Use of patient-reported outcome measures in patients with venous thromboembolism: communication from the ISTH SSC Subcommittee on Predictive and Diagnostic Variables in Thrombotic Disease

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ISTH SSC COMMUNICATION

Use of patient-reported outcome measures in patients with venous thromboembolism: communication from the ISTH SSC Subcommittee on Predictive and Diagnostic Variables in Thrombotic Disease

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Abstract

Patient-reported outcome measures (PROMs) are patient-completed instruments that capture patient-perceived health status and well-being. PROMs measure disease impact and outcomes of care as reported by those who experience the disease. After pulmonary embolism or deep vein thrombosis, patients may face a broad spectrum of complications and long-term sequelae beyond the usual quality-of-care indicators of recurrent venous thromboembolism (VTE), bleeding complications, and survival. The full impact of VTE on individual patients can only be captured by assessing all relevant health outcomes from the patient's perspective in addition to the traditionally recognized complications. Defining and measuring all important outcomes will help facilitate treatment tailored to the needs and preferences of patients and may improve health outcomes. The International Society on Thrombosis and Haemostasis Scientific and Standardization Committee

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Subcommittee on Predictive and Diagnostic Variables in Thrombotic Disease endorsed the International Consortium for Health Outcomes Measurement (ICHOM) VTE project on development of a standardized set of patient-centered outcome measures for patients with VTE. In this communication, the course and result of the project are summarized, and based on these findings, we propose recommendations for the use of PROMs during clinical follow-up of patients with VTE. We describe challenges to implementation of PROMs and explore barriers and enablers.

KEYWORDS
health status, patient-centered care, patient outcome assessment, patient-reported outcome measures, venous thromboembolism

1 | INTRODUCTION

Patient-reported outcome measures (PROMs) are tools, mostly questionnaires, that capture patient perceptions of their health status and well-being [1–3]. As healthcare is now more focused on patient needs and values, PROMs are key to enable patient-centered care [2,4]. Assessment of patient-reported outcomes enables healthcare professionals to better understand the impact of disease and treatments on an individual's life, which improves shared decision making [1,5]. Indeed, a key aim of patient-centered healthcare is to support and empower people to make informed health-related decisions. This transformation in healthcare philosophy was illustrated by a World Health Organization 2015 publication that advocated for a global strategy toward people-centered health care [6].

Patients who experience pulmonary embolism (PE) or deep vein thrombosis experience a spectrum of health effects and disability after a thromboembolic event. Venous thromboembolism (VTE) impacts patient lives [7–15]. The usual healthcare indicators of VTE are recurrent disease, bleeding complications, and survival. Other relevant consequences of VTE include physical disability, psychosocial distress, and impaired quality of life [16–21]. The optimal way for healthcare providers to understand these sequelae is by having VTE survivors define and describe their health outcomes. These survivor-defined outcome measurements may help inform VTE management choices [22,23].

Several VTE-related PROMs are recommended in VTE guidelines and guidance documents. The European Society of Cardiology and European Respiratory Society guideline for diagnosis and management of acute PE recommends a standardized evaluation of dyspnea to assess the need for follow-up echocardiography [24]. In a position paper, the European Society of Cardiology and European Respiratory Society recommend routine assessment for chronic dyspnea and functional limitations using standardized validated instruments [25]. The 2020 American Society of Hematology guideline for the management of VTE advises considering measuring how individual patients may value different outcomes [26]. The 2021 American College of Chest Physicians Guideline on antithrombotic therapy for VTE disease recommends considering patient circumstances, values, and preferences when electing extended phase anticoagulation [27]. However, until now, there is no single internationally sourced standardized guidance to report outcomes of care in VTE.

The International Society on Thrombosis and Haemostasis Scientific and Standardization Committee (SSC) Subcommittee on Predictive and Diagnostic Variables in Thrombotic Disease endorsed this project, which aimed to develop a standardized set of patient-centered outcome measures for patients experiencing VTE. This SSC Subcommittee communication summarizes the methods and results of the International Consortium for Health Outcomes Measurement Venous Thromboembolism "ICHOM-VTE" project. Informed by these findings, we provide recommendations for the use of PROMs during clinical follow-up of patients who experienced VTE.

