ABDR - the evolution over 25 years of a national database for people with bleeding disorders

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Clinical registries have a clear role in monitoring and benchmarking quality of care and health outcomes in many areas of medicine. Registries can be disease or complication specific with a strong clinical or research focus or a broad collection of data relating to a disease or condition – either based on geographic region or area of care, nationally or internationally. The World Federation of Haemophilia (WFH) recommends the establishment of national registries in haemophilia care in order to:

- effectively manage resources
- improve patient well-being and save lives
- save money by improving purchasing processes
- efficiently deliver quality patient care

Strong clinical governance is required for national registries with input from key stakeholders – including clinicians, payers and persons with haemophilia (PWH).

This poster describes the evolution of the Australian Bleeding Disorders Registry (ABDR) since 1991 and covers four phases with advances based on issues identified with governance involving major stakeholders.

INITIAL PHASE

The first demographic Haemophilia registry was established by the Medical Advisory Panel (MAP) in 1991, under the auspices of the Haemophilia Foundation of Australia (HFA), with an initial survey of Haemophilia Treatment Centres (HTC) established in Australia. Following on this initial survey the MAP took on responsibility for developing an ongoing registry and database associated with a university. The registry was based on a Paradox database with a comprehensive data collection including demographics, factor usage and bleed data. It was intended that software would be updated regularly by circulation of floppy disc updates and annual reports produced. Issues identified included no dedicated data entry staff, variability of IT support in institutions, unstable database requiring significant maintenance, time for data entry, and complexity. Unfortunately the registry did not progress..

Demographic data at Sept 1992 highlight possible issues of data collection or management of inherited bleeding disorders.

	NSW ACT	VIC	SA	WA	QLD	TAS	National
HMA	310	305	141	93	76	25	950
HMB	63	58	12	20	17	4	174
VWD	91	135	0	64	13	4	307
OTHER	49	26	53	8	6	3	145
TOTAL	**513**	**524**	**206**	**185**	**112**	**36**	**1,576**

PHASE 2

In view of issues identified, a new database was developed using Access with a single initial page collecting demographic and basic clinical data – a 'medical registry'. Financial support was provided for data entry. Identification was by a code including multiple initials of name and date of birth as used for HIV notifications in Australia. Duplicate entries were identified and individual HTCs were asked to resolve differences. Initial demographics and diagnoses were provided for an annual report – first to Department of Health and Aging, subsequently to National Blood Authority and presented at various forums. Data was vital for identifying product needs of the PWH community at a time of introduction of recombinant products. The ABDR achieved Quality Assurance status with the Commonwealth to assist with concerns about privacy.

Ongoing issues identified were related to privacy, data collection and coverage of the database. Total product usage was not complete, with one state not being involved.

Distribution of Haemophilia by severity 2007

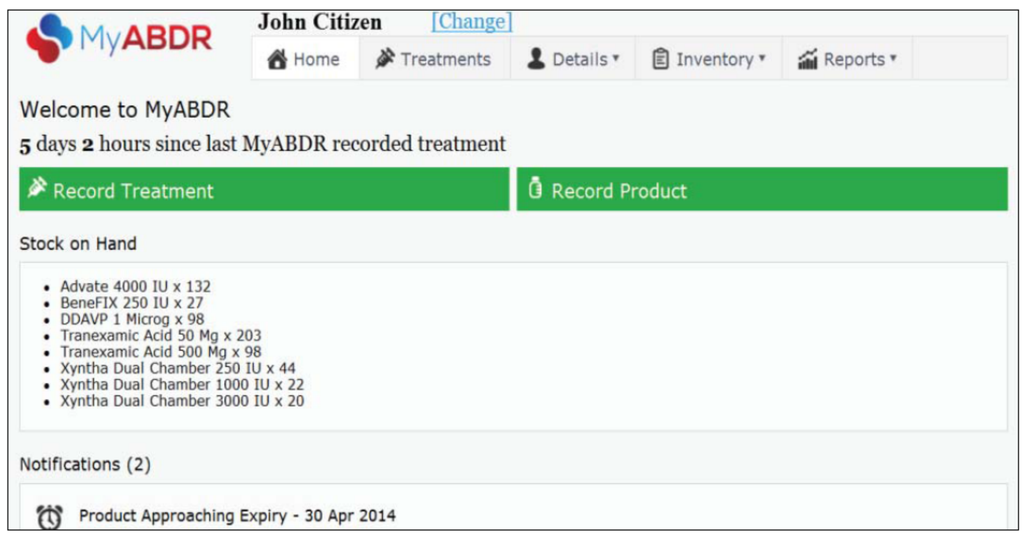
Severity	Haemophilia A(%)	Haemophilia B(%)
Mild (>5%)	683 (49)	183 (52)
Moderate (2-5%)	217 (15)	93 (27)
Severe (<2%)	509 (36)	73 (21)
TOTAL	**1,410 (1 unknown)**	**350 (1 unknown)**

Product use (units) among Haemophilia patients by treatment regimen in 2007

Products	Total	Prophylaxis	On demand
rFVIII	86,737,956	58,707,650	28,030,306
pdFVIII	9,968,000	4,587,250	5,380,750
TOTAL FVIII	96,705,956	63,294,900	33,411,056
rFIX	10,751,350	4,854,350	5,897,000
pdFIX	2,869,750	1,406,000	1,463,750

In HMA, pdFVIII was 10% of total use and for HMB pdFIX was 21% of total use. On Demand regimen was 34% of total use in HMA and 54% of total use for HMB.

