



sis

انج

مَنْ قَتَلَ نَفْسًا بِغَيْرِ نَفْسٍ أَوْ فَسَادٍ فِي الْأَرْضِ فَكَأَنَّمَا قَتَلَ النَّاسَ جَمِيعًا وَمَنْ أَحْيَاهَا فَكَأَنَّمَا أَحْيَا النَّاسَ جَمِيعًا

مائده-۳۲

إِيَّاكَ وَالدَّمَاءَ وَسَفَّكَهَا بِغَيْرِ حِلِّهَا

بپرهیز از خونها و خونریزیهای بناحق ... چون در روز حساب به داوری در میان مردم پردازد، نخستین داوری او در باره خونهایی است که مردم از یکدیگر ریخته اند. پس مباد که حکومت خود را با ریختن خون حرام تقویت کنی، زیرا ریختن چنان خونی نه تنها حکومت را ناتوان و سست سازد، بلکه آن را از میان برمی دارد یا به دیگران می سپارد

[ترجمه و شرح نامه ۵۳ نهج البلاغه \(عهدنامه مالک اشتر\)؛ بخش بیست و پنجم: حرمت خون انسانها](#)

انجمن ترومبوز هموستاز ایران

Iranian Pediatric Thrombosis Registry (IPTR)

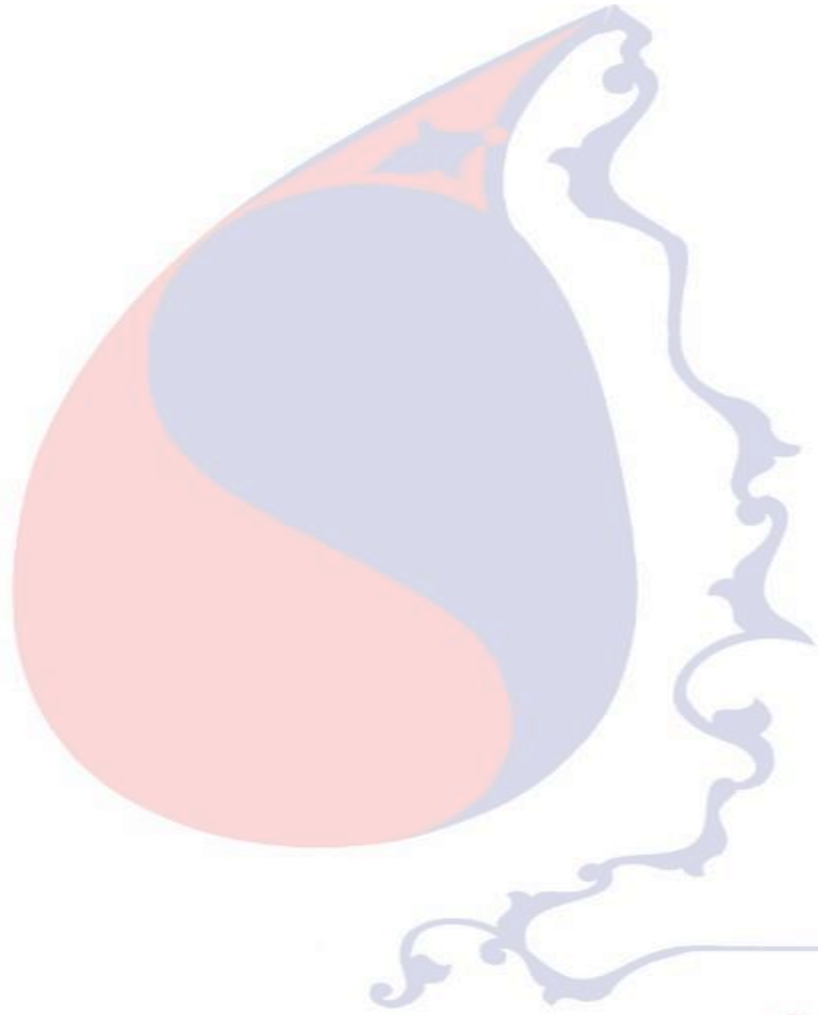
PEYMAN ESHGHI MD.

Professor of Pediatric Hematology&Oncology
Mofid Children Hospital

S.B.M.U.

