Detailed Information of Transferring Data of PWH from the Thai Hemophilia Treatment Centre Registry to the World Bleeding Disorders Registry of WFH

Ampaiwan Chuansumrit, MD[1], Worachanok Youttananukorn, PhD[2],
Nongnuch Sirachainan, MD[1], Rungrote Natesirinilkul, MD[3], Theera Ruchutrakool, MD[4]

[1]Department of Pediatrics, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand
[2]Data and Research Coordinator, World Federation of Haemophilia, Montreal, Canada
[3]Department of Pediatrics, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand
[4]Department of Medicine, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand

Correspondence: Prof. Ampaiwan Chuansumrit, MD, Department of Pediatrics
Faculty of Medicine, Ramathibodi Hospital, Mahidol University, 270 Rama VI Road, Bangkok 10400 Thailand. Tel: +66 2 201 1749; Fax: +66 2 201 1748
E-mail: ampaiwan.jua@mahidol.ac.th

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Aim To avoid duplicate workload of medical personnel interested in entering data into the 'Hereditary Bleeding Disorders Registry (HBDR)' of the Thai Society of Hematology and the 'World Bleeding Disorders Registry (WBDR)' of the WFH, an electronic connection of the HBDR and the WBDR was created between January and December 2020. The minimal and extended dataset of PWH A and B will be transferred from the HBDR to the WBDR.

Methods The HBDR consists of 11 categories of data fields with 26 relational tables (Tables 1 and 2). The minimal and extended dataset of the WBDR is shown in Table 3. The minimal dataset includes 'baseline data' for basic demographic and clinical data; 'baseline visit' for retrospective clinical events experienced in the 6 months before the registration date, and 'follow-up visits' for the same data as the baseline visit prospectively at each follow-up visit following the registration date. They also include the information of hospitalization and replacement therapy. Additional extended datasets include inhibitor, musculoskeletal assessment and mortality.

The computerized program of MySQL (Version 5.7) and phpMyAdmin (Version 4.9.7) were used in this study. MySQL is the world's most popular open-source database, and is fast, reliable, scalable, easy to use and allowed us to define the data into tables, update and query data, and access data in the database. The phpMyAdmin, a web application, has also been used to handle the administration of MySQL over the web and is an open-source tool written in PHP. The combination of MySQL and phpMyAdmin eased our database management on the web.[9]

Upon the completeness of data transfer designation, a virtual conference among HTC in Thailand was organized with the subsequent training of data entering for the physicians and medical personnel. An easy-to-understand instruction has been prepared in Thai and distributed to the participating HTC. HTCs have the alternative of opting out by simply not

pressing the button ‘Connect to WBDR’. This may result in some HTCs not participating in data transfer; however and importantly, it also has the advantage that a data transfer from the HBDR to the WBDR will not be abandoned in the event that not all HTCs agree to participate.

To transfer selected data from the HBDR to the WBDR, two query screens were added to the HBDR for each user at the HTC to complete. First, ‘Would you like to connect to the WDBR?’ and if ’Yes’, the second screen would ask: ‘Does your department/hospital receive ethics approval from a Faculty Ethics Committee?’ If ‘No’, the user will be asked to obtain ethics approval before connecting to the WBDR. If ‘Yes’, the user clicks a button called ‘Connect to WBDR’, the data of the PWH from HBDR would be transferred to 11 Excel tables of the WBDR (Tables 3 to 7).

Written informed consent must be obtained from the PWH and parents for enrolling in both the HBDR and WBDR. The retrospective baseline clinical data for the 6 months before registration will be obtained from medical records and haematology charts before the registration date was reviewed and entered. Upon each follow-up visit, data from the medical record were subsequently entered per calendar year, with no overlapping years permitted. This was deemed to be helpful for the summation of episodes of hospitalization, number of days of hospitalization, number of bleeds, number of joint bleeds as well as the used replacement therapy within one calendar year for the individual annual report (Figure 1).

Comment The Thai method is a novel approach of transferring patient data of the PWH from the HTC to the WBDR using computerized programs, namely, MySQL and phpMyAdmin. This method can be adapted for other existing registries in both economically developed and less developed countries. The real world data of PWH for the WBDR will be useful for the evidence-based advocacy initiatives to serve PWH globally.

