Bleeding Disorder Statistics for

Wales

April 2013 to March 2014

A report from the National Haemophilia Database

January 2015

The following report is based on patients who are registered with the National Haemophilia Database with a Welsh post code, regardless of which Haemophilia Centre they were treated at.

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New Registrations

Table 1 **New Registrations - Number of patients newly registered between April 2013 & March 2014 showing their coagulation defect and gender**

Coagulation Defect	Male	Female	Total
Haemophilia A	9	0	9
Haemophilia B	3	0	3
Females with VIII deficiency		3	3
Females with IX deficiency		3	3
von Willebrand disease	5	13	18
F.V deficiency	0	1	1
F.XI Deficiency	3	3	6
Dysfibrinogenaemia	2	5	7
Hypofibrinogenaemia	0	1	1
Haemophilia A Carrier		2	2
Acquired Haemophilia A	1	0	1
Platelet defects	8	6	14
Miscellaneous	2	1	3
Unclassified	0	3	3
Platelet-type Pseudo von Willebrand Disease	1	0	1
Multiple Diagnoses	0	0	0
Total	**34**	**41**	**75**

Table 2 **New Registrations of Haemophilia A & B between April 2013 & March 2014, by age and disease severity**

Coagulation Defect	Age (years)	Number of Patients (factor level iu/dl)			
		≤1	>1 & <5	≥5	Total
Haemophilia A	0 : 9	2	0	0	2
	10 : 19	1	0	1	2
	20 : 29	0	0	1	1
	30 : 39	0	0	0	0
	40 : 49	0	0	1	1
	50 : 59	0	0	1	1
	60 : 69	0	0	0	0
	70 : +	0	0	2	2
Total		**3**	**0**	**6**	**9**
Haemophilia B	0 : 9	0	2	1	3
	10 : 19	0	0	0	0
	20 : 29	0	0	0	0
	30 : 39	0	0	0	0
	40 : 49	0	0	0	0
	50 : 59	0	0	0	0
	60 : 69	0	0	0	0
	70 : +	0	0	0	0
Total		**0**	**2**	**1**	**3**

N.B Age taken from mid-year, 30/09/2013

In Register

Table 3 **In Register – The total number of registered patients with all types of bleeding disorder as of 31st March 2014 and the number treated between April 2013 & March 2014**

Coagulation Defect	In Register			Treated (n)	Treated %
	Males (n)	Females (n)	Total In Reg		
Haemophilia A	257	1	258	134	51.94%
Haemophilia B	58	0	58	38	65.52%
Females with VIII deficiency		36	36	2	5.56%
Females with IX deficiency		14	14	0	0.00%
von Willebrand disease	149	245	394	51	12.94%
Platelet-type Pseudo von Willebrand Disease	1	0	1	0	0.00%
Probable von Willebrands disease	0	1	1	0	0.00%
F.V deficiency	1	2	3	0	0.00%
F.VII deficiency	13	13	26	0	0.00%
F.X deficiency	0	1	1	0	0.00%
F.XI Deficiency	31	45	76	2	2.63%
F.XIII Deficiency	0	1	1	1	100.00%
Fibrinogen Deficiency	5	4	9	2	22.22%
Dysfibrinogenaemia	5	8	13	1	7.69%
Hypofibrinogenaemia	0	1	1	0	0.00%
Combined II+VII+IX+X Deficiency	1	0	1	0	0.00%
Other combined diagnoses	2	10	12	2	16.67%
Haemophilia A Carrier		4	4	0	0.00%
Acquired Haemophilia A	8	4	12	1	8.33%
Acquired von Willebrands	1	0	1	1	100.00%
Glanzmanns Thrombasthenia	0	1	1	0	0.00%
Bernard Soulier	0	2	2	0	0.00%
Platelet defects	30	45	75	6	8.00%
Miscellaneous	3	5	8	0	0.00%
Unclassified	0	4	4	0	0.00%
Totals	**565**	**447**	**1,012**	**241**	

Table 4 In Register – The total number of patients with all diagnoses currently in the register, by Health Board