12-08-1401

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Why registry

IRSTH

**Iranian Society of
Thrombosis and Hemostasis**

انجمن ترومبوز هموستاز ایران

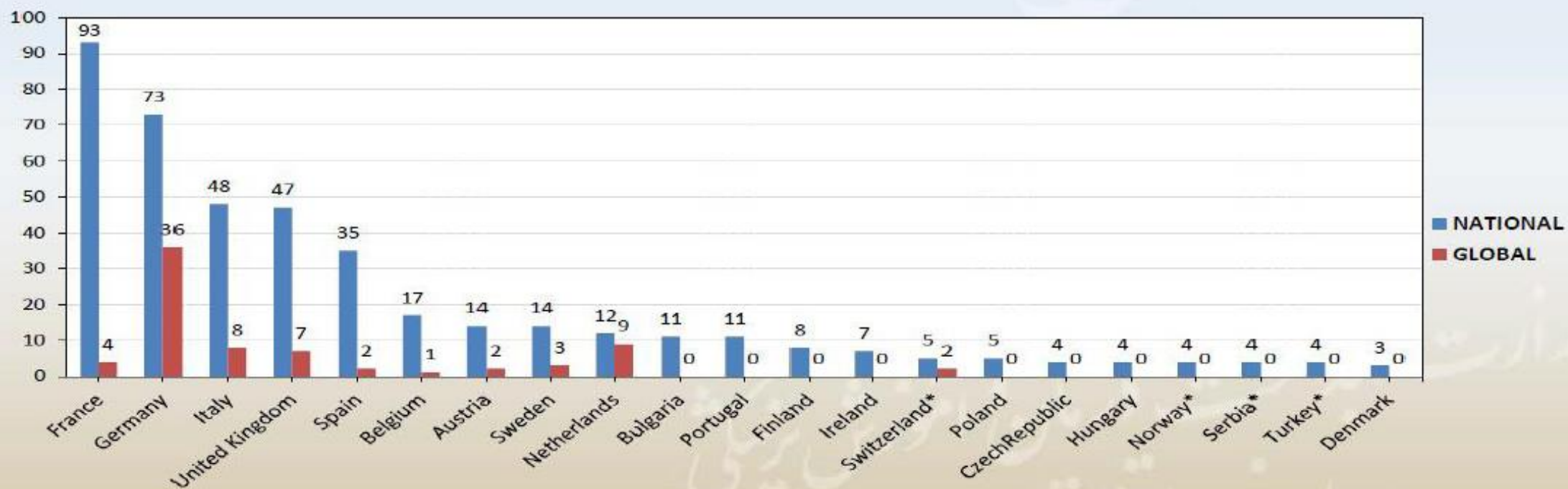
Table 1 Prevalence of patients with leprosy resident in their homes in Norway 1856, 1860 and 1865 with subsequent 5-year incidence by region

Region	Prevalent cases		Subsequent incident cases			
	Year	n_1	Period	n_2	Annual % of initial cases (i.e. 1856)	Annual % of immediate previous prevalent cases
North Norway and Trøndelag	1856	722	1856–60	348	9.6	9.6
	1860	700	1861–65	349	9.7	10.0
	1865	559	1866–70	290	8.0	10.3
Sunnfjord	1856	433	1856–60	209	9.7	9.7
	1860	305	1861–65	153	7.1	10.0
	1865	246	1866–70	112	5.1	9.1
All other regions	1856	1473	1856–60	574	7.8	7.8
	1860	1203	1861–65	496	6.7	8.2
	1865	1060	1866–70	395	5.4	7.5
Total	1856	2628	1856–60	1131	8.6	8.6
	1860	2208	1861–65	998	7.6	9.0
	1865	1865	1866–70	797	6.1	8.5

Source: Adapted from G. Armauer Hansen. *Spedalskhedens Årsager*. Christiania 1874 (p. 70).

The origin of registry-based medical research and care

نمودار فراوانی تعداد برنامه های ثبت بیماری های نادر در کشورهای اروپایی



Definition of a Disease Registry

- A disease registry is a database that contains information about **people diagnosed with specific types of diseases.**
- The registry collects information that can be used for :
 - capturing, managing, and organizing specific information for a population of patients.
 - **providing a systematic and comprehensive care**
- Disease registries are either clinical-based or population-based.

A clinical-based disease registry

- Contains Data on patients with a **specific type of disease**, diagnosed and treated at a practice
- Allows care team members **to proactively manage patients with chronic diseases.**

A population-based disease registry :

- Contains and **Tracks** Records for people :
 - Diagnosed with a **specific type of disease**
 - **Reside within a defined geographic region** (i.e., a community, city, or statewide).

Benefits of a Registry

- **A powerful tool** that can drive significant **practice change** and **improve the health** of the patients being served
- Enable the provider **to ensure** that all their patients are getting proper care
- **Track the progress of high-risk patients**
- Identify the need for **follow-up services**
- **Empower patients** to take an **active role** in their treatment
- **Coordinate care** and identify gaps
- Increase **public awareness** to prevent chronic diseases
- Incorporate **consensus guidelines** for disease and **support studies & evidence-based care**

