

# Paris Portal Vein thrombosis meeting

## IMPACT ON QUALITY OF LIFE

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# Relevance of studying HrQoL

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**Health- related quality of life:** Individuals' or group's perception of their physical and mental health

## Study of HrQoL allows to:

- Identify new problems and health dimensions at risk
- Provide valuable new insights into the relationship between HrQoL and risk factors
- Monitor progress in achieving health objectives
- Design individualized interventions
- Improve patients' understanding and self-management of their disease
- Improve patient's use of resources available from the environment, which impacts on better health outcomes



# Relevance of studying HrQoL

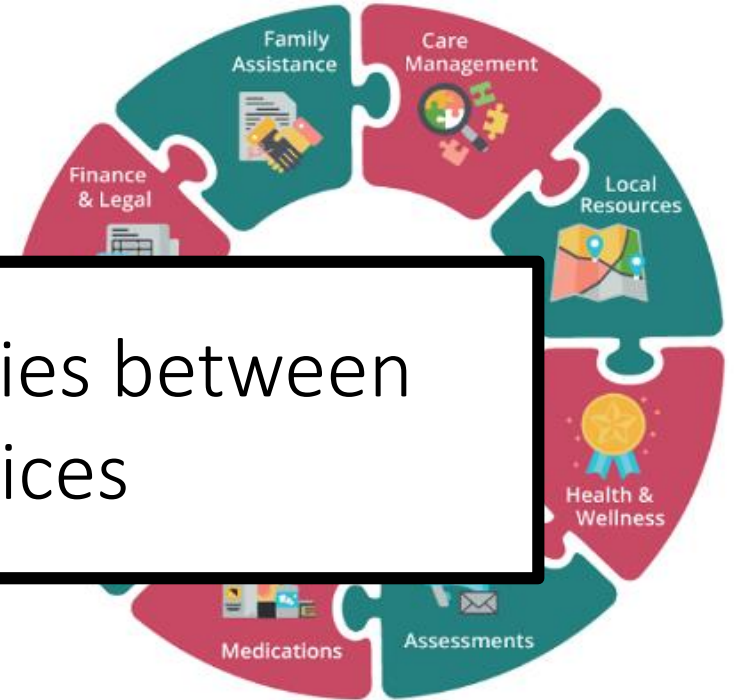
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**Health- related quality of life:** Individuals' or group's perception of their physical and mental health

Study of HrQoL allows to:

- Identify barriers to care
- Monitor patient's health and well-being
- Design individualized interventions
- Improve patients' understanding and self-management of their disease
- Improve patient's use of resources available from the environment, which impacts on better health outcomes

The study of HrQoL can bridge boundaries between social, mental and medical services



# Needs in the assesement of QoL in PVT

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Usual focus on disease-related variables