Coagulation Defect	Abertawe Bro Morgannwg University	Aneurin Bevan	Betsi Cadwaladr University	Cardiff and Vale University	Cwm Taf	Hywel Dda	Powys Teaching	Total
Haemophilia A	62	56	44	47	19	23	7	**258**
Haemophilia B	6	16	9	11	12	3	1	**58**
Females with VIII deficiency	14	3	11	4	2	1	1	**36**
Females with IX deficiency	2	4	1	4	2	0	1	**14**
von Willebrand disease	26	66	153	57	17	27	48	**394**
F.V deficiency	1	1	0	0	0	1	0	**3**
F.VII deficiency	5	1	12	1	0	7	0	**26**
F.X deficiency	0	0	1	0	0	0	0	**1**
F.XI Deficiency	12	37	11	5	4	7	0	**76**
F.XIII Deficiency	0	0	1	0	0	0	0	**1**
Fibrinogen Deficiency	1	1	2	4	1	0	0	**9**
Dysfibrinogenaemia	2	1	1	9	0	0	0	**13**
Hypofibrinogenaemia	0	0	0	0	1	0	0	**1**
Combined II+VII+IX+X Deficiency	0	0	0	1	0	0	0	**1**
Haemophilia A Carrier	0	1	2	1	0	0	0	**4**
Acquired Haemophilia A	3	2	3	3	0	1	0	**12**
Acquired von Willebrands	0	1	0	0	0	0	0	**1**
Glanzmanns Thrombasthenia	0	0	0	0	0	1	0	**1**
Bernard Soulier	0	0	1	1	0	0	0	**2**
Platelet defects	10	13	17	19	9	3	4	**75**
Platelet-type Pseudo von Willebrand Disease	0	0	0	0	0	0	1	**1**
Probable von Willebrands disease	0	0	1	0	0	0	0	**1**
Combined diagnoses	3	2	3	1	1	0	2	**12**
Miscellaneous	1	2	2	1	1	0	1	**8**
Unclassified	1	1	0	0	1	1	0	**4**
Total	**149**	**208**	**275**	**169**	**70**	**75**	**66**	**1,012**

Table 5 **In Register – The total number of patients with Haemophilia A & B currently in the register, by severity and age group**

Coagulation Defect	Age Range	Factor level iu/dl			Total
		≤ 1	>1 & <5	≥ 5	
Haemophilia A	<18 years	25	8	25	**58**
	≥18 years	53	22	125	**200**
Sub Total		**78**	**30**	**150**	**258**
Haemophilia B	<18 years	2	6	9	**17**
	≥18 years	12	11	18	**41**
Sub Total		**14**	**17**	**27**	**58**

Table 6 **In Register – The total number of patients with Von Willebrand Disease currently in the register, by disease severity, age group and gender**

von Willebrand disease	<18 years (VWD Activity iu/dl)				≥18 years (VWD Activity iu/dl)				Total
	<30	≥30	N/K	Sub Total	<30	≥30	N/K	Sub Total	
	Males								
Type 1	5	7	1	**13**	26	20	2	**48**	**61**
Type 2A	0	0	0	**0**	1	3	0	**4**	**4**
Type 2B	0	0	0	**0**	1	0	0	**1**	**1**
Type 2M	0	0	0	**0**	4	0	0	**4**	**4**
Type 2N	0	0	0	**0**	0	0	0	**0**	**0**
Type 2 Unspecified	0	0	0	**0**	1	0	0	**1**	**1**
Type 3	2		0	**2**	0		0	**0**	**2**
Type Unreported	7	4	1	**12**	40	23	1	**64**	**76**
Sub Total				**27**				**122**	**149**
	Females								
Type 1	10	2	0	**12**	33	50	0	**83**	**95**
Type 2A	1	1	0	**2**	4	7	0	**11**	**13**
Type 2B	0	0	0	**0**	1	2	0	**3**	**3**
Type 2M	0	0	0	**0**	5	3	0	**8**	**8**
Type 2N	0	0	0	**0**	0	2	0	**2**	**2**
Type 2 Unspecified	0	0	0	**0**	3	0	0	**3**	**3**
Type 3	0		0	**0**	1		0	**1**	**1**
Type Unreported	8	4	1	**13**	45	58	4	**107**	**120**
Sub Total				**27**				**218**	**245**
Grand Total				**54**				**340**	**394**

Table 7 **In Register – The number of patients with selected rarer bleeding disorders currently registered and the number treated between April 2013 & March 2014, by disease severity**

Coagulation Defect	Number of Patients (factor level iu/dl)							
	<5		≥5		N/K		Total	
	In Reg	Treated	In Reg	Treated	In Reg	Treated	In Reg	Treated
F.V deficiency	0	0	3	0	0	0	3	0
F.VII deficiency	1	0	25	0	0	0	26	0
F.X deficiency	0	0	1	0	0	0	1	0
F.XI Deficiency	2	1	74	0	0	0	76	1
Total	**3**	**1**	**103**	**0**	**0**	**0**	**106**	**1**