2 | METHODS

This SSC Subcommittee project was a multidisciplinary project in collaboration with ICHOM [28]. The aim of the project was to develop a standardized set of patient-centered outcome measures for patients with PE and/or deep vein thrombosis that would cover a core set of "must-have" outcomes that matter to patients and that can be used in clinical practice.

An international working group of 2 patient representatives and 25 VTE experts, including physicians, nurses, and researchers representing a broad range of specialties, and the project administrative team met 9 times between January 2021 and February 2022 (Figure). Comprehensive literature searches were performed by the project team to identify relevant outcomes that had been studied and reported in the past 10 years. A focus group was conducted with patient representatives to explore their perspectives on the importance of the identified outcomes and to discuss potentially missing outcomes that might be added. The scope of the project, ie, target population and relevant patient categories, as well as core outcomes were selected by the working group through a modified Delphi process. Consensus was reached when at least 80% of the working group voted an outcome as "essential" (defined as a score of 7-9 on a 9-point Likert scale) to be included in the standardized set or as "not recommended" and to be excluded (represented by a score of 1-3). In round 3 of the Delphi on

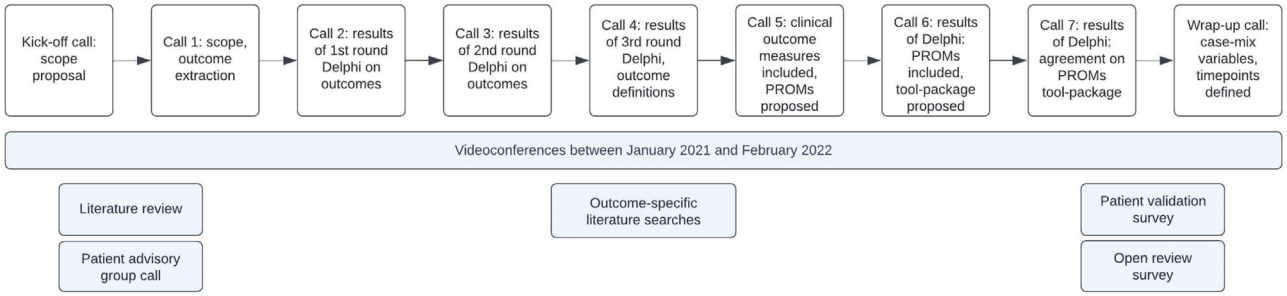

FIGURE The process for the development of the International Consortium for Health Outcomes Measurement Venous Thromboembolism set. PROM, patient-reported outcome measure.

outcomes, 70% agreement was required for outcomes to be included. After reaching consensus on the outcomes to be included in the standardized set, further literature review identified existing validated outcome measurement tools that were then added to the Delphi to select the optimal outcome measures to capture the selected outcomes (70% agreement was required). Also, time points to measure the outcomes were defined during the Delphi process. During each video conference with the working group, special attention was paid to the patient perspective. To gather feedback on the standardized set from professional stakeholders and people with lived experience, an open review survey was sent to patients and healthcare professionals by email and social media. After consideration of the results of the open review survey by the working group, the standardized set of patient-centered outcomes for patients with VTE (including PROMs and clinician-reported outcome measures) was finalized. At the close of the process, a wrap-up survey assured consensus among experts and patients alike.

3 | RESULTS

The final ICHOM-VTE set is targeted at all patients diagnosed with VTE aged ≥16 years. Since subgroup-specific VTE outcomes were not identified in the literature searches or the focus meetings, the ICHOM set does not specify patient subgroups. During the Delphi consensus process, core outcomes (both patient-reported and clinician-reported) that are important to all patients with VTE were selected. After round 3 of the Delphi process, the final selection of outcomes was discussed during the following video conference, and there was consensus among experts and patients. Literature searches were conducted for each patient-important VTE outcome, identifying several disease-specific and generic PROMs, which are shown in Table 1 [19–28,31]. After the group conversations, outcome measures for the outcome "changes in life view" were suggested (Table 1) and potentially useful avenues to identify additional outcome measures for this outcome were put forward: "biographical disruption", which is the sense that the story of your life is altered, "response shift theory", indicating the change in internal values and attitudes due to health, and "positive shifts post-event", which include posttraumatic growth and hope. A response shift measure was considered to be the most appropriate to capture the impact of VTE, and therefore, a generic literature search was performed focused on this. In addition, a generic literature search was performed for the outcome "satisfaction with treatment." These searches yielded generic PROMs shown in Table 2 [63–78]. Moreover, Patient-Reported Outcome Measurement Information System (PROMIS) short forms and the World Health Organization Disability Assessment Schedule were added to the list of outcome measures after project team discussions because of good outcome coverage of these instruments and availability and feasibility reasons (Table 2) [61,79].

