

HemoRec in Poland

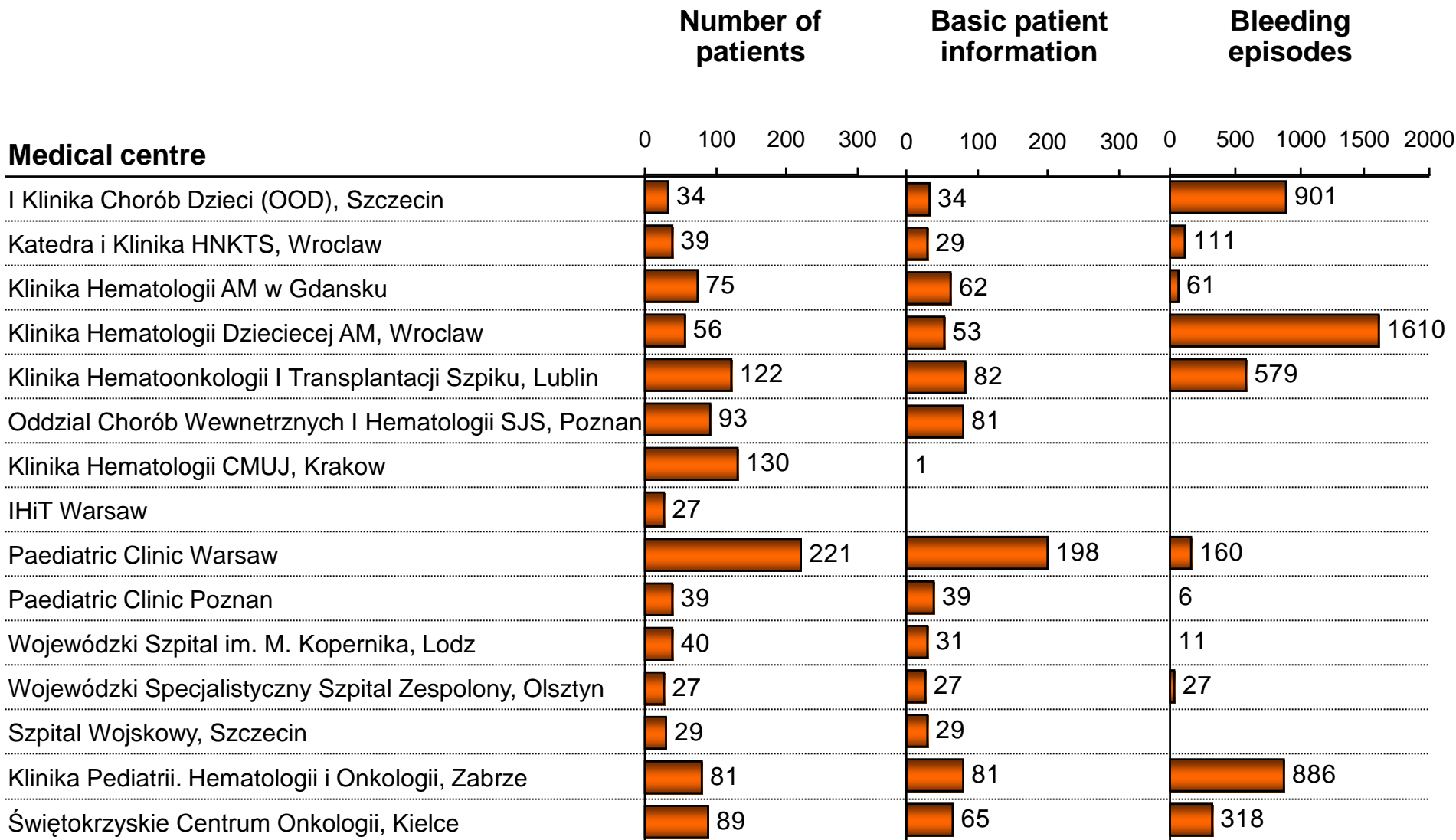
**Summary of bleeding episodes of haemophilia patients
with inhibitor recorded in the years 2008 and 2009**

04/2010

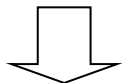


Participating centres:

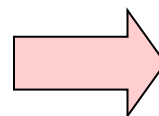
1. I Klinika Chorób Dzieci (OOD). Szczecin
2. Katedra i Klinika HNKTS. Wrocław
3. Klinika Hematologii AM w Gdańsku
4. Klinika Hematologii Dziecięcej AM. Wrocław
5. Klinika Hematoonkologii I Transplantacji Szpiku. Lublin
6. Oddział Chorób Wewnętrznych I Hematologii SJS. Poznań
7. Klinika Hematologii CMUJ. Kraków
8. IHiT Warsaw
9. Paediatric Clinic Warsaw
10. Paediatric Clinic Poznań
11. Wojewódzki Szpital im. M. Kopernika. Łódź
12. Wojewódzki Specjalistyczny Szpital Zespólny. Olsztyn
13. Szpital Wojskowy. Szczecin
14. Klinika Pediatrii, Hematologii i Onkologii. Zabrze
15. Świętokrzyskie Centrum Onkologii. Kielce



Overall number of patients registered in Polish centres: **N = 1102**
(as of 17/08/2009)



Diagnosis	N	%
Haemophilia A	707	67.9
Haemophilia B	124	11.9
Haemophilia A with inhibitor	105	10.1
Von Willebrand disease	51	4.9
Coagulation factor deficiency	43	4.1
Haemophilia B with inhibitor	5	0.5
Haemophilia A & Haemophilia B	3	0.3
Haemophilia A & Von Willebrand disease, type other	1	0.1
Haemophilia A with inhibitor & Haemophilia B with inhibitor	1	0.1
Haemophilia A with inhibitor & Von Willebrand disease, type unknown	1	0.1
Haemophilia B & Von Willebrand disease, type 1	1	0.1
Total	1042*	100.0



Overall number of patients with inhibitor:
N = 112

* Diagnosis is not filled for 60 patients.

