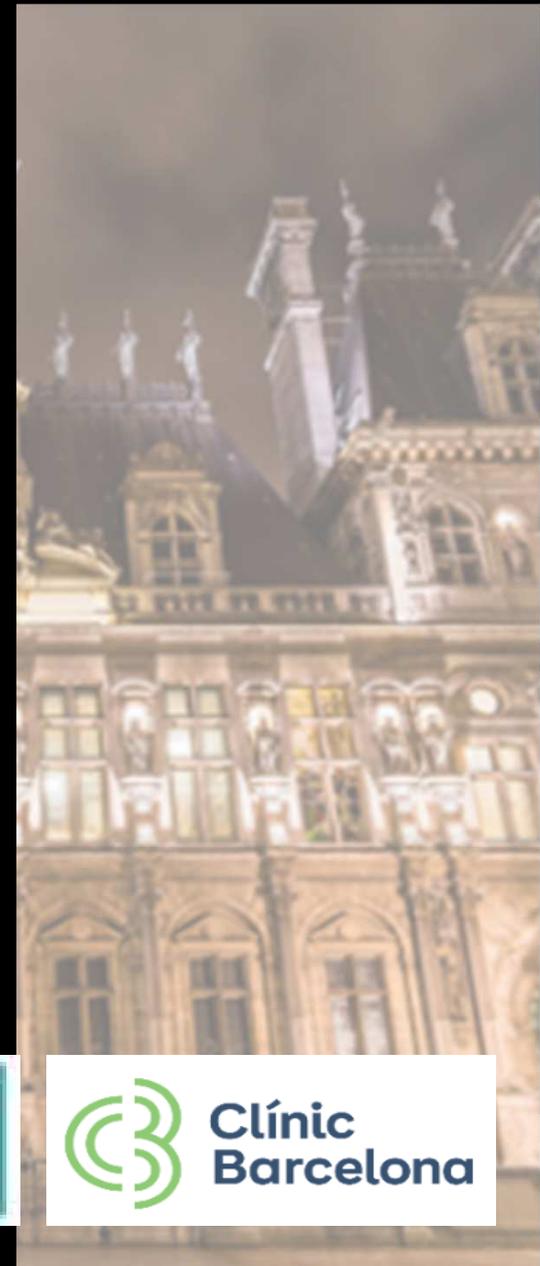




Paris Portal Vein thrombosis meeting

IMPACT ON QUALITY OF LIFE

Anna Baiges, Liver Unit, Clinic Barcelona



Relevance of studying HrQoL

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



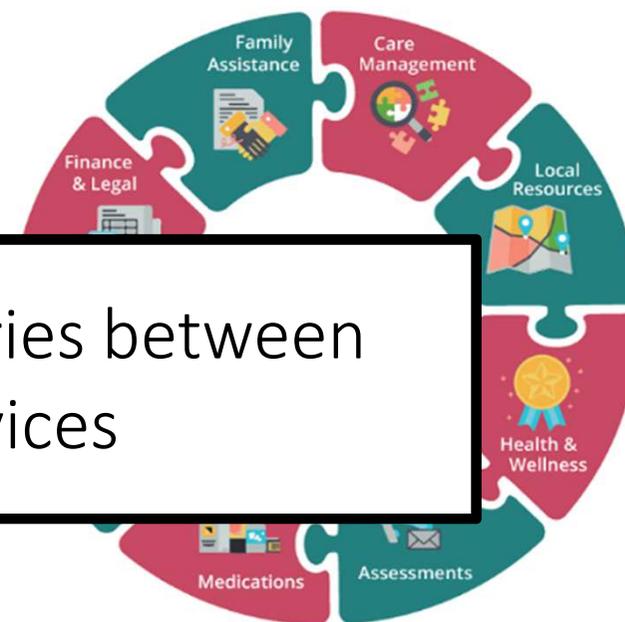
Relevance of studying HrQoL