Coagulation Defect	<2		≥2		N/K		Total	
	In Reg	Treated	In Reg	Treated	In Reg	Treated	In Reg	Treated
F.XIII Deficiency	1	1	0	0	0	0	1	1
Total	**1**	**1**	**0**	**0**	**0**	**0**	**1**	**1**

Table 8 Inhibitors by disease severity

Coagulation Defect	Inhibitor Status	≤ 1 iu/dl			>1 and <5 iu/dl			≥ 5 iu/dl		
		In Reg *	Inhib. Pts	%	In Reg *	Inhib. Pts	%	In Reg *	Inhib. Pts	%
Haemophilia A	Inhibitor ever reported	78	22	28.21%	30	0	0.00%	150	9	6.00%
	Inhibitor still present		10	12.82%		0	0.00%		5	3.33%
Haemophilia B	Inhibitor ever reported	14	0	0.00%	17	0	0.00%	27	0	0.00%
	Inhibitor still present		0	0.00%		0	0.00%		0	0.00%

** Including patients not regularly treated*

N.B. There are no patients with VWD and a history of or a current inhibitor

Treatment

Treatment by Region and Health Board

Table 9 **Patients with a Welsh postcode, treated between April 2013 & March 2014, all severities, by diagnosis and treatment region**

Coagulation Defect	Region	Patients Treated (n)
Haemophilia A	Cheshire, Warrington & Wirral	16
	London	1
	Wales	**119**
Haemophilia B	Cheshire, Warrington & Wirral	6
	South Yorkshire & Bassetlaw	1
	Wales	**32**
von Willebrand disease	Birmingham & Black Country	1
	Cheshire, Warrington & Wirral	3
	Wales	**48**
Females with VIII deficiency	**Wales**	**2**
F.XI Deficiency	**Wales**	**2**
F.XIII Deficiency	Cheshire, Warrington & Wirral	1
Fibrinogen Deficiency	Cheshire, Warrington & Wirral	**1**
	Wales	**1**
Dysfibrinogenaemia	**Wales**	**1**
Combined diagnoses	**Wales**	**2**
Acquired Haemophilia A	**Wales**	**1**
Acquired von Willebrands	**Wales**	**1**
Platelet defects	**Wales**	**6**
	Total	**245**

N.B This table may contain duplicates where one patient received treatment from more than one region

Tables 9 & 10 show the number of patients with a Welsh postcode treated and the Region which issued the treatment.

Table 10 Factor VIII usage by region for *Severe Haemophilia A* patients only (incl. treatment for inhibitors)

Region	Patients treated (n) Severe Haemophilia A	Total FVIII Units Severe Haemophilia A	Mean Usage Severe Haemophilia A
Cheshire, Warrington & Wirral	12	1,966,500	163,875
Wales	66	13,424,750	203,405
	78	**15,391,250**	**197,324**

N.B This table may contain duplicates where a patient received treatment from more than one region

Table 11 Factor VIII usage by Health Board for *Severe Haemophilia A* patients only (incl. treatment for inhibitors)

Health Board	General Population *	Patients treated (n) Severe Haemophilia A	Total FVIII Units Severe Haemophilia A	Mean Usage Severe Haemophilia A	FVIII Units Per Capita Severe Haemophilia A
Abertawe Bro Morgannwg University Local Health Board	499,379	16	3,472,000	217,000	6.95
Aneurin Bevan Local Health Board	560,483	15	2,862,750	190,850	5.11
Betsi Cadwaladr University Local Health Board	678,543	20	4,802,750	240,138	7.08
Cardiff and Vale University Local Health Board	445,017	11	2,231,500	202,864	5.01
Cwm Taf Local Health Board	289,353	7	1,131,000	161,571	3.91
Hywel Dda Local Health Board	375,237	6	452,250	75,375	1.21
Powys Teaching Local Health Board	131,963	1	439,000	439,000	3.33
Wales	**2,979,975**	**76**	**15,391,250**	**202,516**	**5.16**

** Source data: Office for National Statistics (ONS): Mid Year Population Estimates 2007*

Table 12 Factor IX usage by region for *Severe Haemophilia B* patients only (incl. treatment for inhibitors)

Region	Patients treated (n) Severe Haemophilia B	Total FIX Units Severe Haemophilia B	Mean Usage Severe Haemophilia B
Cheshire, Warrington & Wirral	1	60,000	60,000
South Yorkshire & Bassetlaw	1	22,000	22,000
Wales	13	2,124,016	163,386
	15	**2,206,016**	**147,068**

