Capturing venous thromboembolism: imaging and outcomes of venous thromboembolism

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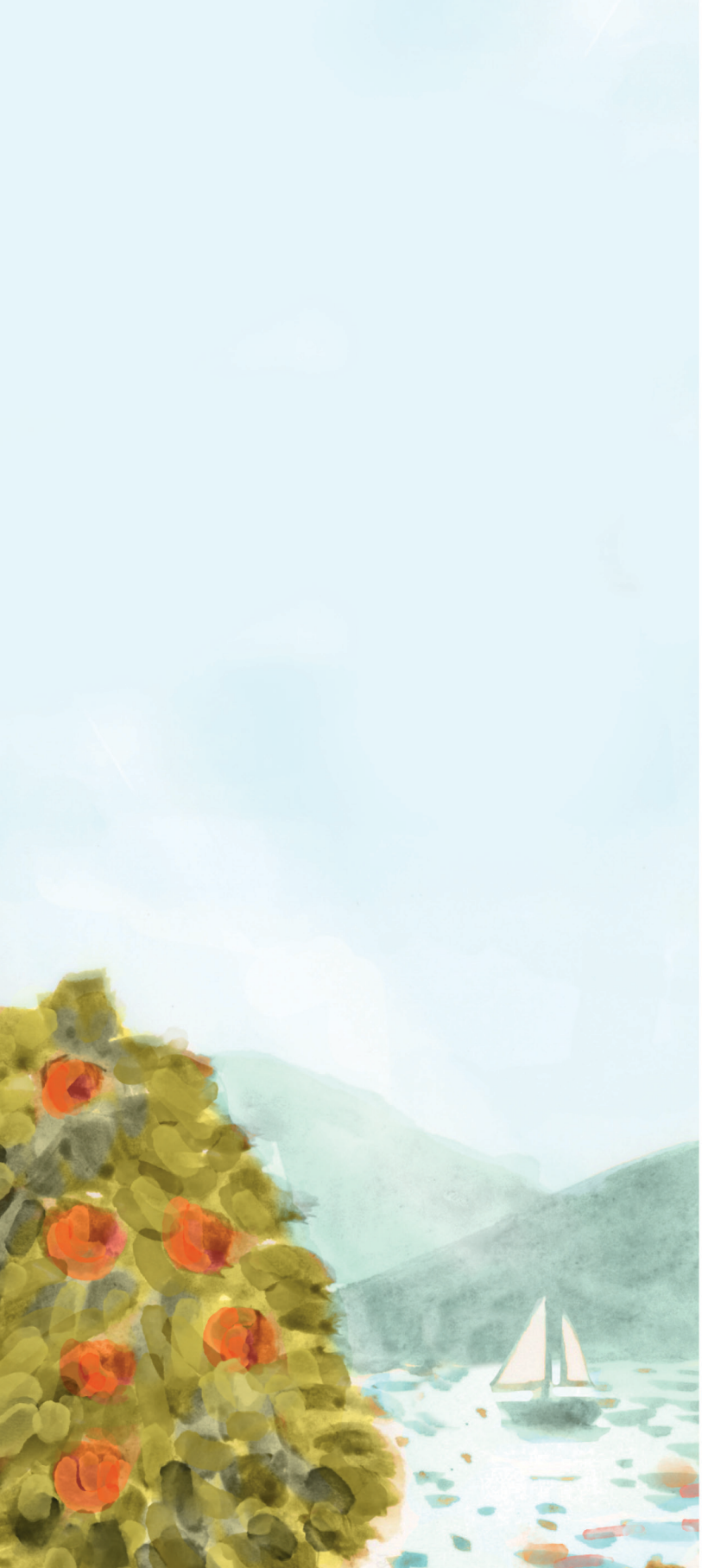

CHAPTER 6

Development of an international standard set of outcome measures for patients with venous thromboembolism: an International Consortium for Health Outcomes Measurement consensus recommendation

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Abstract

The International Consortium for Health Outcomes Measurement assembled an international working group of venous thromboembolism experts and patient representatives to develop a standardised minimum set of outcomes and outcome measurements for integration into clinical practice and potentially research to support clinical decision-making and benchmarking of quality of care. 15 core outcomes important to patients and health-care professionals were selected and categorised into four domains: patient-reported outcomes, long-term consequences of the disease, disease-specific complications, and treatment-related complications. The outcomes and outcome measures were designed to apply to all patients with venous thromboembolism aged 16 years or older. A measurement tool package was selected for inclusion in the core standard set, with a minimum number of items to be measured at predefined timepoints, which capture all core outcomes. Additional measures can be introduced to the user by a cascade opt-in system that allows for further assessment if required. This set of outcomes and measurement tools will facilitate the implementation of the use of patient-centered outcomes in daily practice.