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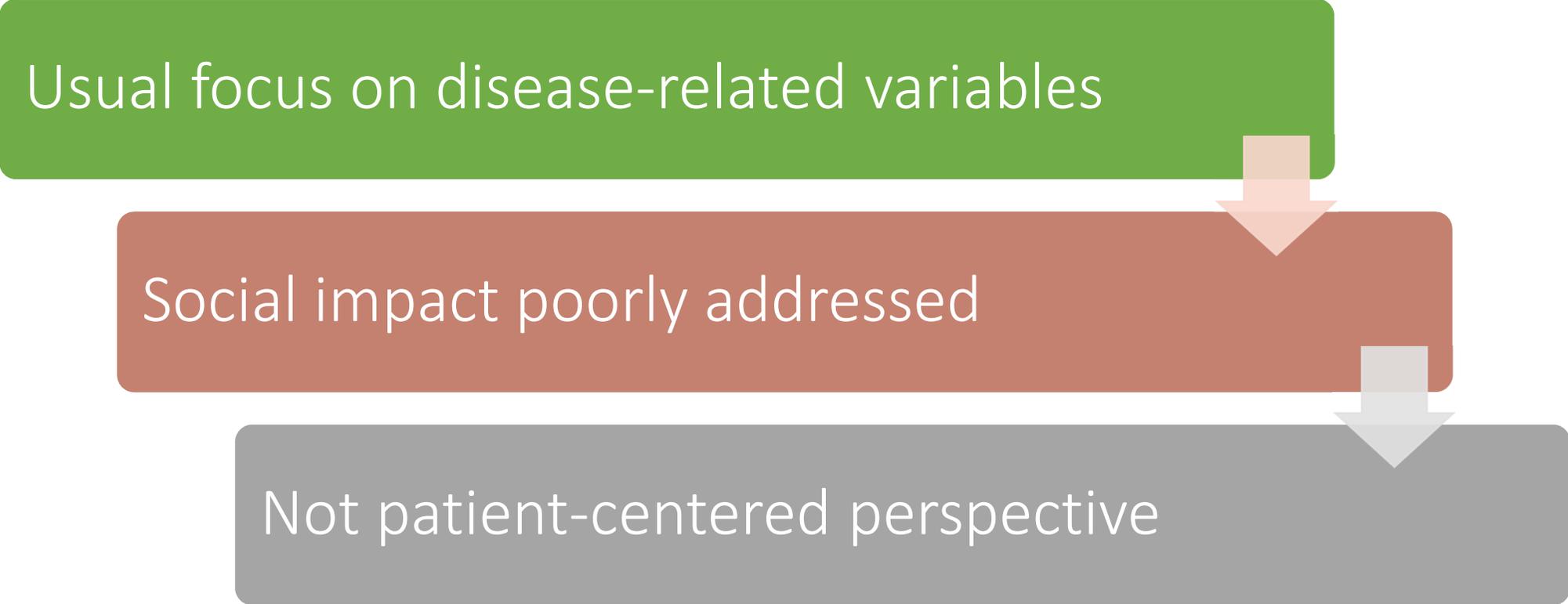
- Identify gaps in care
- Improve patient's use of resources available from the environment, which impacts on better health outcomes
- Design individualized interventions
- Improve patients' understanding and self-management of their disease

