

FREQUENTLY ASKED QUESTIONS (FAQ)

Questions

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...and Answers!

What is the ABDR?

The Australian Bleeding Disorders Registry (**ABDR**) is a database that collects all clinical information relating to the treatment of people with bleeding disorders, like an electronic medical file. This includes information about patient diagnosis, treatment details, hospital admissions and administrative information as well as details on ordering, supply and use of clotting factor products. Information is entered into the ABDR by staff at haemophilia treatment centres. The ABDR is managed by the National Blood Authority (NBA). The ABDR was first established in 1988 and has been upgraded many times with the latest significant upgrade in 2012.

How does the National Blood Authority (NBA) know that I've ordered clotting factor product?

Governments fund blood and blood products free only to entities or doctors that have been 'Approved'. Approval entails the supplier and the NBA validating the details of the recipient placing the order. Under contractual obligations, these details are included on invoices sent to the NBA. No personal information about patients is included.

Which bleeding disorders are within the scope of the ABDR?

Disorders within the scope of the ABDR include Haemophilia A and B and other factor deficiencies including fibrinogen, all types of von Willebrand's Disease (**vWD**), platelet dysfunction, acquired factor VIII inhibitor, acquired von Willebrand's Disease and some vascular disorders. Please refer to the reverse of the ABDR Patient Registration Form, which can be downloaded from www.ahcdo.org.au, for a complete list of disorders. Any patient diagnosed with a disorder on this list, and who requires treatment with clotting factor product funded by governments, must be registered on the ABDR.

What products do you classify as clotting factor products?

Products classified as 'clotting factors' for the treatment of bleeding disorders that are currently available in Australia under the *National Blood Agreement* are tabled below. Bleeding disorder patients treated with these products must be registered on the ABDR.

Product Type	Product Name	Supplier
Bypassing Agent	Factor Eight Inhibitor Bypass Agent (FEIBA)	Baxter
Plasma Derived FVII	Factor VII Concentrate	Baxter
Plasma Derived FVIII	Biostate	CSL BioPlasma
Plasma Derived FIX	MonoFIX - VF	CSL BioPlasma
Plasma Derived FXI	Factor XI Concentrate	CSL BioPlasma
Plasma Derived FXI	Factor XI bpl	CSL BioPlasma
Plasma Derived FXI	Factor XI Hemoleven	CSL BioPlasma
Plasma Derived FXIII	Fibrogammin P	CSL BioPlasma
Plasma Derived FXIII	Haemocomplettan	CSL BioPlasma
Plasma Derived PCC	Prothrombinex – VF*	CSL BioPlasma
Protein C	Ceprotrin	Baxter
Recombinant FVIIa	NovoSeven*	NovoNordisk
Recombinant FVIIa	NovoSeven RT*	NovoNordisk
Recombinant FVIII	Advate	Baxter
Recombinant FVIII	Recombinate	Baxter
Recombinant FVIII	Kogenate FS	Bayer
Recombinant FVIII	Xyntha	Pfizer
Recombinant FVIII	Xyntha Dual Chamber	Pfizer
Recombinant FIX	BeneFIX	Pfizer

*IMPORTANT NOTES:

- NovoSeven is only available under the *National Blood Agreement* when it is indicated for the control of bleeding in patients with haemophilia with inhibitors and for patients with rare bleeding disorders.
- Prothrombinex is not used exclusively in the treatment of bleeding disorders. However bleeding disorder patients treated with Prothrombinex must be registered on the ABDR.

What about other products that are used to treat bleeding disorders?

Fresh Frozen Plasma (FFP), Platelets, Cryoprecipitate, Intravenous Immunoglobulin (IVIg), DDAVP and Tranexamic Acid are all used, although, the ABDR only requires patients treated with the products tabled above to be registered. To maintain clinical accuracy of treatment information in the ABDR, clinicians are encouraged to include the use of these products in the treatment information provided when registering patients.

Why do I have to register my patients?

To understand properly the demographic profile, incidence and prevalence of bleeding disorders in Australia, it is essential that peak clinical bodies and governments responsible for the supply of clotting factor products are aware of patient needs. Without full visibility of the demand for these products it is not possible to plan accurately and guarantee supply of products to meet clinical demand.

How are governments briefed on clinical issues relating to the supply of clotting factor products?

