

Validation of patient reported bleeds

Goedhart G¹, Taal EM¹, Fischer K², Driessens MHE³, Van der Meer FJM¹ and HemoNED Steering Committee[†]

¹ Dep. of Thrombosis and Hemostasis, Leiden University Medical Center, Leiden, The Netherlands; ² Van Creveld Clinic, University Medical Center Utrecht, Utrecht, The Netherlands; ³ Netherlands Hemophilia Patient Society, Nijkerk, The Netherlands; [†] Fijnvandraat K (Amsterdam UMC, University of Amsterdam), Kruip MJHA (Erasmus University Medical Center Rotterdam), Laros-van Gorkom BAP (Radboud University Medical Center Nijmegen), Schipper J (Netherlands Hemophilia Patient Society), Tamminga RYJ (University Medical Center Groningen), Uitslager N (University Medical Center Utrecht)

Introduction

The Annual Bleed Rate (ABR) is one of the most important treatment outcomes within the area of bleeding disorders. Therefore validation of patient reported bleeds is essential. The use of mobile or online applications to collect bleeding data is increasing, but the validity of this method has not been examined.

Objective

To validate the bleeds reported by patients through a mobile/online app.

Methods

Since April 2018, patients registered in the Dutch Hemophilia Registry HemoNED started to use the mobile and/or web application 'VastePrik' to log their home treatment and bleeds (figure 3):

- Treatment: date/time of infusion, reason, product, dose & batch number
- Bleeds: date/time of bleed, cause, location & severity

The entries are summarized on a dashboard for both the patient and the hemophilia treatment center (HTC; all six Dutch HTCs are involved) (figure 2), supporting the evaluation of individual treatment plans. After anonymization the data can also be used for research and post marketing surveillance.

Reported bleeds were analyzed for a 'double bleed' – defined as a bleed logged at the same or next day and at the same location of the body as the previous bleed.

Results

- Data collection period: 1-Aug-'18 to 31-Jul-'19
- Participants characteristics: 107 patients (or parents) on prophylactic treatment using the app for ≥ 1 year; mean age 35 years (range 3 - 77); 84% had Hemophilia A, 9% Hemophilia B (mostly moderate or severe levels), 7% had another bleeding disorder.
- Data characteristics: 14.257 infusions were logged: 90% prophylaxis, 2% precautionary (expected higher risk due to e.g. sport activities), 4% for a recent bleed and 4% follow-up treatment after a bleed. In total, 515 bleeds were logged, of which 282 joint bleeds.
- Results: 54 (10.5%) bleeds, of which 32 joint bleeds, appeared to be a 'double bleed' (table 1; figures 1a&b). The median ABR (IQR) changed from 4.0 (1.0-6.0) to 3.0 (1.0-6.0) after removing the 'double bleeds'. The median AJBR did not change (table 1).

Conclusion

Validation of the mobile/online app data revealed that about 10% of bleeds at home were registered twice by patients, affecting the Annual Bleed Rate.

Discussion

- ✓ The use of registry data, including patient reports on home treatment and bleeds, is encouraged by the European Medicines Agency for post-authorization studies.
- ✓ It is important that hemophilia treatment teams check and assure the quality of bleeding data reported by patients through a mobile/online app.
- ✓ Improved instructions for patients are needed explaining the importance of accurate registration of their bleeds and treatment.

Figure 1a # Bleeds/year: all vs without 'double bleeds'