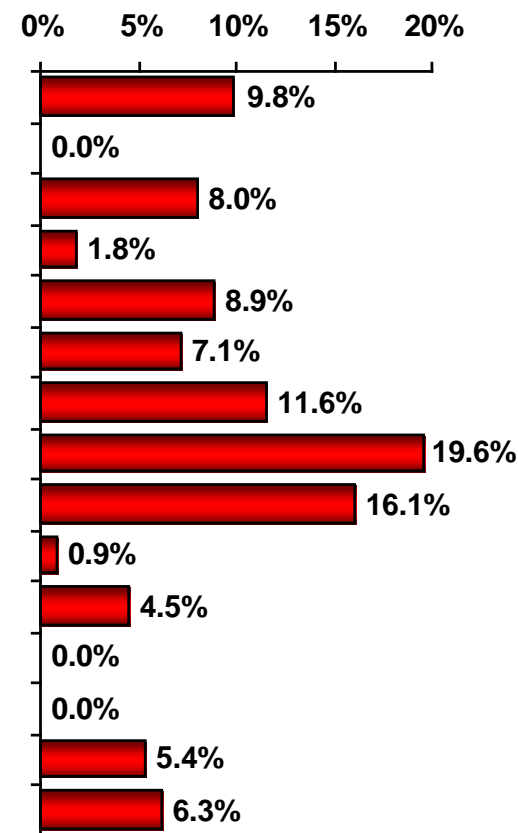
Number of patients according to centres

Overall number of patients registered in Polish centres: **N = 1102**

Overall number of patients with inhibitor : **N = 112**

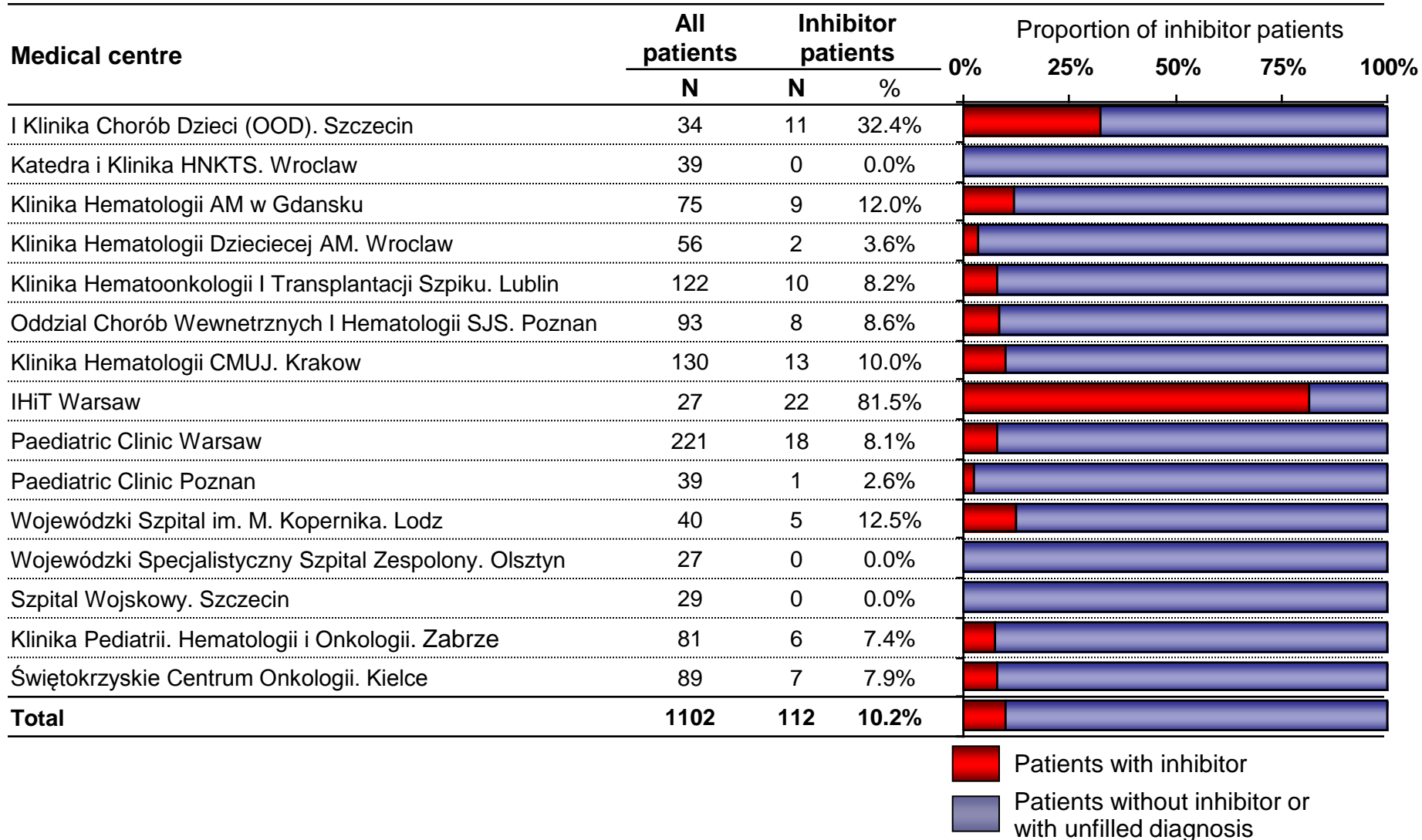
Medical centre	All patients		Inhibitor patients	
	N	%	N	%
I Klinika Chorób Dzieci (OOD). Szczecin	34	3.1	11	9.8
Katedra i Klinika HNKTS. Wroclaw	39	3.5	0	0.0
Klinika Hematologii AM w Gdansk	75	6.8	9	8.0
Klinika Hematologii Dzieciecej AM. Wroclaw	56	5.1	2	1.8
Klinika Hematoonkologii I Transplantacji Szpiku. Lublin	122	11.1	10	8.9
Oddzial Chorób Wewnetrznych I Hematologii SJS. Poznan	93	8.4	8	7.1
Klinika Hematologii CMUJ. Krakow	130	11.8	13	11.6
IHiT Warsaw	27	2.5	22	19.6
Paediatric Clinic Warsaw	221	20.1	18	16.1
Paediatric Clinic Poznan	39	3.5	1	0.9
Wojewódzki Szpital im. M. Kopernika. Lodz	40	3.6	5	4.5
Wojewódzki Specjalistyczny Szpital Zespolony. Olsztyn	27	2.5	0	0.0
Szpital Wojskowy. Szczecin	29	2.6	0	0.0
Klinika Pediatrii. Hematologii i Onkologii. Zabrze	81	7.4	6	5.4
Świętokrzyskie Centrum Onkologii. Kielce	89	8.1	7	6.3
Total	1102	100.0	112	100.0