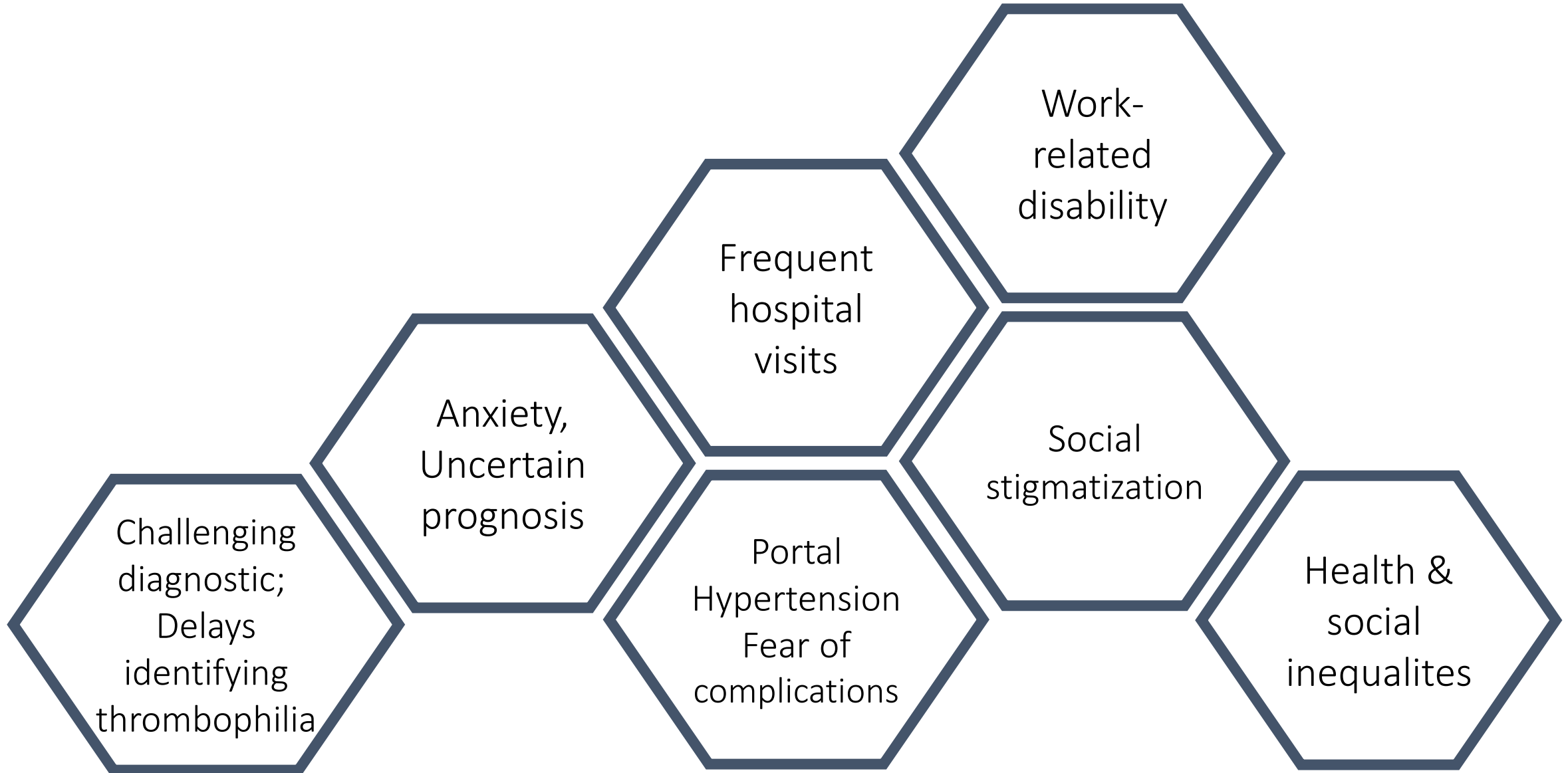
Social impact poorly addressed



Not patient-centered perspective

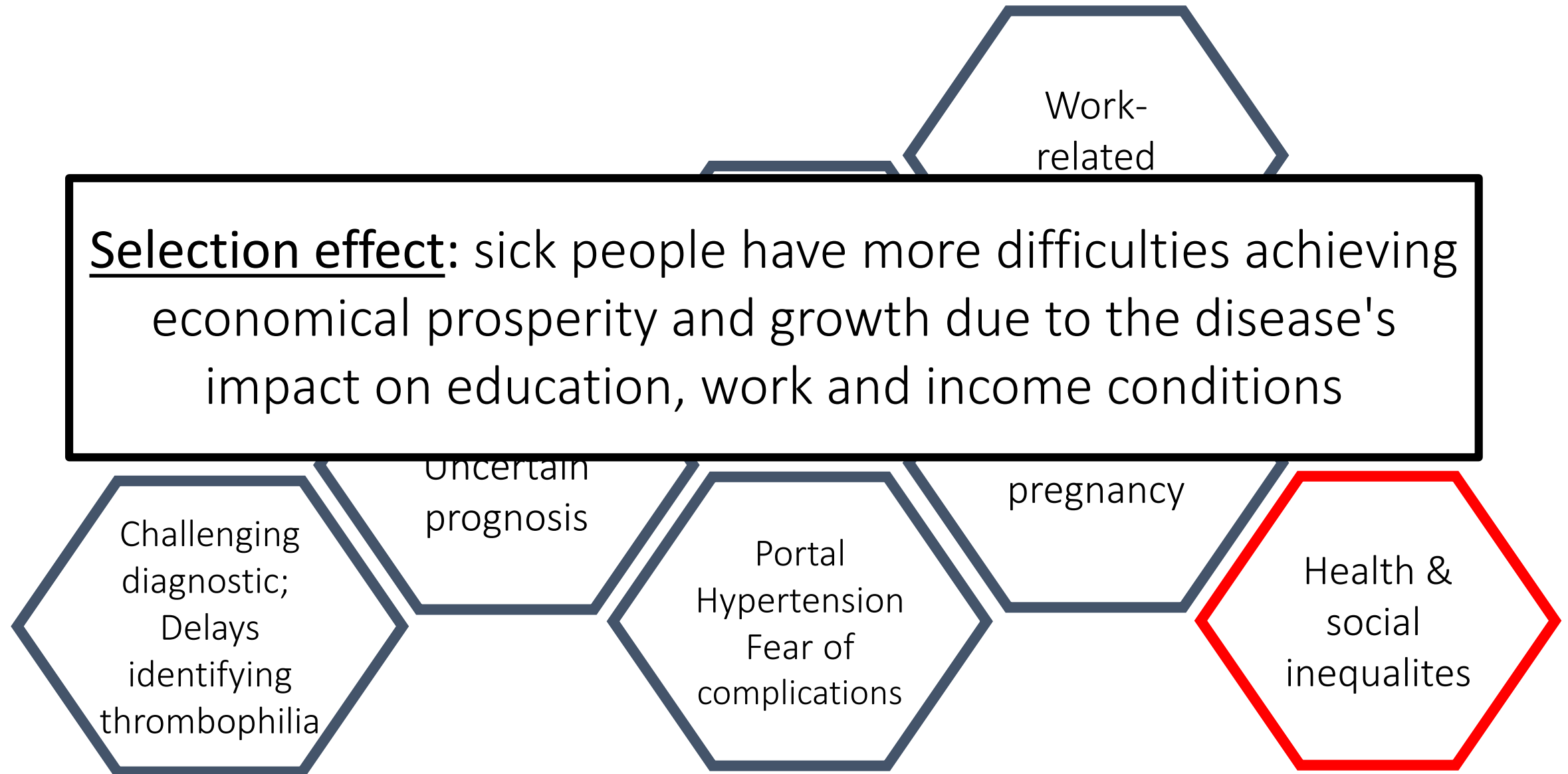
# Impact of PVT on QoL

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# Impact of PVT on QoL

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# Impact of **PVT** on QoL

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Lack of evidence addressing HrQoL in PVT patients

# Evaluation of new-onset depression and anxiety in patients with PVT

Variable	Patients with Portal Vein Thrombosis (n = 547)	Patients without Portal Vein Thrombosis (n = 2735)	p Value
Women	38.9	38.7	0.907
Men	61.1	61.3	
Mean age in years (standard deviation)	57.3 (16.1)	57.5 (16.0)	0.898
Age ≤50 years	32.2	32.3	0.998
Age 51–60 years	22.7	22.3	
Age 61–70 years	21.2	21.1	
Age >70 years	24.0	24.2	
Mean number of consultations per year	5.3 (7.4)	4.9 (6.7)	0.411
Diagnoses documented within 12 months prior to the index date			
Cancer	21.9	21.3	0.727
Obesity	10.6	10.3	0.835
Liver cirrhosis or chronic hepatitis	18.8	16.4	0.125
Thrombophlebitis	16.8	15.4	0.406
Varicose	27.6	25.4	0.275

