

Introductory course in questionnaire technique and clinimetrics

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Measuring with well-designed and appropriate tests are central



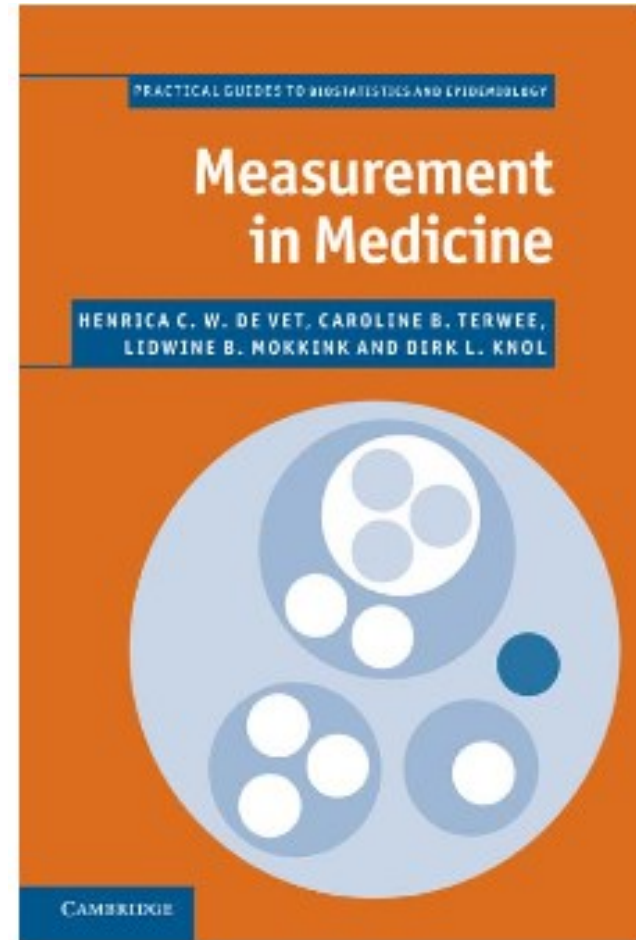
We need to know what we are measuring, if we are measuring correct, and a real difference?



Clinemetrics

A methodological discipline with a **focus on the quality of measurements** in medical research and clinical practice.

The quality of measurements includes both the **quality of the measurement** instruments and the **quality of the performance of the actual measurements**



The COSMIN taxonomy

Validity:

The degree to which an instrument truly measures the construct(s) it purports to measure