N.B This table may contain duplicates where a patient received treatment from more than one region

Table 13 Factor IX usage by Health Board for *Severe Haemophilia B* patients only (incl. treatment for inhibitors)

Health Board	General Population *	Patients treated (n) Severe Haemophilia B	Total FVIII Units Severe Haemophilia B	Mean Usage Severe Haemophilia B	FVIII Units Per Capita Severe Haemophilia B
Abertawe Bro Morgannwg University Local Health Board	499,379	2	126,440	63,220	0.25
Aneurin Bevan Local Health Board	560,483	5	687,000	137,400	1.23
Betsi Cadwaladr University Local Health Board	678,543	1	60,000	60,000	0.09
Cardiff and Vale University Local Health Board	445,017	1	452,000	452,000	1.02
Cwm Taf Local Health Board	289,353	4	805,528	201,382	2.78
Hywel Dda Local Health Board	375,237	1	75,048	75,048	0.20
Powys Teaching Local Health Board	131,963	0	0	0	0.00
Wales	**2,979,975**	**14**	**2,206,016**	**157,573**	**0.74**

** Source data: Office for National Statistics (ONS): Mid Year Population Estimates 2007*

Haemophilia A and Factor VIII use

Table 14 Factor VIII units used by patients with a Welsh postcode

Coagulation Defect	Patients Treated	Plasma FVIII (IU)	Recombinant FVIII (IU)	Total FVIII (IU)
Haemophilia A	120	1,275,000	16,689,500	17,964,500
Females with VIII deficiency	1	-	4,000	4,000
von Willebrand disease	29	381,820	-	381,820
Acquired von Willebrands	1	9,000	-	9,000
Total	**151**	**1,665,820**	**16,693,500**	**18,359,320**

Table 15 Products used to treat Haemophilia A (including inhibitors)

Manufacturer	Product	Total Units
Baxter	Advate	1,709,750
	FEIBA	1,095,000
Bayer	Kogenate	6,237,000
BPL	Optivate	264,000
CSL Behring	Helixate Nexgen	327,750
Grifols	Fanhdi	1,011,000
Novo Nordisk	NovoSeven (mg)	707
Pfizer	ReFacto AF	7,451,000
	Investigational Factor VIII	964,000

Units in IU unless otherwise stated

Potentially anomalous product use is accounted for as follows: -

BPL Optivate was administered to a single patient undergoing immune tolerance induction.

Figure 1 **Market share of factor VIII concentrates known to have been issued to patients with a Welsh postcode between April 2013 & March 2014**