Introduction

Venous thromboembolism (VTE) comprising of deep vein thrombosis (DVT) and pulmonary embolism (PE) affects 1-3% of the population and has an annual incidence of 1-2 per 1000 in high-income countries.[1-3] Approximately 60% of all VTE instances present as DVT with the other 40% presenting as PE with or without DVT.[4] The management of VTE involves anticoagulation and can be complicated by sequelae, which include recurrent VTE, anticoagulant therapy associated bleeding, post-thrombotic syndrome (PTS), and post-PE syndrome (PPES), with PTS and PPES affecting 40-50% of all VTE survivors.[5-8] VTE has a substantial negative affect on patients' lives, causing a reduced quality of life, a higher prevalence of unemployment, and emotional distress including anxiety and post-thrombotic panic syndrome.[9-14]

Globally, the management of VTE is inconsistent and highly diverse. Not only are there country level differences in health-care systems, availability of resources, and socio-religious circumstances, but guidelines also differ regarding recommendations on risk stratification, management of VTE, and long-term follow-up, with little consideration to the patients' perspective or values. There are major differences in treatment outcomes, such as, mortality[15-17], loss of quality-adjusted life-years[18], and chronic thromboembolic pulmonary hypertension (CTEPH) [19] across countries and continents. Other differences involve the use of health-care resources measured by rate of hospital admissions[20, 21], duration of hospital admission[21], and use of interventional techniques. Moreover, inability to work due to VTE and psychosocial consequences, such as persisting anxiety and depression, which are of considerable importance to the individual patient and society, receive minimal attention in VTE patient pathways.[11-14]

There is increasing recognition of the importance of integrating all aspects of health care to focus on the delivery of value-based health care. Value-based health care assesses value by measuring health outcomes against the cost of their delivery, and these approaches lead to improved health outcomes for patients with fewer clinical visits, medical tests, and procedures.[22] Therefore, rather than a system within which clinicians and health-care providers are paid on the basis of the number of health-care services they deliver,[23] a shift to a value-based approach for VTE would more directly reward clinicians for helping patients improve their health, reduce the effects and incidence of chronic disease, and live healthier lives in an evidence-based way. A fully standardised approach for value-based health care would include both clinical and patient-reported outcome measures (PROMs), assessed at fixed timepoints, using well-defined instruments and definitions.

To support improvements in care for patients with VTE globally via a value-based health-care approach, the International Consortium for Health Outcomes Measurement

(ICHOM) assembled a geographically diverse working group of 27 clinical or scientific VTE experts and patient representatives from 13 countries in Europe, North America, Latin America, and Asia-Pacific. ICHOM is a not-for-profit organization that has previously developed 40 standard sets of value-based outcomes for different disease states. The aim of this project was to propose a broadly applicable and easy-to-use standardised minimum set of outcomes for VTE patients, including PROMs, clinical outcomes, and case-mix factors. The ICHOM-VTE set has three specific goals: to standardise and improve the care for individual patients with VTE, to facilitate the standardization of outcomes to make meaningful comparisons across institutions and countries and, to empower patients to manage their disease and seek the optimal care for their individual needs.

Strategy

A project team (FAK, SAB, CMMdJ, AMG, FS, PBJ, TL, and LSF) guided the working group's efforts over 13 months. By drawing on connections within the project team's network and identifying experts in the field of thrombosis through a PubMed search of relevant scientific outputs, experts and patient representatives were engaged to participate in the working group, with the aim of creating a diverse team. In line with other ICHOM working groups, we aimed for a working group of 25-30 people. A broad range of specialties was represented: methodologists and epidemiologists, vascular specialists, pulmonologists, haematologists, angiologists, internists, surgeons, primary care physicians, nurses, and one palliative care physician, one emergency physician, and one psychologist. During the project, three patient representatives participated in the working group, of whom one stopped after contributing to more than half of the development process. The patient representatives all had experienced VTE themselves at some point in their life courses. The working group convened through nine video conferences between Jan 7, 2021, and Feb 3, 2022, following a structured process that involved professionals and patients in all meetings. The development of the standard set of outcome measures involved several phases: defining the scope of the project, prioritising and defining outcome domains, evaluating and selecting appropriate outcome measurement tools, and selecting and defining relevant case-mix variables and timepoints.