Example of MyABDR data entry screen



PHASE 3

The National Blood Authority (NBA) was established in 2003 and in 2007 it was proposed to develop the ABDR further with a web based clinical registry.

Funding from Australian governments via the NBA allowed updating of the database. Widespread consultation was undertaken with HTCs to draw up specifications for a clinical database. The project was tendered to a commercial provider to enable 'third party custody' of data. In addition to recording product use as before, the ABDR was intended to support ordering of products in 'real time' by HTCs. Governance of the development and operation was by a steering committee consisting of Australian Haemophilia Centre Directors Organisation (AHCDO), HFA, NBA and jurisdictional representatives.

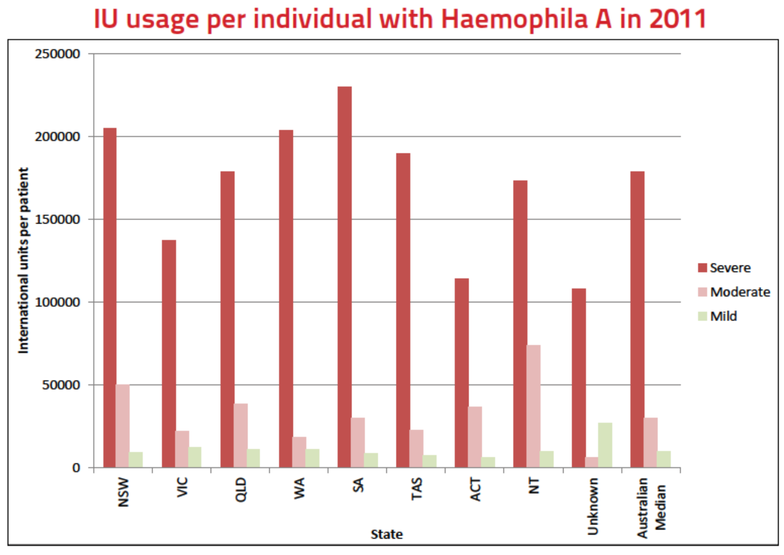
An internet-based, standardised data entry database involving all states was introduced in 2008. The implementation of the database highlighted significant resource and IT issues in HTCs and hospitals with slow response and significant variation of practice between HTCs. This hampered data collection and quality, and capacity to provide reporting for HTCs and to prepare nationalreports.

At this stage annual reports only provided broad information with NBA providing figures for factor usage from other data sources.

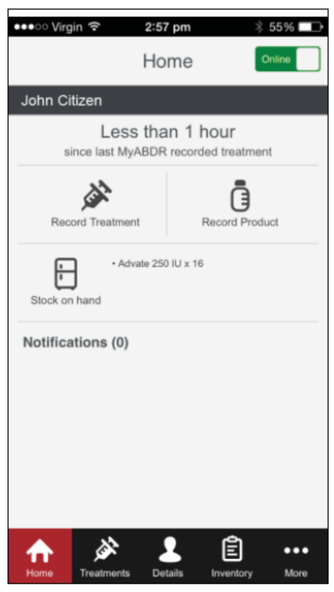
Demographic data as June 2011

	Paediatric 0-19 yrs		Adult 20 yrs & over		Total	
	Number in registry at 30 Jun 2011	Number who received product in 2010-11	Number in registry at 30 Jun 2011	Number who received product in 2010-11	Number in registry at 30 Jun 2011	Number who received product in 2010-11
HmA	**587**	**334**	**1524**	**513**	**2111**	**847**
Severe	289	242	362	256	651	498
Moderate	71	46	190	83	261	129
Mild	219	44	856	171	1075	215
Not applicable	1	0	29	2	30	2
Unknown	7	2	87	1	94	3
HmB	**125**	**57**	**392**	**126**	**517**	**183**
Severe	49	37	54	38	103	75
Moderate	23	16	88	38	111	54
Mild	50	4	226	49	276	53
Not applicable	1	0	3	0	4	0
Unknown	2	0	21	1	23	1
vWD	**446**	**29**	**1520**	**122**	**1966**	**151**
TOTAL	**1158**	**420**	**3436**	**761**	**4594**	**1181**