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



Needs in the assesement of QoL in PVT

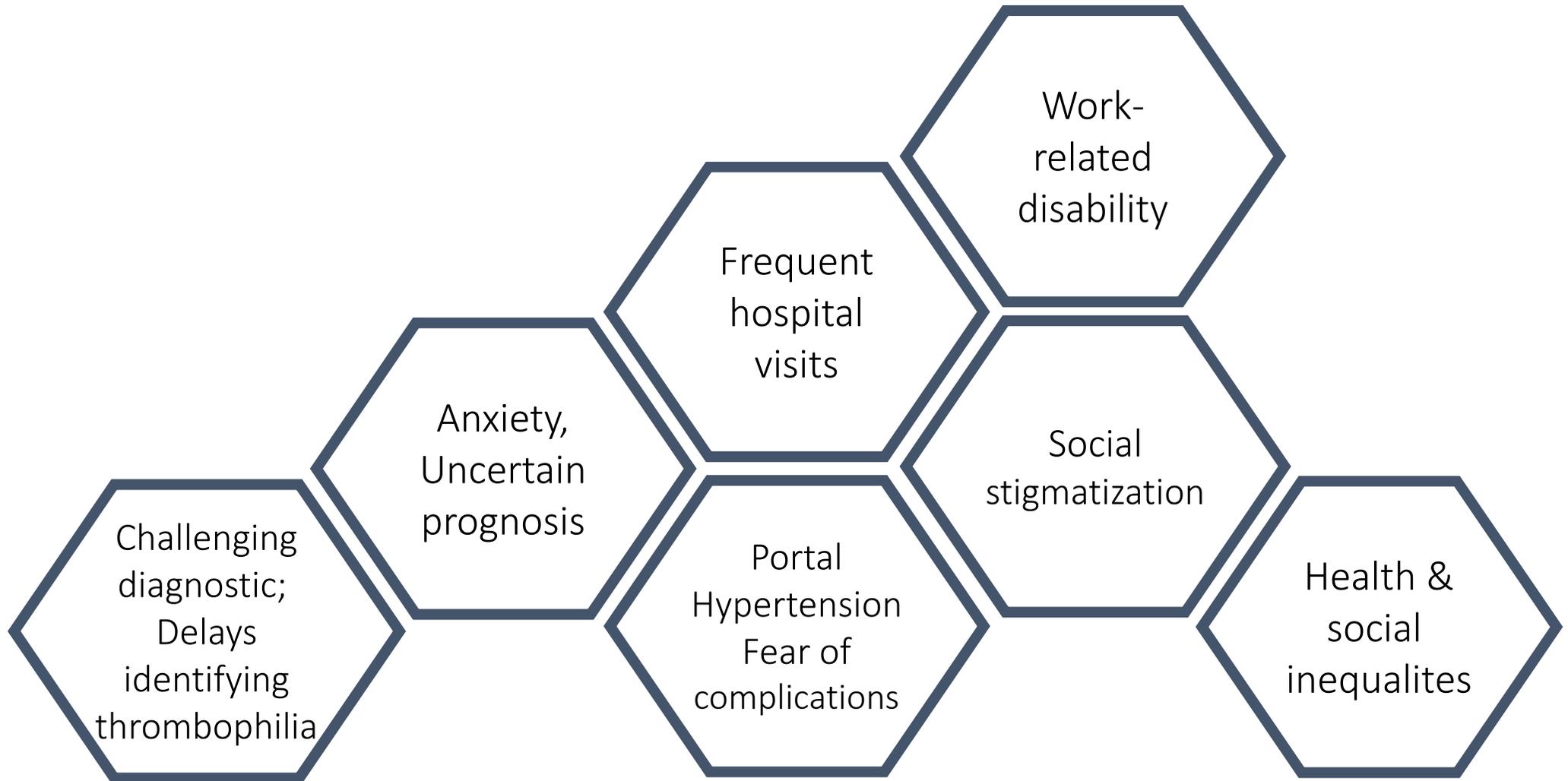
Usual focus on disease-related variables