Table 1 Eleven categories of HBDR data fields

1.	**Personal history**	Name, sex, birth date, blood group, date of first bleed, date of diagnosis, severity, genetic analysis, age at first prophylaxis
2.	**Hemostatic tests**	Levels of factor VIII, IX, von Willebrand's factor
3.	**Investigation**	Infectious markers, chemistry, inhibitor.
4.	**Vaccination**	Hepatitis A and B vaccination
5.	**Hospitalization**	Date of admission and discharge, BW, height, chief complaint of bleeding, surgery, and dentistry, cause of bleeding, site of bleed, factor and nonfactor replacement therapy, adjuvant therapy
6.	**Home treatment**	Date of start and stop bleeding and other information similar to hospitalization, person providing factor concentrate administration, outcome of early episodic treatment at home
7.	**Prophylaxis**	Date of start and stop, type of prophylaxis, BW, unit of administered factor concentrate, frequency, total amount of factor concentrate, person providing factor concentrate administration, outcome of prophylaxis
8.	**Immune tolerance induction (ITI)**	Date of start and stop, initial and peak inhibitor, BW, unit of administered factor concentrate, frequency, total amount of factor concentrate, person providing factor concentrate administration, outcome of ITI
9.	**Musculoskeletal system**	HJHS of bilateral knee, ankle, elbow, global gait, occurrence of target joints
10.	**Quality of life**	Using CHO-KLAT or Haemo-QoL
11.	**Patient status**	Date of last visit, status of follow-up, refer or death, cause of death

HBDR, hereditary bleeding disorders registry; HJHS, haemophilia joint health score

Table 2. Eleven categories of HBDR defined in 26 relational tables

Categories of HBDR	Relational tables	Common data used to relate tables
1.Personal history	1.1 Identification number 1.2 Birth date, sex, blood group, date of registration & address 1.3 Nationality 1.4 Family history 1.5 Diagnosis, severity, mutation 1.6 Site of first bleed	Identification number
2. Hemostatic tests	2.1 Coagulation factor 2.2 Other hemostatic tests 2.3 Platelet study	Identification number
3. Investigation	3.1 Inhibitor assessment 3.2 Infectious marker 3.3 Chemistry	Identification number
4. Vaccination	4. Hepatitis A & B vaccination	Identification number
5. Hospitalization	5.1 Chief complaint of bleeding, surgery, dental, other; site of bleeding, spontaneous/trauma/ unknown, days of hospitalization, BW & height 5.2 Amount of replacement therapy 5.3 Other treatment e.g., desmopressin, fibrin glue	Identification number Date of admission Date of discharge
6. Home treatment	6.1 Site of bleeding, spontaneous /trauma 6.2 Amount of replacement therapy, BW, outcome of treatment	Identification number Date of start Date of stop
7. Prophylaxis	7.1 Dose of replacement, type of prophylaxis, duration, BW 7.2 Amount of replacement therapy, outcome of treatment	Identification number Date of start Date of stop

8. Immune tolerance induction	8.1 Levels of inhibitor, BW, outcome of ITI 8.2 Amount of replacement therapy	Identification number Date of start Date of stop
9. Musculoskeletal assessment	9. HJHS score & presence/absence of target joint	Identification number
10. Quality of life	10. Tests and score	Identification number
11.Patient status	11.1 Patient status of follow-up, refer, death 11.2 Cause of death	Identification number

HBDR, hereditary bleeding disorders registry; HJHS, haemophilia joint health score; WBDR, world bleeding disorders registry

Table 3. Data transferred from HBDR to the 11 Excel tables of WBDR

	WBDR	Data transferred from HBDR
	Minimal dataset	
1.	**Baseline data**	sex, birth date, date of first bleed, date of diagnosis, level of FVIII:C/IX:C, genetic analysis, age of first prophylaxis
2.	**Baseline visit**	number of total bleeds, joint, muscle, CNS and other site bleed for the previous 6 months before the registration date
3.	**Follow-up visit**	similar to baseline visit but included the data after the registration date to the end of the year for the first year of registration. For the consecutive year, the data from January to December of the same year were collected.
4.	**Baseline hospitalization**	days of hospitalization, cause and sites of bleeding and outcome for the previous 6 months before the registration date
5.	**Follow-up hospitalization**	similar to baseline hospitalization but included the data after the registration date to the end of the year for the first year of registration. For the consecutive year, the data from January to December of the same year were collected.
6.	**Baseline treatment**	total amount of replacement therapy for the previous 6 months before the registration date from hospitalization, early episodic treatment, prophylaxis and ITI.
7.	**Follow-up treatment**	similar to baseline treatment but included the data after the registration date to the end of the year for the first year of registration. For the consecutive year, the data from January to December of the same year were collected.
8.	**Weight and height**	date of measurement for weight and height
Extended dataset		
9.	**Inhibitor assessment**	date of test, levels of inhibitor titer in Bethesda units (BU)
10.	**Musculoskeletal system**	HJHS score and presence/absence of target joints.
11.	**Mortality**	date of last communication, patient status of follow-up, referred, or death and the cause of death.

