

Anticoagulation: the Patients' Perspective

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Disclosures

None relevant to the present talk

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Advisory board: Astellas

Grants: Compremium

Why are we talking about this topic?

Anticoagulants carry benefits (recanalization, prevention of extension, ecc) and risks (bleeding, sometimes life-threatening)



Recognizing and mitigating risk for harm from anticoagulants requires evidence-based approach to management

After choice of anticoagulant has been made:

Optimal management of anticoagulants
for preventing and treating thrombosis/TE

In patients with liver disease/VLDs

Very different risk profiles among VLDs

Anticoagulants carry benefits (reducing thrombus extension, recanalization, ecc) and risks (bleeding)

Recognizing and mitigating risk for harm from anticoagulants requires evidence-based approach to management

Evidence is limited in this field

Choice to anticoagulate not always black or white

After choice of anticoagulant has been made:
Optimal management of anticoagulants
for preventing and treating thrombosis

Evidence is limited

A real case

71 y/o lady with compensated cirrhosis Child B7 due to MASLD; large esophageal varices on primary prophylaxis with NSBBs; normal kidney function; platelet count 91 G/L.

Abdominal discomfort, else asymptomatic:

- ultrasound diagnosis of large (~70% of the lumen) partial portal vein thrombosis (trunk and right branch)
- Started on Enoxaparin 1 mg/Kg twice a day
- After 4 weeks: improvement (no pain; on US PVT less than 30%).
- Shifted to Apixaban after discussing with the patient the pros- and cons- of VKA and DOACs

3 months later: hospitalization after fall at home → large **hematoma** (back/right leg) with **compartment syndrome requiring surgery** and prolonged hospital stay; ultrasound: **no residual PVT**.

*From a **clinical** perspective: treatment success on PVT.*

*From a **patient** perspective: treatment-related harm.*

Physicians' perspective vs. patients' perspective on anticoagulation in thrombosis

Clinical outcomes \neq patient-perceived outcome

Clinical outcomes:

Imaging

Complications

Mortality

Patient outcomes:

Fear/anxiety of complications

Burden of treatment (e.g. LMWH)

Quality of life

What Is Value in Health Care?

Author: Michael E. Porter, Ph.D. [Author Info & Affiliations](#)

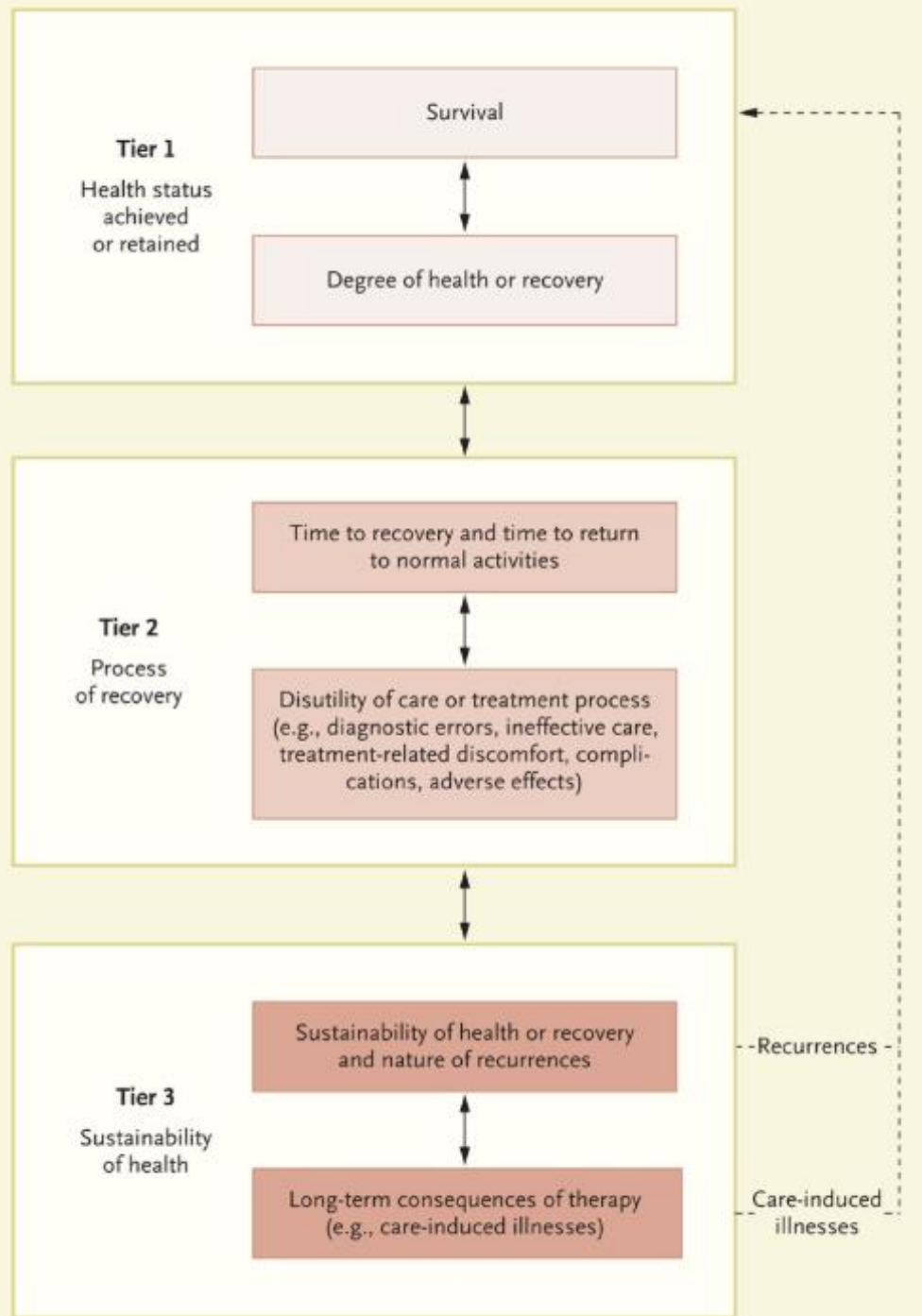
Published December 23, 2010 | N Engl J Med 2010;363:2477-2481 | DOI: 10.1056/NEJMp1011024