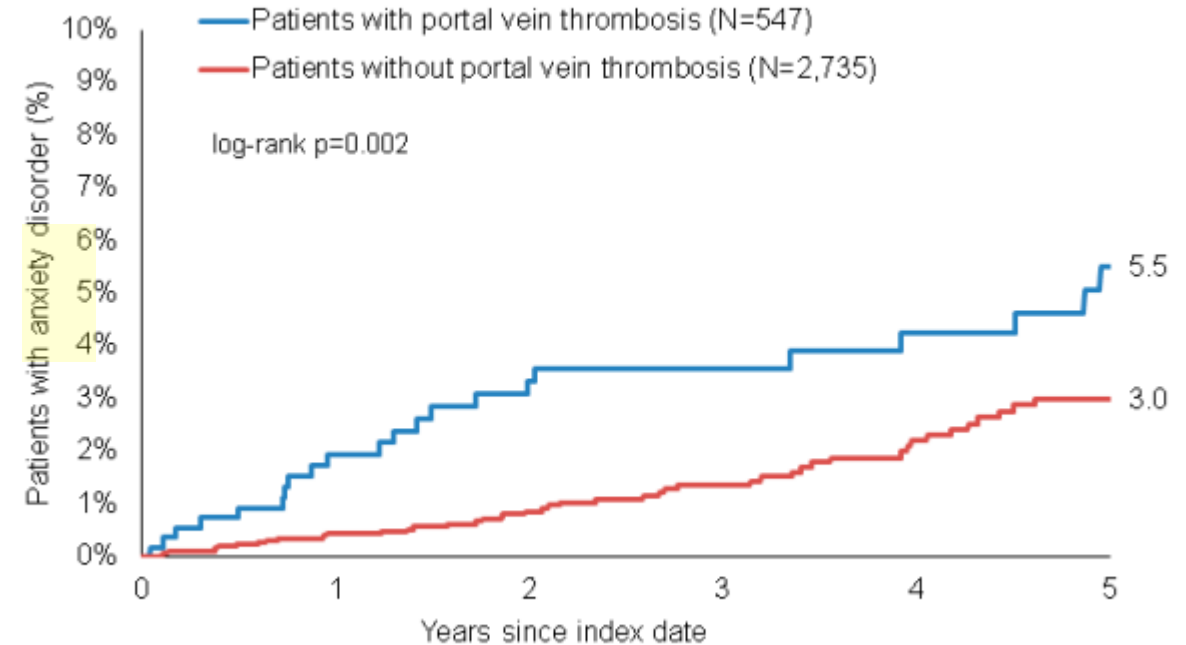
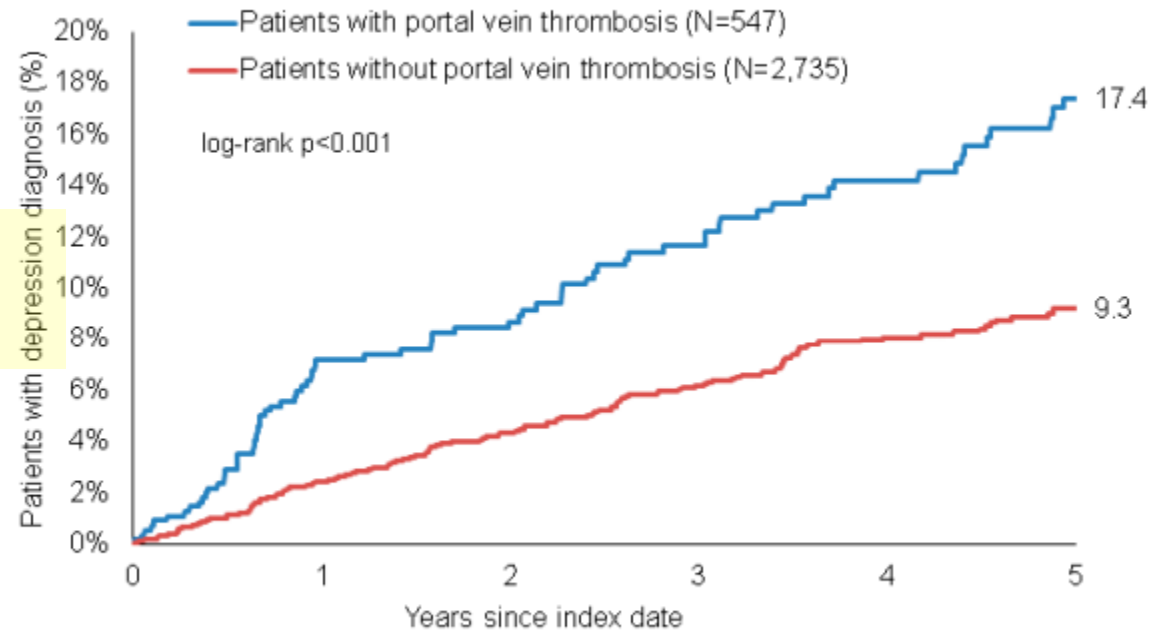
Data are percentages unless otherwise specified.

Evaluation of the incidence of anxiety and depression within 5 years of the index date based on the diagnosis codification of a primary care cohort



# PVT is associated with an increased incidence of depression and anxiety disorders

	Depression		Anxiety Disorder	
	Hazard Ratio (95% CI)	<i>p</i> Value	Hazard Ratio (95% CI)	<i>p</i> Value
Overall	2.01 (1.53–2.64)	<0.001	2.16 (1.35–3.46)	0.001
Women	1.62 (1.30–2.54)	0.017	1.82 (0.89–3.73)	0.101
Men	2.45 (1.68–3.57)	<0.001	2.42 (1.30–4.54)	0.005
Patients with liver cirrhosis	2.27 (1.27–4.04)	0.006	2.31 (0.55–9.68)	0.253
Patients without liver cirrhosis	1.93 (1.42–2.63)	<0.001	2.18 (1.26–3.77)	0.006