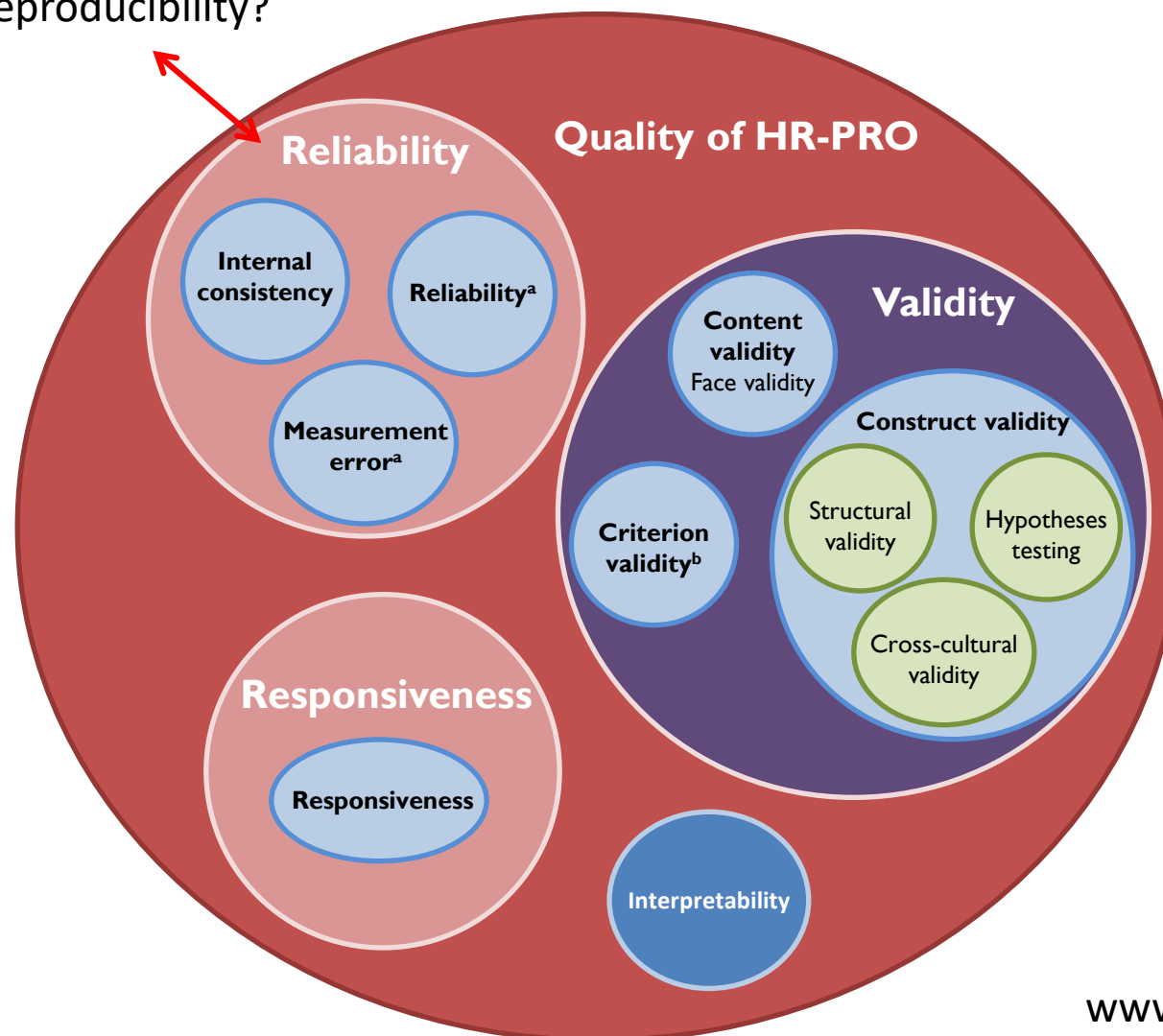
Reliability:

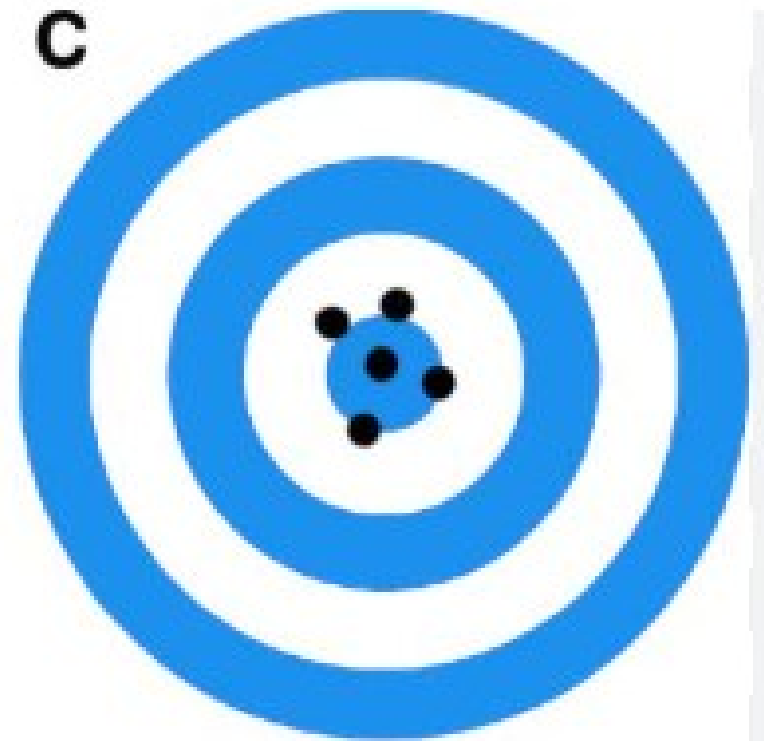
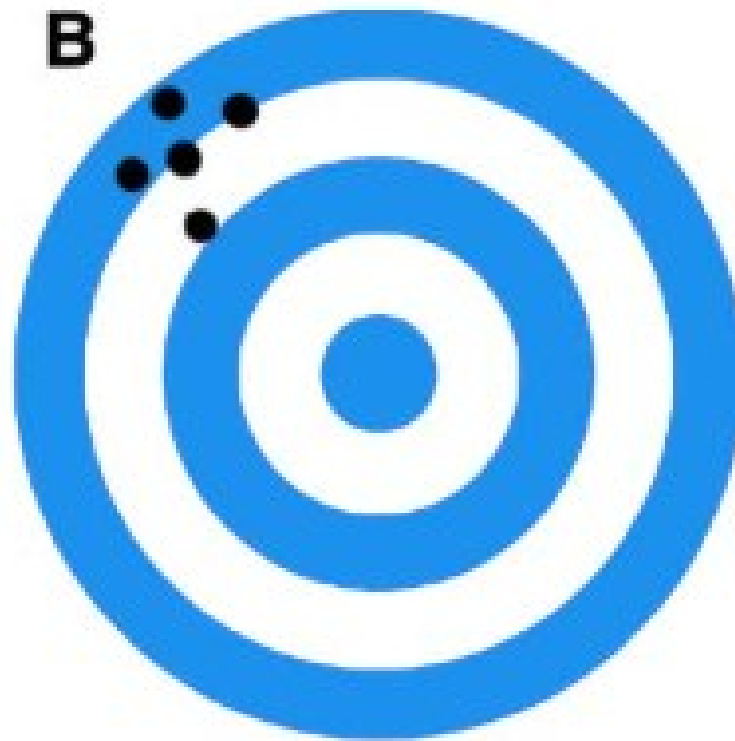
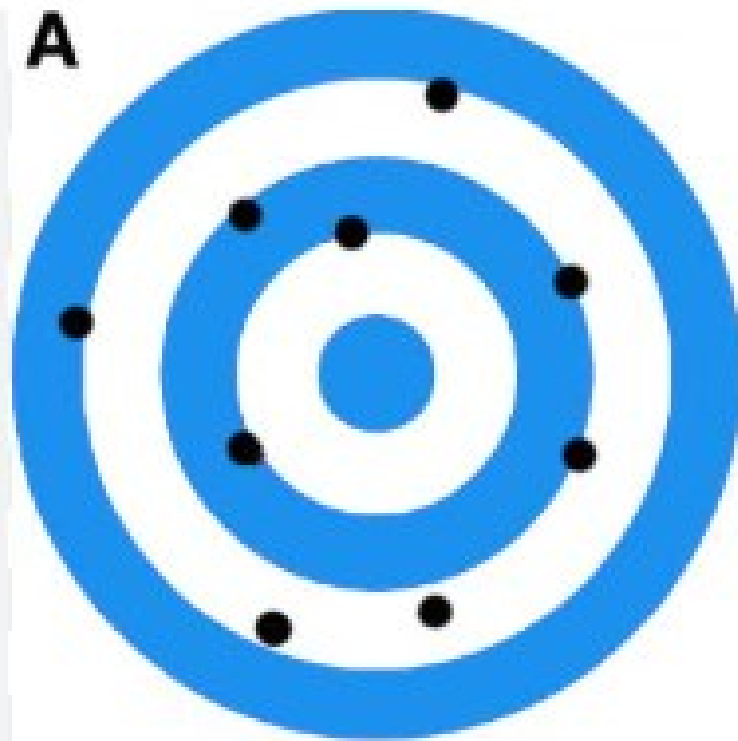
The extent to which scores for patients who have not changed are the same for repeated measurement under several conditions: e.g. test-retest; inter-rater; intra-rater

Responsiveness:

The validity of change scores

Reproducibility?





Why this course?

There exists a well-defined research methodology that, if used properly, ensures high scientific quality!



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**Reporting guideline
provided for?**
(i.e. exactly what the
authors state in the paper)

Patient-reported outcomes in randomized trials

**Full bibliographic
reference**

Calvert M, Blazeby J, Altman DG, Revicki D
PRO Group. Reporting of patient-reported o