Iranian Society of

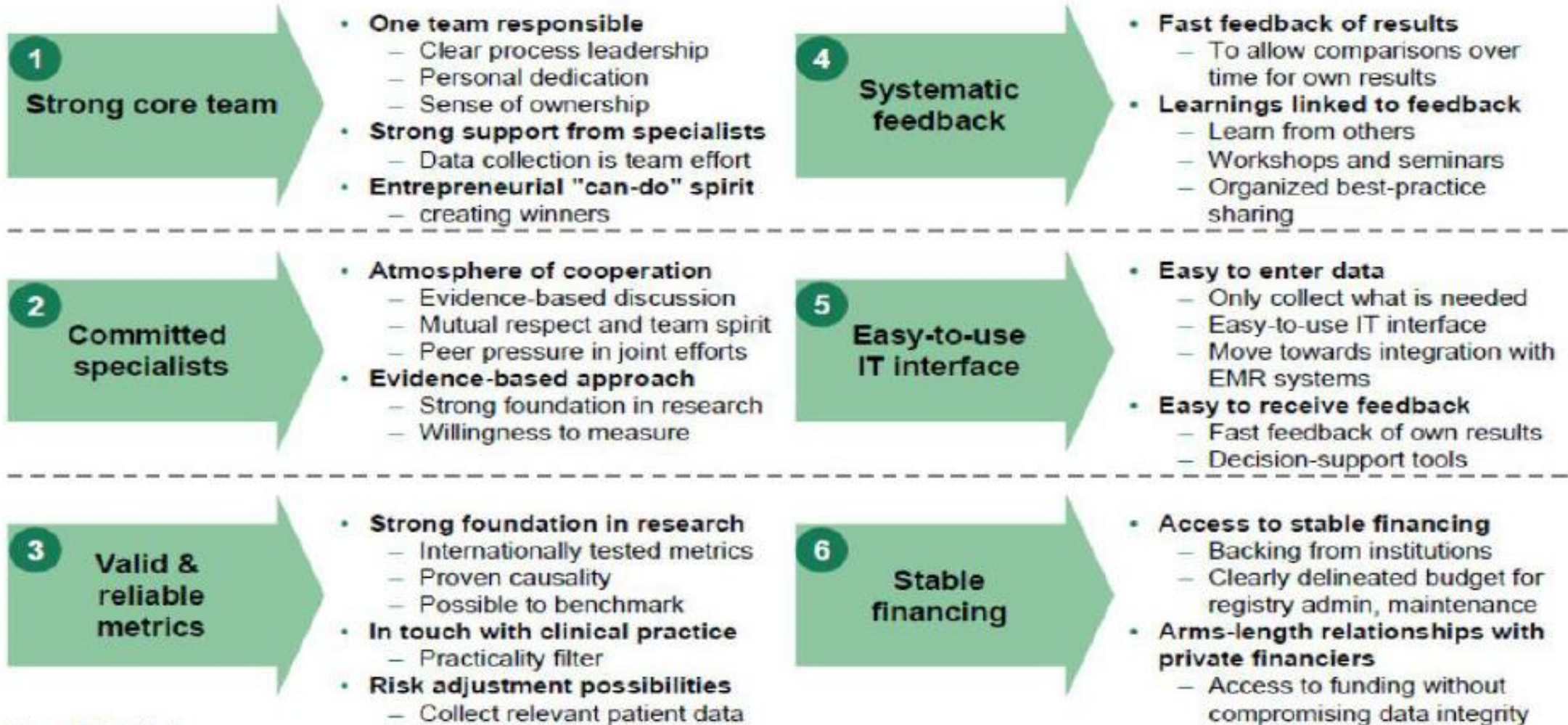
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Registry is a system



First-class quality registry fulfill six requirements



Source: BCG analysis

Value guided healthcare_Final Documentation_Aug09.ppt

Selection bias

- Site selection (i.e. if sites with a non-representative population are preferably included),
- Patient enrolment (i.e. if not all patients are enrolled or patients enrolled are not representative of the patient population)
- Patient loss to follow-up.
- Influenced by many factors, including clinical, demographic and socio-economic factors.

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Key points and steps

- To clearly define **the purpose of the registry**
- To translate the corresponding **target population**. definition : **WHO,WHEN,WHERE,HOW** to be enrolled
- To establish processes allowing for enrolment of **ALL** eligible patients :

Prospective or RELIABLE Retrospective

- To create a system that best **minimizes loss to follow-up**
- Consider potential confounders and effect modifiers



Pediatric thrombosis as an object for
Disease registry

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- Pediatric thrombosis is not only a rare, but also a heterogeneous disease with regard to Incidences, age, sex, risk factors, location, diagnosis , treatment, comorbidity, and outcome.

- High-quality evidence for the management of most types of pediatric TE is not available on scarce and low-level pediatric guidelines. (ASH 2019)

- Performing RCTs is very challenging.
- Many disease registries, by gathering clinical data, have shown to be invaluable sources of information in larger, more heterogeneous populations, especially in rare diseases

- Even regulatory agencies like the European Medicines Agency have not been able to regulate the use of heparin in thromboprophylaxis

Jones S, James E, Prasad S. Disease registries and outcomes research in children: focus on lysosomal storage disorders. *Paediatr Drugs*. 2011;13:33-47.

Lacasse Y, Krishnan JA, Maltais F, Ekstrom M. Patient registries for home oxygen research and evaluation. *Int J Chron Obstruct Pulmon Dis*. 2019;14:1299-1304.

Lopez-Beret P, Orgaz A, Fontcuberta J, et al. Low molecular weight heparin versus oral anticoagulants in the long-term treatment of deep venous thrombosis. *J Vasc Surg*. 2001;33:77-90.

<https://www.fda.gov/about-fda/innovation-fda/fda-facts-postmarket-patient-registry-ensures-access-safe-and-effective-devices>. Accessed January 19, 2021.