Distribution of inhibitor patients



Proportion of inhibitor patients

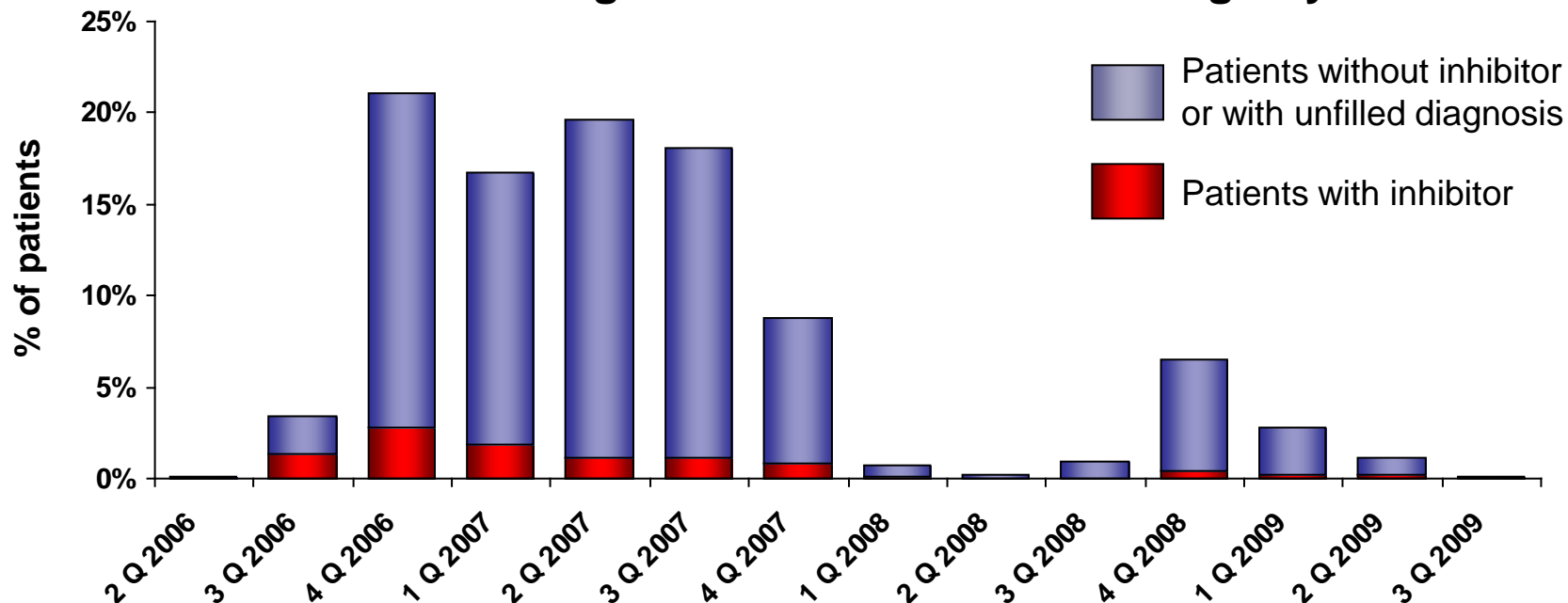
Overall number of registered patients with inhibitor : **N = 112**



Overall number of patients registered in Polish centres: **N = 1102**

Overall number of patients with inhibitor : **N = 112**

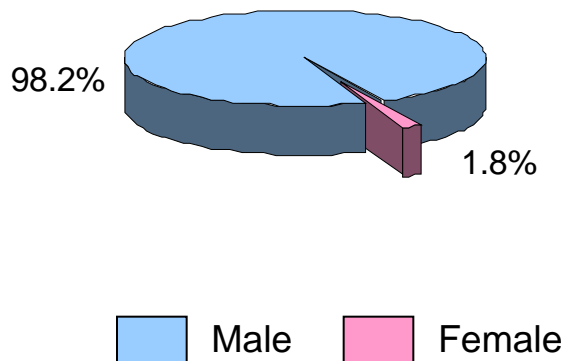
Date of registration in the HemoRec registry



