

# The Dutch Hemophilia Registry HemoNED - Building an Ecosystem

---

Dr. Geertje Goedhart  
*Leiden University Medical Center &  
HemoNED Foundation, the Netherlands*

WFH congress, 18 June 2020

# Disclosures for: Geertje Goedhart

Conflict	Disclosure - if conflict of interest exists
Research Support	Grant/Research support from: Bayer, CSL Behring, Novo Nordisk, Octapharma, Pfizer, Roche, Sobi and Takeda
Director, Officer, Employee	-
Shareholder	-
Honoraria	-
Advisory Committee	-
Consultant	-

# Introduction

European Principles of  
Haemophilia Care  
(*Fischer, Haemophilia 2008*)

European Medicines Agency  
(*McGettigan, Drug Safety  
2019*)

National hemophilia registry essential for  
quality of care and pharmacovigilance

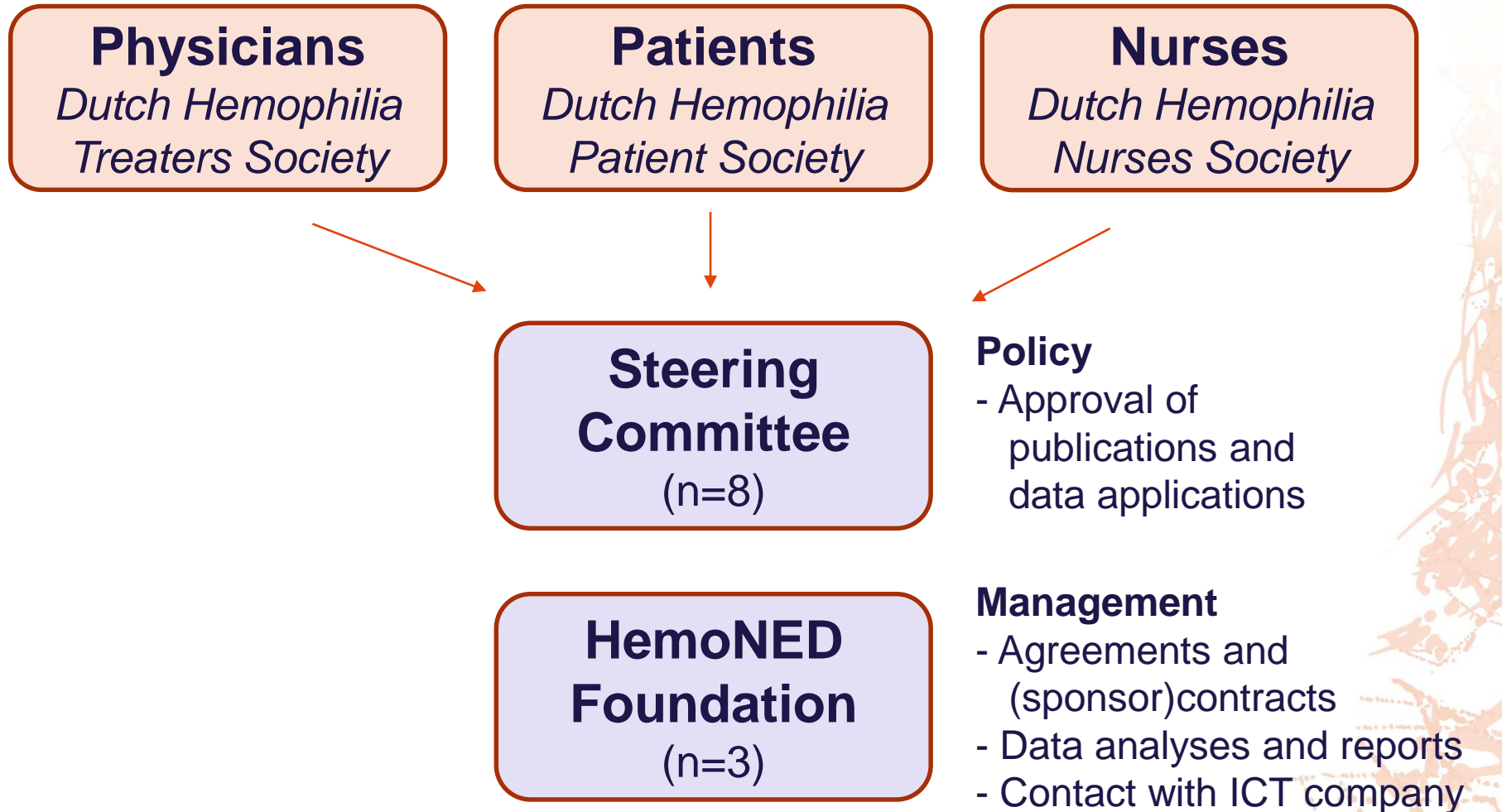
National initiative:  
Control of registries for expensive medicines  
(*National Health Care Institute & Ministry of  
Health, 2019*)