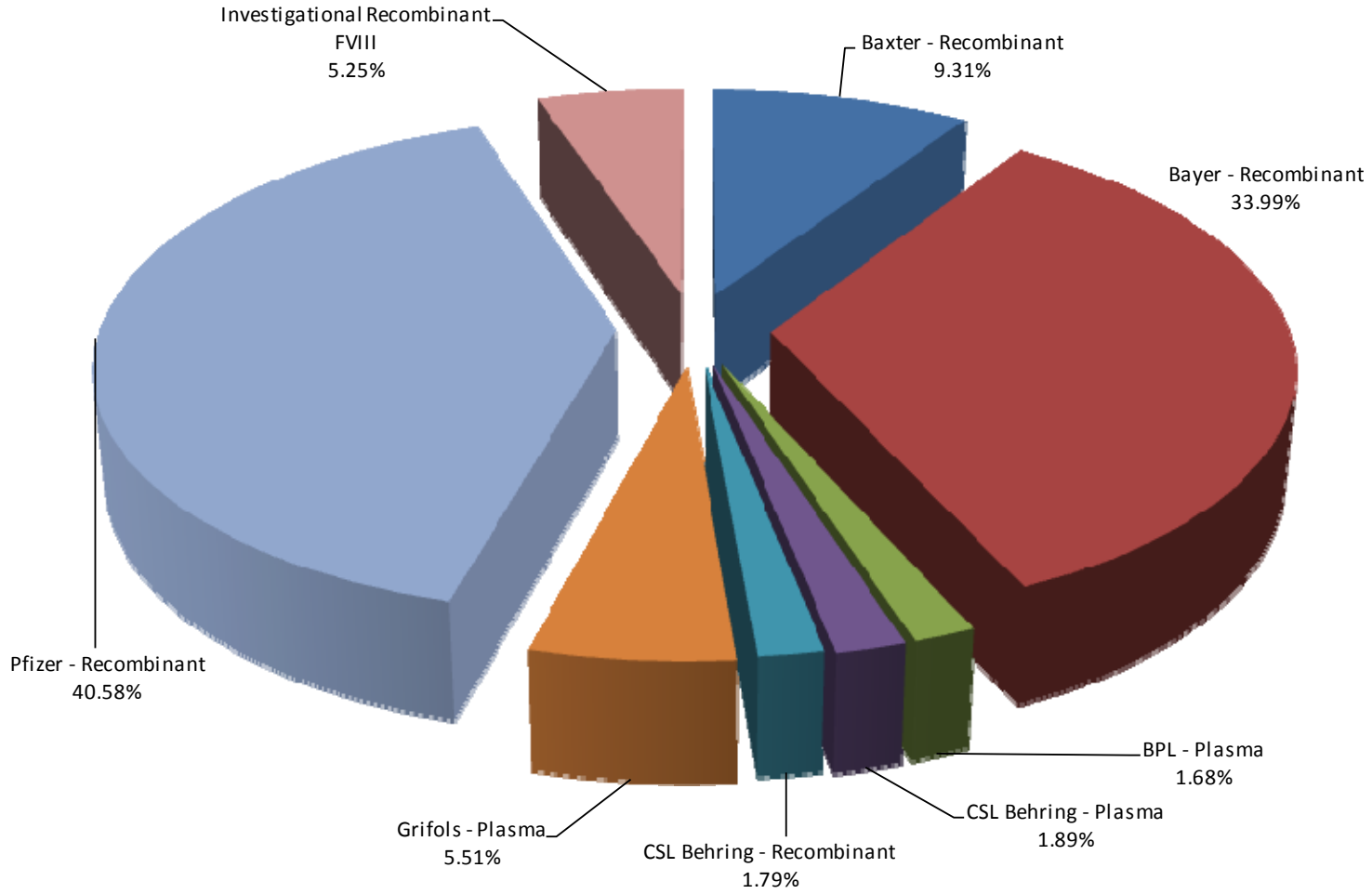

Figure 2 **Factor VIII units by financial year from April 2008 – March 2014 – all diagnoses, all severities**

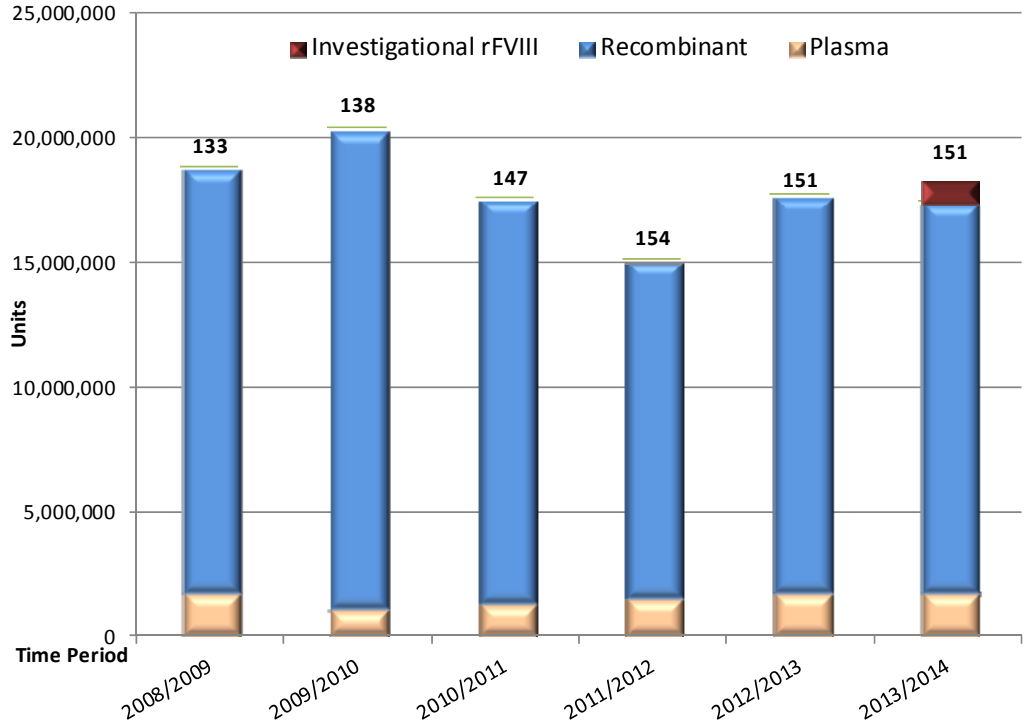

Figure 3 **Factor VIII units by financial year from April 2008 –March 2014 – *Severe Haemophilia A only***