Relevant PROMs (from Tables 1 and 2) were evaluated for their psychometric qualities and implementation feasibility, including the availability of the questionnaires, existing translations, and cost or licensing fee associated with use of the questionnaires. The Delphi process identified the PROMs that were included in the final ICHOM-VTE set (Table 3).

3.1 | Quality of life

To measure disease-specific quality of life, the commonly used Venous Insufficiency Epidemiological and Economic Study–Quality of Life/Symptoms (VEINES-QOL/Sym) and Pulmonary Embolism Quality of Life questionnaires (PEmb-QoL) were included [16,29,30,80]. In addition, generic PROMs to measure quality of life, such as the EuroQoL-5 dimension and 36-item Short Form Health Survey (and its 12-item version), were considered [32–34]. Based on the coverage of all quality of life domains, good psychometric quality, availability, and number of items, the PROMIS Scale Global Health was selected as the generic quality of life PROM over all other measures [59].

3.2 | Functional outcomes

To measure functional outcomes, we selected the single-item Post-VTE Functional Status scale, which determines functional disability and measures change in functional status over time [39,40,81,82].

TABLE 1 Generic and disease-specific patient-reported outcome measures used in venous thromboembolism research or added based on focus group input.

Outcome	Patient-reported outcome measure
Quality of life	- VEINES-QOL/Sym questionnaire [29] - PEmb-QoL questionnaire [30] - Deep Venous Thrombosis Quality of Life questionnaire [31] - EuroQoL-5 dimension [32] - 36-item Short Form Health Survey; 12-item Short Form [33,34] - Chronic Venous Insufficiency Questionnaire [35] - Venous Thrombosis–Quality of Life questionnaire [36] - HRQOL questionnaire by Mathias et al. [37] - Deep Vein Thrombosis Leg Symptom Index [38]
Functional limitations	- Post-VTE Functional Status scale [39,40]
Pain	- Visual Analog Scale, or Pain Score (scale 0-10) [41]
Dyspnea	- (Modified) Medical Research Council Dyspnea Scale [42] - Rose Dyspnea Scale [43] - (Modified) Borg Dyspnea Scale [44]
Psychosocial well-being	- Hospital Anxiety and Depression Scale [45] - Patient Health Questionnaire [46] - Generalized Anxiety Disorder [47] - "Brief screening instrument to assess VTE-related emotional distress" by Keddington et al. [48] - Short Form Health Survey (36-item; 12-item) dimensions: social functioning, role emotional, mental health [33,34] - Social Network and Support Scale [49] - The ENRICHD Social Support Inventory [50] - "Detailed question guide" by Etchegary et al. [51]
Satisfaction with treatment	- Anti-Clot Treatment Scale [52] - Duke Anticoagulation Satisfaction Scale [53] - Perception of Anticoagulant Treatment Questionnaire [54]
Changes in life view	- Mastery scale [55] - Patient Generated Index [56][a] - Posttraumatic Growth Inventory [57][a] - Dispositional Hope Scale [58][a] - PROMIS-10 [59][a] - Environmental Mastery subscale of the Ryff Psychological Well-Being scale [60][a]

ENRICHD, Enhancing Recovery in Coronary Heart Disease Patients; HRQOL, health-related quality of life; PEmb-QoL, Pulmonary Embolism Quality of Life; PROMIS, Patient-Reported Outcome Measurement Information System; QoL, quality of life; VEINES-QOL/Sym, Venous Insufficiency Epidemiological and Economic Study–Quality of Life/Symptoms; VTE, venous thromboembolism.

[a] Generic and disease-specific patient-reported outcome measures added based on focus group input.