# Objectives

National hemophilia registry essential for:

- ❖ Numbers of patients by disorder and severity of disease  
e.g., number and localization of severe patients
- ❖ Benchmarking  
e.g., comparison of treatment between treatment centers
- ❖ International comparison  
e.g. WHF Annual Global Surveys
- ❖ Pharmacovigilance & PMS studies  
e.g., central reports to EUHASS
- ❖ Research  
Prescribing trends
- ❖ Monitoring & evaluation of treatment  
'VastePrik' app for patients and dashboard for health care providers

# Methods: Organization



# Methods: Support

## Netherlands Organization for Health Research and Development

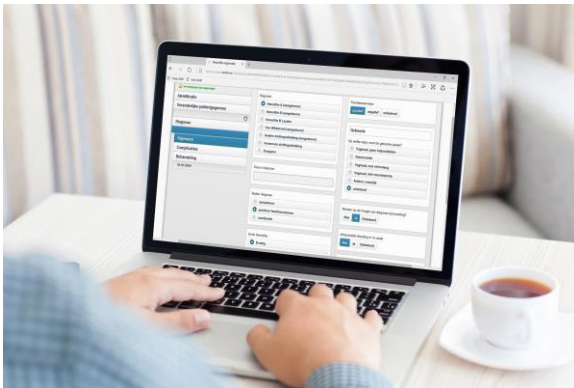
2-year grant to set up registry

### Public-private partnerships

- Sponsor contracts with pharmaceutical companies
- No data access
- Annual general report and specific reports for pharmaceutical companies and hemophilia treatment centers
- Future
  - Annual pharmacovigilance reporting
  - PMS studies

# Registry items

- **Patient data** *(for privacy reasons only visible for local treatment center)*
  - Name, patient number, birth date, gender etc.
- **Diagnosis, severity / type**
  - Hemophilia A / B (incl carriers)
  - Von Willebrand disease
  - Other factor deficiencies or platelet disorders
- **Inhibitor & viral infection**
  - Baseline: current, ever, never
- **Treatment plan**
  - Prophylaxis: product(s), dose & frequency
  - On demand: product(s)
- **Adverse events**
  - Inhibitors
  - Transfusion transmitted infections
  - Allergic reactions
  - Thrombosis
  - Deaths
  - Malignancies



*Items are manually entered, pilot on automated import from electronic health records*



# 'VastePrik' app & web page

Digital infusion log for patients on home treatment

- **Treatment**
  - Date/time, product, dose, batch number, reason
- **Bleeds**
  - Date/time, type, location, severity, cause
- **Extra**
  - Medication stock, barcode scanning, notifications, allergic reactions & joint pain