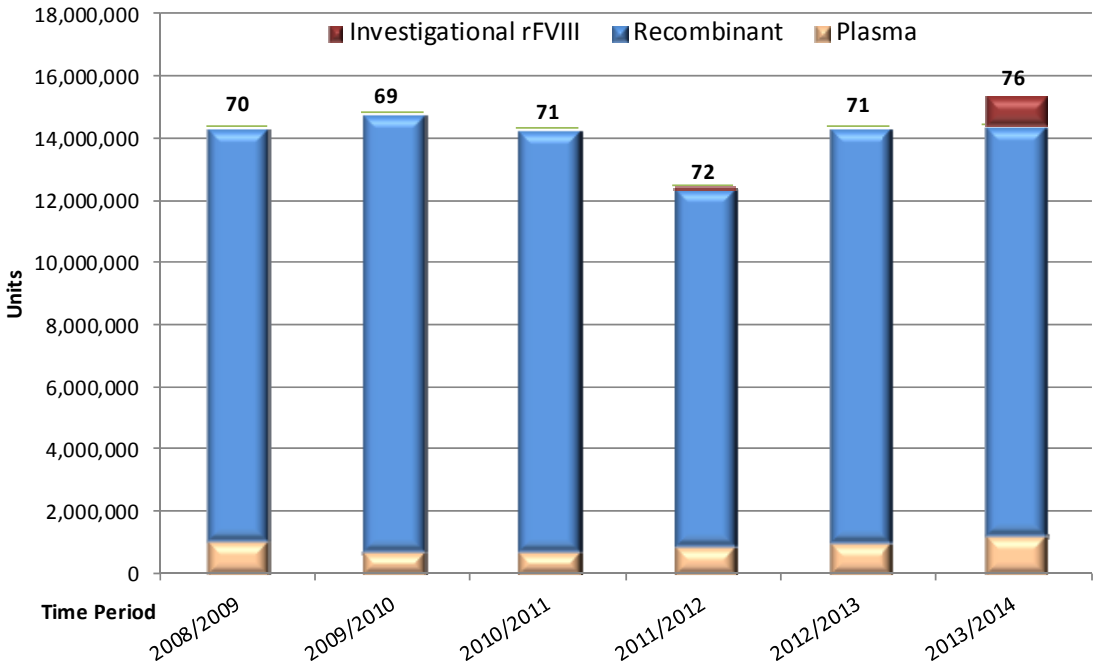

Table 16 Data table related to Figure 2 - Factor VIII units by financial year from April 2008 –March 2014

Year	Plasma		Recombinant		Investigational rFVIII		Total		Patients	
	IU	% difference since 2008/09	IU	% difference since 2008/09	IU	% difference since 2011/12	IU	% difference since 2008/09	n	% difference since 2008/09
2008/2009	1,697,005	100.00%	17,093,342	100.00%	0		18,790,347	100.00%	133	100.00%
2009/2010	1,083,410	63.84%	19,234,286	112.53%	0		20,317,696	108.13%	138	103.76%
2010/2011	1,272,665	74.99%	16,234,282	94.97%	0		17,506,947	93.17%	147	110.53%
2011/2012	1,490,895	87.85%	13,534,738	79.18%	121,000	100.00%	15,146,633	80.61%	154	115.79%
2012/2013	1,684,650	99.27%	15,992,092	93.56%	0	0.00%	17,676,742	94.07%	151	113.53%
2013/2014	1,665,820	98.16%	15,729,500	92.02%	964,000	796.69%	18,359,320	97.71%	151	113.53%

Table 17 Data table related to Figure 3 - Factor VIII units by financial year from April 2008 –March 2014 – *Severe Haemophilia A only*

Year	Plasma		Recombinant		Investigational rFVIII		Total		Patients	
	IU	% difference since 2008/09	IU	% difference since 2008/09	IU	% difference since 2011/12	IU	% difference since 2008/09	n	% difference since 2008/09
2008/2009	1,116,000	100.00%	13,223,382	100.00%	0		14,339,382	100.00%	70	100.00%
2009/2010	758,000	67.92%	14,077,104	106.46%	0		14,835,104	103.46%	69	98.57%
2010/2011	744,560	66.72%	13,572,324	102.64%	0		14,316,884	99.84%	71	101.43%
2011/2012	930,000	83.33%	11,509,738	87.04%	121,000	100.00%	12,560,738	87.60%	72	102.86%
2012/2013	1,009,150	90.43%	13,344,592	100.92%	0	0.00%	14,353,742	100.10%	71	101.43%
2013/2014	1,275,000	114.25%	13,152,250	99.46%	964,000	796.69%	15,391,250	107.34%	76	108.57%