HBDR, hereditary bleeding disorders registry; HJHS, haemophilia joint health score; WBDR, world bleeding disorders registry

Table 4. Baseline data transferred from HBDR to WBDR

Baseline data fields in WBDR	Data transferred to the WBDR	Data sent from relational tables of the HBDR
A. Identification	Identification	Personal history 1.1
B. Consent to participate in WBDR	Yes	Written informed consent
C. Date of registration in WBDR	Date	Personal history 1.2
D. Clinic	Name of department, hospital	Information of the enrolling physician
E. Date of birth	Date	Personal history 1.2
F. Sex	Male/Female	Personal history 1.2
G. Country of residence	Thailand	Information of the enrolling physician
H. Date of first visit to HTC	Date	Haemostatic test: date of the first test 2.1
I. Date of diagnosis	Date	Personal history1.5
J. Haemophilia type	Haemophilia A/B	Personal history 1.5
K. Severity	Mild/ Moderate/ Severe	Personal history 1.5
L. Factor level (%)	FVIII/FIX (%)	Hemostatic test 2.1
M. Date of test	Date	Hemostatic test 2.1
N. Bleeding history	Ecchymosis, joint, etc.	Personal history 1.6
O. Age at first bleed (month)	Months	Access from database of Personal history 1.6
P. Joint bleed history	Yes/No	Personal history 1.6: first bleed with haemarthrosis
Q. Age of first joint bleed (month)	Months	Personal history 1.6: the same age as ‘O’ if patient exhibited haemarthrosis
R. Blood group	A, B, O, AB	Personal history1.2
S. Rh	Positive/Negative	Personal history 1.2
T. Date of genetic testing	Date	Personal history1.5
U. DNA variant	Mutation	Personal history: genetic defect 1.5

HBDR, hereditary bleeding disorders registry; HJHS, haemophilia joint health score; HTC, haemophilia treatment center; WBDR, world bleeding disorders registry

Table 5. Baseline visit transferred from HBDR to WBDR

Baseline visit fields in WBDR	Data transferred to the WBDR	Data sent from relational tables of the HBDR
A. Identification	Identification	Personal history 1.1
B. Date of baseline visit	Date	Personal history 1.2: date of registration
C. Total number of bleeds experienced in the past 6 months	Summation of E+G+I+K	Hospitalization & home treatment
D. Location of bleeds experienced in the past 6 months	Bleeding sites of E+G+I+K	Hospitalization & home treatment
E. Indicate number of bleeds for joint	Number	Count the number of joint bleeds*
F. Of these joint bleeds, how many were traumatic?	Number	Count the number of joint bleeds with traumatic cause*
G. Indicate number of bleeds for muscle	Number	Count the number of muscle bleed*
H. Of these muscle bleeds, how many were traumatic?	Number	Count the number of muscle bleed with traumatic cause*
I. Indicate number of bleeds for CNS	Number	Count the number of CNS bleed (brain & spine)*
J. Of these CNS bleeds, how many were traumatic?	Number	Count the number of CNS bleed with traumatic cause*
K. Indicate number of bleeds for others	Number	Count the number of other bleeds excluding joint, muscle & CNS*
L. Of these other bleeds, how many were traumatic?	Number	Count the number of other bleeds with traumatic cause, excluding joint, muscle & CNS*
M. Inhibitor assessment in the past 6 months	Yes/No	Investigation: inhibitor 3.1
N. Please enter further information in the module inhibitor assessment below	Fill the inhibitor in Bethesda units	Investigation: inhibitor 3.1