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The Outcomes Measures Hierarchy

Severity of the disease/symptoms set priority both for patients and for physicians. Values are often shared in severe disease (risk of death)

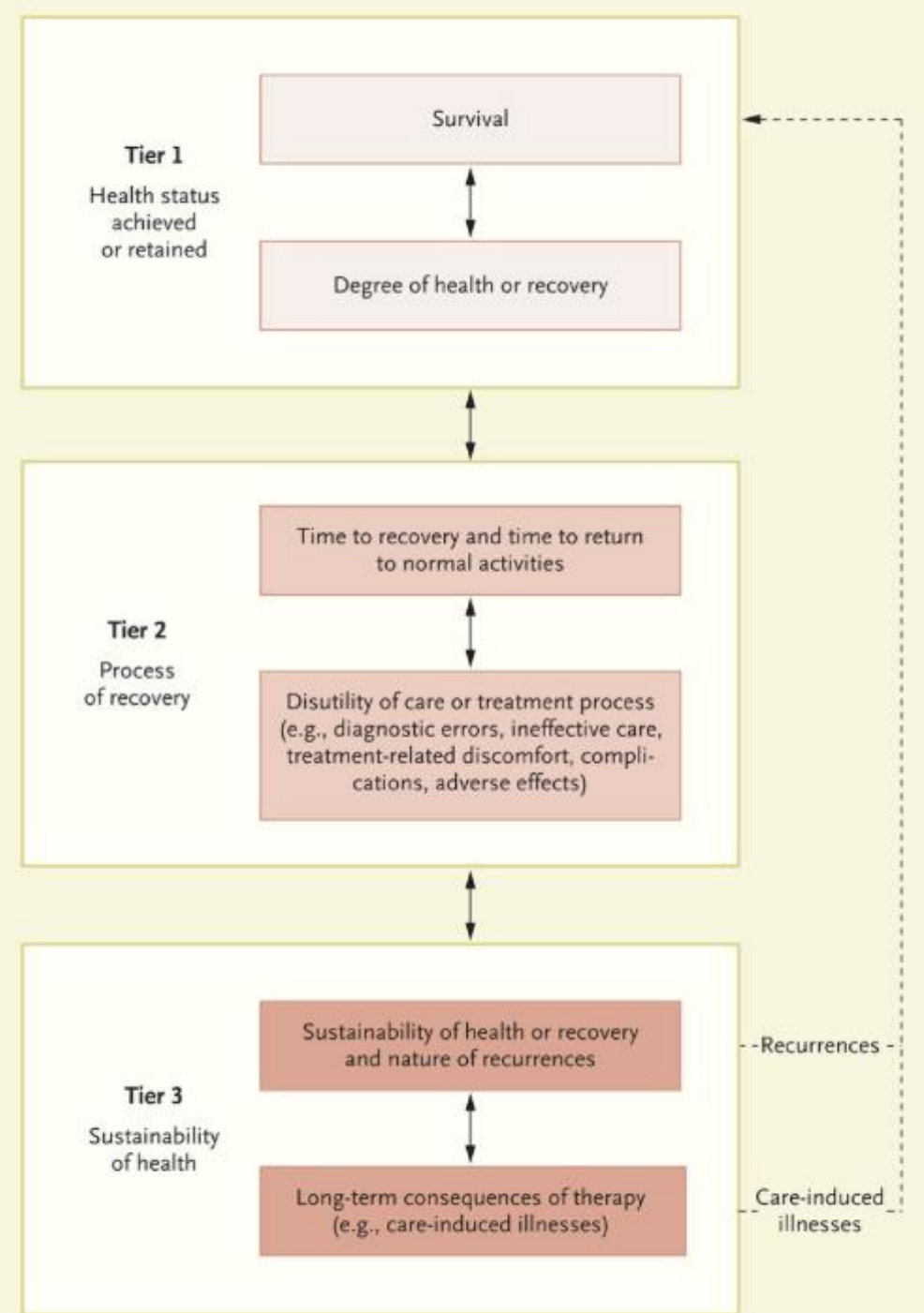


Porter ME. What is value in health care? NEJM 2010

The example of stroke (Tier 1 is priority): patients' perspective on anticoagulation

Patients generally prioritize the prevention of severe clinical events over the immediate risks associated with treatment.

- **Stroke Prevention Over Bleeding:** Most patients are willing to accept higher bleeding risks if a specific threshold in stroke risk reduction is met.