Identification of potential outcomes and case-mix variables

The project team did a systematic literature review, following Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines[24] to identify potentially relevant outcome domains, clinical and patient-reported outcomes, treatment-related complications, and case-mix variables. Appropriate medical subject heading terms and

free word searches were used (online **Appendix A**). The literature search identified 1004 articles. Two reviewers (CMMdJ and AMG) independently screened the articles and selected original research papers in which clinical and patient-reported outcomes were reported in a population of patients with PE or DVT. Any disputes were resolved by a third reviewer (FS). This resulted in the inclusion of 188 articles for full-text review. Patient representatives from the working group participated as a patient advisory group in a separate breakout session to explore their perspectives on which of the various outcomes identified from the literature affected them the most during their day-to-day activities. The predefined criteria by which outcomes were assessed for inclusion in the set were: frequency of the outcome, the effect on the patients, the potential for modifying the outcome, and the feasibility of measuring the outcome. Variables to be used as case-mix factors, which considers how different risk profiles affect outcomes and allows standardised risk adjustment across different populations, were assessed on relevance, independence, and measurement feasibility. All potentially relevant outcomes and case-mix variables were discussed during the video conferences and put to vote in a three-round modified Delphi process.

Selection of (patient-reported) outcome measures and definitions

We mapped the standard set outcomes to corresponding PROMs and definitions identified from the literature review. We applied widely used definitions by scientific organizations (e.g. International Society on Thrombosis and Haemostasis, World Symposium on Pulmonary Hypertension), in guidelines or applied in studies to define the clinical outcomes. If multiple definitions were found, all were put to vote in the Delphi voting process. We identified original and validation studies on relevant PROMs and evaluated their psychometric quality (i.e., validity, reliability, and sensitivity to change), domain coverage, and the feasibility of measurement and implementation. Feasibility considerations included the availability of translations and potential costs associated with the wide implementation of the individual instruments.

Modified Delphi process and open review

Outcome selection was done in an online three-round modified Delphi process. Following each working group video conference, all working group members were required to vote. The consensus process followed the RAND/University of California (Los Angeles, CA) method to reach consensus on which outcomes should be included.[25] The results of each vote were reviewed by the working group during the subsequent video conference. Inclusion in the standard outcome set required that at least 80% of the

working group voted an item as essential, best instrument, or relevant case-mix variable (represented by a score 7-9 on a 9-point Likert scale) in either voting round. Outcomes and case-mix variables were excluded if at least 80% of the working group members voted an item as not recommended (score 1-3). All inconclusive outcomes were voted on in the final round with 70% consensus required for the outcome to be included; if the 70% majority was not met, the outcome was left out of the final set. For the PROMs and case-mix variables, 70% agreement was required for inclusion. On the basis of the discussion with the working group, a tool-package (i.e. a combination of instruments to measure the outcomes) with a cascade opt-in system was proposed and included after the voting round that followed the video conference.

To allow for input from people with current or previous VTE and professional stakeholders outside of the formal working group, an open review period was held in English before the last working group video conference. The project team contacted English-speaking patients and professional stakeholders outside the project's working group through email and social media. The contacted individuals were shown an overview of the set and asked to provide independent feedback and to rate the importance of outcomes using a 9-point Likert scale, via an online survey. The results of this survey were presented to the working group during the final video conference.

Consensus recommendations

ICHOM set target population and the question of patient subgroups

The outcomes and measures included in the VTE standard set were defined for a target population of patients diagnosed with VTE aged 16 years and older, including those with incidental VTE. Although the working group initially decided that subcategories for patients with cancer-associated VTE, pregnant women with VTE, and VTE patients at the end of life should be considered, these subgroups were later deselected, because we could not identify any subgroup-specific outcomes not already covered in the overarching set. Of note, separate ICHOM sets are available for pregnancy and several cancer types.[26,27] The working group considered these ICHOM sets complementary to the VTE set in relevant patients.

Core outcomes in the ICHOM-VTE set

After consolidating the literature review findings and focus group meetings, a proposed list of 87 outcomes was identified for discussion and voting, from which the working group selected 15 core outcomes as crucial to patients with VTE and health-care professionals (**Figure 1**; **Table 1**). The results of the Delphi process regarding the selection of outcomes are summarised in online **Appendix B**.