Online dashboard for patient and local center to monitor & evaluate treatment





# Results: inclusion & demographics

Inclusion period:  
Dec 2017 – Dec 2019

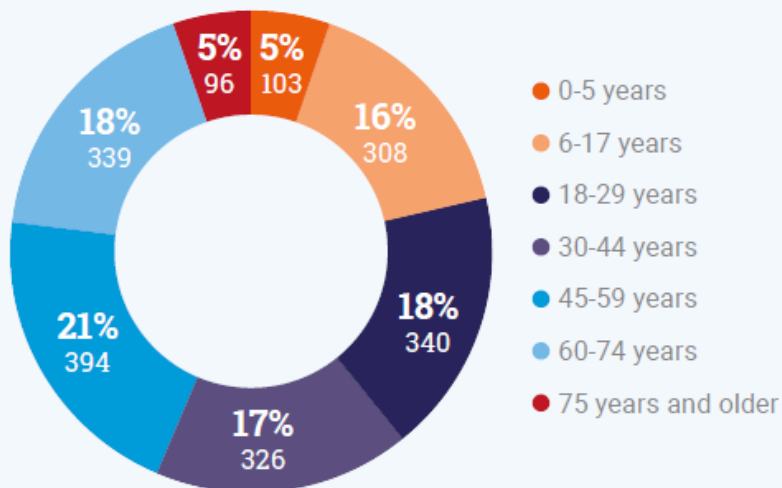
## Total participants

Total completed **1907** (100%)

## Age

Total completed **1906** (100%)

Missing **1**



## Gender

Man **1529** (80%)

Woman **374** (20%)

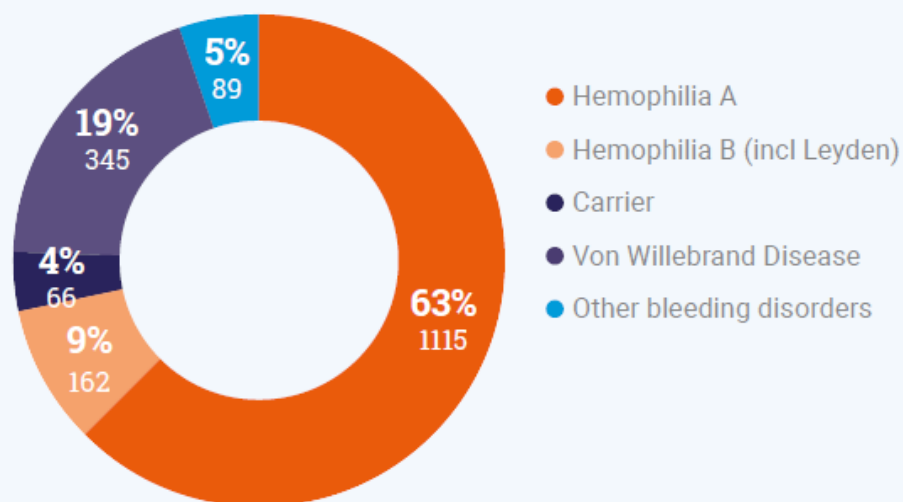
Missing **4**

# Results: diagnoses registered

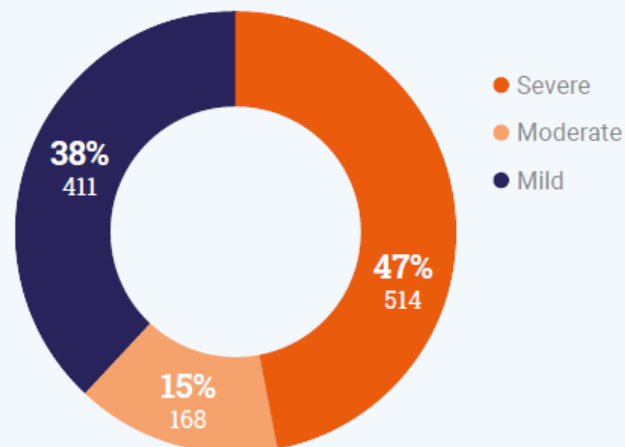
## Diagnosis

Total completed **1777** (100%)