- On average, patients accept a maximum of **17.4 excess bleeds** per 100 people over two years to justify warfarin, while physicians accept only **10.3**.
- 74% of patients would initiate warfarin even if it prevented only **1 in 100 strokes** over two years.
- **Experience-Based Valuation:** Patients who have previously experienced a stroke or myocardial infarction show significantly higher willingness to accept risks for the benefits of anticoagulants.



In the recovery/long-term, value in health care is very much associated to QoL and patients' perspective domains

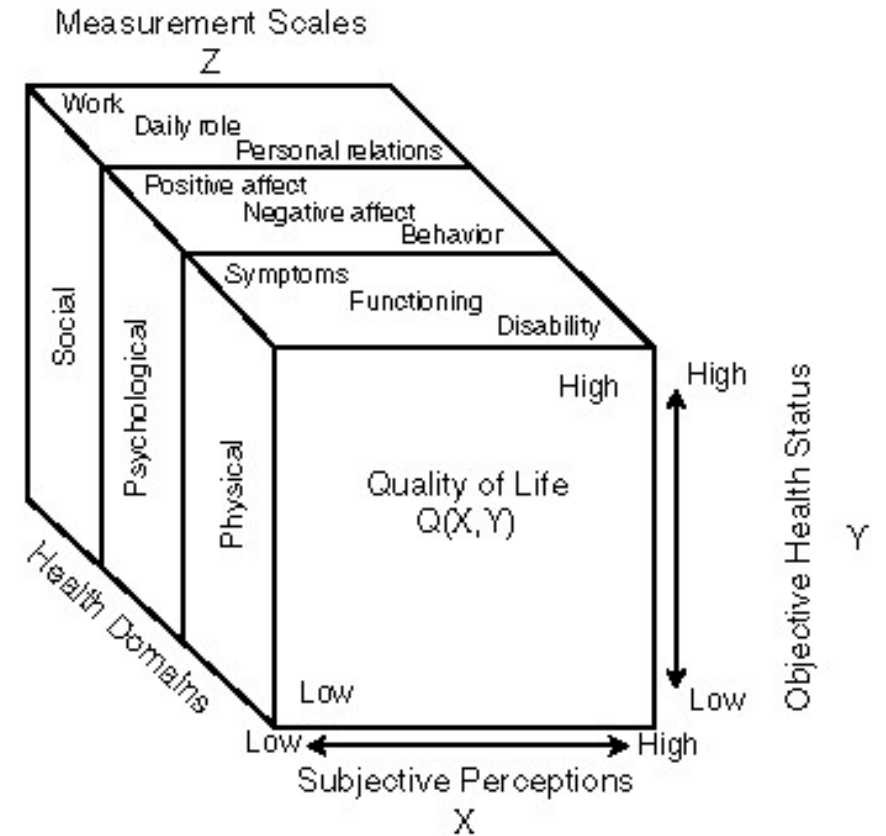
Clinical success does not guarantee a patient net benefit on QoL.