# Impact of PVT on QoL

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Rational to assess the incidence of depression and anxiety in PVT  
**not purely interest in QoL**

Suggested bi-directional relationship between cardiovascular diseases and depression

Depression could induce physiological derangements (hypercortisolism) that could contribute to adverse vascular outcomes

# Impact of **ANTICOAGULATION** on QoL

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Anticoagulation is associated with  
numerous practical limitations  
frequent anticoagulation monitoring (*vitamin K antagonists*)  
lifestyle and dietary restrictions that can complicate patient management

**IMPACT in HRQoL**

# Impact of ANTICOAGULATION on QoL

## Evaluation of patients' perceptions and quality of life in patients chronically anticoagulated

Cross-sectional study; n = 905 patients

SF-36 survey

Perception of protection from thrombotic complications vs fear of haemorrhage

Positive perceptions	
Protection from thrombosis	71.5%
Felt better since OAT	61.5%

Negative perceptions	OR	95% CI	<i>p</i>
Female sex	1.58	1.06–2.36	0.01
< 1 year of OAT	2.16	1.34–3.48	0.006
Habit modification	2.75	1.49–4.91	0.0002
Dissatisfaction with medical attention	2.86	1.53–5.18	0.0001

Bleeding episodes (major and minor) were similar in both QoL groups

# Impact of ANTICOAGULATION on QoL

Evaluation of HrQoL in patients under  
**WARFARIN vs DABIGATRAN**  
in the absence of outcome events  
(strokes, major bleeding)