A Historical Perspective

- The first reported case of inherited thrombophilia described a Norwegian family (Egeberg Thromb Diath Haemorrh 1965; 13: 516–530.)
- In the pediatric literature, the scarce information on TEs was generally represented by case reports or by autopsy-based manuscripts with limited value till **1968**
- From **1968 to 1971**, an all-Scottish pediatric inpatient hospital database started to collect data, then after national and/or international databases started to define the characteristics of thrombosis in children
 - Jones DR, Macintyre IM: Venous thromboembolism in infancy and childhood. Arch Dis Child 1975; 50: 153–155.
- In the **early 1990s**, Dr. Andrew started the first surveillance program across Canada : “ the Canadian Childhood Thrombophilia Registry”
 - Andrew M, et al. VTE in children: first analyses of the Canadian Registry of VTE. *Blood*. 1994;83:1251-1257.
 - Monagle P, et al: Outcome of pediatric thromboembolic disease: *Pediatr Res* 763-766:47; 2000

- Pediatric VTE:

- The incidence of VTE in children was reported to be between **0.07 and 0.14 case per 10,000** children, and more recently **58 cases per 10,000 hospital admissions** on a bimodal pattern with a peak occurring in infants <1 year and adolescence Andrew M, et al. VTE in children: first analyses of the Canadian Registry of VTE. *Blood*. 1994;83:1251-1257
- 70% increment of pediatric VTE in hospitalized patients during a 6-year period in the United States from 2001 to 2007 : **1 in 200 children** admitted to a complex pediatric health care facility develop a VTE (Raffini L . et al.,Pediatrics 2009; 124: 1001–1008.)
- In contrast to VTE in adults, idiopathic VTE is rare, and **95% of VTEs in children are associated with predisposing risk factors**:including CVCs (the single most important risk factor), cardiovascular disease, nephrotic syndrome, surgery, infection, malignancy, and anatomic anomalies.
- **Direct thrombosis-related mortality** in children depending on the type of predisposing factor AND the location of the vessel occlusion may be as high as **7–9%**
- **Morbidity** was also substantial with **8%** having recurrent thrombosis, and **12%** having postthrombotic syndrome
- The initial cost estimates related to **VTE alone** in children in the US, likely an underestimation, are in the order of **USD 90 million per year**

- ATE:

- Arterial ischemic stroke (AIS) occurs in both neonates and children with an estimated incidence between 1 per 1600 to 5000 live births, and about 1.2 to 7.9 per 100,000 children per year, respectively.
- Pediatric AIS in North America: (Agrawal N. et al., Stroke 2009; 40: 3415–3421 Golomb MR., et al., Stroke 2009; 40: 52–57.)
 - The incidence has been estimated as 2.4/100,000/year
 - Neonates comprise 25% of pediatric patients with AIS
 - AIS is one of the top ten causes of death in the pediatric population

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Some knowledge gaps in pediatric thrombosis

ASH 2018 guideline for treatment of pediatric venous thromboembolism

Natural history & Diagnosis of:

- (A)Symptomatic catheter-related VTE, renal VTE, and (a)symptomatic SVT in neonates
- Asymptomatic VTE, (catheter-related) superficial VTE, large DVT and submassive and massive PE, (A)Symptomatic SVT, and right atrial thrombosis in children
- Catheter-related ATE in infants and young children
- Radiological screening for asymptomatic catheter-related VTE and ATE?

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Some knowledge gaps in pediatric thrombosis

ASH 2018 guideline for treatment of pediatric venous thromboembolism

Treatment(1):

- **What are the benefits of anticoagulation versus no anticoagulation in:** neonates and children with asymptomatic VTE, portal vein thrombosis, and SVT; in neonates with renal VTE; and in children with (catheter-related) superficial VTE?
- **When is thrombolysis or thrombectomy indicated in:** neonates and children with right atrial thrombosis and SVT; and in children with large DVT, submassive and massive PE?
- **What is the risk/benefit and the minimal infrastructure, experience, and annual case load needed of:** catheter-directed thrombolysis compared to systemic thrombolysis in treatment of VTE?
- **What is the optimal timing of catheter removal in:** children with catheter-related VTE?

Some knowledge gaps in pediatric thrombosis

Treatment(2):

- **When and in which subgroups of patients is antithrombin replacement therapy appropriate in addition to heparin in the treatment of thrombosis?**
- **What is the optimal duration of anticoagulation in (catheter-related) superficial VTE, if needed, in SVT, and in unprovoked VTE in children?**
- **What is the impact of various risk factors to the optimal duration of anticoagulation in VTE?**
- **What is the mortality, recurrence risk, major bleeding risk, and quality of life outcomes for various treatment duration in children with unprovoked VTE?**
- **Which biomarkers or other factors can be used to predict recurrence in children with unprovoked VTE?**
- **What is the optimal intensity, duration, and modality of antithrombotic treatment for pediatric patients with catheter-related ATE?**

Some knowledge gaps in pediatric thrombosis

ASH 2018 guideline for treatment of pediatric venous thromboembolism

Outcome

- What are the risk factors for poor acute and long-term outcome of catheter-related ATE?
- What is the impact of vitamin K antagonists versus low-molecular weight heparin on bone density for long-term treatment?
- What is the effect of direct oral anticoagulants on menstrual bleeding in teenagers?