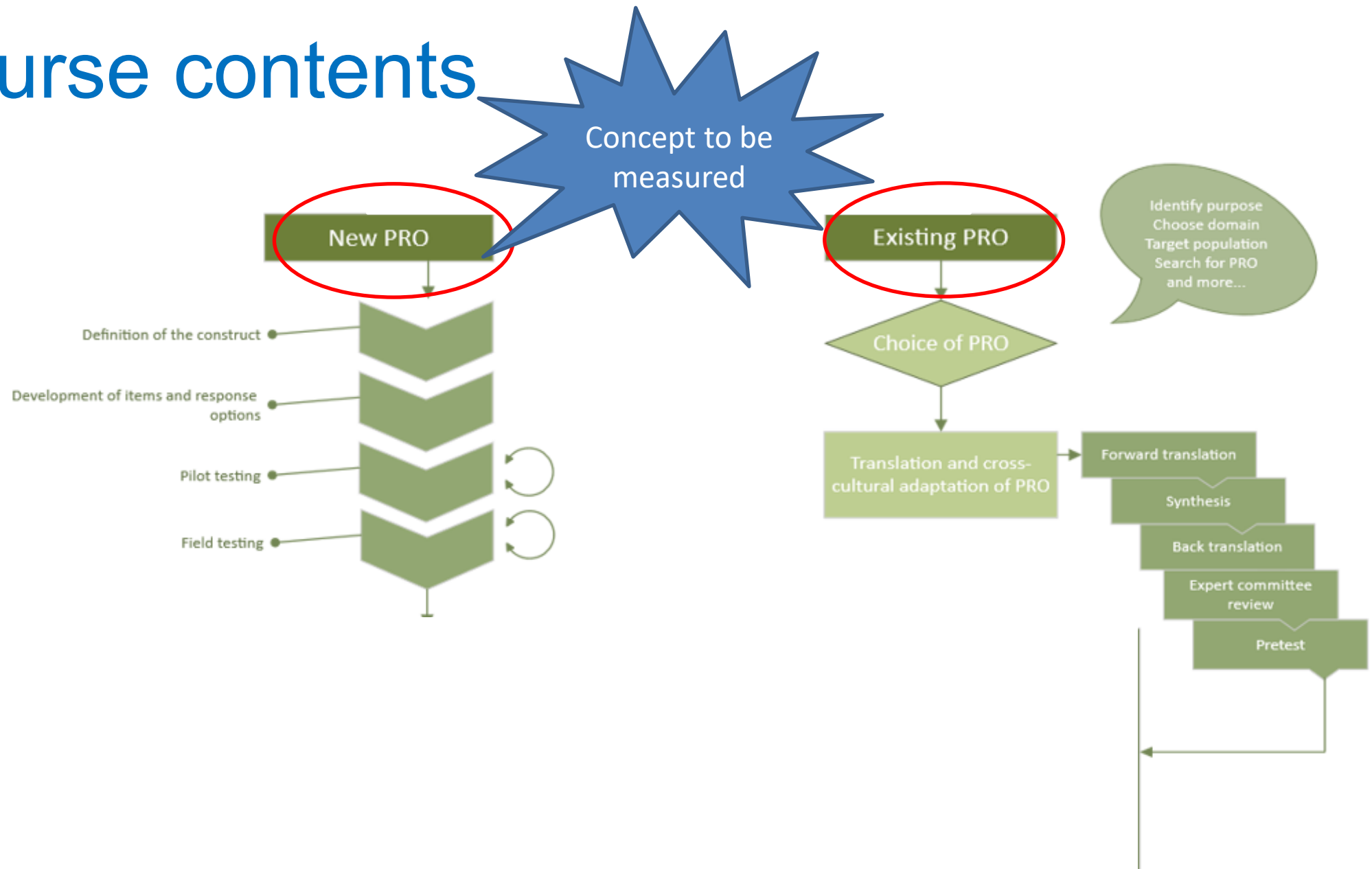
which PROs are primary or important secondary end points. These recommendations urge that the PROs be identified as a primary or secondary outcome in the abstract, that a description of the hypothesis of the PROs and relevant domains be provided (ie, if a multidimensional PRO tool has been used), that evidence of the PRO instrument's validity and reliability be provided or cited, that the statistical approaches for dealing with missing data be explicitly stated, and that PRO-specific limitations of study findings and generalizability of results to other populations and clinical practice be discussed. Examples and an updated