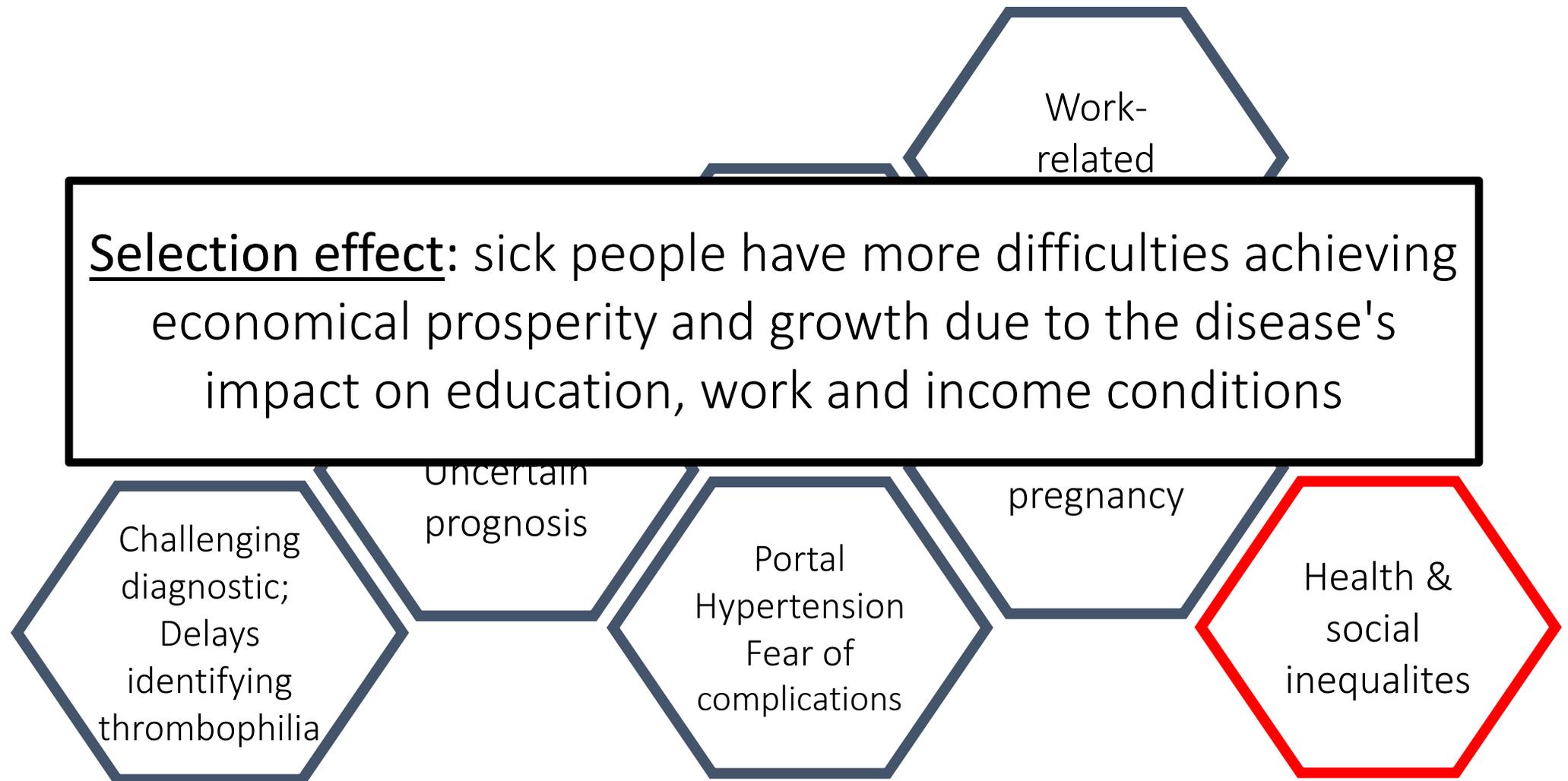
Social impact poorly addressed

Not patient-centered perspective

Impact of PVT on QoL



Impact of PVT on QoL



Impact of PVT on QoL

Lack of evidence addressing HrQoL in PVT patients

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

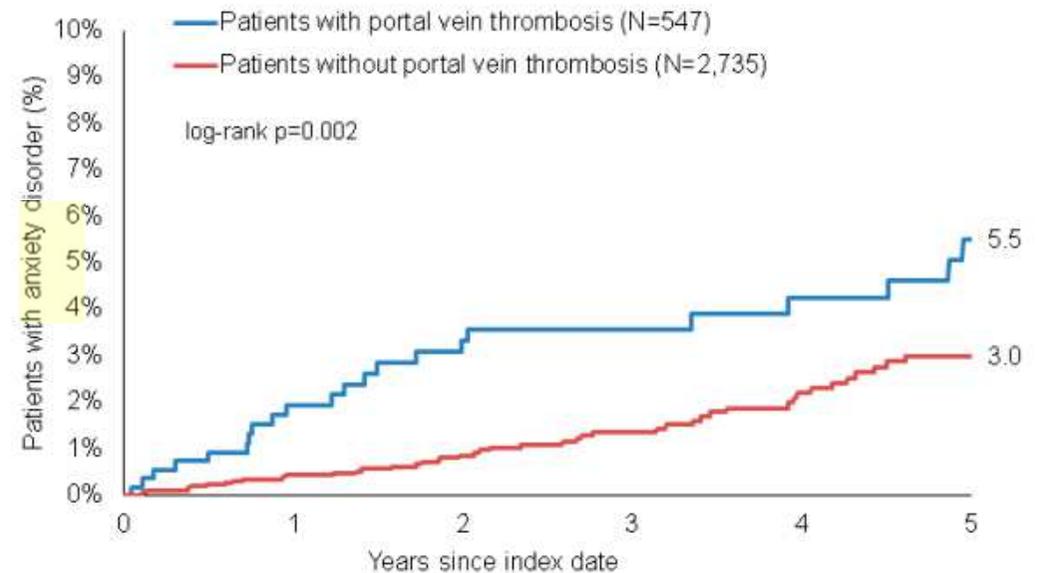
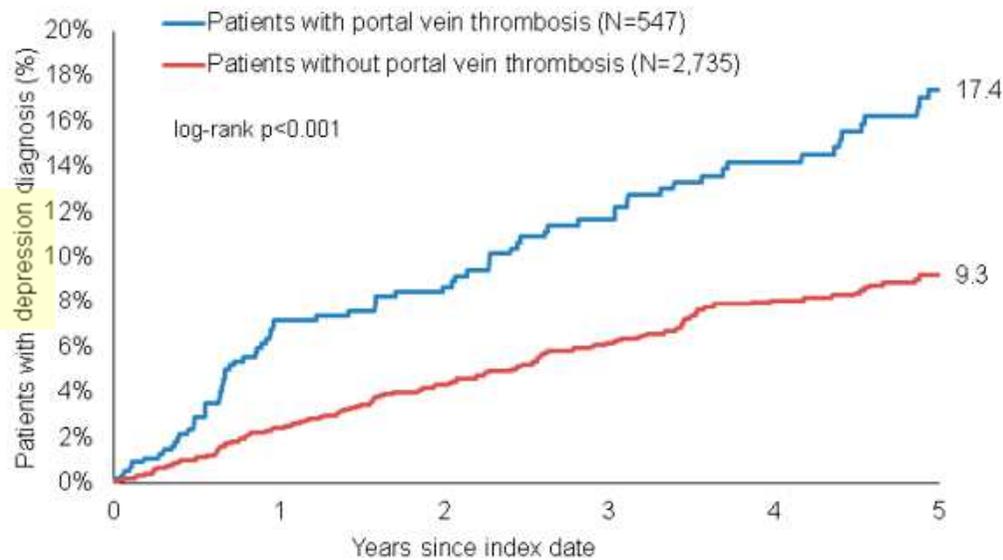
| Variable | Patients with Portal Vein Thrombosis (<i>n</i> = 547) | Patients without Portal Vein Thrombosis (<i>n</i> = 2735) | <i>p</i> Value |
|---|--|--|----------------|
| Women | 38.9 | 38.7 | 0.907 |
| Men | 61.1 | 61.3 | |
| Mean age in years (standard deviation) | 57.3 (16.1) | 57.5 (16.0) | 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

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

Yamanaka G et al. Biomed Pharmacother. 2005;59(Suppl 1):S31–S39

Jiang W, et al CNS Drugs. 2002;16(2):111–127.