Internat

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DOI: 10.1111/jth.15260

RECOMMENDATIONS AND GUIDELINES



Network

- the ISTH SSC and Hemostasis Network (IPED)
- The aims of the network are:
 - (1) Develop a prospective registry
 - (2) Establish a network of centers effectively collaborating
- At this moment, the network consists of 17 countries.
- By January 2021, the network will be expanded to include 25 countries.

International pediatric thrombosis network to advance pediatric thrombosis research: Communication from the ISTH SSC subcommittee on pediatric and neonatal thrombosis and hemostasis

C. Heleen van Ommen¹ | Manuela Albisetti² | Mohir Bhatt³ | Marianne Bonduel⁴ | Brian Branchford⁵ | Elizabeth Chalmers⁶ | Anthony Chan⁷ | Neil A. Goldenberg^{8,9} | Susanne Holzhauser¹⁰ | Paul Monagle^{11,12} | Ulrike Nowak-Göttl¹³ | Shoshana Revel-Vilk¹⁴ | Gabriela Sciuccatie¹⁵ | Nongnuch Sirachainan¹⁶ | Christoph Male¹⁷ | for the Subcommittee on Pediatric, Neonatal Thrombosis, Hemostasis

¹Department of Pediatric Hematology-Oncology, Erasmus MC Sophia Children's Hospital, Rotterdam, the Netherlands

²Division of Hematology, University Children's Hospital, Zurich, Switzerland

³Department of Pediatrics, McMaster University, Hamilton, Ontario, Canada

⁴Servicio de Hematología y Oncología, Hospital de Pediatría Prof. Dr. Juan P. Garrahan, Buenos Aires, Argentina

⁵Department of Pediatrics, University of Colorado Anschutz Medical Campus, Denver, Colorado, USA

⁶Department of Hematology, Royal Hospital for Children, Glasgow, UK

⁷Department of Pediatrics, McMaster University, Hamilton, Ontario, Canada

⁸Departments of Pediatrics and Medicine, Division of Hematology, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA

⁹Thrombosis and Stroke Programs, Johns Hopkins All Children's Hospital, and Johns Hopkins All Children's Institute for Clinical and Translational Research, St. Petersburg, Florida, USA

¹⁰Department of Pediatric Hematology-Oncology, Charité, Berlin, Germany

¹¹Department of Pediatrics, Hematology Research Group, Murdoch Children's Research Institute, The University of Melbourne, Melbourne, Australia

¹²Department of Clinical Hematology, The Royal Children's Hospital, Melbourne, Australia

¹³Department of Pediatric Hematology-Oncology, Münster and Institute of Clinical Chemistry, University Hospital Kiel-Lübeck, University of Münster, Kiel, Germany

¹⁴Pediatric Hematology/Oncology Unit, Shaare-Zedek Medical Center, Hebrew University, Jerusalem, Israel

¹⁵Servicio de Hematología y Oncología, Hospital de Pediatría Prof. Dr. Juan P. Garrahan, Buenos Aires, Argentina