Inhibitor	2 Q 2006	3 Q 2006	4 Q 2006	1 Q 2007	2 Q 2007	3 Q 2007	4 Q 2007	1 Q 2008	2 Q 2008	3 Q 2008	4 Q 2008	1 Q 2009	2 Q 2009	3 Q 2009	Total
yes	0	15	31	21	13	13	9	1	0	0	5	2	2	0	112
no or N/A	1	22	201	163	203	186	88	7	2	10	67	29	10	1	990
Total	1	37	232	184	216	199	97	8	2	10	72	31	12	1	1102

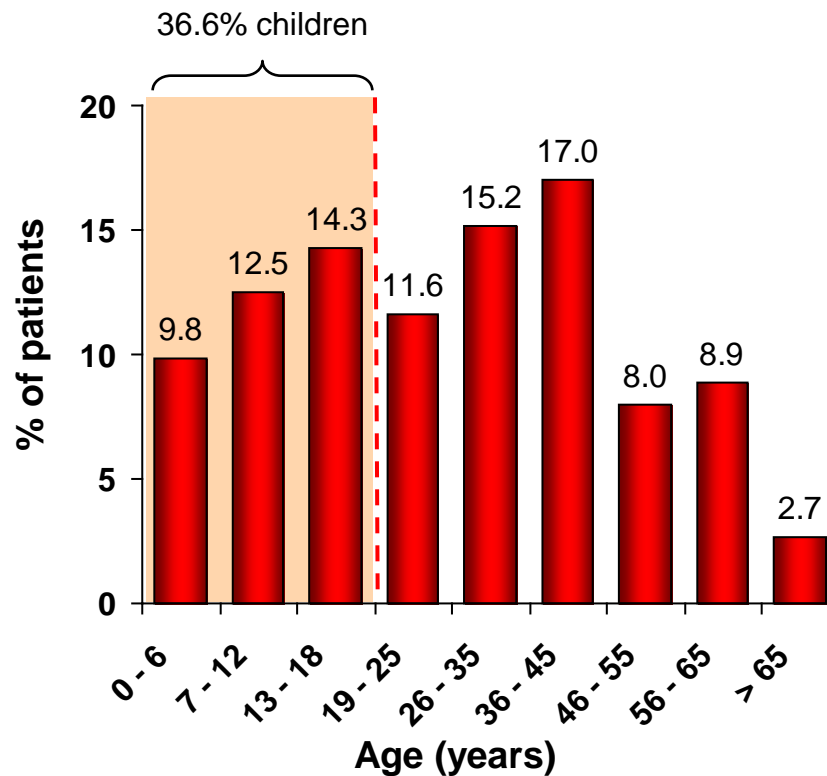
Overall number of patients with inhibitor : **N = 112**

Sex



	N	%
Male	110	98.2
Female	2	1.8
Total	112	100.0

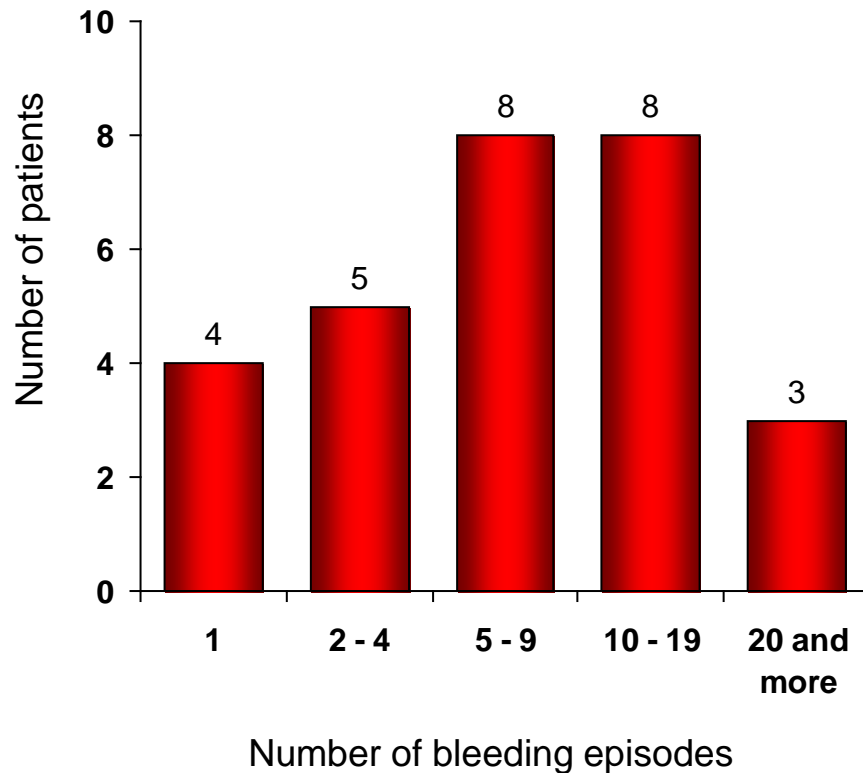
Current age



N	112
Mean	29.6
Median (Min - Max)	28.8 (1.2 – 75.7)

Overall number of recorded bleeding episodes of patients with inhibitor is **270** (for 28 different patients).