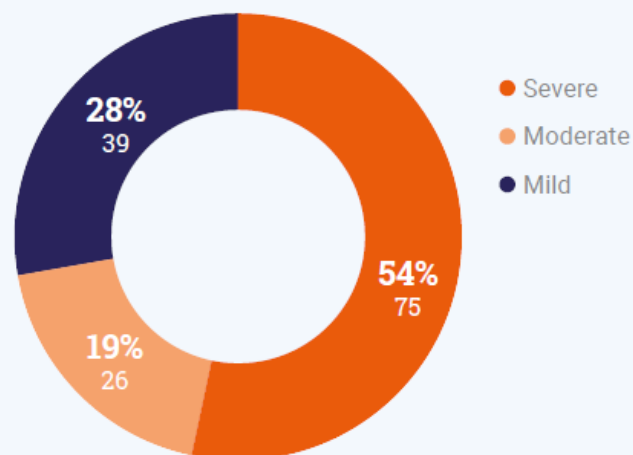
Missing **130**



## Hemophilia A



## Hemophilia B



# Results: VastePrik app

VastePrik users (n=547) mainly severe hemophilia A / B

## Infusions and bleeds

**Table 11** Number of infusions by reason reported in VastePrik (2018-2019)

Reason infusion	Number of infusions	%
Prophylaxis	47851	88
Precaution (risky activities)	1372	3
(Directly following a) Bleed	2657	5
Aftercare (after a bleed or surgery)	2388	4
<b>Total completed</b>	<b>54268</b>	<b>100</b>

**Table 12** Type of bleeds reported (2018-2019)

Type of bleed	Number of bleeds	%
Joint	1347	51
Muscle	528	20
Subcutaneous	185	7
Mucous membranes	138	5
Other	459	17
<b>Total</b>	<b>2657</b>	<b>100</b>

**Table 13** Bleed severity and cause of reported bleeds (2018-2019)

Bleed severity	Number of bleeds	%
Low	714	27
Average	1468	55
High	475	18
<b>Total</b>	<b>2657</b>	<b>100</b>

Cause	Number of bleeds	%
Spontaneously	1158	44
Overload	620	23
Accident or trauma	478	18
Postoperative	24	1
Other	377	14
<b>Total</b>	<b>2657</b>	<b>100</b>

# Discussion

- ✓ Dutch Hemophilia Registry successfully implemented in all Comprehensive Care Centres
  - Challenges: building organizational structure, lots of agreements, pushing the ICT company, privacy issues, finances, burden of manual registration, etc.
  
- ✓ 'VastePrik' digital infusion log used by severe patients
  - Challenges: bugs in mobile app, irregular use, registration errors, etc.
  
- ✓ From 1/1/2020 central registration of adverse events
  - Challenges: adverse events of not registered patients, data export from HemoNED to EUHASS

# Future perspectives

- Automated import from electronic health records to HemoNED Registry to minimize manual registration
- Postmarketing surveillance for new treatments, e.g., Emicizumab, gene therapy
- Benchmarking, national & international
- Structural (financial) embedding of registry in Dutch governmental system of expensive medicines reviews

# Presented on behalf of

## **Dutch Hemophilia patient society (NVHP)**

MHE (Mariette) Driessens

J (Jan) Schipper

## **Leiden University Medical Center**

FJM (Felix) van der Meer

EM (Liesbeth) Taal

## **University Medical Center Utrecht, Van Creveldkliniek**

K (Kathelijn) Fischer

N (Nanda) Uitslager

## **Amsterdam UMC, University of Amsterdam**

CJ (Karin) Fijnvandraat

## **Radboud University Medical Center**

BAP (Britta) Laros-van Gorkom

## **University Medical Center Groningen**

RYJ (Rienk) Tamminga

## **Erasmus University Medical Center**

MJHA (Marieke) Kruip





# Thank you for your attention!

## Contact

Email: [info@hemoned.nl](mailto:info@hemoned.nl)

Website: [www.hemoned.nl/en](http://www.hemoned.nl/en)

## HemoNED Foundation Board

Dr. Felix van der Meer

Dr. Kathelijn Fischer

Dr. Mariette Driessens

## Project coordinator

Dr. Geertje Goedhart

## Data manager

Dr. Liesbeth Taal



Felix van der Meer



Kathelijn Fischer



Mariëtte Driessens



Geertje Goedhart



Liesbeth Taal