¹⁶Department of Pediatrics, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

¹⁷Department of Pediatrics, Medical University of Vienna, Vienna, Austria

Thrombosis

International

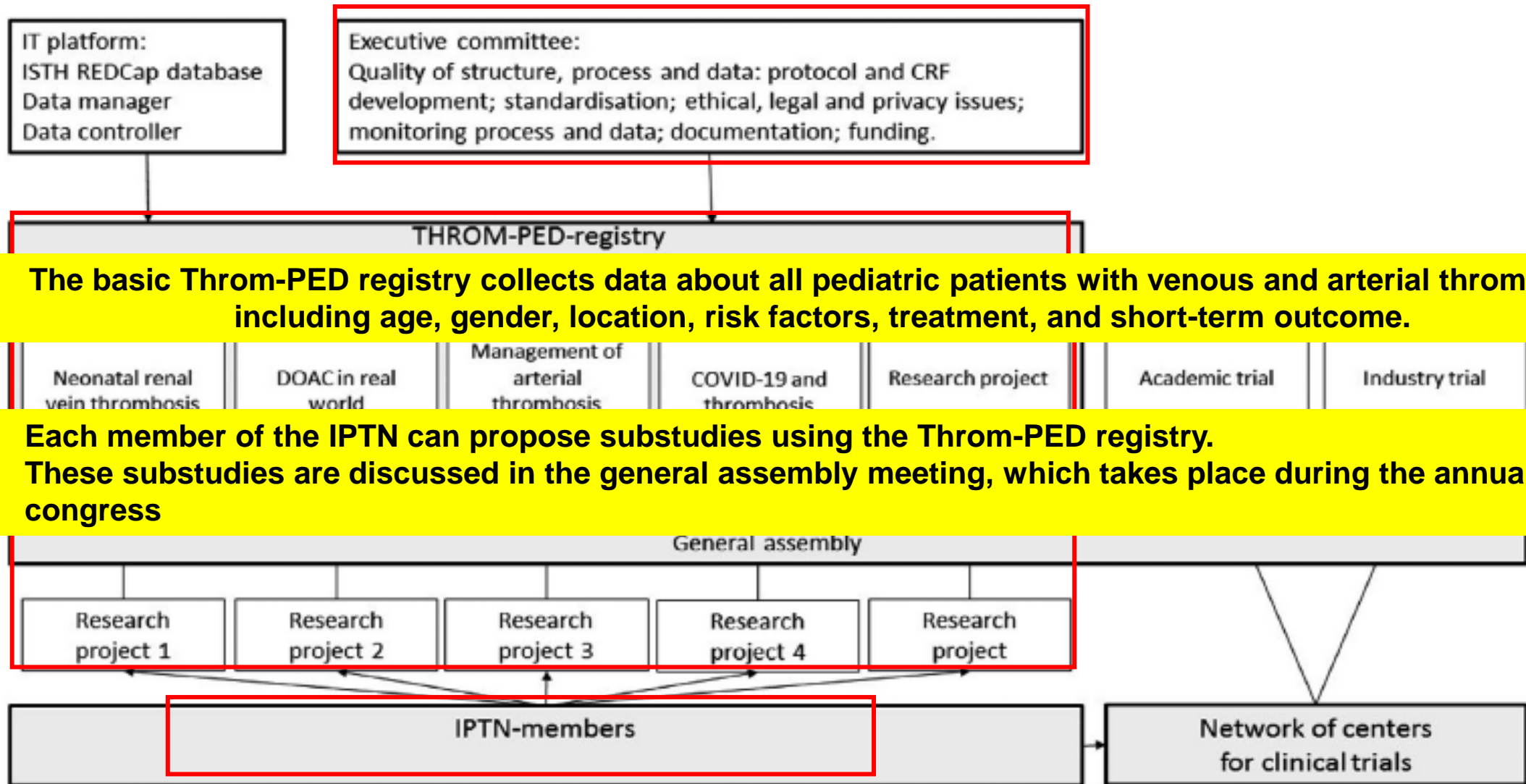
centers experienced in

7 countries.

included in



Current structure of the International Pediatric Thrombosis Network (IPTN)



THROM-PED REGISTRY:

Systematic and Prospective collecting patient data

- Understanding the **natural history** of certain types of pediatric TE
- Identifying **risk factors** and groups at high risk for TE
- Understanding **diagnostic methods**
- Monitoring clinical **effectiveness, safety, and cost effectiveness** of anticoagulant drugs in all types of TE
- **New drug trials**
- Patient-reported **outcomes AND quality of life** assessments
- To evaluate long-term clinical outcomes



INTERNATIONAL PEDIATRIC THROMBOSIS NETWORK

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The International Pediatric Thrombosis Network is a group of pediatric thrombosis experts whose **ultimate goal** is to bring the best treatment to children with thrombosis.

Although thromboembolic events are increasingly recognized in children, the incidence remains relatively rare. Current guidelines for clinical care are based on low evidence and mainly extrapolated from adult studies. Large pediatric DOAC trials are underway, but many important questions remain to be answered.

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- [Membership Info \(Renew!\)](#)
- [Refer a Friend](#)



Membership Form

Please fill out and complete the form below.

Thank you!

1) Investigator Name:

2) Investigator Institution:

3) Institution Address:

4) Institution Country:

5) Investigator Email:

6) Investigator Phone Number:

Submit



Logged in as mbordbar | Log out

- My Projects
- Project Home or Project Setup
- REDCap Messenger
- Project status: **Production**

Data Collection

- Record Status Dashboard
- Add / Edit Records
- Record ID 12-8 [Select other record](#)
- Data Collection Instruments:
 - Pediatric Thrombosis Network**
 - Renal Vein Thrombosis
 - Outcomes

Applications

- Field Comment Log

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature
- Contact REDCap administrator

International Pediatric Thrombosis Network

Save & Exit Form

Save & Go To Next Record

-- Cancel --

Actions: [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

Pediatric Thrombosis Network

➕ Adding new Record ID 12-8

Record ID	12-8
Center Number: <small>* must provide value</small>	<input type="text"/>
Investigator Name: <small>* must provide value</small>	<input type="text"/>
Investigator email address: <small>* must provide value</small>	<input type="text"/>
Patient number: <small>* must provide value</small>	<input type="text"/>
Informed consent for this patient? <small>* must provide value</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
General Information	
Age at Diagnosis of Thrombosis (years):	<input type="text"/> <small>Enter whole numbers only (no text).</small>
Age at Diagnosis of Thrombosis (months):	<input type="text"/> <small>Enter the number of months over the age listed above. Enter whole numbers only (no text).</small>
Age at Diagnosis of Thrombosis (days)	<input type="text"/>
Gender:	<input type="radio"/> Male <input type="radio"/> Female reset
Type of Thrombosis: <small>* must provide value</small>	<input type="checkbox"/> Venous <input type="checkbox"/> Arterial <small>Please check all that apply.</small>

Location:

* must provide value

- Upper Extremity
- Lower Extremity
- Inferior Caval Vein
- Superior Caval Vein
- Kidney
- Lung
- Liver
- Intracardiac
- Intracranial
- Other (specify below)



Please check all that apply.