Number of episodes per patient



Location of bleeding

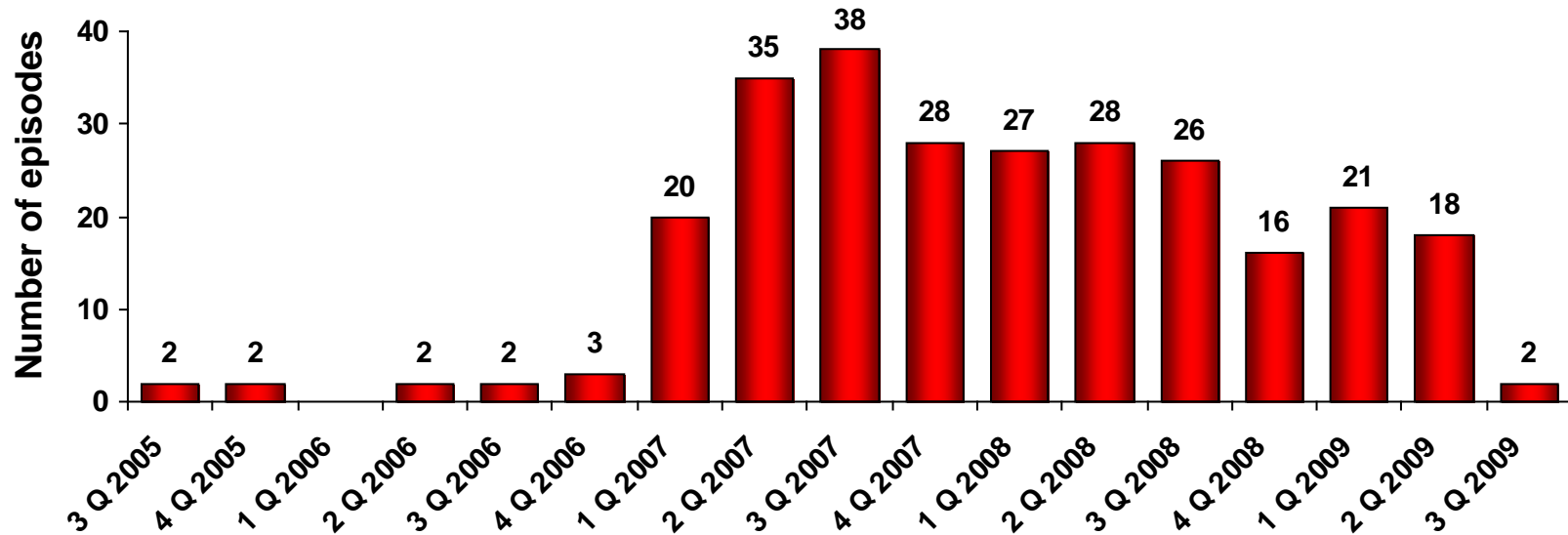
	N	%
Joints	175	65.8
<i>Joints & Muscle**</i>	10	3.8
Muscle	32	12.0
<i>Muscle & Subcutaneous**</i>	3	1.1
Head	31	11.7
<i>Head & Torso**</i>	1	0.4
Genital	6	2.3
Subcutaneous	4	1.5
Torso	2	0.8
Skin	1	0.4
<i>Skin & Subcutaneous**</i>	1	0.4
Total	266*	100.0

* Location is not filled for 4 bleeding episodes.

** 15 bleeding episodes (5.6%) were into more than one location

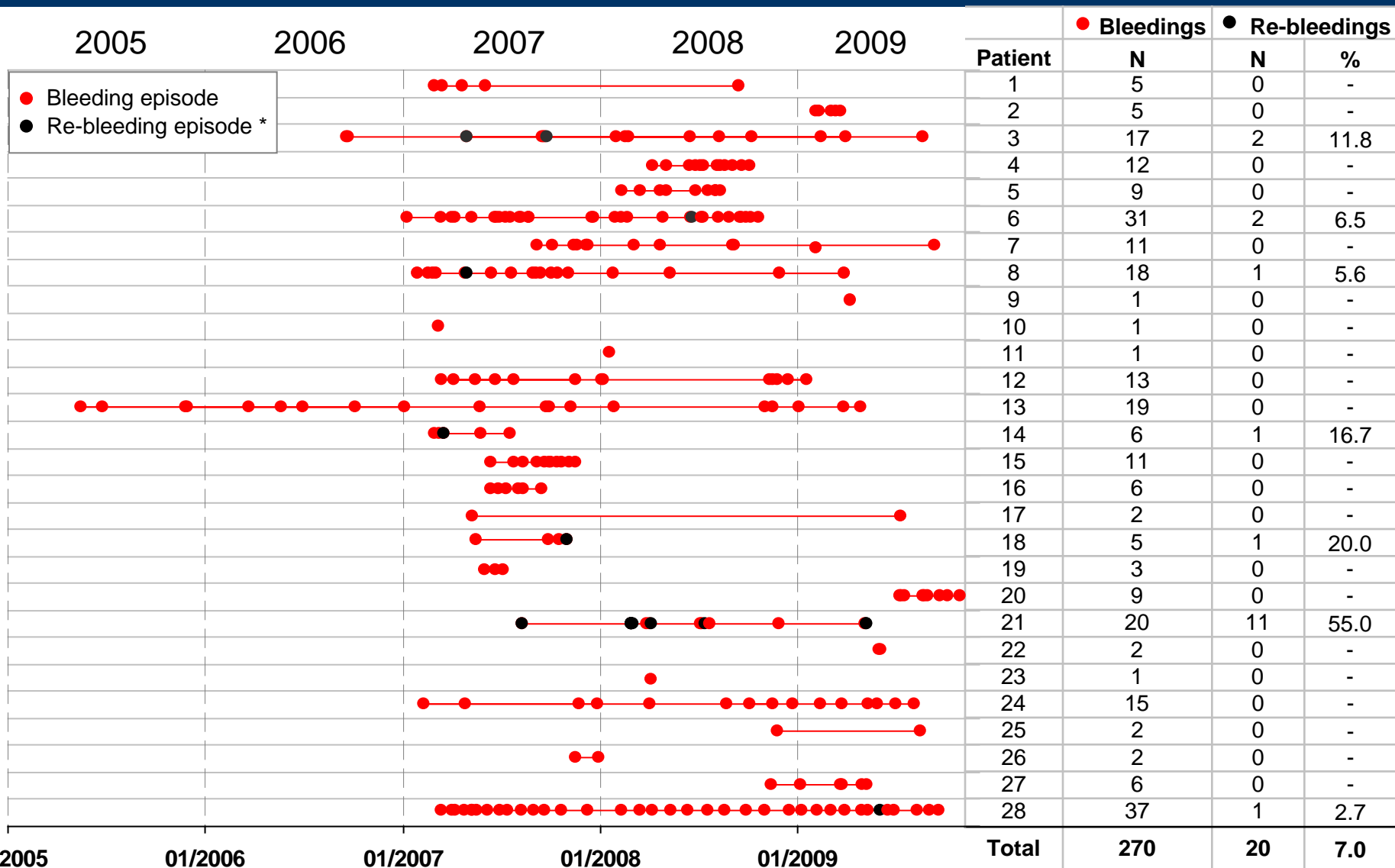
Overall number of recorded bleeding episodes of patients with inhibitor is **270** (for 28 different patients).