Patient-reported outcomes should be prioritized as highly as clinical outcomes

Porter ME. What is value in health care? NEJM 2010

Quality of life (QoL) Components

- Physical health
- Mental health
- Social functioning
- Energy/fatigue
- Pain
- General health perception



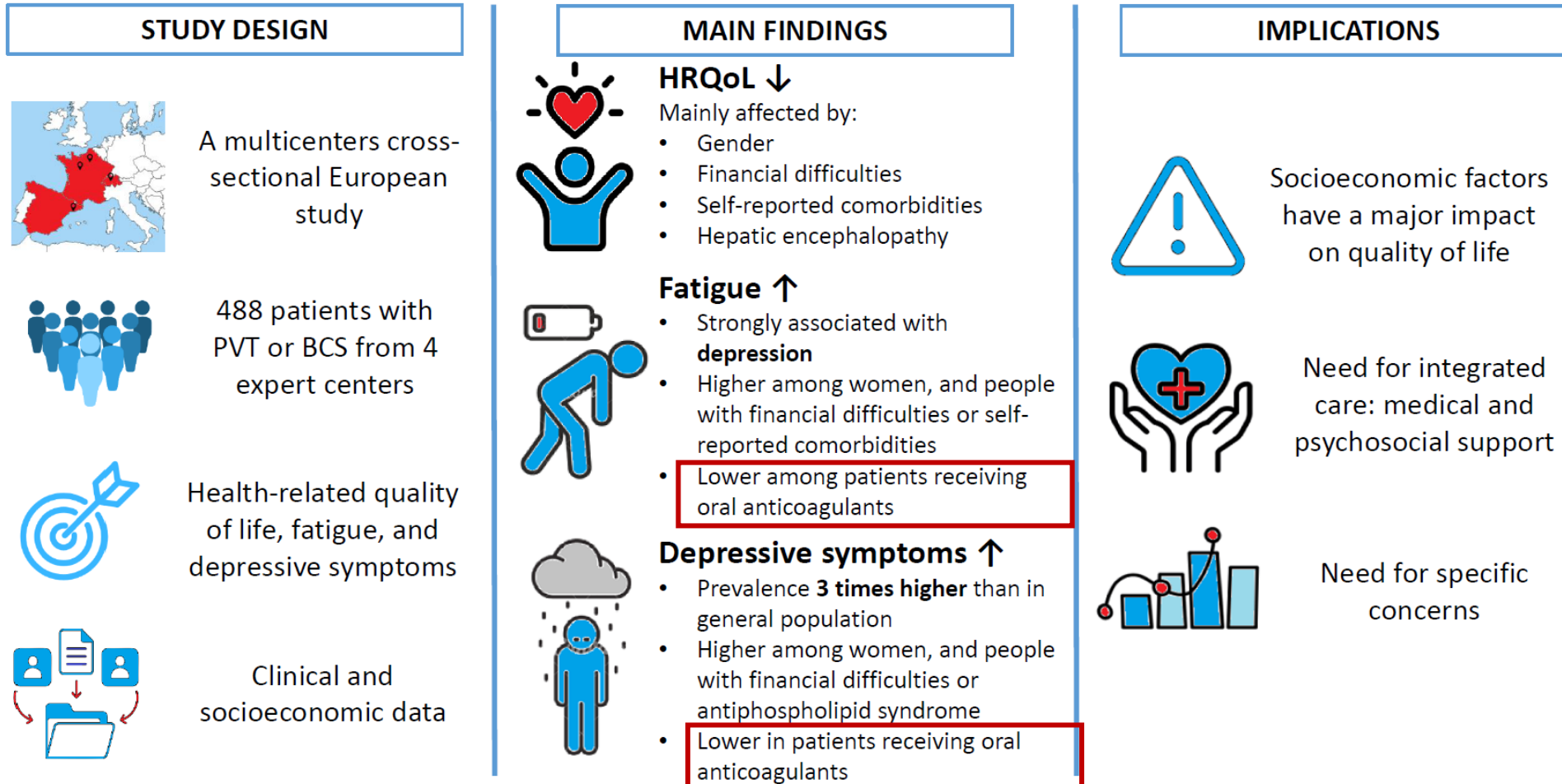
Marcia A. Testa and Donald C. Simonson
N Engl J Med 1996;334:835-840