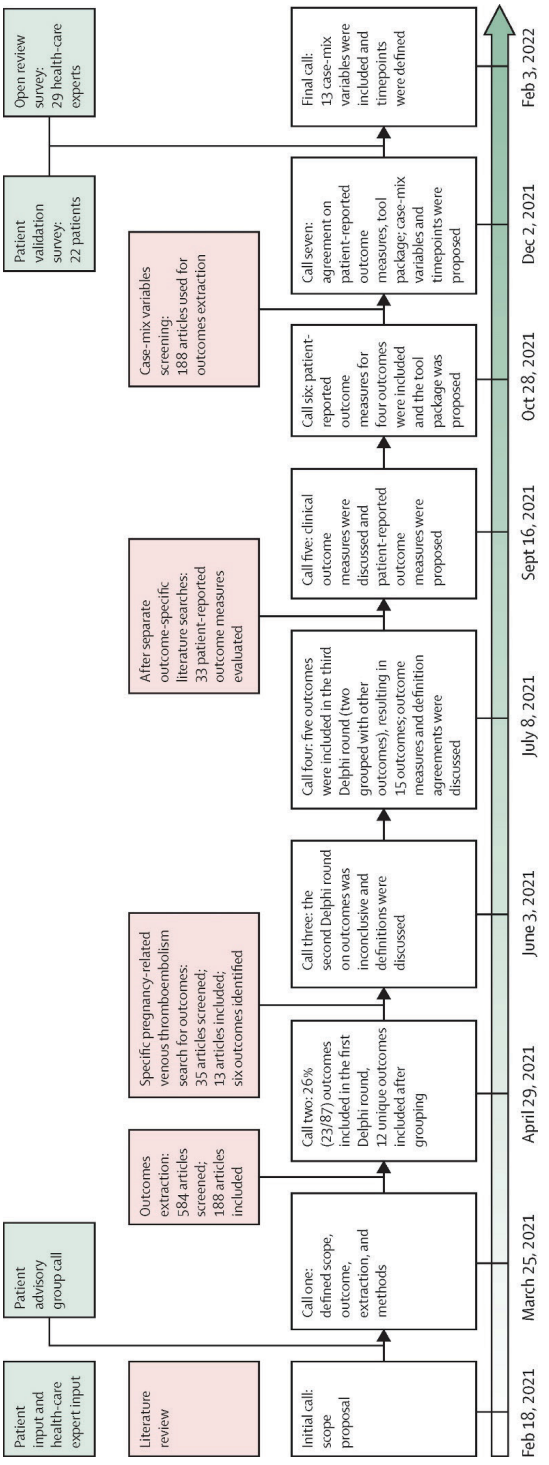


Figure 1: Development of the ICHOM set of patient-centered outcome measures for venous thromboembolism through a structured working group process.

Abbreviation ICHOM: International Consortium for Health Outcomes Measurement.

The outcomes were categorised into four domains: patient-reported outcomes, long-term consequences of the disease, disease-specific complications, and treatment-related complications.

Table 1: Summary of ICHOM venous thromboembolism standard set of outcomes.

Domain	Outcome	Details*	Timing	Data source
Patient-reported outcomes	Quality of life	(1) Measured using the PROMIS Scale v1·2 - Global Health, PEmb-QoL, and VEINES-QOL questionnaires	3 months and 6 months; 1 year and then annually**	Patient
	Functional limitations (including ability to work)	(2) Measured using the Post-VTE Functional Status scale	Index event; 3 months and 6 months; 1 year and then annually**	Patient
	Pain (including symptom severity)	(1) and if required (3) measured using the PROMIS Short Form v2·0 - Pain Intensity - 3a	Index event; 3 months and 6 months; 1 year and then annually**	Patient
	Dyspnea (including symptom severity)	(4) Measured using the PEmb-QoL and PROMIS Short Form v1·0 - Dyspnea Severity - 10a	Index event; 3 months and 6 months; 1 year and then annually**	Patient
	Psychosocial wellbeing	(1) and if required (7) measured using the PHQ-9 and GAD-7 questionnaires	Index event; 3 months and 6 months; 1 year and then annually**	Patient
	Satisfaction with treatment	(5) Measured through the question: "Are you satisfied with your VTE treatment?" and if required (6) measured using the Anti-Clot Treatment Scale	3 months and 6 months; 1 year and then annually**	Patient
	Changes in life view	(8) Measured through the question: "Have you experienced a change in your expectations, aspirations, values, or perspectives on life opportunities since the diagnosis of VTE?"	3 months and 6 months; 1 year and then annually**	Patient
Long-term consequences of disease	Health-care resource utilization	- Number of hospitalizations, and length of stay - Number of emergency room visits - Number of non-hospital activities (including general practice, outpatient clinic visits, home health care, and rehabilitation)	Index event; 3 months and 6 months; 1 year and then annually**	Clinician
	Chronic thromboembolic pulmonary hypertension	Clinical diagnosis	3 months and 6 months; 1 year and then annually**	Clinician