3.3 | Pain and dyspnea

The working group Delphi process identified PROMIS Short Forms Pain Intensity and Dyspnea Severity [62]. If the patient reports pain and/or dyspnea based on the PROMIS Scale Global Health or Pulmonary Embolism Quality of Life questionnaire, the ICHOM-VTE cascade system prompts completion of the PROMIS Short Form Pain Intensity and PROMIS Short Form Dyspnea Severity.

3.4 | Mental health

The Patient Health Questionnaire and Generalized Anxiety Disorder scale were selected for measurement of psychosocial well-being based on outcome coverage, good psychometric quality, and availability [46,47]. These 2 outcome measures are triggered by the PROMIS Scale Global Health responses indicating mental health issues or emotional problems.

3.5 | Satisfaction with treatment

The working group discussed using a general satisfaction measure vs a medication-specific or anticoagulant-specific measure to capture satisfaction with management of VTE. A single question was developed to assess satisfaction along with a cascade option: "Are you satisfied with your VTE treatment?" Yes/No. In case the patient is not satisfied with the VTE treatment based on the single question, the Anti-Clot Treatment Scale is proposed as an additional outcome measure [52].

3.6 | Changes in life view

The working group did not reach consensus about the evaluated outcome measures. Therefore, a single question to assess changes in life view was developed and included in the set. Since none of the outcome measures were selected during the Delphi process, no cascade option was added; if the patient experiences changes in expectations, aspirations, values, or perspectives on life opportunities since the diagnosis of VTE, which could be both positive and negative changes, no additional outcome measure is proposed by the set, but this gives reason to discuss the patient's experience.

The complete ICHOM-VTE set is available online via https://connect.ichom.org/patient-centered-outcome-measures/venous-thromboembolism/ where all materials related to the set can be downloaded (flyer, reference guide, and data dictionary). For patients with specific conditions or in specific settings, such as pregnancy,

TABLE 2 Patient-reported outcome measures identified with generic literature searches or added based on team discussions.

Outcome	Patient-reported outcome measure
Quality of life	- WHO Disability Assessment Schedule [61][a] - PROMIS Scale v1.2—Global Health [59][a]
Functional limitations	
Pain	- PROMIS Short Form v2.0—Pain Intensity—3a [62][a]
Dyspnea	- PROMIS Short Form v1.0—Dyspnea Severity—10a [62][a]
Psychosocial well-being	- Outcome Questionnaire-45 [63] - PROMIS Short Form v1.0 Emotional Distress–Anxiety [62][a] - PROMIS Short Form v1.0 Emotional Distress–Depression [62][a]
Satisfaction with treatment	- Treatment Satisfaction Questionnaire for Medication [64] - Short Assessment of Patient Satisfaction scale [65] - Treatment Adherence Perception Questionnaire [66] - Functional Assessment of Chronic Illness Therapy–General Treatment Satisfaction [67] - 4-item Morisky Green Levine questionnaire, Morisky Medication Adherence Scale [68,69] - Medication Adherence Rating Scale [70] - Medication Adherence Report Scale [71,72] - Beliefs about Medicines Questionnaire [73] - Measure Treatment Adherence [74]
Changes in life view	- Brief Appraisal Inventory [75] - QOL Appraisal Profile-version 2 [76] - Schedule for Meaning in Life Evaluation [77] - Schedule for the Evaluation of Individual Quality of life (Direct Weighting) [78]

PROMIS, Patient-Reported Outcome Measurement Information System; QOL, quality of life; WHO, World Health Organization.
[a] Patient-reported outcome measures added based on team discussions.

separate ICHOM sets are available that can be used complementary to the VTE set.

4 | DISCUSSION

The use of PROMs during VTE management aligns with current healthcare expectation and allows for a more patient-centered approach to healthcare, where patients are actively involved in the assessment and management of their health. PROMs standardize the measurement of patient-important outcomes. During the "ICHOM-VTE" project, a standardized set of generic and disease-specific patient-centered outcome measures for patients with VTE was developed, which is expected to inform treatment choices. The ICHOM-VTE measures should be used in the clinical environment to aid individualized patient management.