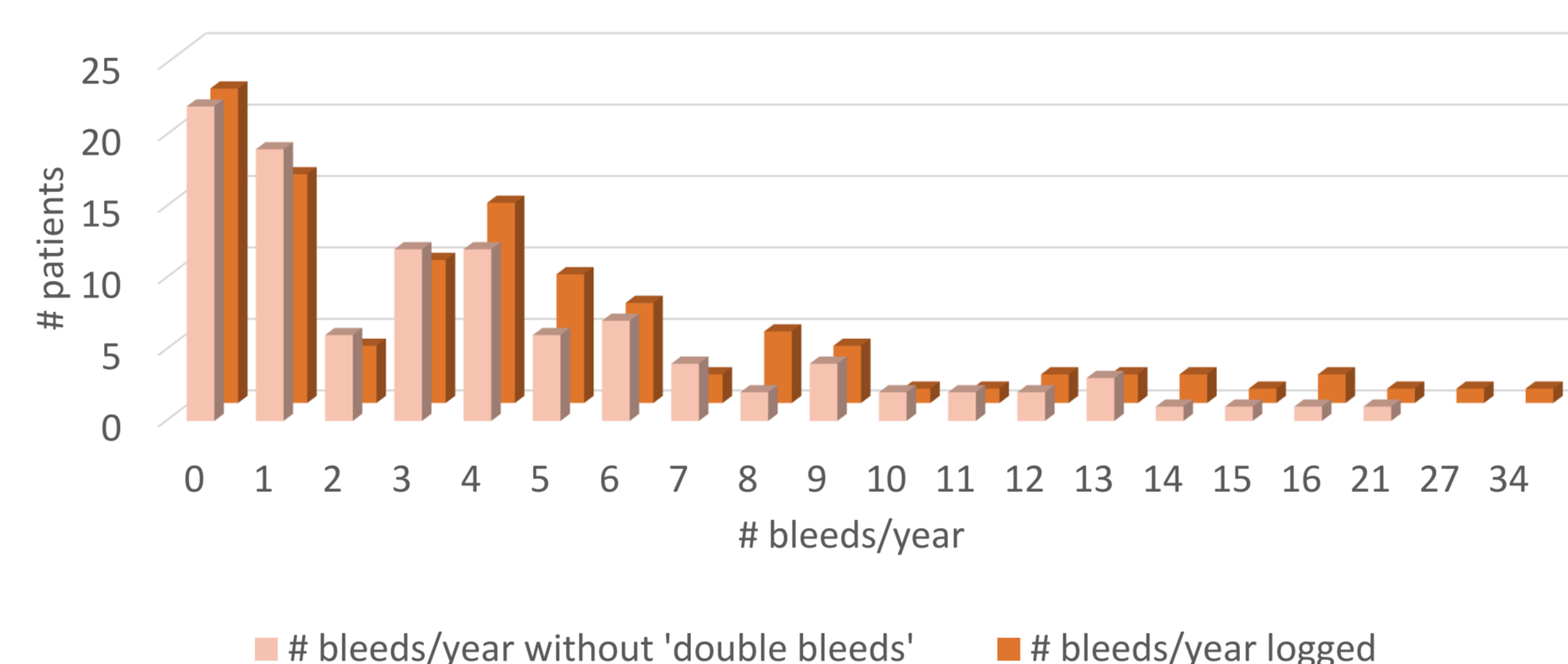


Figure 1b # Joint bleeds/year: all vs without 'double bleeds'