Haemophilia B and Factor IX use

Table 18 Factor IX units used by patients with a Welsh postcode

Coagulation Defect	Patients Treated	Plasma FIX (IU)	Recombinant FIX (IU)	Total FIX (IU)
Haemophilia B	38	274,000	3,296,536	3,570,536

Table 19 Products used to treat Haemophilia B (including inhibitors)

Manufacturer	Product	Total Units
CSL Behring	Mononine	274,000
Pfizer	BeneFIX	2,947,520
	Investigational Factor IX	349,016

Units in IU unless otherwise stated

Figure 4 Market share of factor IX concentrates known to have been issued to patients with a Welsh postcode between April 2013 & March 2014

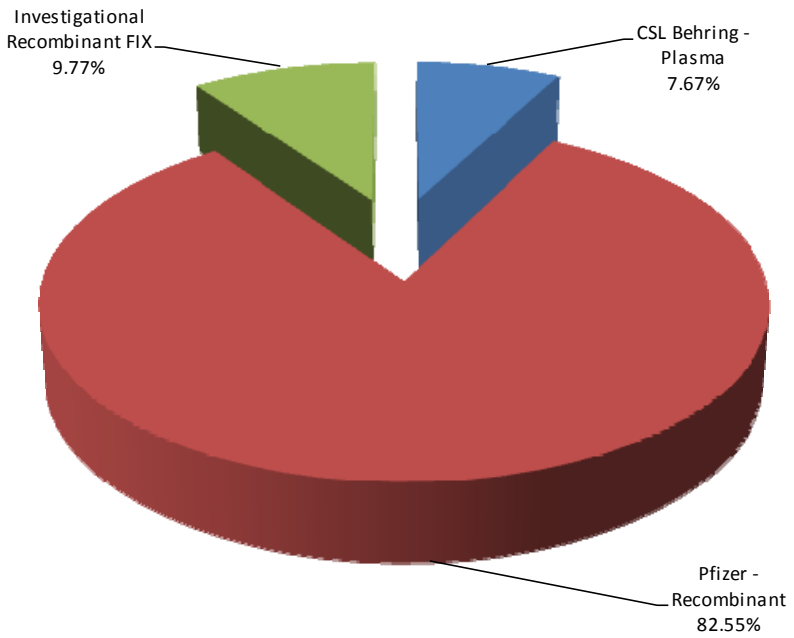

Figure 5 **Factor IX units by financial year from April 2008 –March 2014 – all diagnoses, all severities**