Table 1: Continued

Domain	Outcome	Details*	Timing	Data source
	Chronic thromboembolic pulmonary disease	Clinical diagnosis	3 months and 6 months; 1 year and then annually**	Clinician
	Post-thrombotic syndrome	Villalta Score	3 months and 6 months; 1 year and then annually**	Clinician
Disease-specific complications	Recurrence	Has the patient had recurrent VTE according to the ISTH definition? - Yes/No	Index event; 3 months and 6 months; 1 year and then annually**	Clinician
	Survival	Death regardless of cause	Index event; 3 months and 6 months; 1 year and then annually**	Clinician
Treatment-related complications	Bleeding	Did the patient have any bleeding that was worrisome to the patient or the clinician, impacted daily activities or required medical treatment? - Yes/No	Index event; 3 months and 6 months; 1 year and then annually**	Clinician
	Procedure-related complications	Has the patient experienced an undesirable and/or unintended outcome that is a direct result of a procedure? - Yes/No	Index event; 3 months and 6 months; 1 year and then annually**	Clinician

*The numbers in parentheses are reported along with the measurement tools to be used to measure the outcomes. The tool(s) to be used to measure the outcome are written out in full with a number in parentheses, when reported for the first time. After the first mention, the number in parentheses refers to the measurement tool(s) as introduced along with that specific number.

**For as long as the patient is under care.

Abbreviations ICHOM: International Consortium for Health Outcomes Measurement, PROMIS: Patient-Reported Outcomes Measurement Information System, PEmb-QoL: Pulmonary Embolism Quality of Life, VEINES-QOL: Venous Insufficiency Epidemiological and Economic Study–Quality of Life, VTE: venous thromboembolism, PHQ-9: Patient Health Questionnaire-9, GAD-7: Generalized Anxiety Disorder-7, ISTH: International Society on Thrombosis and Haemostasis.

The working group recommended specific patient-reported outcomes in all the following subdomains be captured: disease-specific and general quality of life; functional limitations including the ability to work; pain; dyspnea; satisfaction with treatment; psychosocial wellbeing including anxiety, depression, and post-thrombotic panic syndrome; and changes in life view. The outcome domain focussing on the long-term consequences of VTE was recommended to consist of the following sub-domains: health-care resource utilization (e.g., hospitalizations, diagnostic tests, and visits to medical professionals such as physiotherapists), chronic thromboembolic pulmonary hypertension (CTEPH), chronic thromboembolic pulmonary disease (CTEPD), and post-thrombotic syndrome (PTS). Relevant disease-specific or treatment-related complications

included survival (an ICHOM term representative of death), VTE recurrence, bleeding, and procedure-related complications.