O. Target joint	Yes/No/Unknown	Count the number of target joints: Musculoskeletal HJHS Yes, if ≥1; No, if 0; Unknown, if no data
P. Indicate the number of target joint	Number	Count the number of target joints: Musculoskeletal HJHS
Q. Admission to hospital in the past 6 months	Yes/No	See Table 6 'Baseline hospitalization'
R. Treatment received in the past 6 months	Yes/No	See Table 7'Baseline treatment'

(* refer to Table 3: Relational tables: Hospitalization 5.1 & Home treatment 6.1)

HBDR, hereditary bleeding disorders registry; HJHS, haemophilia joint health score; WBDR, world bleeding disorders registry

Table 6. Baseline hospitalization transferred from HBDR to WBDR

Hospitalization fields in WBDR	Data transferred to the WBDR	Data sent from relational tables of the HBDR
A. Identification	Identification	Personal history 1.1
B. Start date	Date	Date of admission**
C. Number of days of hospitalization	Number	Number of days of hospitalization**
D. Reason for hospitalization	Bleeding/Surgery/Dental/other	Chief complaint of bleeding, surgery dental, or other**
E. Haemophilia related hospitalization	Bleeding at the joint, mucosa, CNS, etc. excluding muscle, surgery and dental procedure	Bleeding at the joint, mucosa, CNS, etc. excluding muscle, surgery and dental procedure**
F. Other-please specify	Dental procedure	Dental procedure of scaling, filling, extraction**
G. Other bleed-please specify	Bleeding at other sites excluding muscle, surgery and dental procedure	Bleeding at other sites excluding muscle, surgery and dental procedure**
H. Other muscle bleed-please specify	Bleed at upper and lower extremities, iliopsoas, and other muscles	Bleeding at upper and lower extremities, iliopsoas, and other muscles**
I. Surgery-please specify	Surgery	Surgery of orthopedic, general or other surgeries**

(** refer to Table 2: Relational tables: Hospitalization 5.1)

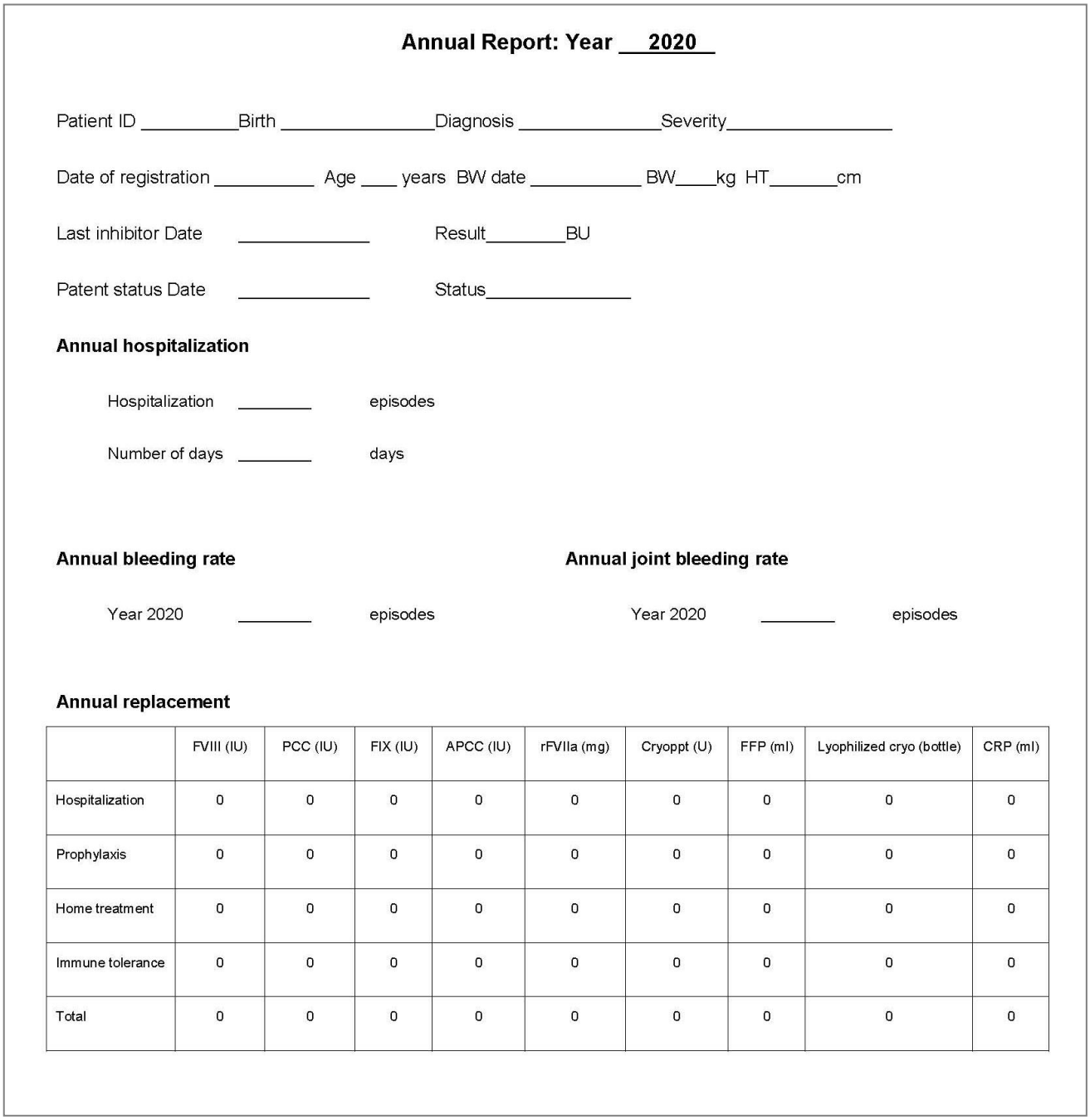
HBDR, hereditary bleeding disorders registry; WBDR, world bleeding disorders registry