Number of recorded bleeding episodes



	3 Q 2005	4 Q 2005	1 Q 2006	2 Q 2006	3 Q 2006	4 Q 2006	1 Q 2007	2 Q 2007	3 Q 2007	4 Q 2007	1 Q 2008	2 Q 2008	3 Q 2008	4 Q 2008	1 Q 2009	2 Q 2009	3 Q 2009	Total
Number of bleeding episodes	2	2	0	2	2	3	20	35	38	28	27	28	26	16	21	18	2	270
Number of registered inhibitor patients	0	0	0	0	15	46	67	80	93	102	103	103	103	108	110	112	112	112
Number of inhibitor patients with bleeding	1	1	0	1	2	2	8	14	11	13	19	7	13	8	9	7	1	-
Average number of episodes per patient	2.0	2.0	-	2.0	1.0	1.5	2.5	2.5	3.5	2.2	1.4	4.0	2.0	2.0	2.3	2.6	2.0	-

Bleeding patterns of 28 inhibitor patients



* Bleeding into the same location within 48 hours after the end of the previous bleeding.

	2005	2006	2007	2008	2009	2005-2009
Number of inhibitor patients	0	46	102	108	112	112
Bleeding episodes						
Number of bleeding episodes	4	7	121	97	41	270
% of re-bleeding episodes	0.0%	0.0%	5.0%	10.3%	7.3%	7.0%
Number of patients with recorded bleeding episode	1	2	20	17	13	28
Average number of bleeding episodes per patient	4.0	3.5	6.1	5.7	3.2	9.6
Dosage						
Number of bleeding episodes with medication	4	6	119	97	40	266
Number of medications	4	10	165	101	62	342
Average number of medications per bleeding episode	1.0	1.7	1.4	1.0	1.6	1.3
Number of bleeding episodes with more than one medication	0	4	22	7	3	36
% of bleeding episodes with more than one medication	0.0%	66.7%	18.5%	7.2%	7.5%	13.5%

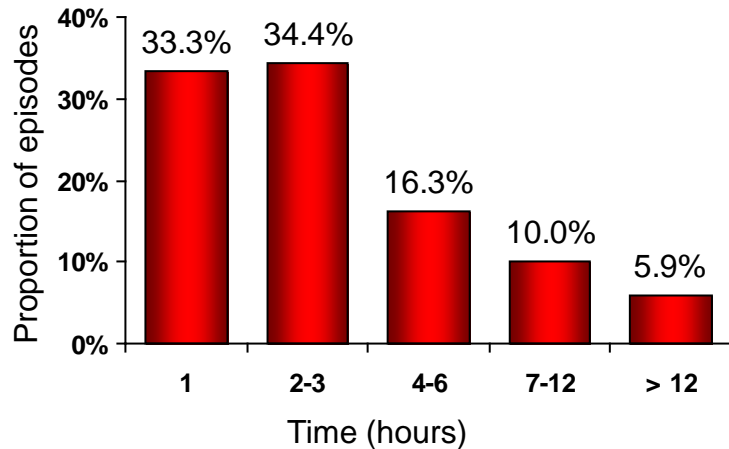
Bleeding and medication - non-inhibitor patients HemoRec ●

	2005 and earlier	2006	2007	2008	2009	2005-2009
Number of non-inhibitor patients	0	124	864	9850	990	990
Bleeding episodes						
Number of bleeding episodes	2	178	2218	1681	320	4400*
Number of patients with recorded bleeding episode	2	27	237	192	59	286
Average number of bleeding episodes per patient	1.0	6.6	9.4	8.8	5.4	15.4
Dosage						
Number of bleeding episodes with medication	2	176	2211	1680	320	4389
Number of medications	5	193	2469	1869	358	4894
Average number of medications per bleeding episode	2.5	1.1	1.1	1.1	1.1	1.1
Number of bleeding episodes with more than one medication	0	16	168	114	32	330
% of bleeding episodes with more than one medication	0.0%	9.1%	7.6%	6.8%	10.0%	7.5%

* There is missing date for 1 bleeding episode.

Overall number of recorded bleeding episodes of patients with inhibitor is **270** (for 28 different patients).