QoL Measurement Tools

- SF-36 (generic)
- EQ-5D
- CLDQ (liver disease)
- VEINES-QoL (DVT)
- **No validated specific tools for PVT/BCS**
 - Rare conditions
 - Severe in many cases: focus on survival
 - Very heterogeneous populations

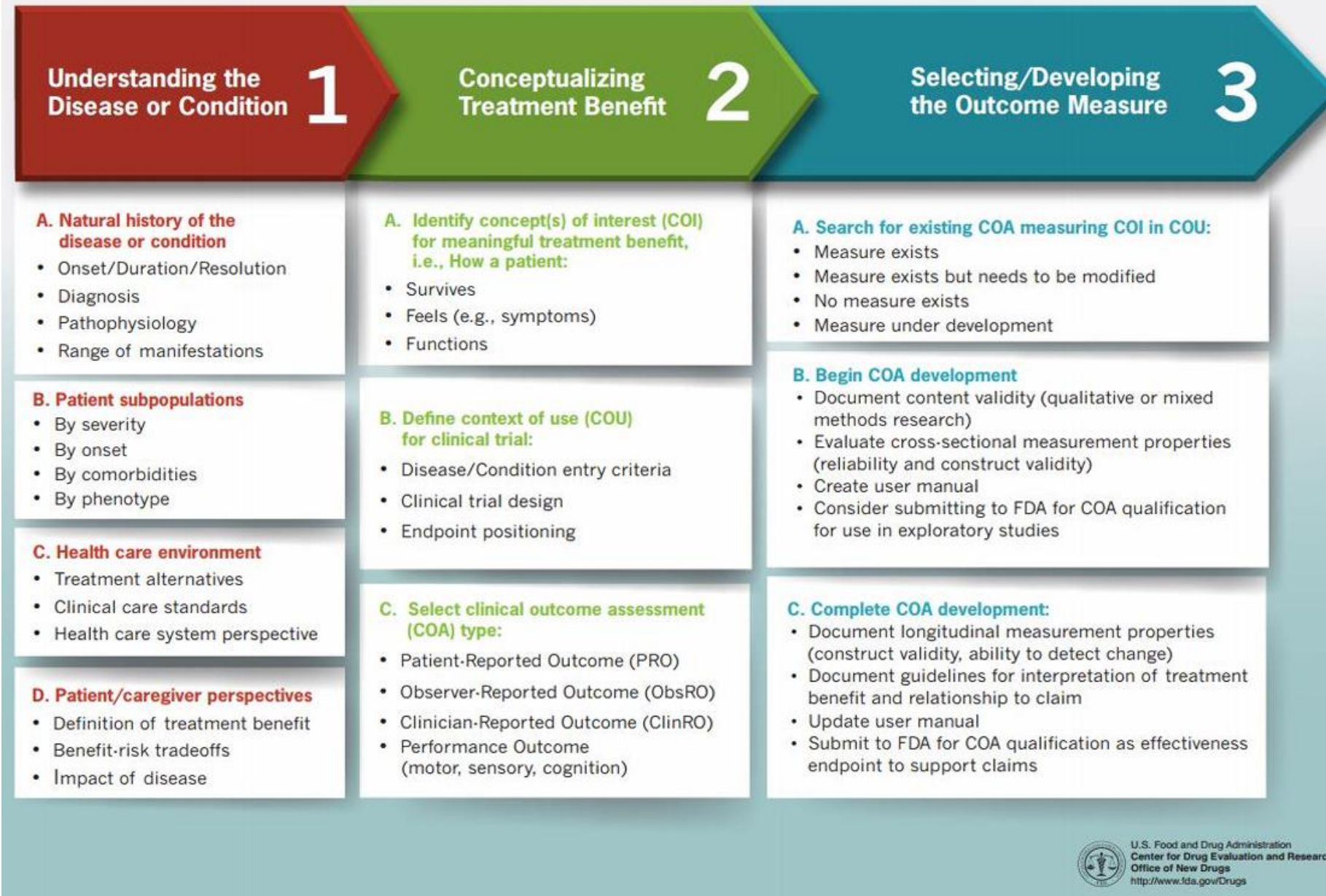
Specific data on QoL in PVT and BCS: the LIVES Study

Health-related quality of Life, Fatigue and Depression in patients with vascular liver diseases : a multicenter study in three European countries (LIVES project)



Roadmap to **PATIENT-FOCUSED OUTCOME MEASUREMENT** in Clinical Trials

FDA Roadmap



For QoL in trials both generic and disease-specific questionnaires should be used

Getting back to my title – what's patients' perspective (QoL) on anticoagulation in other fields?