Table 7. Baseline treatment transferred from HBDR to WBDR

Treatment fields in WBDR		Data sent from relational tables of the HBDR			
		Hospitalization	**Home treatment**	**Prophylaxis**	**ITI**
A.	Identification	Personal history 1.1	Personal history 1.1	Personal history 1.1	Personal history 1.1
B.	Indication	Episodic	Episodic	Prophylaxis	ITI
C.	Drug	Factor VIII, PCC, factor IX, aPCC, rFVIIa, FFP, frozen or lyophilized cryoprecipitate, cryo-removed plasma	Factor VIII, PCC, factor IX, aPCC, rFVIIa	Factor VIII, PCC, factor IX, aPCC, rFVIIa, nonfactor replacement	Factor VIII, factor IX
D.	Strength	Total amount administered: Hospitalization 5.2	Total amount administered: Home treatment 6.2	Total amount administered: Prophylaxis 7.2	Total amount administered: ITI 8.2
E.	Unit	Unit/mg/mL: Hospitalization 5.2	Unit/mg: Home treatment 6.2	Unit/mg: Prophylaxis 7.2	Unit: ITI 8.2
F.	Start date	Admission date: Hospitalization 5.2	Date start: Home treatment 6.2	Date start: Prophylaxis 7.2	Date start: ITI 8.2
G.	End date	Discharge date: Hospitalization 5.2	Date stop: Home treatment 6.2	Date stop: Prophylaxis 7.2	Date stop: ITI 8.2
H.	Reason for stopping treatment.	On demand treatment complete when discharge	Good, fair, fail: Home treatment 6.2	Good, fair, fail Prophylaxis 7.2	Success, partial success, ongoing, fail: ITI 8.1

HBDR, hereditary bleeding disorders registry; ITI, Immune Tolerance Induction; WBDR, world bleeding disorders registry

Figure 1. Individual person with haemophilia annual report



Annual Report: Year __2020__

Patient ID _____Birth _____Diagnosis _____Severity_____

Date of registration _____ Age ___ years BW date _____ BW____kg HT_____cm

Last inhibitor Date _____ Result_____BU

Patent status Date _____ Status_____

Annual hospitalization

Hospitalization _____ episodes

Number of days _____ days

Annual bleeding rate

Year 2020 _____ episodes

Annual joint bleeding rate

Year 2020 _____ episodes

Annual replacement

	FVIII (IU)	PCC (IU)	FIX (IU)	APCC (IU)	rFVIIa (mg)	Cryoppt (U)	FFP (ml)	Lyophilized cryo (bottle)	CRP (ml)
Hospitalization	0	0	0	0	0	0	0	0	0
Prophylaxis	0	0	0	0	0	0	0	0	0
Home treatment	0	0	0	0	0	0	0	0	0
Immune tolerance	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0