The ICHOM-VTE set differs from the VTE core outcome set (VTE-COS). Current VTE research outcome measurement is inconsistent across studies and does not include all outcomes that are patient-important [83]. The outcomes being measured in VTE research are often limited to clinical or pathophysiological outcomes of VTE [84] and do not reflect what matters most to patients with VTE, which makes it challenging to interpret results and draw conclusions. The VTE-COS project (underway) will define outcomes most important to patients in VTE research. As part of the VTE-COS project, important themes were identified based on a literature review of qualitative studies to understand the impact of VTE from patients' perspectives, which showed large overlap with the core outcomes in the ICHOM-VTE set [85]. Findings of the VTE-COS project are expected in the next 2 years. In contrast, the ICHOM-VTE set is designed to be applied in clinical practice and for individual patient management.

There are several challenges to overcome when implementing PROMs in routine practice. The first is how to record, capture, and display the PROM data. This relies on 3 components: 1) the time required for data capture, 2) the simplicity of each questionnaire, and 3) reliable incorporation of PROM results in clinical encounters. The number of items in the full ICHOM set is considerable. There are 79 PROM items in the core set and, including the cascading questions, a total of 123 PROM items. Some PROMs assume a certain level of patient literacy, and most are available only in select languages and dialects, limiting widespread implementation. Further PROM efforts would help address these barriers to use. Opportunities for PROM refinement could include assessing for redundancy and replacing multi-item instruments with single-item instruments informed by future research [2]. A synchronous web-based patient data entry incorporating electronic data capture might be ideal. Future options could also consider direct patient data entry into the health record and integration in the electronic health records or use of a "personal health environment," which is a digital tool in which patients can manage and share data about their health. Healthcare professional data interpretation can be facilitated by providing meaningful PROM score outcomes displayed in a visually intuitive way. The availability of resources and clinical setting will influence the implementation process.

The second challenge to PROMs is how to integrate PROM data into routine healthcare. One solution is to have the PROM data available to the healthcare professional before the scheduled patient appointment. This enables healthcare professionals to optimally prepare. The conversation between the patient and healthcare professional could focus on those symptoms or issues that require attention, which may lead to a better understanding of the patient's experiences and provide treatment that efficiently meets the patient's needs [5]. PROM outcomes can be used to visualize the course of recovery over time. Actionable thresholds can be established, such as referral for echocardiography to rule out chronic thromboembolic pulmonary hypertension in case of a certain degree of dyspnea and referring patients with high anxiety or depression for counseling.

TABLE 3 The patient-reported instruments included in the International Consortium for Health Outcomes Measurement Venous Thromboembolism set [28].

Patient-reported outcomes	Outcome measure
Quality of life	PROMIS Scale v1.2—Global Health PEmb-QoL questionnaire VEINES-QOL questionnaire
Functional limitations (including ability to work)	Post-VTE Functional Status Scale
Pain (including symptom severity)	PROMIS Short Form v2.0—Pain Intensity—3a
Dyspnea (including symptom severity)	PROMIS Short Form v1.0—Dyspnea Severity—10a
Psychosocial well-being	Patient Health Questionnaire Generalized Anxiety Disorder
Satisfaction with treatment	Single question: "Are you satisfied with your VTE treatment?" Yes/No If answer to the single question is "No": Anti-Clot Treatment Scale
Changes in life view	Single question: "Have you experienced a change in your expectations, aspirations, values, or perspectives on life opportunities since the diagnosis of VTE?" Yes/No

PEmb-QoL, Pulmonary Embolism Quality of Life; PROMIS, Patient-Reported Outcome Measurement Information System; VEINES-QOL, Venous Insufficiency Epidemiological and Economic Study–Quality of Life; VTE, venous thromboembolism.