CHEST

2012

Supplement

ANTITHROMBOTIC THERAPY AND PREVENTION OF THROMBOSIS, 9TH ED: ACCP GUIDELINES

Patient Values and Preferences in Decision Making for Antithrombotic Therapy: A Systematic Review

Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines

Samantha MacLean, MSc; Sohail Mulla, BHSc; Elie A. Akl, MD, MPH, PhD; Milosz Jankowski, MD, PhD; Per Olav Vandvik, MD, PhD; Shanil Ebrahim, MSc; Shelley McLeod, MSc; Neera Bhatnagar, MLIS; and Gordon H. Guyatt, MD, FCCP

48 studies (16 atrial fibrillation, 5 VTE, 4 stroke or myocardial infarction prophylaxis, 6 thrombolysis in acute stroke or myocardial infarction, 17 with burden of antithrombotic treatment).

Conclusion: Patient values and preferences regarding thromboprophylaxis treatment are **highly variable**.

Participant responses **may depend on their prior experience** as well as on the **methods used for preference elicitation**.

It should be standard for clinical practice guidelines to conduct systematic reviews of patient values and preferences in the specific content area.

Does the type of anticoagulation impact QoL in venous thromboembolism?

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Thrombosis Research

journal homepage: www.elsevier.com/locate/thromres



Health-related quality of life associated with warfarin and direct oral anticoagulants in venous thromboembolism

Margaret C. Fang^{a,*}, Alan S. Go^{b,c,d,e,f}, Priya A. Prasad^a, Hui X. Zhou^g, Anna L. Parks^h, Dongjie Fan^b, Cecilia Portugal^g, Sue Hee Sung^b, Kristi Reynolds^{c,g}

2230 patients (43.1 % women; 31.8 % >75 years of age) taking anticoagulants
975 taking DOACs and 1255 taking warfarin
Questionnaire SF 36

Results: type of anticoagulation does not really matter to patients

General health-related QoL was similar between DOAC and warfarin users
(women had in general lower scores for mental and physical function on both groups)

Treatment satisfaction was slightly higher with DOACs (reason: lack of need of monitoring), although the difference was small

In VTE

QoL is driven by:

- Bleeding
- Comorbidities
- Socioeconomic factors
- Drug choice has minimal impact on QoL

Ghanima W et al. Thrombosis Research 2018

Physician sometimes focus on aspects that are not so relevant for patients

Assessing QoL and PROMs, in addition to efficacy and safety, is fundamental to aligning anticoagulant decision-making with patient-centered goals and values

A qualitative research study centered on care of VLDs – LIVES study

Challenges in the Care of Rare Vascular Liver Diseases: Insights from Patients, Health Care Providers, and Members of Patient Organizations from four European Countries (LIVES study funded by Horizon 2020 Research and Innovation Programme, EJP RD JTC 2021)

QUALITATIVE RESEARCH

37 in-depth interviews were conducted in 4 European countries. A total of 17 healthcare providers, 13 patients diagnosed with a vascular liver disease (VLD), and 7 members of patient advocacy organizations were involved.



FINDINGS

Anxiety also due to the use of anticoagulants



Incidental diagnosis

Delayed, uncertain, and fragmented diagnosis
Lack of awareness in non-specialist settings



Poor coordination

Poor continuity across care levels, especially when multiple specialists are involved
Gaps in psychological support



Difficult communication

Issues include lack of empathy, time, and message clarity
Lack of structured educational



Adherence issues

Uncertainty about VLDs' etiology, prognosis and treatment
Follow-up and adherence to treatments concerns



Low involvement

Limited patient involvement in clinical decisions
Invisibility of informal caregivers

As one patient noted about **anticoagulants**, “*I don't see why I have to keep taking them*” (PT3). Overall, uncertainty contributed to a weak sense of agency.

Guilabert M, Dumas A et. submitted

Shared decision-making: facts and tools to improve

Shared decision-making is critical to address discrepancies between patient and physician perceptions.

- **The "Refusal" Disconnect:**

- Physicians often mention "patient refusal" as a reason for non-treatment, yet nearly **25% of these patients** report they would be willing to take anticoagulants if re-approached.

- **Communication Gaps**

- About 50% of patients do not feel sufficiently informed about the risks and benefits at the time of their first prescription.