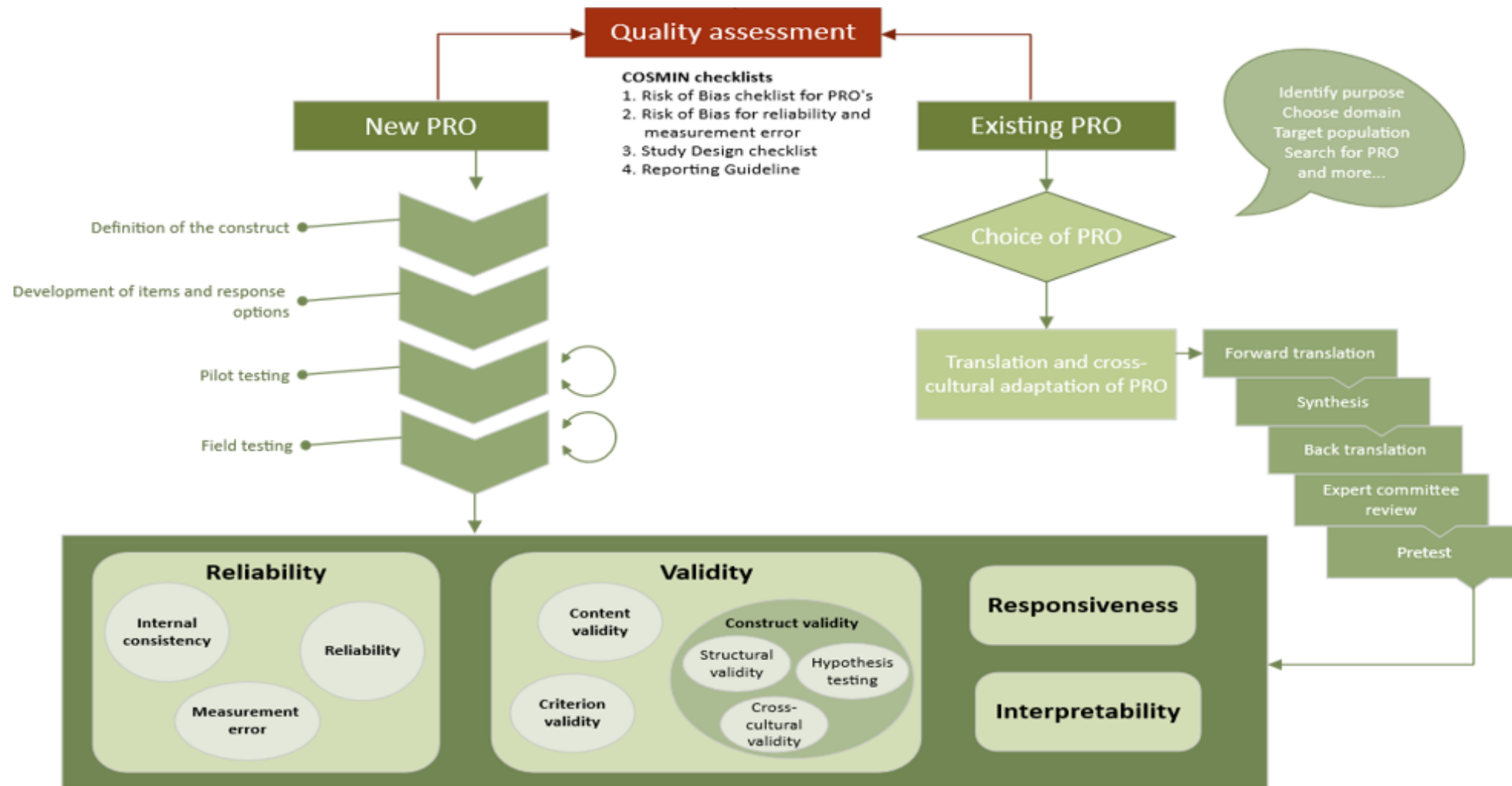
Course contents

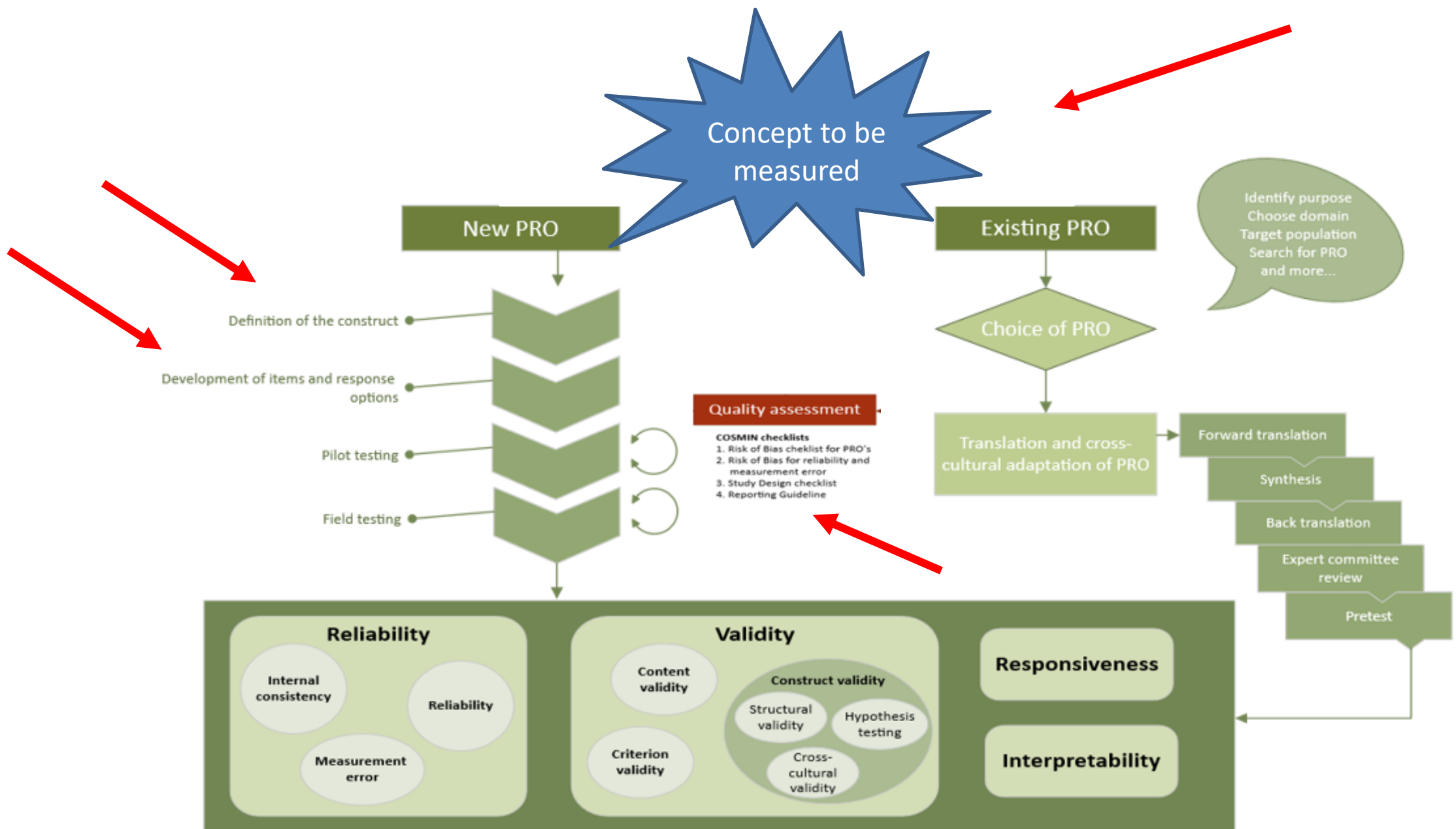
Basic knowledge of questionnaire technique

- Understanding the terminology
- Understanding the basic concepts
- Selecting the best questionnaire
- Translation and cross-cultural adaptation of a questionnaire
- Developing a new questionnaire
- Introduction to validity and reliability

Course contents







Practical information

Time	Contents	Pages	Teacher
9.00– 10.00	Introduction to questionnaires - conceptualisation	7-13, 33-35	AØH
10.00 – 11.00	Exercise: Conceptualisation		AØH
11.00 – 12.30	Concepts in questionnaire technique • Observed vs. latent variables • Conceptual frameworks • Reflective and formative models • Scales vs. indexes COSMIN taxonomy and requirements to questionnaire validation	13-17, 35-37 Vodcast Articles on www*	AØH
12.30 – 13.00	<i>Lunch</i>		
13.00 – 13.45	How to measure the construct – operationalisation • Preparing items and answer categories	35-37 41-50	AØH
13.45 – 14.30	Exercise: Preparing items and answer categories		AØH
14.30 – 15.00	Structure and design of a questionnaire study Q & A about own study		AØH

* www = see www.clinimetrics.sdu.dk

Coffee breaks and lunch - Whenever we want 😊

ASK STUPID QUESTIONS.
IF YOU DON'T ASK, YOU REMAIN STUPID.
Alvan Feinstein



Practical information

Who are you?

- Name, profession and background
- Experience with the use of questionnaires
- Are you using questionnaires in your research



The use of questionnaires

- Measuring with questionnaires is central to clinical practice and health research
- Increased need for measuring patient reported outcomes (PRO's)
 - Create new knowledge
 - Monitor disease course
 - Evaluate treatment effects (does the "intervention" work for the patient)
- Many questionnaires for a single disease
- Can we trust conclusions drawn from questionnaires?



