the treatment in order to safely dispense	

Component of Patient Record	Medical Officer	Authoriser	Nurse	Dispenser	System Admin
		treatment		product for treatment.	
Clinical Outcomes (identifiable)	Yes	No	No	No	Yes
- Condition	Own - Can only see clinical outcomes for authorisations for which the Medical Officer is the Treating Medical Specialist.				
- Rationale	The Medical Officer cannot gather any more information from clinical outcomes than that which they have entered themselves.	The authoriser only needs to know about demonstrated efficacy based on the criteria that will qualify the patient for continued treatment. Clinical Outcomes may contain data in addition to that required above.	A nurse does not need to understand the clinical outcomes of the treatment in order to safely administer treatment.	A dispenser does not need to understand the clinical outcomes of the treatment in order to safely dispense product for treatment.	