IU usage per individual with Haemophila A in 2011



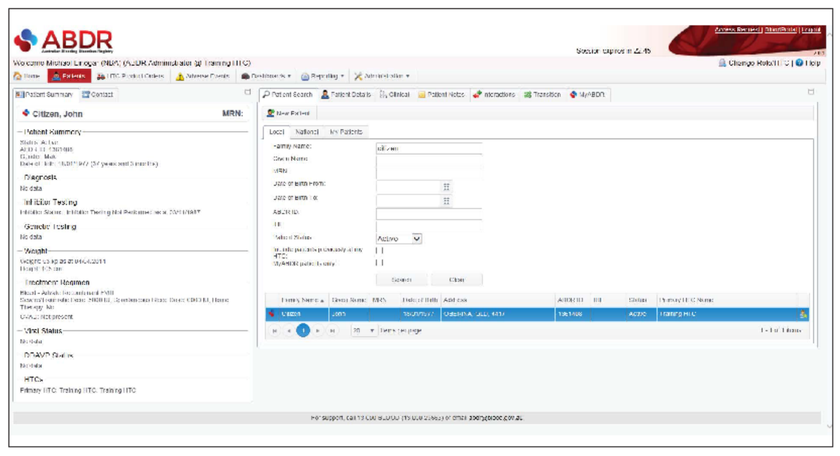
Example of MyABDR App



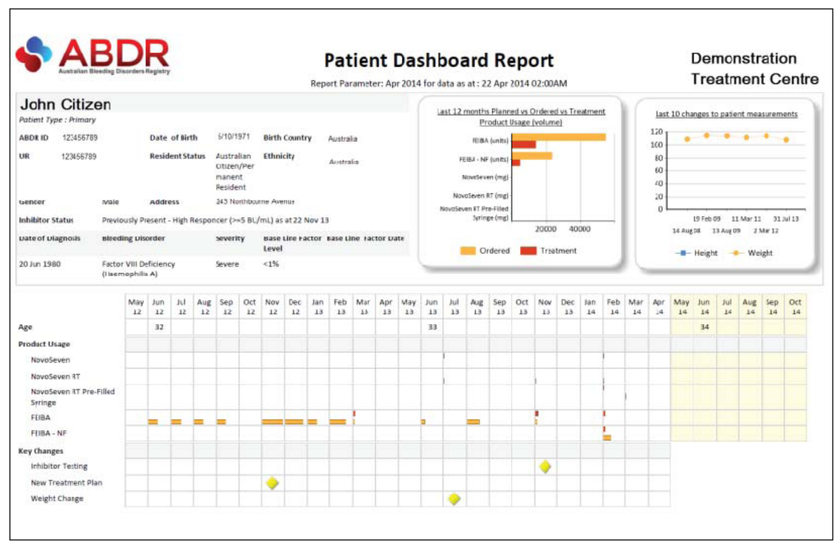
PHASE 4

Issues with the software, and support capacity of the commercial provider, necessitated a different approach. Further funding from all governments via the NBA enabled redevelopment of the ABDR using industry standard software in a 'like for like' development. The NBA is now the data custodian and strict security protocols have been implemented to ensure separation of staff analysing data from those managing the system and to protect privacy. Deficiencies of previous software were addressed with development of online reports to assist HTC management. Further expansion to include data from physiotherapy and social work, counselling pages and adverse events were developed. The 4th generation ABDR was released August 13, 2012. Projects to monitor tolerisation and benchmarking of HTCs are being undertaken.

ABDR Screenshot 1



ABDR Screenshot 2



Demographic data at 30 June 2013 - HTC State

	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	National
HMA	635	591	474	268	294	61	14	54	2,391
HMB	156	156	139	45	51	6	3	8	564
VWD	377	400	505	210	506	63	20	46	2,127
OTHER	123	180	153	102	151	6	6	4	725
TOTAL	**1,291**	**1,327**	**1,271**	**625**	**1,002**	**136**	**43**	**112**	**5,807**

CONCLUSION

The ABDR has evolved and improved with changes in technology and feedback from stakeholders. The system has enabled substantial identification and characterisation of PWHs and significant standardisation of data terminology. There is wide involvement of the range of professionals involved in providing comprehensive care to PWH, including nurses, physiotherapists, social workers and counsellors. Consistent annual reporting has commenced, and benchmarking between HTCs is possible, enabling opportunities for improvement. Adverse event reporting has also commenced. The ABDR has improved communication for patient transfers and movements between HTCs, and also enables improved management external to the HTC, such as at outreach clinics. A key area of focus going forward is the continuous improvement of a robust framework for data governance, maintaining current levels of data security while increasing data integrity, responding to new expectations and requirements for privacy and ethics, and processing increasingly frequent requests for data access. In 2014 the ABDR has entered a new phase with MyABDR – a smartphone application to enable patient input of bleed data and factor usage directly to the ABDR.

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