

**AHDC Factor IX Subcommittee  
Report 1998-99**

**Committee Members:**

- [Dr. M - C. Poon](#) (Chairperson)
- [Dr. R. Card](#)
- [Dr. D. Lillicrap](#)
- [Dr. M.-F. Scully](#)

**Sub-committee Activities:**

**Thrombogenicity monitoring:**

No case of thrombosis or DIC as a result of using factor IX concentrates has been reported from Canadian hemophilia clinics.

**Recombinant factor IX (BeneFIX®) efficacy and safety monitoring**

**a. Recovery.**

- BeneFIX®: Data reported and analyzed: 50 infusions from 46 patients (Age: range 1-74, mean 30, median 30)
- Immunine®: Data reported and analyzed: 26 infusions from 26 patients (Age: range 5-74, mean 33, median 28.5)

**Analysis of RECOVERY (U per IU/kg infused)**

<b>A,B: all infusions from all patients</b>							
Product	Infusions	Patients	min/max	Mean	SD	SE	95% CI
A BeneFIX	50	46	0.371/1.592	0.794	0.253	0.036	0.722-0.866
B Immunine	26	26	0.48/1.706	1.06	0.58	0.070	0.916-1.205
A vs. B: 0.0001							
<b>C,D: only infusions from patients <math>\leq</math> 15 years age</b>							
Product	Infusions	Patients	min/max	Mean	SD	SE	95% CI
C BeneFIX	16	12	0.371/0.917	0.669	0.158	0.040	0.585-0.754
D Immunine	5	5	0.580/1.142	0.841	0.215	0.096	0.574-1.108
C vs. D: 0.0898							
<b>E,F: only infusions from patients <math>&gt;</math> 15 years age</b>							
Product	Infusions	Patients	min/max	Mean	SD	SE	95% CI
E BeneFIX	34	34	0.492/1.159	0.852	0.270	0.046	0.758-0.946
F Immunine	21	21	0.480/1.706	1.116	0.362	0.079	0.951-1.281
E vs. F: 0.0024							
<b>Nineteen (19) patients had values</b>							

from both BeneFIX and Immunine infusions							
G,H: Infusions from all 19 patients							
Product	Infusions	Patients	min/max	Mean	SD	SE	95% CI
G BeneFIX	19	19	0.492/1.592	0.821	0.305	0.070	0.675-0.968
H Immunine	19	19	0.480/1.679	1.058	0.354	0.081	0.887-1.229
G vs. H: 0.0024							
I,J: Infusions from patients ≤15 years age							
Product	Infusions	Patients	min/max	Mean	SD	SE	95% CI
I BeneFIX	4	4	0.580/0.917	0.700	0.149	0.075	0.463-0.930
J Immunine	4	4	0.500/1.142	0.883	0.268	0.134	0.426-1.281
I vs. J: 0.1486							
K,L: Infusions from patients >15 years age							
Product	Infusions	Patients	min/max	Mean	SD	SE	95% CI
K BeneFIX	15	15	0.492/1.592	0.854	0.331	0.085	0.671-1.037
L Immunine	15	15	0.480/1.679	1.113	0.361	0.093	0.913-1.313
K vs. L: 0.0072							

### Discussion:

1. Data is still limited
2. Recovery of BeneFIX significantly lower than Immunine overall and among those >15 years age. However, data for those <15 years age is very limited for comparison.
3. Multiplication factor for BeneFIX based on available data

	Age group	Infusions	Patients	Multiplication factor (1/recovery)
A	all	50	46	1.26 (95% CI: 1.155-1.39)
C	≤15 years	16	12	1.49 (95% CI: 1.326-1.709)
E	>15 years	34	34	1.17 (95% CI: 1.057-1.319)

4. The multiplication factor is higher in younger children. All patients should have recovery studies done to help with proper dosing.
5. The influence of pre-infusion factor IX value (severity) on recovery: needs to be analyzed as we have more data
6. Consistency of recovery for a given patient from year to year: needs to be determined

### b. Half-disappearance time

32 of the 47 BeneFIX infusions and 12 of 23 Immunine infusions include factor IX values from 4 time points (pre, post 15-30 min, 1 hr, 4 hr). The t<sub>1/2</sub> based on manual plotting proved to be difficult. Further data manipulation is required and suggestions will be welcome.

### **c. Inhibitors**

No report of factor IX inhibitors during this initial period of BeneFIX usage has been reported. The Kingston Laboratory (D. Lillicrap) has analyzed 50 post-BeneFIX infusion samples for non-neutralizing factor IX antibody by a modified ELISA technique and all samples were negative

### **d. Patient satisfaction questionnaire:**

Insufficient submissions for analysis

### **e. Discussion:**

All centers are urged to submit data on all their patients to allow meaningful analysis. Each patient receiving BeneFIX should have the studies done for patient care purpose, and the extra work involved include completion of the forms for submission. The Monitoring protocol is attached.