Comparable scores between  
dabigatran and warfarin

B U Monz et al, Int J Cardiol 2013

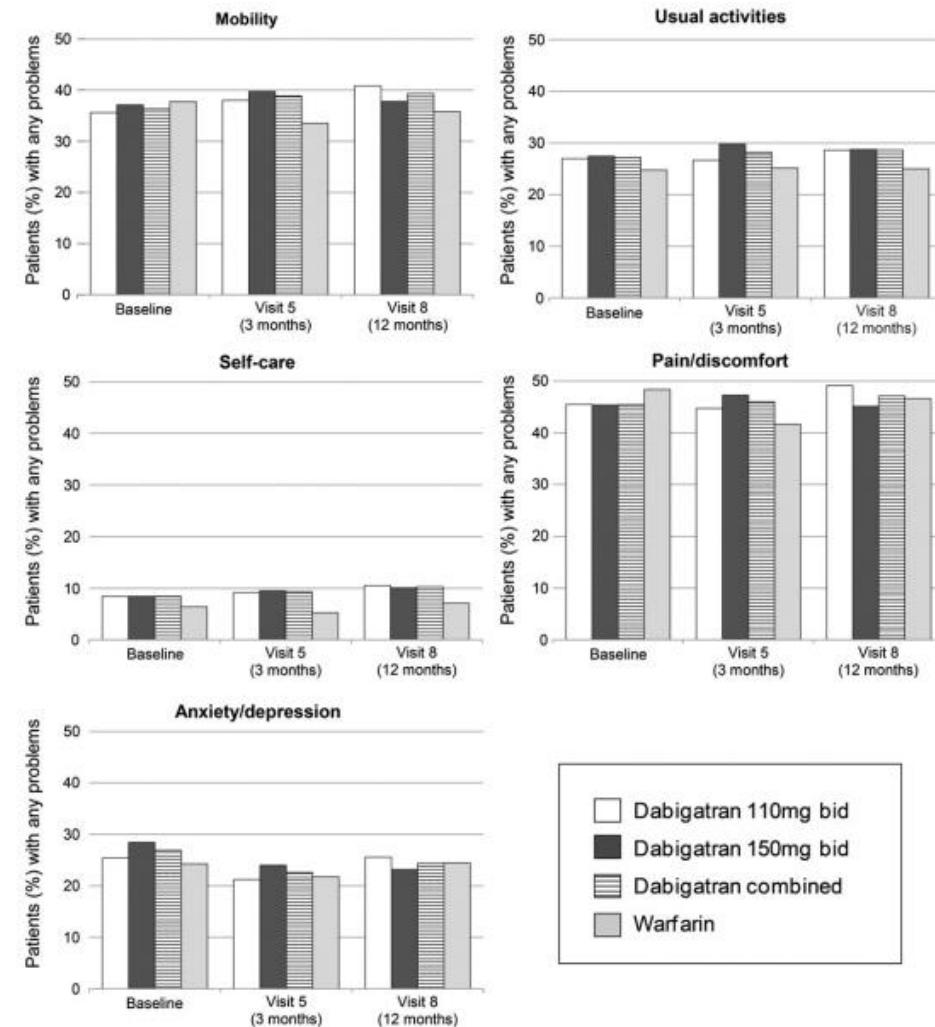


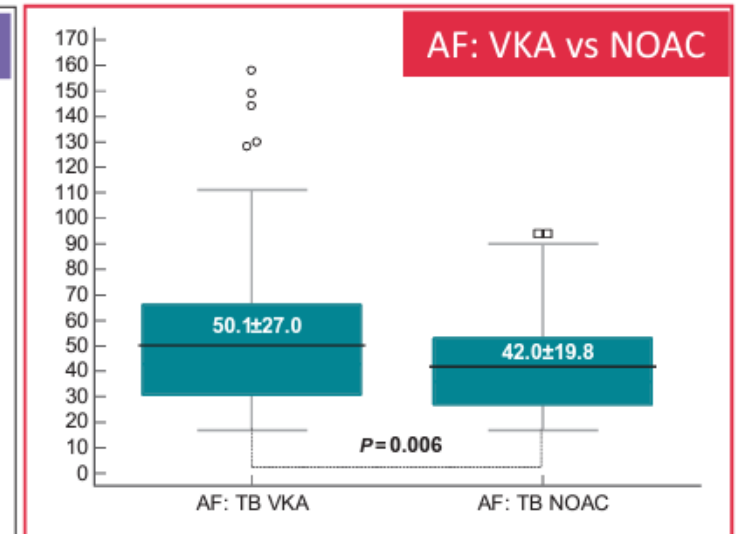
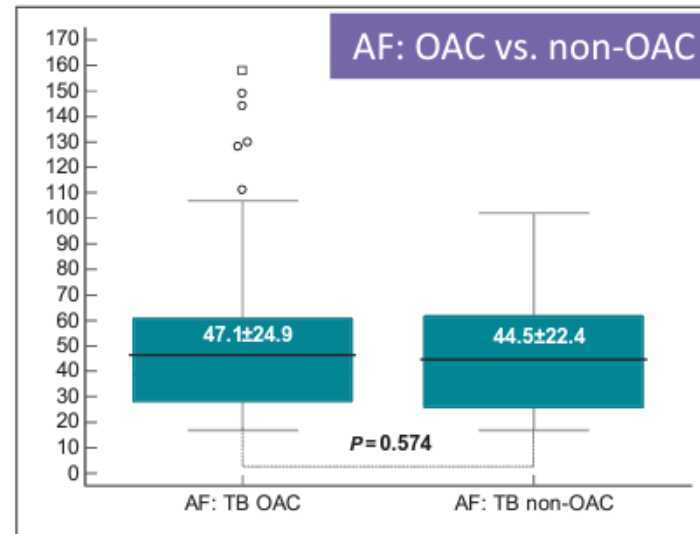
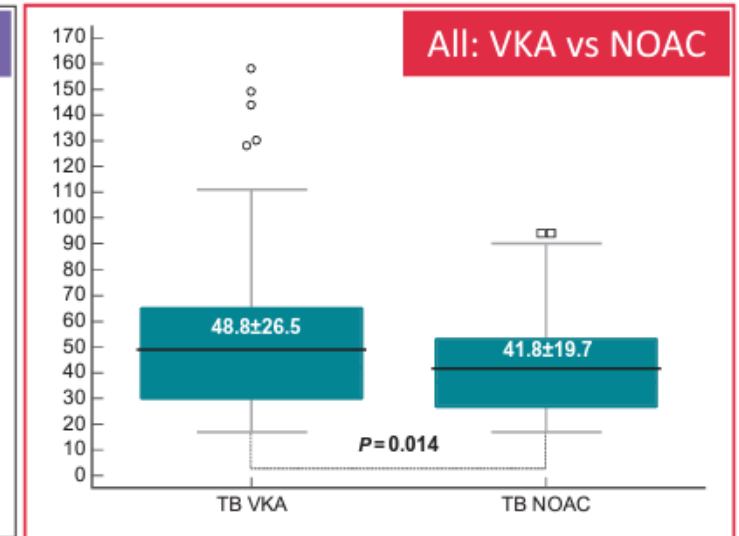
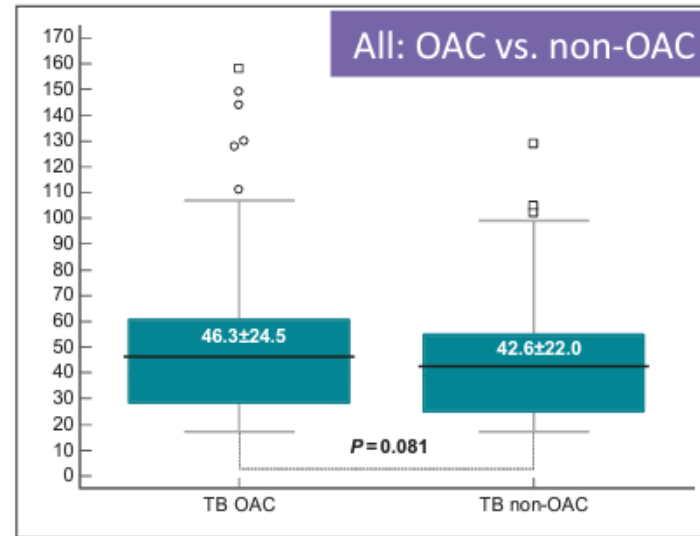
Fig. 1. Distribution of patients with any problem over time, by health dimension of EQ-5D.