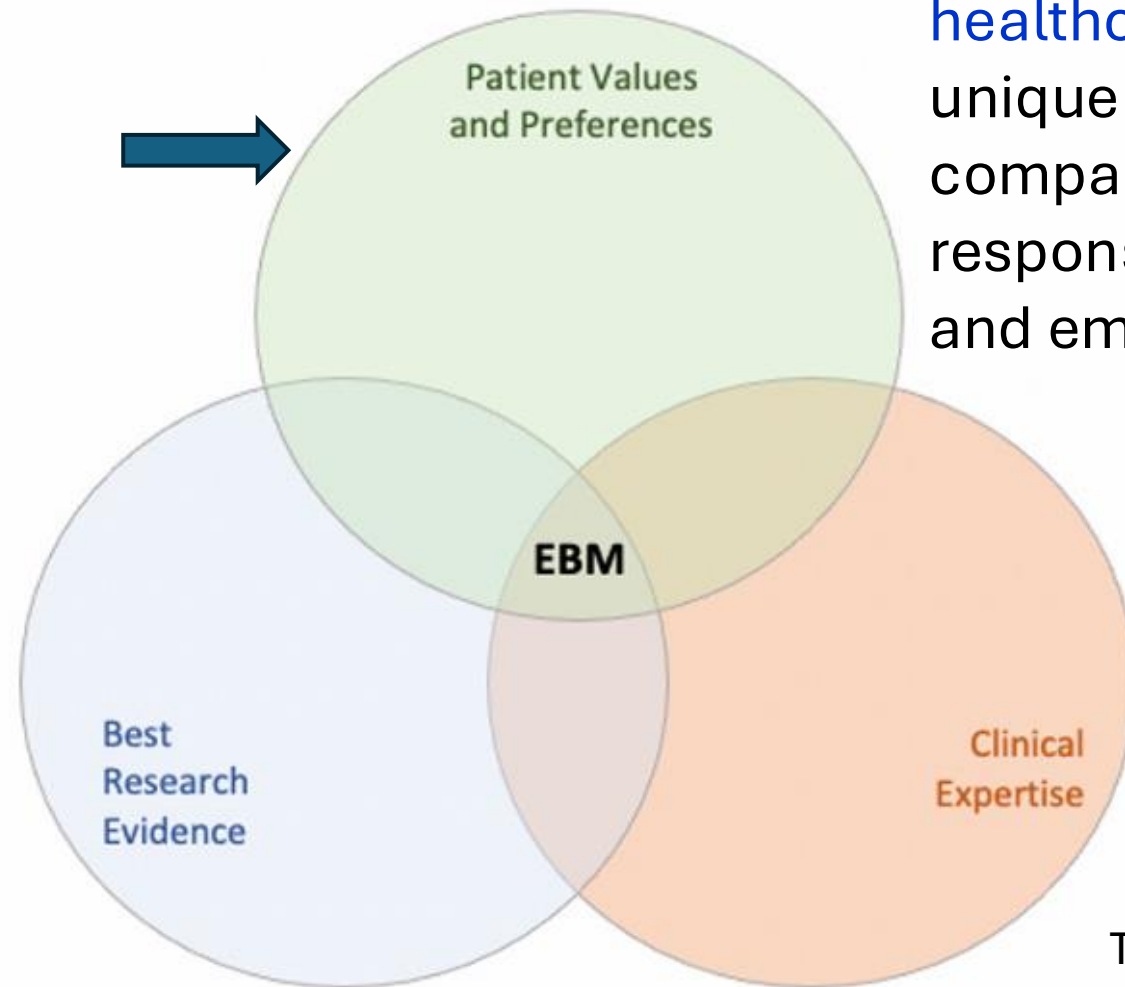
- **Impact of Education:**

- Multimedia-based and pharmacist-led education significantly improve short-term knowledge and reduce readmission rates (from **12.1% to 1.8%** in some pilot studies).