Impact of ANTICOAGULATION on QoL

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

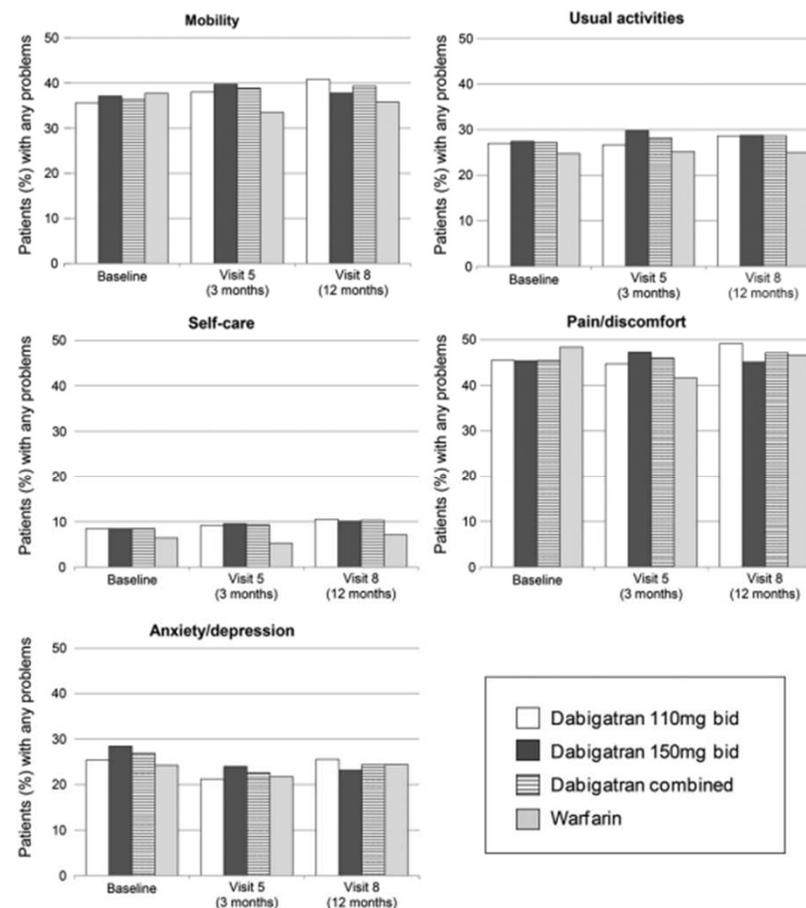


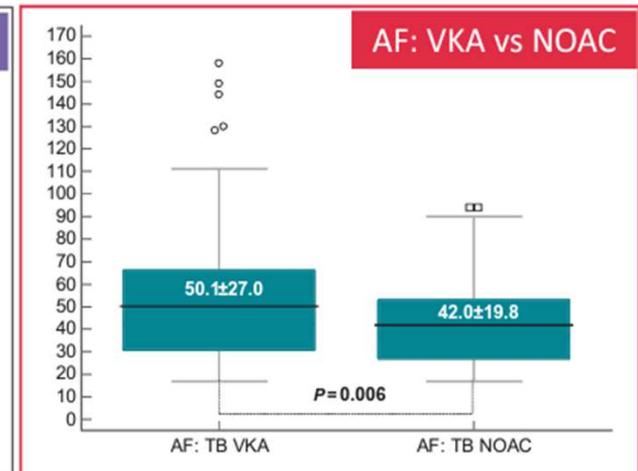
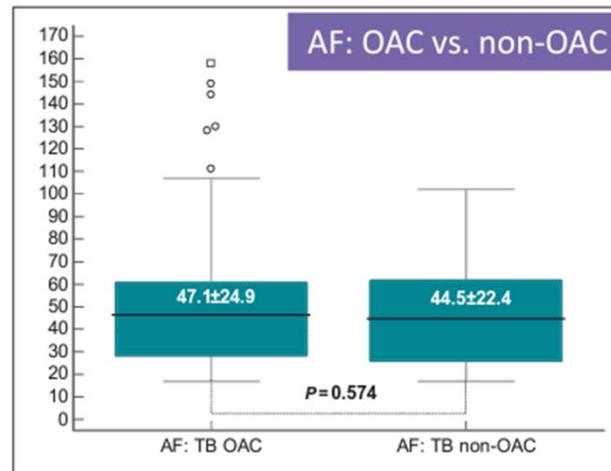
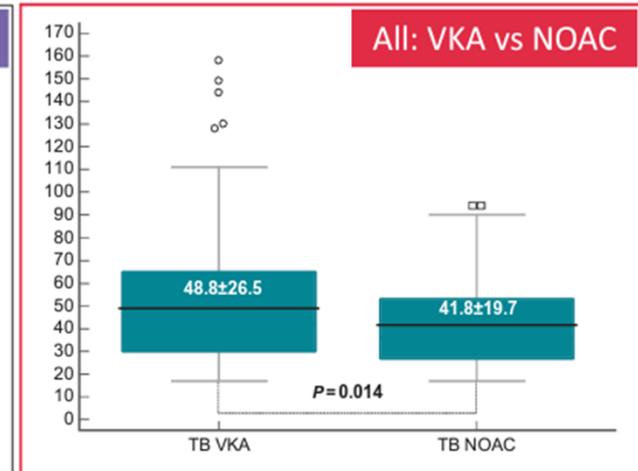
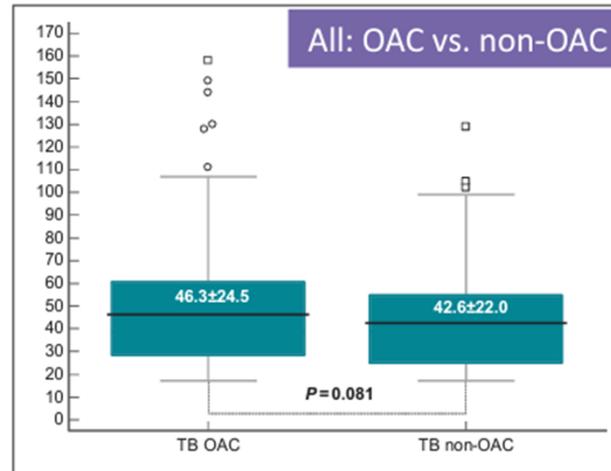
Fig. 1. Distribution of patients with any problem over time, by health dimension of EQ-5D.