Optimal instruments to capture these outcomes

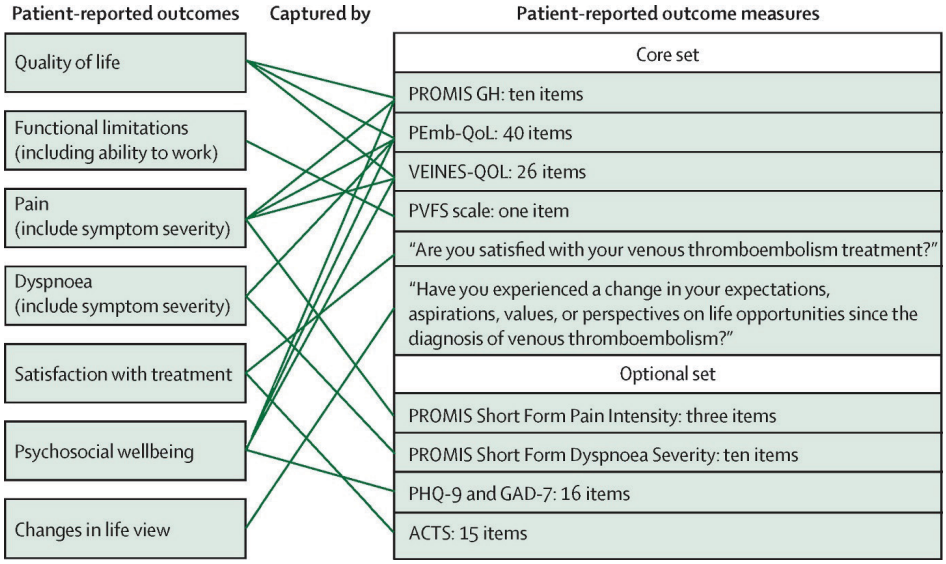
The working group decided on a measurement tool package that captures all these core outcomes. Because several of the optimal instruments identified by the working group have partly overlapping questions and domains, a cascade opt-in system was used to ensure that a minimum number of items would capture all core outcomes (**Figure 2**). The measurement tools for the core set include the Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form Global Health[28], Pulmonary Embolism Quality of Life (PEmb-QoL) questionnaire[29], Venous Insufficiency Epidemiological and Economic Study on Quality Of Life (VEINES-QOL) questionnaire[9], and the single item Post-VTE Functional Status (PVFS) scale[30], along with a single question on treatment satisfaction and changes in life view. If patients indicated the presence of pain, dyspnea, anxiety, depression, or treatment dissatisfaction (all single questions in the core set of instruments), the cascade opt-in system proposed additional instruments to acquire relevant dimensions and details using PROMIS Short Form v2.0 Pain Intensity 3a[31], PROMIS Short Form v1.0 Dyspnea Severity 10a[32], Patient Health Questionnaire-9 (PHQ-9) [33], Generalized Anxiety Disorder-7 (GAD-7) questionnaire[34], and the Anti-Clot Treatment Scale (ACTS) [35].

Long-term consequences of disease and complications are health-care professional-reported. Definitions of these outcomes were primarily derived from the International Society on Thrombosis and Haemostasis set of common data elements for VTE research and can be found in detail in the online Reference Guide. [36]

Baseline characteristics and case-mix variables relevant to the ICHOM set

The working group selected the most important baseline characteristics and case-mix variables to allow standardised risk adjustment across different populations. The working group identified several patient demographics, measures for baseline health status, and treatment-related factors that affected outcomes included in the core standard set (**Table 2**). The demographic risk-adjustment factors selected for inclusion were age, sex, race, ethnicity, and educational attainment. The clinical risk-adjustment factors (baseline and treatment-related) include body mass index, comorbidities according to the Self-Administered Comorbidities Questionnaire[37], history of VTE, high risk or massive PE, phlegmasia, unprovoked VTE, actual use of antithrombotic medication, and specific interventions for the treatment of VTE.

Figure 2: Overlap between the patient-reported outcomes and patient-reported outcome measures.



By introducing a cascade option (core set versus optional set), relevant overlap is mostly avoided. The PROMIS short forms Pain Intensity and Dyspnea Severity are triggered by PROMIS short form Global Health (GH) and PEmb-QoL, respectively. The PHQ-9 and GAD-7 are triggered by PROMIS short form Global Health. The ACTS is triggered by the single question on satisfaction with treatment.

Abbreviations PROMIS: Patient-Reported Outcomes Measurement Information System, PEmb-QoL: Pulmonary Embolism Quality of Life, VEINES-QOL: Venous Insufficiency Epidemiological and Economic Study–Quality of Life, PVFS: Post-VTE Functional Status, PHQ-9: Patient Health Questionnaire-9, GAD-7: Generalized Anxiety Disorder-7, ACTS: Anti-Clot Treatment Scale.

Final set

The final ICHOM standard set of patient-centered outcome measures for VTE patients including relevant timepoints is shown in **Figure 3**. Of the recommended patient-reported outcome measures, quality of life, treatment satisfaction, and changes in life view are not to be captured at baseline. The PVFS scale can be used to assess the pre-VTE functional status for comparison.

This set was subjected to open review by 22 people with lived experience of VTE and 29 expert professionals who completed an online survey. Most participants who had a history of VTE were aged 46-60 years, six (27%) patients had PE at some point in their life course, five (23%) had DVT, and 11 (50%) had both PE and DVT. The 29 health-care professionals were mostly physicians (90%; 26 of 29); two (7%) were researchers and one (3%) was a health-care administrator. At least 65% of individuals with lived experience of VTE and health-care professionals rated 12 of the 15 core outcomes in the standard set as essential. For the other three outcomes, there was discrepancy

between the two groups. The outcome of CTEPH was rated as essential by ten (50%; two individuals did not rate this outcome) of those with lived experience of VTE, and CTEPD by nine (45%; two individuals did not rate this outcome), while 24 (83%) of the 29 health-care professionals rated CTEPH as essential, and 23 (79%) CTEPD. By contrast, the outcome changes in life view was rated as essential by 48% of professionals, while 70% of those with lived experience considered this outcome to be essential.