- **Decision Aids:**

- The use of patient decision aids (booklets or videos) reduces "decisional conflict" and improves the accuracy of patient expectations regarding thrombosis and hemorrhage

Modern evidence-based medicine is a triad



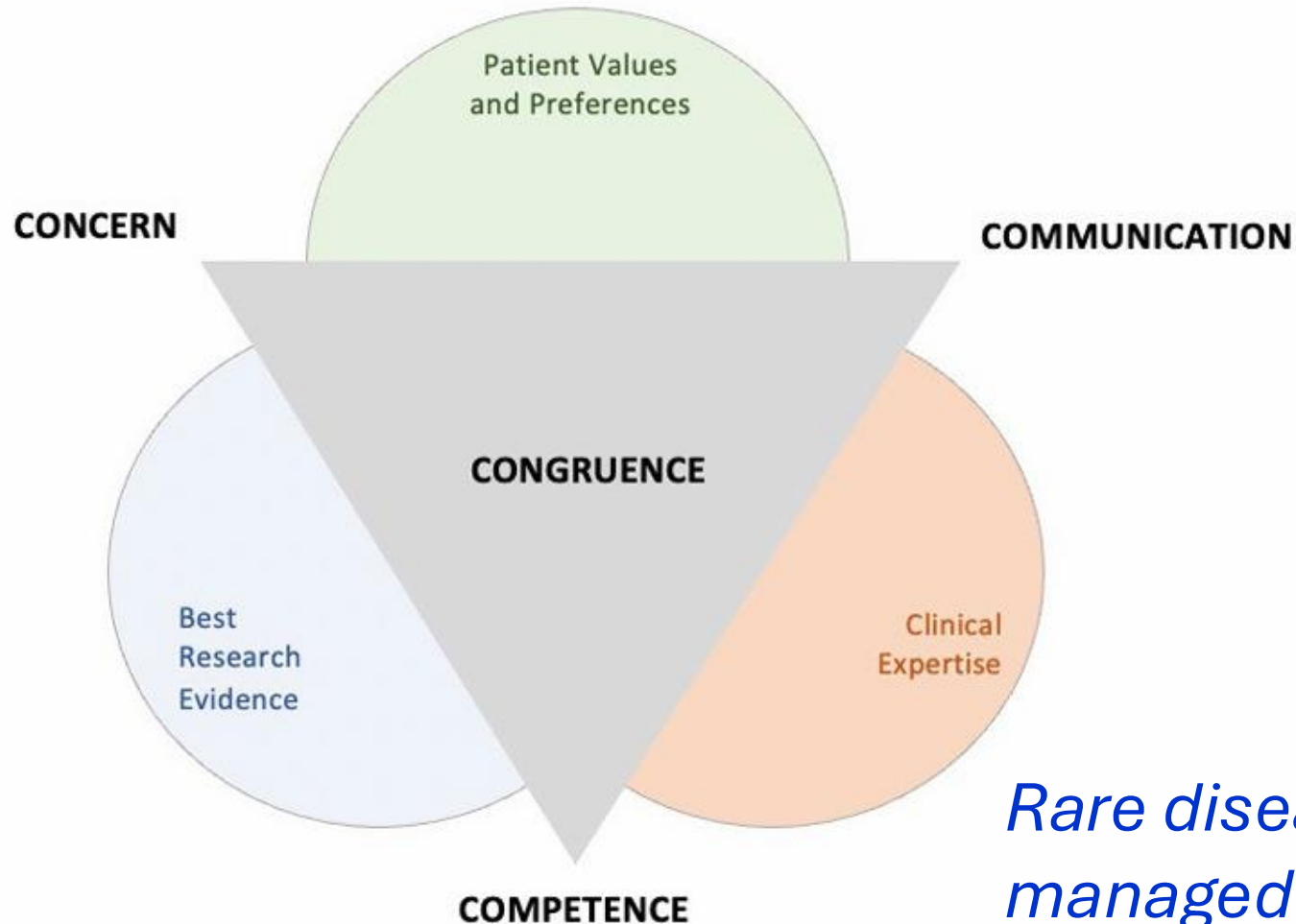
Patients value the following in healthcare:

uniqueness, autonomy, compassion, professionalism, responsiveness, partnership and empowerment

Key aspects to better take patients' perspective into account



Interdisciplinary teams
(physicians, specialized nurses; psychologists)



Time!!!

Rare diseases should be managed by experts

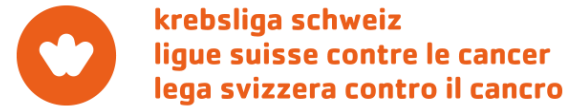
Take home messages

- Patient-centered outcomes should become an important part of research in PVT/VLDs
- Patients' perspective on anticoagulation in VLDs should be better understood and integrated in each step of care (value-based care)
- Standardized disease-specific tools (qualitative and quantitative) should be developed in this field



Image created with Chat GPT

Thank you for your attention



Hepatological Diseases
(ERN RARE-LIVER)