Risk Factors:

* must provide value

- Central Venous Catheter
- (Congenital) Heart Disease
- Oral Contraceptives
- Malignancy
- Infection
- Surgery
- Immobility
- Renal Disease
- Obesity
- Arterial Catheter
- Previous Thrombotic Event
- Thrombophilia
- Positive Family History
- Maternal or Delivery Factors (specify below)
- Other (specify below)

Save & Exit Form

Save & Go To Next Record

-- Cancel --

- Maternal or Delivery Factors (specif
 - Other (specify below)
- Please check all that apply.

- Treatment:**
** must provide value*
- No Antithrombotic Treatment
 - Unfractionated Heparin
 - LMWH (specify below)
 - Vitamin K Antagonist (specify below)
 - Argatroban
 - Fondaparinux
 - Bilivarudin
 - DOAC (specify below)
 - Thrombolysis (specify below)
 - Antiplatelet drugs (specify below)
 - Other (specify below)

Save & Exit Form

Save & Go To Next Record ▾

-- Cancel --

Form Status

Complete?

Save & Exit Form Save & Go To Next Record ▾

-- Cancel --

International registry

- Better study design and scientific analysis
- More opportunity for development and to upgrade our system
- Stricter compliance with GCP
- More scientific credibility
- Fewer scientific defects such as selection bias, etc
- More supervision on potential confounders and effect modifiers
- More chance to be published

National registry

- More patients and cases independently
- More chance for representing our sites and potentials
- More chance for our submitted studies to be approved
- An opportunity to learn HOW CAN WE WORK TOGETHER
- An opportunity for an attempt to establish a national network and regional leadership

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Iranian Pediatric Thrombosis Registry (IPTR)

- Modelling from –but not the same as- IPTN to be able to synchronized with them if needed.
- **National data base** :Off line data transport
- **Data collection site**: IRSTH and/or one of the research centers in IRAN .(MOFID(2); Shiraz; ...) provides financial , technical and human resources support for a network of centers , sites , offices and clinics,etc.
- Based on a cooperation agreement between the research centers and the resource provider association (IRSTH), the ownership of information is defined and an Executive Committee (**EC**) is formed.
- Each center, site ,physician or investigator own their own information.
- In order to use the collected information from all over the country for studies, the study proposal must be submitted to **EC** and the research center introduced by the researcher.
- The principal investigator of the study undertakes to involve all of the centers to as partners of the study in the final result.
- **ICF** should be taken from the patients and parents /legal guardians

اطلاعات الزامی و شرطی

- (۱) اطلاعات هویتی و دموگرافیک فردی بیمار :
❖ نام و نام خانوادگی , نام پدر, کد ملی , تاریخ تولد , جنسیت , قومیت, آدرس و تلفن همراه و ثابت تماس , شماره پرونده بیمارستانی
- (۲) نام مرکز مراجعه و ثبت اطلاعات:
- (۳) نام و مشخصات پزشک/محقق مسئول بیمار :
❖ نام و نام خانوادگی , رشته و تخصص , تلفن ثابت و همراه , ایمیل
- (۴) سن تشخیص بیماری : (ماه/سال)
- (۵) نوع ترومبوز : وریدی ؛ شریانی (* تنها پس از قطعی شدن نوع ترومبوز ثبت صورت میگیرد)
- (۶) محل ترومبوز + علامت منجر به تشخیص : ۱۶ گزینه محل ترومبوز به همراه علائم و نشانه های تشخیصی مرتبط)
- (۷) ریسک فاکتورهای در شرح حال و سوابق بیمار*
- (۸) اقدامات درمانی
❖ داروهای ضد پلاکتی + نام/آنتی کواگولانت های مصرفی + نام/ترومبولیتیک سیستمیک/لوکال + نام/ترومبکتومی /هیچکدام
- (۹) سیر بیماری :
❖ بهبود کامل/بهبود نسبی/تحت نظر و در حال درمان/عود ترومبوز/مرگ / عدم پیگیری و نامشخص