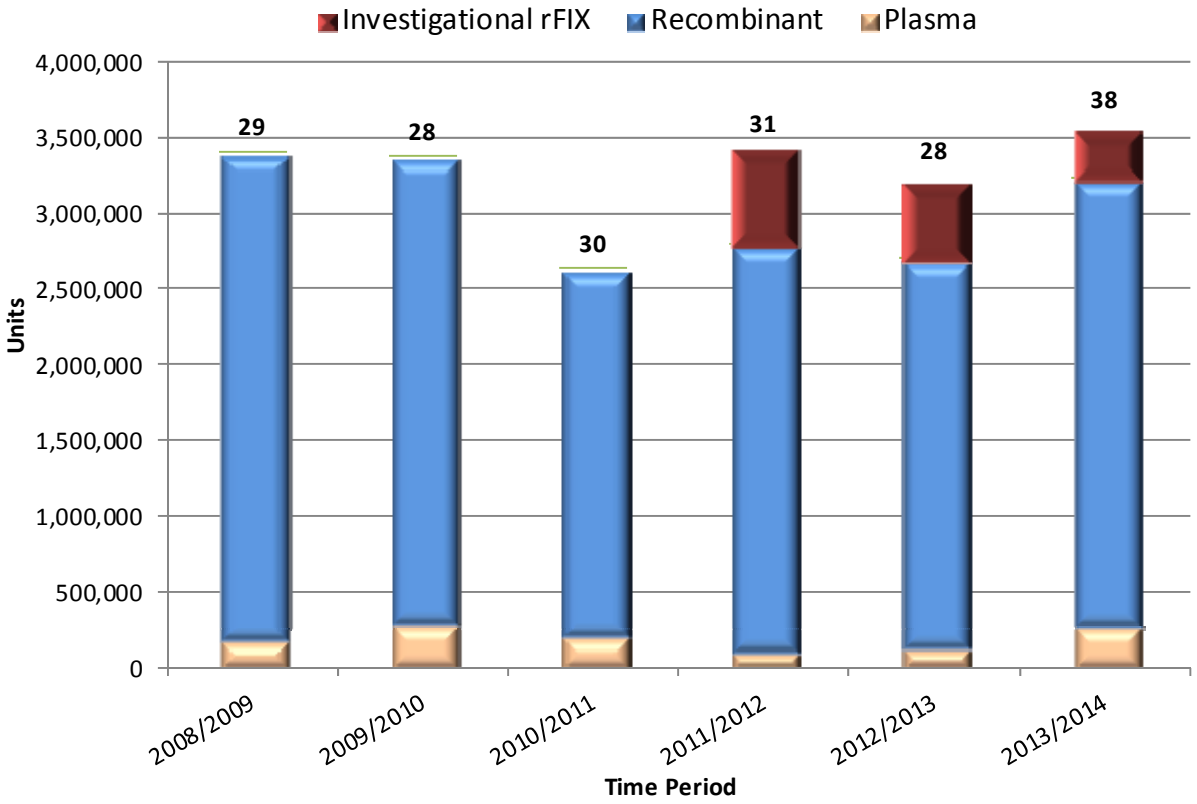

Table 20 Data table related to figure 5 - Factor IX units by financial year from April 2008 –March 2014

Year	Plasma		Recombinant		Investigational rFIX		Total		Patients	
	IU	% difference since 2008/09	IU	% difference since 2009/10	IU	% difference since 2011/12	IU	% difference since 2008/09	n	% difference since 2008/09
2008/2009	185,000	100.00%	3,213,000	100.00%	0		3,398,000	100.00%	29	100.00%
2009/2010	294,000	158.92%	3,071,500	95.60%	0		3,365,500	99.04%	28	96.55%
2010/2011	212,000	114.59%	2,413,000	75.10%	0		2,625,000	77.25%	30	103.45%
2011/2012	106,000	57.30%	2,679,500	83.40%	647,689	100.00%	3,433,189	101.04%	31	106.90%
2012/2013	133,000	71.89%	2,562,000	79.74%	517,180	79.85%	3,212,180	94.53%	28	96.55%
2013/2014	274,000	148.11%	2,947,520	91.74%	349,016	53.89%	3,570,536	105.08%	38	131.03%

Von Willebrand Disease, Rarer Bleeding Disorders and Acquired Defects

Table 21 Concentrates used to treat von Willebrand Disease

Manufacturer	Product	Total Units
BPL	FVIII 8Y	43,820
CSL Behring	Haemate P	338,000

Table 22 Concentrates used to treat Rarer Bleeding Disorders

Manufacturer	Product	F.XI Deficiency	F.XIII Deficiency
		Units	Units
BPL	FXI	4,320	-
CSL Behring	Fibrogammin P	-	14,500
Novo Nordisk	NovoSeven (mg)	11	-

Units in IU unless otherwise stated

Table 23 Concentrates used to treat Acquired Defects

Manufacturer	Product	Acquired Haemophilia A	Acquired von Willebrands
		Units	Units
Baxter	FEIBA	75,000	-
CSL Behring	Haemate P	-	9,000

Deaths and Adverse Events

Table 24 Causes of Death

Diagnosis	Cause of Death	Severity (factor level iu/dl)				Total
		≤1	>1 and <5	≥5	N/K	
Haemophilia A	Carcinoma	0	0	1	0	**1**
	Ischaemic Heart Disease	0	0	1	0	**1**
	Liver Failure	0	0	1	0	**1**
Haemophilia B	Infection (Bacterial)	0	0	1	0	**1**
von Willebrand disease	Infection (Bacterial)	0	0	2	0	**2**
	Liver Failure	0	0	1	0	**1**
	Unknown	0	0	1	0	**1**
Combined diagnoses	Carcinoma	0	0	1	0	**1**
Acquired Haemophilia A	Infection (Bacterial)	0	0	0	1	**1**
	Ischaemic Heart Disease	0	0	0	1	**1**
Other platelet defects	Infection (Bacterial)	0	0	0	1	**1**
		0	**0**	**9**	**3**	**12**

Table 25 Adverse Events

Adverse Event	Number of Events
Allergy Event	0
Infection Event	0
Inhibitor Event	1
Malignancy Event	0
Other Event	0
Poor Efficacy Event	0
Thrombotic Event	0
Total	**1**