Members of the Australian Haemophilia Centre Directors' Organisation (AHCDO) regularly communicate with Australian governments to provide advice on clinical issues that have an impact on the availability of clotting factor product in Australia. In some cases their direction and collaboration is required to manage intensively some products where supply shortages occur.

Advice from AHCDO extends to interpretation of data and insight into why changes to trends in product use may appear in invoices received from clotting factor suppliers.

How will governments use ABDR information made available to them?

Demand models, incorporating information available from the ABDR, such as patient weight and the number of new patients, along with current clinical protocols, are used to estimate product demand in the future. These estimates are critical to the NBA's contract negotiations with national and international suppliers of blood and blood products.

By understanding the demand for clotting factor products, the NBA can ensure these contracts cover worst case scenarios and ensure there is enough product available in the country at any given point in time.

All ABDR data available to governments is depersonalised and, together with the Governance framework and security protocols, patients' privacy is protected at all times.

How can I be confident that the information I provide will be adequately protected?

There is an extremely robust Governance framework that oversees the management and operation of the ABDR. An AHCDO member chairs the Steering Committee tasked with these responsibilities. The Steering Committee also includes the Executive Director of Haemophilia Foundation Australia to ensure patient needs are met. Patient privacy and confidentiality are paramount to these arrangements.

In addition, there are stringent security protocols embedded into the technical architecture of the ABDR. These effectively control access to personal data ensuring this information is only accessible to treating health professionals and authorised support staff.

Will I lose clinical autonomy over my patients if I have to register them in the ABDR?

No, you won't! Treatment Centres, Clinics and Governments just need to know you have a patient/s that require/s clotting factor replacement therapy and an estimate on the frequency they use the clotting factor product. Otherwise forward planning for product may be erroneous and lead to difficulties in supply.

Treatment Centres and Clinics are only involved to provide the administrative resources required to register the patients on the ABDR. Governments have funded part-time Data Managers in Treatment Centres and Clinics across Australia to manage clinical data in their Centre and to undertake this initial registration process. Data Managers are employees of the Hospitals where treatment centres and clinics are located; this is to ensure that appropriate privacy controls over access to medical records are maintained.

What do patients think about the ABDR?

The ABDR is not new, it's been around since 1988 and patients have provided data since that time; in fact it was initially set up with funding from Haemophilia Foundation Australia. Patients also understand that making their information available is important to ensure they receive the treatment and care they require.

Consultation with the bleeding disorders community has been ongoing throughout the redevelopment process.

What happens if I don't provide information for all mandatory fields?

Mandatory fields are identified by an asterisk (*) on the ABDR Patient Registration Form. An ABDR Data Manager will contact you for the information missing from mandatory fields.

Why do I have to include weight on the ABDR Patient Registration Form?

As dosing for clotting factor products is based on weight, this will enable more accurate forecasting to take place.

What is minimum data?

Minimum data is the least amount of information about a patient that is required to provide accurate statistics on bleeding disorders and to undertake adequately supply planning, demand forecasting and discuss future planning on product ordering processes.

The agreed minimum data set on patients with bleeding disorders is:

- Full name and address details (to ensure only one unique record is created for patients across Australia)

- Date of birth (to calculate age cohorts)
- Gender
- Diagnosis
- Severity
- Base line factor level and date (where relevant - for example, it is not applicable for vWD or platelet disorders). It is required to assess international standards on classification of severity.
- Weight
- Treatment regimen – the product used, dosing and frequency of treatment. (For example, if patients are mild and are only treated on demand infrequently, please provide comments to indicate as such.)
- Attending physician and clinic/hospital details (to enable follow up and contact where required/appropriate).

When do I need to have my patients registered?

You should aim to register a patient the first time they attend your clinic. This is to ensure you can discuss the need to capture your patients' information and can provide them with a copy of the ABDR Patient Pamphlet.

Visit www.ahcdo.org.au for details on how to download or obtain additional copies of the ABDR Patient Pamphlet and ABDR Patient Registration Form. Please note a copy of the text on the ABDR Patient Pamphlet is included on the reverse of the ABDR Patient Registration Form.

How do I get access to the ABDR?

Access to the ABDR is not readily available and is tightly controlled by the ABDR Steering Committee. Please contact AHCDO for further information.

Where can I get more information?

Contact AHCDO, visit www.ahcdo.org.au or call **(03) 9885 1777** or email info@ahcdo.org.au.