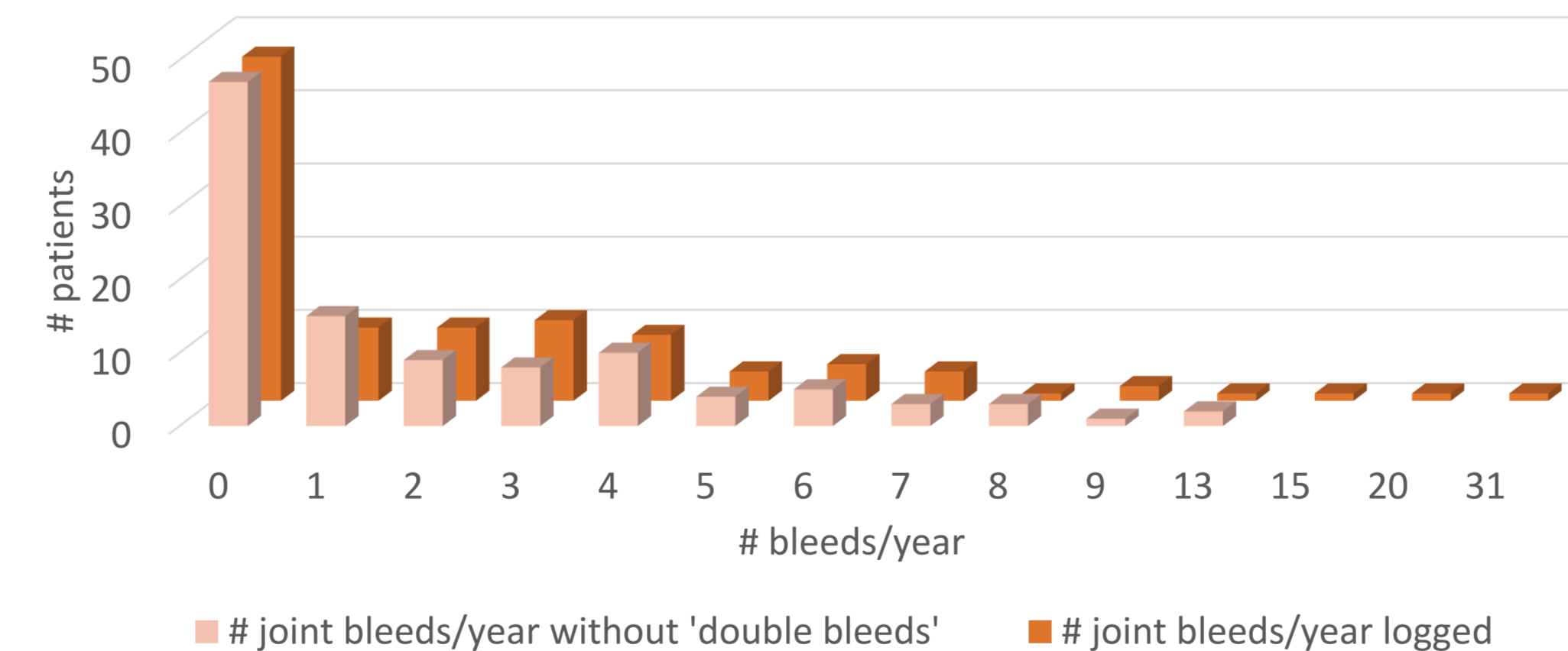


Figure 2 'VastePrik' dashboard for patient and HTC, supporting evaluation of individual treatment.

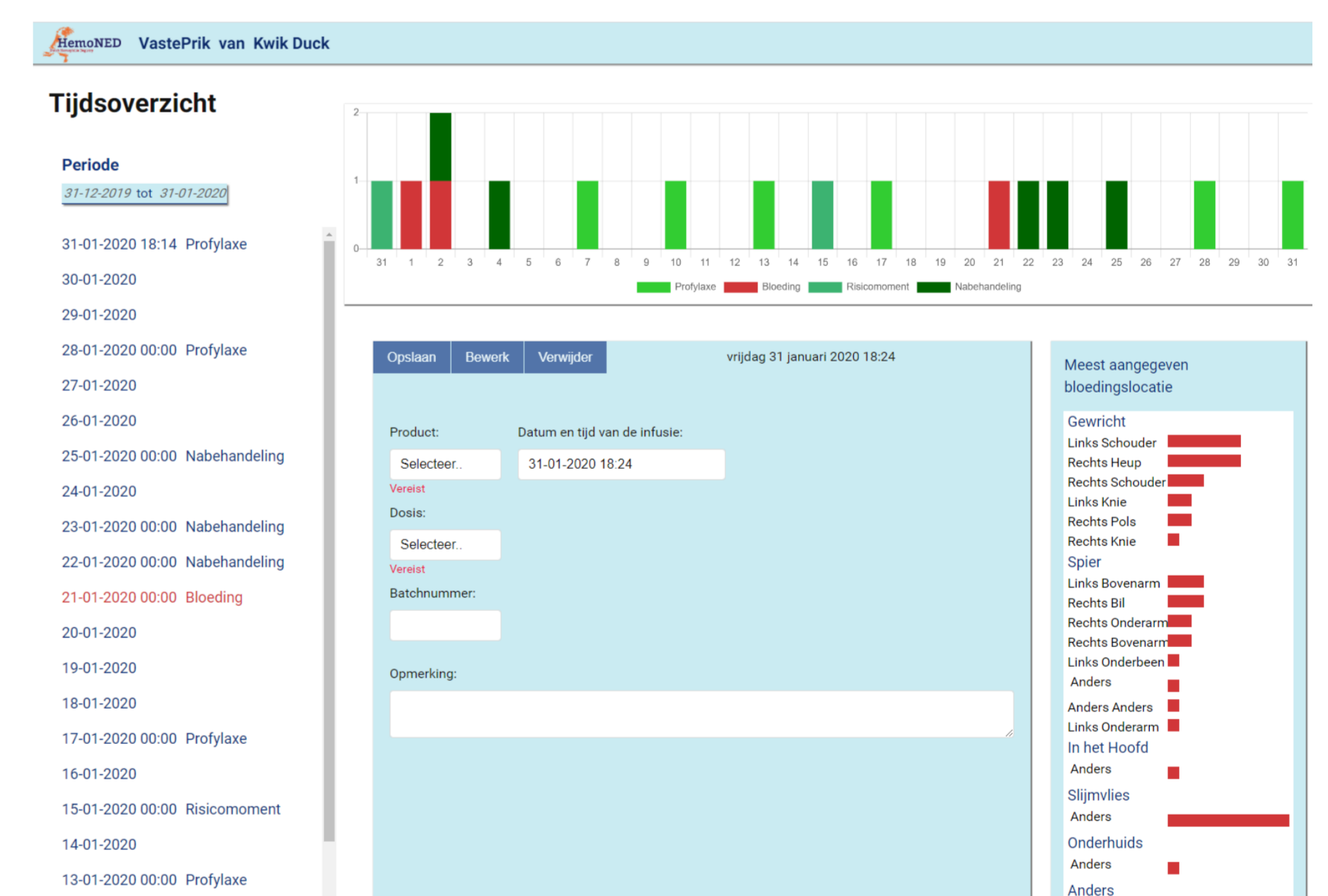


Figure 3 'VastePrik' mobile app for patient to log home treatment and bleeds.