Why use questionnaires?

- The best way to answer the research question
- Particularly effective for measuring
 - Subject behavior
 - Preferences
 - Intentions
 - Attitudes
 - Opinions
- Fast, efficient and inexpensive means of gathering large amounts of information from a sizeable sample
- Their use of open and closed questions enable reserachers to obtain both quantitative and qualitative data

Pros and cons...

PROS

- Practical
- Cost-effective
- Simple to administer
- Speed
- Comparability
- Scalability
- Standardisation
- Respondent comfort
- "Automated" scoring
- Anonymity

CONS

- Dishonest answers
- Unanswered questions
- Reluctance towards sensitive questions
- May appear impersonal
- Difficult to interpret
- Analysis challenges (open-ended questions)
- May be unreliable

Patient reported outcomes (PROs)

“any report of the status of a patients health condition that comes directly from the patient without interpretation of the patient’s response by a clinician or anyone else”

- US Food & Drug Administration

What is a good questionnaire?



A good questionnaire

- Standardized measurement instrument
- Measures a certain phenomenon – as it is experienced
- Developed for our specific purpose and population – or (re)validated
- It is comprehensible to the target population and easy to complete
- We can interpret our results and say something about the concept we are measuring
- It is valid and reliable (responsive) for the target population

Conceptualization - what do we want to measure



Conceptualization

Conceptualization before operationalization

- Have an open end enquiring approach to the ideas
- At first, try not to think about
 - Solutions
 - Methods/procedure/approach
 - Practical circumstances

Conceptualization

The variables we want to measure

- (often) doesn't exist
- rarely have an unambiguous meaning

What we end up measuring depends on our definition

What counts as stress to you as a Ph.D student?



Conceptualization



Definition:

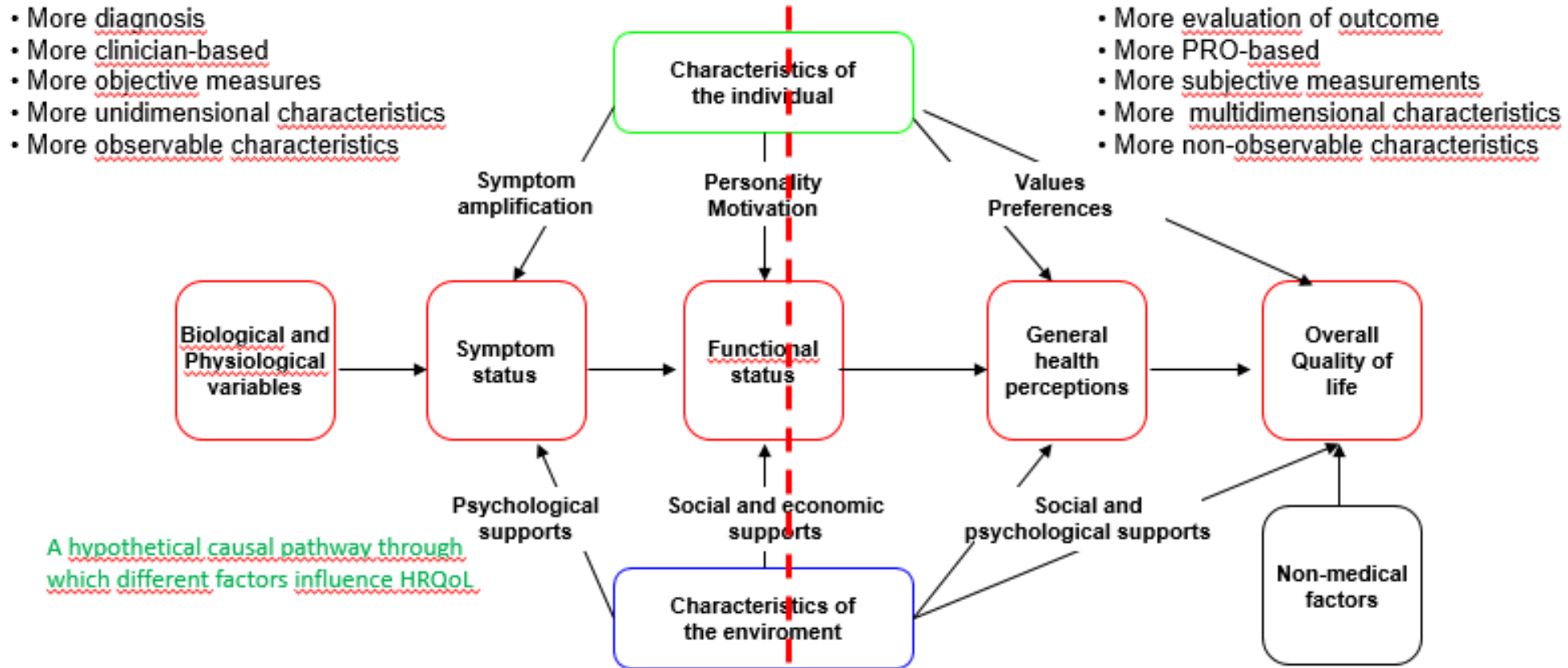
The process of coming to agreement about what terms mean