Despite significant challenges, studies evaluating the implementation of other (ICHOM) patient-centered outcome sets have demonstrated the feasibility of PROM implementation in various settings including hospital care, primary care, and outpatient consultation setting [86–88]. In a 2016 mixed-methods evaluation of the implementation experiences at 2 hospitals where the ICHOM outcome set for hip and knee osteoarthritis were implemented, interviews with patients revealed that completion of PROMs was perceived to be valuable and was a minimal burden [86]. In this study, PROMs were administered depending on patient preferences: paper-based administration, web-based administration, or administration with the use of portable electronic devices. However, the portable devices were abandoned due to data extraction challenges. A web-based portal was developed but not implemented due to lack of information technology support. Most patients in this study preferred paper-based questionnaires, while more than half of the professionals who were interviewed in this study reported challenges and difficulties associated with managing paper-based questionnaires. An implementation study of the digital pregnancy and childbirth outcome set showed that the women's self-reported time to complete the electronic questionnaires was on average 10 minutes (90% of the women considered this "good" or "short") [87]. Obstetric care professionals reported needing a mean duration of 10 minutes to discuss the patient's answers. Professionals saved time by having a clearer picture of the issues that were important to their patients. Active engagement of healthcare professionals and agreement regarding responsibilities and how to act upon outcomes were considered to be determinants of successful implementation [86,87]. During implementation of electronic assessment for a depression and anxiety outcome set in an outpatient psychiatry practice, patients spent 22 to 26 minutes completing the intake set, spent 6 to 7 minutes on follow-up sets, and ranked the collection tool 4.0 to 4.4 out of 5 [88]. Patients were presented with the questions relevant to their responses, shortening the questionnaires and reducing the administrative burden. The cascade system that was adopted in the ICHOM-VTE set allows for further assessment of specific symptoms when relevant for the patient. We acknowledge that these studies evaluated different sets of PROMs for different conditions, and therefore, not all findings can be extrapolated to the VTE population.

The recommendations for outcome measurement and the use of PROMs during follow-up of patients with VTE included in this International Society on Thrombosis and Haemostasis SSC Communication are based on available data and consensus among the committee. We propose priorities for future studies to obtain a better understanding of the results of implementation and optimization of PROMs and the value that PROMs add to VTE care.

5 | RECOMMENDATIONS

1. We advocate the routine use of PROMs to capture the impact of VTE on patient lives and guide clinical decision making.
2. We advocate using the core set of outcomes as defined by ICHOM-VTE in daily clinical practice as a comprehensive set of VTE patient-relevant outcomes that proposes a clear timeline for the measurements [89].
3. We advocate carefully planning the implementation of ICHOM-VTE outcome ascertainment in the clinical setting, including planning questionnaire timing, administration, preparation of response summaries for the medical record, and predefined thresholds that trigger adaption of the VTE management plan.
4. We advocate that study clinical endpoints use PROMs. The ongoing VTE-COS project aims to provide a core set of valid and relevant outcomes specifically for use in clinical trials. Until this set is available, the ICHOM set—although developed for use in clinical practice—may serve as a source of inspiration.
5. We advocate the use of electronic tools for collection of PROMs to minimize the administrative burden of collecting the data and interpreting the responses, adopting when feasible direct patient data entry.
6. We advocate that future studies should focus on implementation of PROMs integrated in routine practice; developing novel, succinct instruments to minimize overlap between PROMs, thus reducing the number of PROMs that need to be completed; and patient and provider perceptions of the value that PROMs add to the VTE-related care provided and the impact of the use of PROMs on outcomes.

6 | CONCLUSION

The routine use of PROMs provides an opportunity to optimize patient-centered care. Based on the ICHOM-VTE project, we provided recommendations for outcome measurement and the use of PROMs during follow-up of patients with VTE. We acknowledged several challenges that must be faced when it comes to implementing PROMs in practice and described barriers and enablers to implementation.

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AUTHOR CONTRIBUTIONS

The Subcommittee on Predictive and Diagnostic Variables in Thrombotic Disease endorsed the project and approved the writing of this International Society on Thrombosis and Haemostasis Scientific and Standardization Committee Communication. During the International Consortium for Health Outcomes Measurement Venous Thromboembolism project, S.A.B., F.A.K., A.M.G., and C.M.M.d.J. participated in the project team and K.d.W. participated in the working group. This manuscript was primarily drafted by C.M.M.d.J. and F.A.K. after interpretation of data. K.d.W., S.A.B., A.M.G., C.M., A.L.P., H.R.-E., R.T., and S.C.W. revised the manuscript critically for important intellectual content and interpreted the findings of the project. The Subcommittee on Predictive and Diagnostic Variables in Thrombotic Disease met to review the manuscript and approved its submission as a Scientific and Standardization Committee Communication. All authors approved submission of the manuscript.

DECLARATION OF COMPETING INTERESTS

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