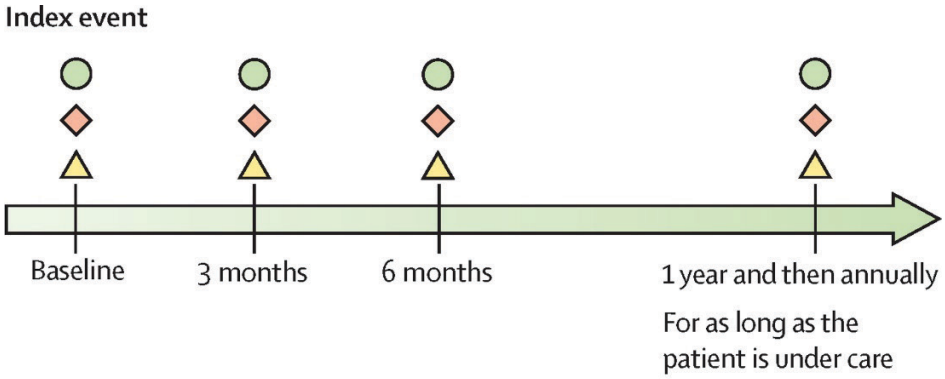
Table 2: Case-mix variables included in the ICHOM set of patient-centered outcome measures for venous thromboembolism.

Variable	Details	Timing	Reporting source
Demographic Factors			
Year of birth	Year of birth as YYYY	Index event	Clinical, patient-reported or administrative data
Sex	Sex at birth	Index event	Clinical, patient-reported or administrative data
Race	The biological race of the person	Index event	Patient-reported
Ethnicity	The cultural ethnicity of the person that they most closely identify with	Index event	Patient-reported
Level of education	Highest level of education completed based on local standard definitions of education levels; to consult the International Standard Classification of Education	Index event	Patient-reported
Baseline Health Status			
BMI	Calculated in kg/m^2: weight in kilograms divided by height in meters squared	Index event; 1 year and annually*	Clinical
Previous history of VTE	Yes/No	Index event	Clinical
Comorbidities	Based on the Self-Administered Comorbidities Questionnaire	Index event; 1 year and annually*	Patient-reported
High-risk/Massive PE	Yes/No	Index event	Clinical
Phlegmasia	Yes/No	Index event	Clinical
Unprovoked VTE	Yes/No	Index event	Clinical
Treatment-related Factors			
Antithrombotic treatment	Yes/No; generic name of the drug; dose; medical indication; drug class	Index event; 3 months and 6 months; 1 year and annually*	Clinical
Underwent interventional treatment for VTE	Yes/No	Index event; 3 months and 6 months; 1 year and annually*	Clinical

*For as long as the patient is under care.

Abbreviations ICHOM: International Consortium for Health Outcomes Measurement, BMI: Body Mass Index, VTE: venous thromboembolism, PE: pulmonary embolism.

Figure 3: The final ICHOM standard set of outcome measures for patients with venous thromboembolism including relevant timepoints.



Index event=Date of the venous thromboembolism diagnosis
Baseline=Data collection date

- Patient-reported outcome measures
- Clinical outcome measures
- Case-mix variables

Of the recommended patient-reported outcome measures, quality of life, treatment satisfaction and changes in life view are not to be captured at baseline. The Post-VTE Functional Status (PVFS) scale can be used to assess the pre-VTE functional status for comparison.

Abbreviations ICHOM: International Consortium for Health Outcomes Measurement, VTE: venous thromboembolism.

21 (95%) of the 22 individuals with lived experience of the disease felt that the proposed outcomes broadly captured all the important aspects that matter most to patients with VTE, and that applying the set and collecting the information would be helpful to support patient care. Health-care professionals were asked to provide feedback on the entire set. 92–100% of professionals rated the included PROMs, clinical outcome measures, and case-mix variables as essential, and 88–100% rated the timepoints proposed to measure the outcomes and variables as essential. Additionally, four professionals who completed the survey commented that the set might have too many instruments and measurements. After discussion and consideration by the working group during the final video conference, all outcomes, and their capture at the proposed timepoints, were considered crucial, with the core set of selected instruments and additional instruments via the cascade opt-in system.