Time from start of bleeding to the first infusion



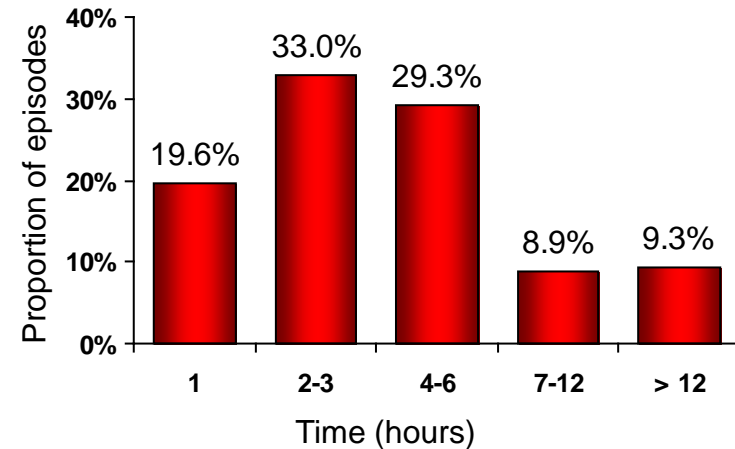
N = 270

Mean: 4.4 hours

Median: 2 hours

Min - Max: 1 - 24 hours

Time from the first infusion to the end of bleeding



N = 270

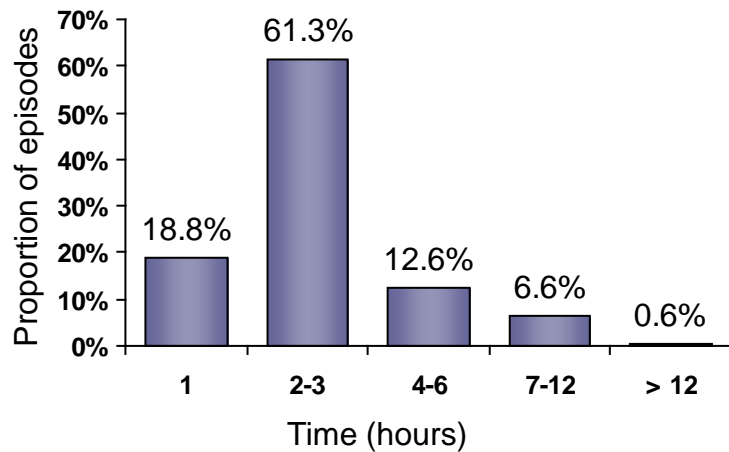
Mean: 5.2 hours

Median: 3 hours

Min - Max: 1 - 24 hours

Overall number of recorded bleeding episodes of patients without inhibitor is **4400** (for 286 different patients).

Time from start of bleeding to the first infusion



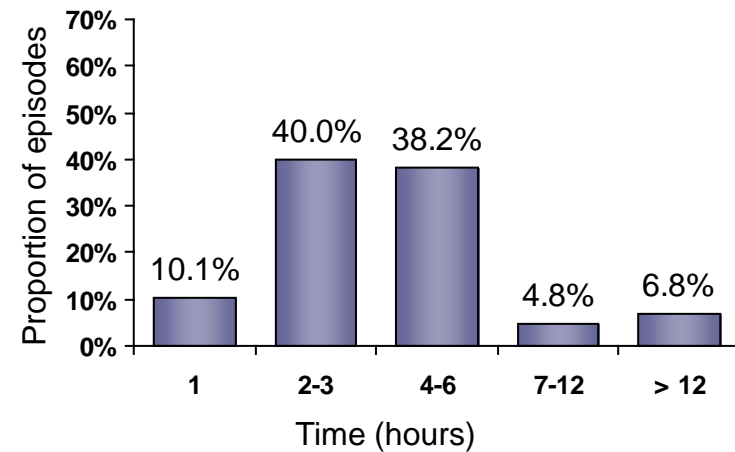
N = 4297*

Mean: 2.8 hours

Median: 2 hours

Min - Max: 1 - 24 hours

Time from the first infusion to the end of bleeding



N = 4266**

Mean: 4.9 hours

Median: 3 hours

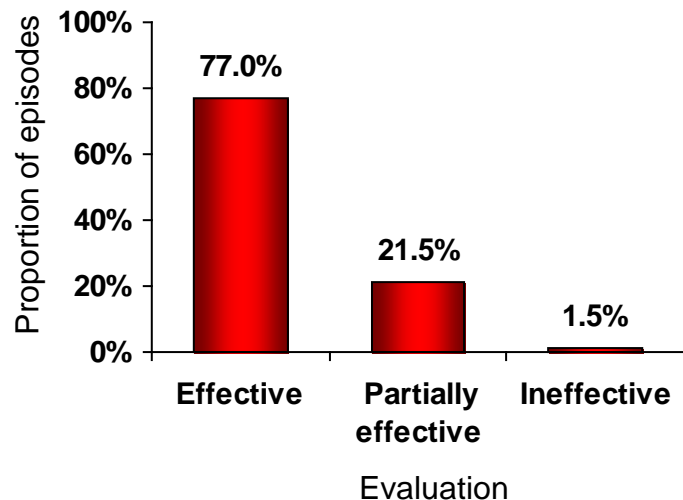
Min - Max: 1 - 24 hours

* Information missing for 103 bleeding episodes.