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.

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





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
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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

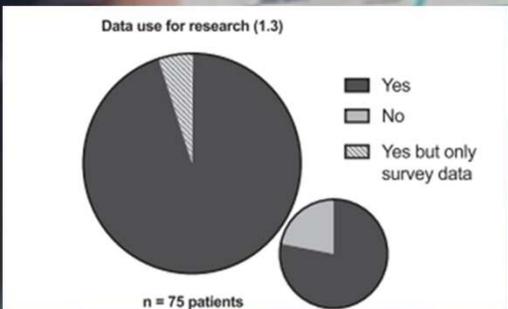
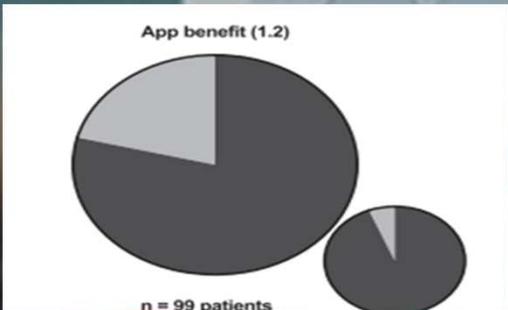
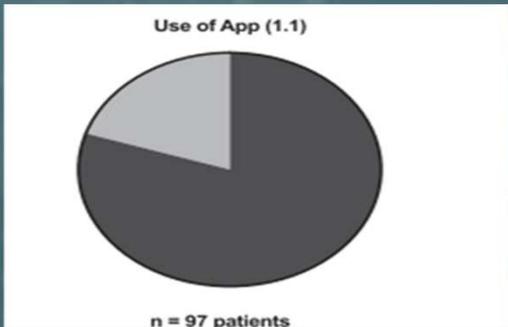


Table 3. Functional requirements of the app deduced from survey results.

| Functional Requirements | Rationale |
|--|--|
| Must have: | |
| <ul style="list-style-type: none"> • Possibility to fill-in surveys (e.g. PROM) | Initial motivation for app; Increase and improve available data of QoL of patients |
| <ul style="list-style-type: none"> • Receive information about disease, new developments and clinical trials based on the individual disease of the user • Give access to entered data | 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 |
| Nice to have: | |
| <ul style="list-style-type: none"> • Possibility to enter appointments, lab values and medication plan • Symptom trackers for recording of health concerns | 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 |
| <ul style="list-style-type: none"> • Reminders of medical appointments and to take medication | Of greater importance for experts than patients; supportive feature to increase medication adherence but users should be enabled to deactivate it if opposed |
| Future: | |
| <ul style="list-style-type: none"> • Notification of treating physician in case of concerns | Very much desired by patients, but IT infrastructure not yet given and not feasible with initial budget |
| <ul style="list-style-type: none"> • Generate treatment suggestions | 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 |
| <ul style="list-style-type: none"> • Automatic ordering of follow-up prescriptions | Very much desired by patients, but IT infrastructure not yet given and not feasible with initial budget |
| <ul style="list-style-type: none"> • Pediatric version of app | Very much desired by experts, but not feasible with initial budget |

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

Conclusions

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



Hepatological Diseases
(ERN RARE-LIVER)