# Impact of ANTICOAGULATION on QoL

## Self-reported treatment burden on AF

TS Potpara et al, Europace 2020, ESC

Self-perceived cumulative work patients do to manage their health is significantly higher in patients taking vitamin K antagonists vs DOACs



# Assessment of QoL in liver diseases



# Assessment of QoL in liver diseases

## SF 36

Physical functioning  
Limitations by physical  
health & emotional  
problems  
Social functioning  
Emotional well being  
Fatigue  
Pain  
General perception

## SF 12

Fatigue  
Psychological outcomes  
Social Outcomes

## CLDQ

29 items  
Fatigue, activity, emotional function,  
abdominal symptoms, systemic symptoms,  
worry



# Patient-centered perspective.

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Identify useful **PRO**  
[patient reported outcome]  
for the study of PVT

Identify / Create  
HrQoL  
questionnaires for PVT

Monitor progress in  
the achievement of health  
objectives  
Identify unnecessary  
procedures

Promote shared  
decision-making and  
educated choices

Consideration of social  
health needs when  
prescribing treatments

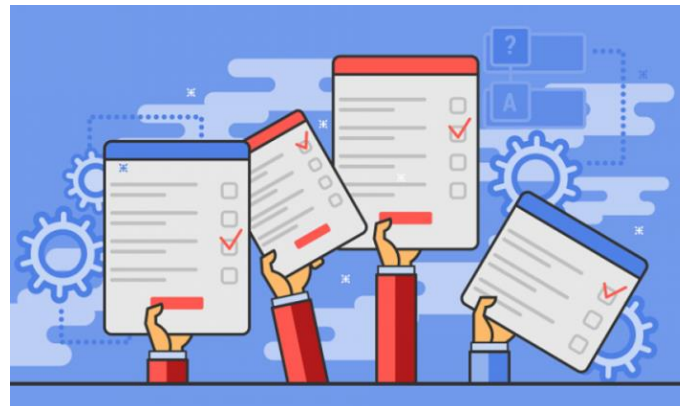
Involve patient associations  
to promote  
patient-centered research

# LIVES PROJECT



## AIMS

- To develop a specific questionnaire able to assess the impact of **vascular liver diseases** on quality of life, including variables identified by patients themselves
- Use of the new questionnaire to assess the QoL in patients with VLD



## INVOLVEMENT OF PATIENTS ASSOCIATION



A hand is holding a smartphone. Overlaid on the phone's screen are four semi-transparent app interface mockups. The central mockup shows a 'Welcome' screen with a purple triangle icon and a circular progress indicator. To its left is a mockup with a bar chart and a line graph. To its right is a mockup with a purple triangle icon and a circular progress indicator. Below these is a mockup with a grid of colorful icons. The background is a blurred image of a person's face.