ریسک فاکتورهای ترومبوز در شرح حال شخصی و خانوادگی

۱. سابقه خانوادگی ترومبوز:  سابقه سکته مغزی در سنین زیر ۵۰ سال / سابقه سکته قلبی در سنین زیر ۵۰ سال / سابقه سقط های مکرر / سابقه ترومبوز ثابت شده اندام، آمبولی ریوی و ... / سابقه هیپر کلسترولمی
۲. کاتتر ورید مرکزی
۳. کاتتر شریانی / نافی
۴. بیماری قلبی مادرزادی / دریچه ای
۵. انواع بدخیمی:  انتخاب گزینه ها
۶. عفونت شدید منجر به بستری
۷. دهیدراتاسیون شدید / متوسط
۸. بیحرکتی کامل:  چند روز
۹. تروما منجر به کوفتگی، کشیدگی، در رفتگی، شکستگی، و ..
۱۰. چاقی: اگر بلی آنگاه BMI
۱۱. بستری در ICU
۲۱. بیماری کلیوی ثابت شده
۳۱. بیماری کبدی ثابت شده
۴۱. حادثه ترومبوتیک ثابت شده: اگر بلی آنگاه  نوع (شریانی / وریدی) و محل
۵۱. ترومبوفیلی ارثی یا اکتسابی ثابت شده: اگر بلی آنگاه انتخاب گزینه: 
- PC; PS; AT; F2G20220; APCR/FVLeiden; Homocysteinemia; high FVIII
- APLA syndrome; high Lp(a)
- OTHER
۴۱. مصرف OCP
۵۱. آنمی های ارثی: 
- سندروم های داسی شکل
- تالاسمی اینترمدیا
- تالاسمی ماژور
- سایر همو گلوبینوپاتی ها و بیماری های هماتولوژی (نام ببرید)
۶۱. بیماری اتوایمون یا روماتیسمی ثابت شده
۷۱. فشار خون بالا
۸۱. دیابت / بیماری متابولیک

اطلاعات انتخابی و ترجیحی

(۱) تصویر برداری های منجر به تشخیص (۱۰ گزینه):

- DUS; CT; CTV; CTA; CTPA; MRI; MRV; MRA; ECHO; OTHER

(۱) آزمایشات پاراکلینیک تشخیصی/ پانل ترومبوفیلی ارثی و اکتسابی

(۲) طول دوره درمان تجویز شده برای بیمار در زمان ثبت : کمتر از ۶ هفته/۶

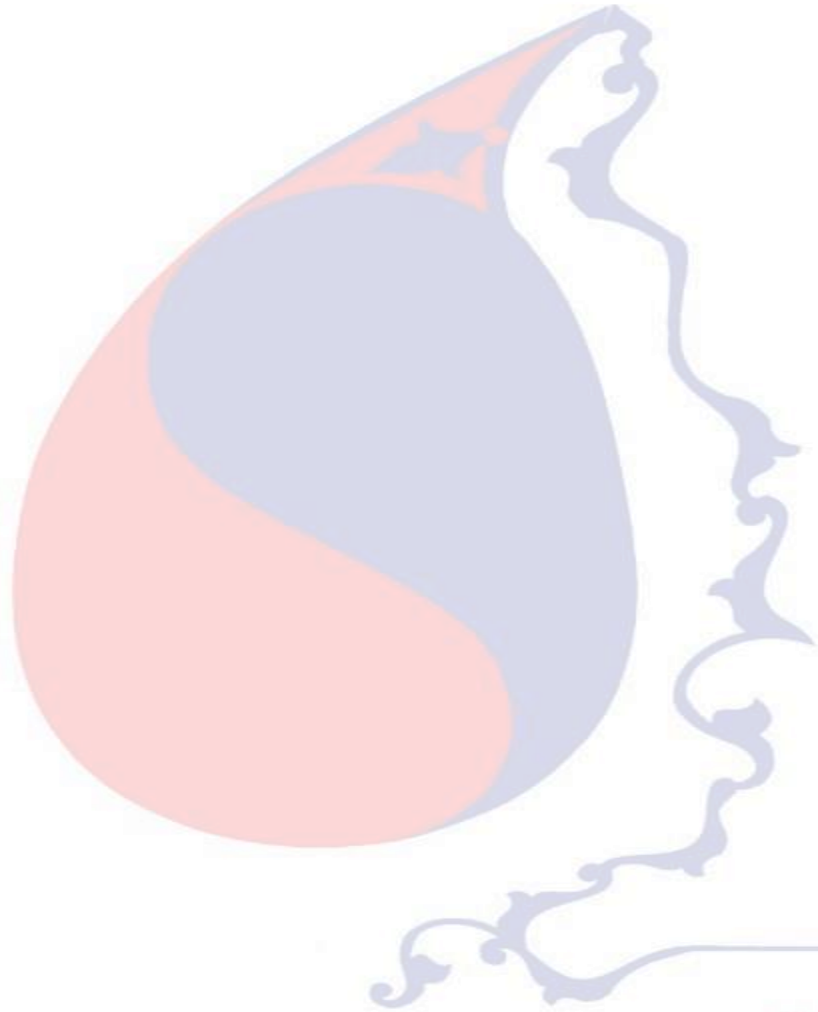
هفته تا ۳ ماه/ ۳ تا ۶ ماه/بیش از ۶ ماه/مادام العمر/نامشخص

(۳) عوارض درمان ثبت شده

(۴) پیگیری تا زمان ثبت : طول مدت پیگیری ؛ تعداد دفعات مراجعه

Thrombosis and Hemostasis

انجمن ترومبوز هموستاز ایران



سپاس از توجه شما
پرسش و پاسخ

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