The set has several limitations that need to be acknowledged. Despite considerable efforts to engage VTE experts from Asia and Africa, and despite the diversity of our team in terms of nationality, culture, and religion, the majority of working group members live in Europe and North America, which could have affected the decision-making process.

Furthermore, the PROMs included in the standard set were developed in Europe or North America and have little country-specific or region-specific validation (i.e. validation of the translated version), which is a major limitation of this set and other standard outcome sets.

Implementation

The final set is now available online for use within clinical practice and potentially research. After signing up for free through ICHOM Connect, all materials related to the set (i.e. a flyer, reference guide, and data dictionary) can be downloaded. By signing up before downloading the materials, all users can be contacted when an updated version of the set is published. Although we have drawn on publicly accessible tools where possible, to implement the set, colleagues must first assess what technology, informatics, and access infrastructures are available within an individual health-care institution or regional health-care system. We advise preparing an implementation plan in the relevant context, with a roll out phase including pilot data collection and refinement of the workflow, ahead of implementing the full set for all patients within our stated scope. From here, data can be collected on every patient according to the defined timepoints for measurement of the outcomes. The Data Dictionary (part of the online Reference Guide) gives all details to guide data collection and supports the implementation of outcome measurement as consistently as possible, which is crucial to make comparisons across institutions and countries.

Embedding PROMs into electronic health records would ease cross-care integration into clinical practice and enhance routine measurement of patient-reported outcomes. Furthermore, in recognition of the time challenges of completing PROMs, incorporating them as digital measures could provide the necessary flexibility to automatically direct patients and providers to the relevant questions (through the cascade opt-in system), shortening the time needed to complete the questionnaires. We are aware of the need to minimise data collection to avoid burden on both health-care providers and patients but recognise the need to encompass all important outcomes for meaningful comparisons. The feasibility of the measurement and implementation of these outcome measures were considered during the working group discussions and selection of outcome measures, as were the realities of being a patient with VTE or a health-care provider. So far, ICHOM has developed more than 40 standard sets. Because ICHOM sets are publicly available, it is difficult to track implementation precisely; even so, implementation of at least one ICHOM set has been reported for 650 institutions and 13 registries across 32 countries, highlighting the success of existing ICHOM standard sets.[38] Implementation studies have been done for different ICHOM sets, showing the feasibility of implementing ICHOM sets. Help and support with implementation and with the measurement of outcomes and the application of PROMs is provided by ICHOM. Because the set includes existing outcome measures that best capture the recommended outcomes,

the tools should be interpreted according to the original scoring manuals. To enquire about support or to contact other ICHOM Connect members, the online ICHOM Connect portal can be visited. Of note, the questionnaires can be easily included in an online survey that will also facilitate the correct post-processing and interpretation of the PROMs.

Although the aim is to achieve a globally adopted standard set, we recognise that there are different resources, digital infrastructures and health-care contexts in low-income, middle-income, and high-income countries that can affect the speed and success of implementation. Training and education, commitment, and enabling attitudes of health-care professionals are believed to facilitate implementation[39], which can offset more structural challenges within the health-care system. The PROMs suggested in our standard set do not require a fee or license, can be completed on paper, and can be implemented with minimum resources. Nonetheless, implementation in low-income and middle-income countries poses more challenges than in most high-income countries. ICHOM and the working group will continuously promote global use of the standard set and provide help to local institutions where possible. Also, if a desired translation is not available, ICHOM provides guidance in translating PROMs following a defined process in accordance with the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Principles of Good Practice.[40]

Conclusions

On the basis of the principles of evidence-based medicine: integrating patients' values, best available evidence, and medical expertise; we have developed a consensus recommendation for a standardised minimum set of outcomes that cover all of the aspects of VTE treatment and clinical course that matter most to patients and health-care professionals: ICHOM-VTE. As with all ICHOM sets, the process of development is unique through the extensive engagement of patient representatives in all steps and decisions. Following the focus groups, several outcomes that had previously not been studied in VTE were considered relevant and therefore were included in the final set (e.g., changes in life view). The working group targets integration of the standard set into routine clinical practice and, potentially, research. The substantial patient involvement in the development phase of the set is expected to improve patient compliance to completing the instruments in daily practice. We anticipate that the introduction of this set will contribute substantially towards increasing value in VTE care. Health-care professionals and policymakers will be able to use these measures to identify effective, high-value practices in the therapeutic management and in follow-up of VTE patients, which in turn helps to better target efforts towards quality improvement. Moreover, implementation of this set will empower patients with VTE to actively participate in their care and, together with involved professionals, make better informed decisions about health-care options.

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