**ERN RARE LIVER**

**APP DEVELOPMENT**

**PATIENT REPORTED OUTCOMES on  
QUALITY of LIFE  
for RARE DISEASE PATIENTS**



ERN RARE LIVER

APP DEVELOPMENT

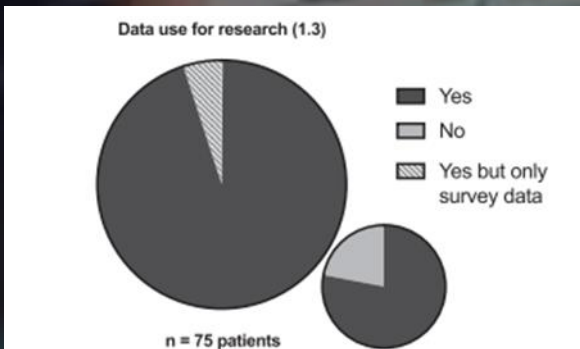
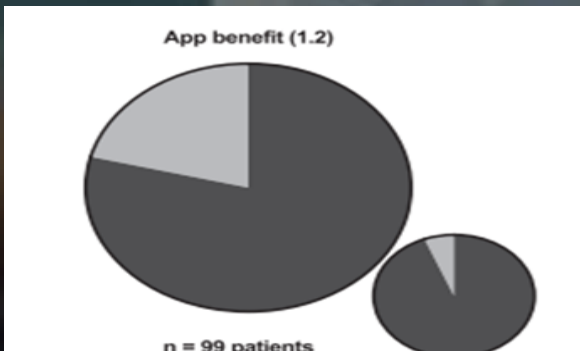
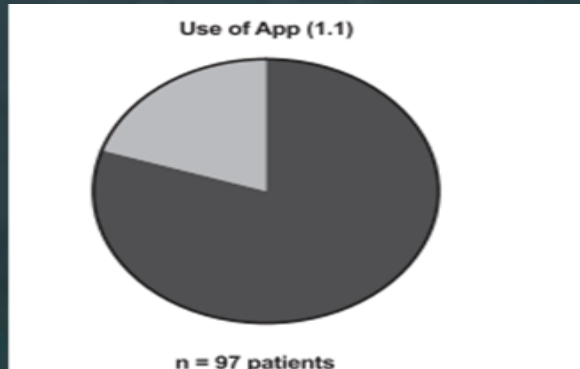
PATIENT REPORTED OUTCOMES on  
QUALITY of LIFE  
for RARE DISEASE PATIENTS

Mobile Health apps enable exhaustive data collection

Implementation of an app for patients with rare liver diseases that will collect and transfer all the information to an international registry

Patients and health care providers will answer questionnaires to select which features will be included in the app





**Table 3.** Functional requirements of the app deduced from survey results.

Functional Requirements	Rationale
<b>Must have:</b> <ul style="list-style-type: none"> <li>• Possibility to fill-in surveys (e.g. PROM)</li> </ul>	Initial motivation for app; Increase and improve available data of QoL of patients
<ul style="list-style-type: none"> <li>• Receive information about disease, new developments and clinical trials based on the individual disease of the user</li> <li>• Give access to entered data</li> </ul>	Very much desired by patients; Increase patients' ability for self-management Very much desired by patients; Required for showing course of disease to treating physician
<b>Nice to have:</b> <ul style="list-style-type: none"> <li>• Possibility to enter appointments, lab values and medication plan</li> <li>• Symptom trackers for recording of health concerns</li> <li>• Reminders of medical appointments and to take medication</li> </ul>	Moderately desired by patients; useful to track course of disease; appointments required as trigger for survey Moderately desired by patients; useful to track course of disease Of greater importance for experts than patients; supportive feature to increase medication adherence but users should be enabled to deactivate it if opposed
<b>Future:</b> <ul style="list-style-type: none"> <li>• Notification of treating physician in case of concerns</li> <li>• Generate treatment suggestions</li> <li>• Automatic ordering of follow-up prescriptions</li> <li>• Pediatric version of app</li> </ul>	Very much desired by patients, but IT infrastructure not yet given and not feasible with initial budget Desirable feature especially for patients in remote regions but would lead to classification of the app as a (legally more complex) medical device; IT infrastructure not yet given and not feasible with initial budget Very much desired by patients, but IT infrastructure not yet given and not feasible with initial budget Very much desired by experts, but not feasible with initial budget

PROM: Patient Reported Outcome Measures; QoL: Quality of Life.

# Conclusions

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Presently there is a marked lack of evidence in the field of HrQoL and PVT

New projects focused on PROs involving patients' associations in the design of the studies, promoting a patient centered approach, are going to radically change the current scenario in the following years.

# Thank you

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Hepatological Diseases  
(ERN RARE-LIVER)



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