** Information missing for 134 bleeding episodes.

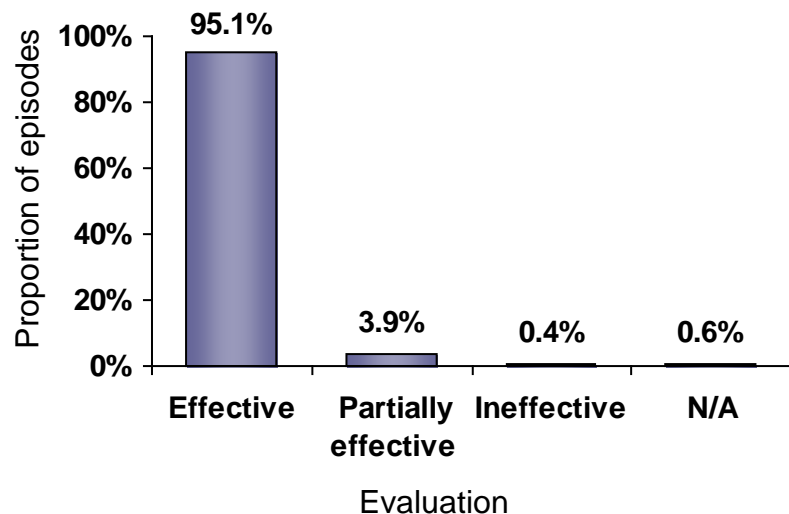
Overall number of recorded bleeding episodes of patients with inhibitor is **270** (for 28 different patients).

Evaluation of entire episode



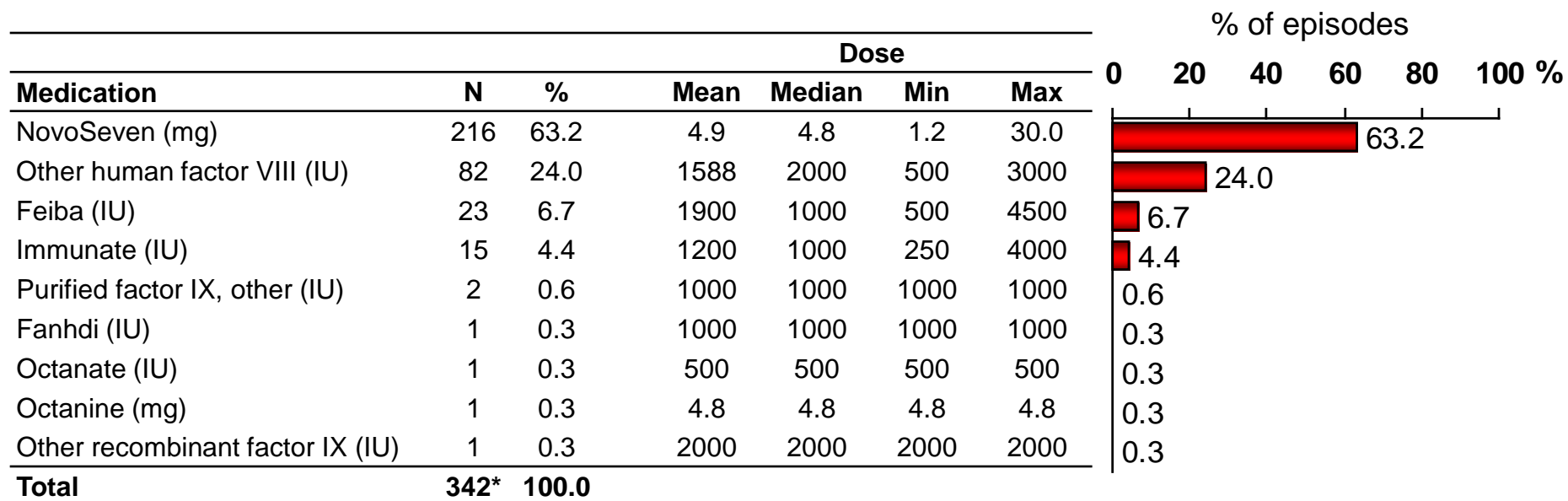
Overall number of recorded bleeding episodes of patients without inhibitor is **4400** (for 286 different patients).

Evaluation of entire episode



Medication of bleeding episodes - inhibitor patients

Overall number of applied medications is 342.
Medication was filled for 266 of 270 bleeding episodes.



* more than one medication was used for 36 bleeding episodes

Medication of bleeding episodes – non-inhibitor patients

Overall number of applied medications is 4894.

Medication was filled for 4389 of 4399 bleeding episodes.

Medication	N	%	Dose				% of episodes
			Mean	Median	Min	Max	
Immunate (IU)	2014	41.2	2555	1500	150	17500	41.2
Other human factor VIII	1760	36.0	-	-	-	-	36.0
Octanate (IU)	404	8.3	1519	1000	250	8000	8.3
Immunine (IU)	224	4.6	1676	1500	3	6000	4.6
Fanhdi (IU)	184	3.8	1330	1000	250	6000	3.8
Purified factor IX, other (IU)	142	2.9	1324	1200	500	2400	2.9
Prothrombin complex, other (IU)	76	1.6	979	1200	500	1200	1.6
Octanine (IU)	42	0.9	1548	1500	500	6000	0.9
Hemofil M (IU)	12	0.2	576	500	306	1000	0.2
Other recombinant factor IX (U)	9	0.2	1425	1000	325	4000	0.2
Recombinant, other (IU)	7	0.1	943	1200	600	1200	0.1
Coagulation FVIII (Red cross) (IU)	6	0.1	1333	1000	1000	2000	0.1
Hyate C (IU)	6	0.1	750	750	500	1000	0.1
Activated prothrombin complex, other (U)	2	0.0	1100	1100	1000	1200	0.0
NovoSeven (mg)	2	0.0	3.6	3.6	2.4	4.8	0.0
Koate (IU)	1	0.0	1000	1000	1000	1000	0.0
Kogenate (IU)	1	0.0	1000	1000	1000	1000	0.0
Plasma derived factor I (IU)	1	0.0	1200	1200	1200	1200	0.0
Recombinant factor IX, other (IU)	1	0.0	2000	2000	2000	2000	0.0
Total	4894*	100.0					

* more than one medication was used for 330 bleeding episodes