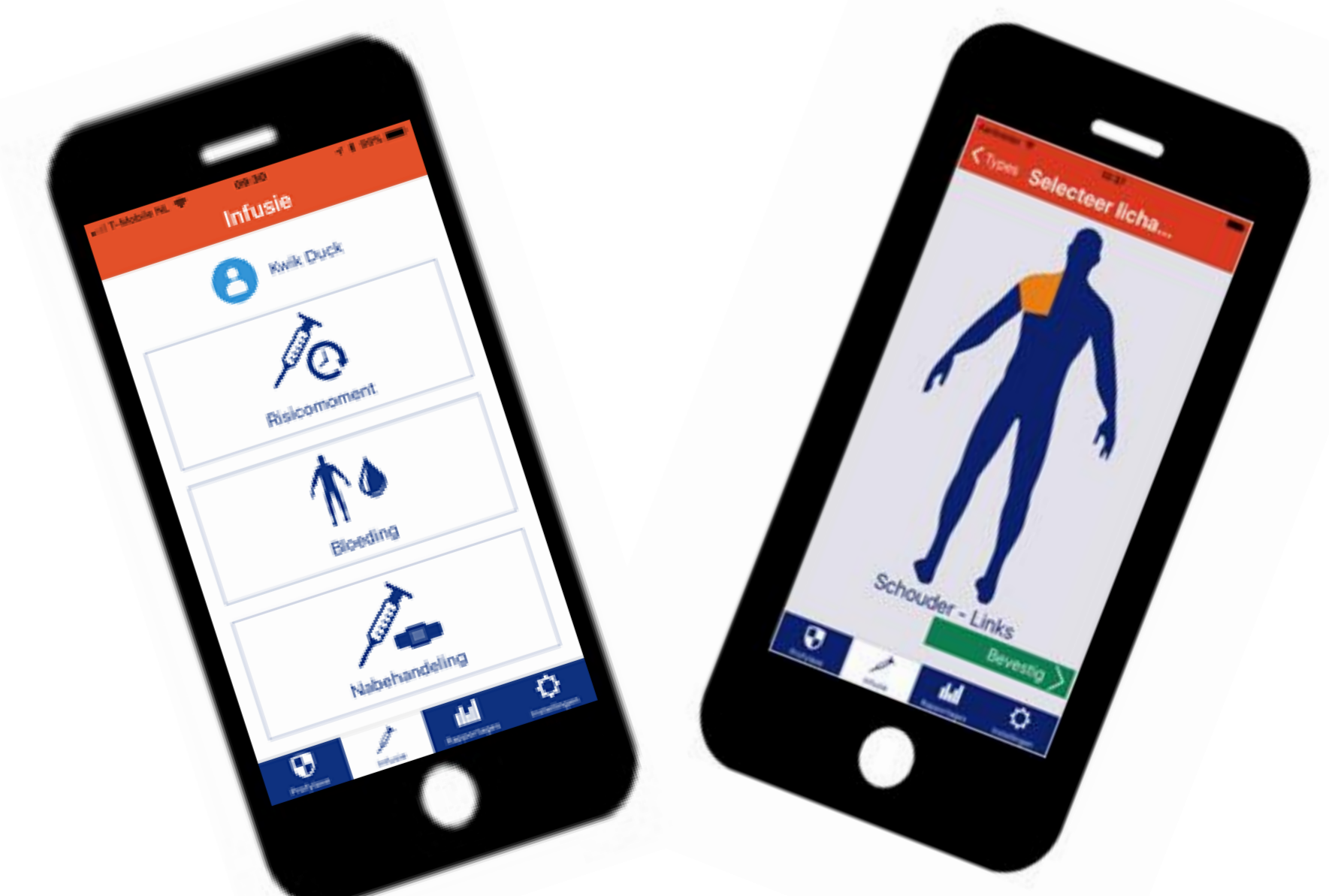


Table 1 A(J)BR of all bleeds logged vs without 'double bleeds'

Type of bleeds	# patients	# pts 0 bleeds logged (%)	# bleeds logged	A(J)BR all bleeds		# double bleeds (%)	A(J)BR without 'double bleeds'	
				Median (IQR)	Range		Median (IQR)	Range
All	107	22 (20.6)	515	4.0 (1.0 – 6.0)	0 – 34	54 (10.5)	3.0 (1.0 – 6.0)	0 – 27
Joint bleeds	107	47 (43.9)	282	1.0 (0.0 – 4.0)	0 – 31	32 (11.4)	1.0 (0.0 – 4.0)	0 – 20