Or the refinement and specification of abstract ideas

Conceptual models

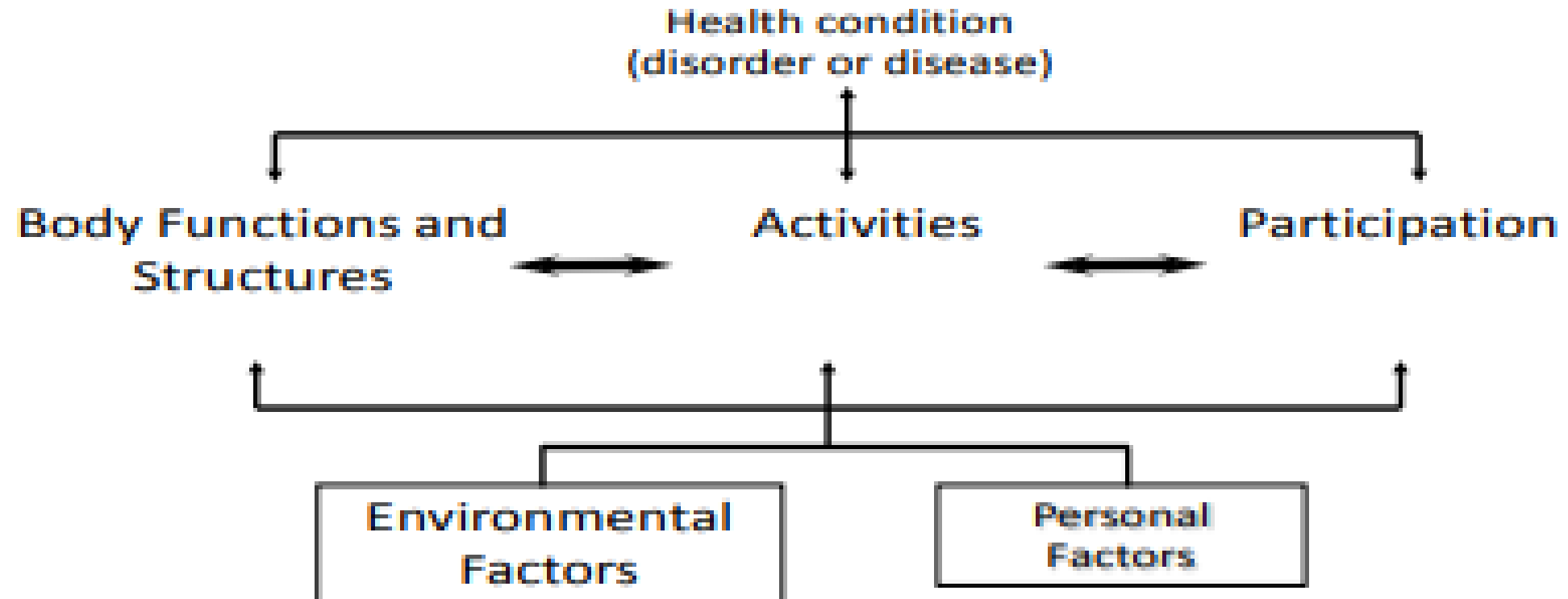
"Theoretical model of how different constructs within a concept are related"

Conceptual model – Health related quality of life (HRQL)



Wilson, I.B. & Cleary, P.D. (1995). Linking clinical variables with health related quality of life *Journal of the American Medical Association*, 275, 59-65

International classification of functioning, disability and health (ICF)



Definition of the construct to be measured

Concept: “*Global definition and demarcation of the subject of measurement*”

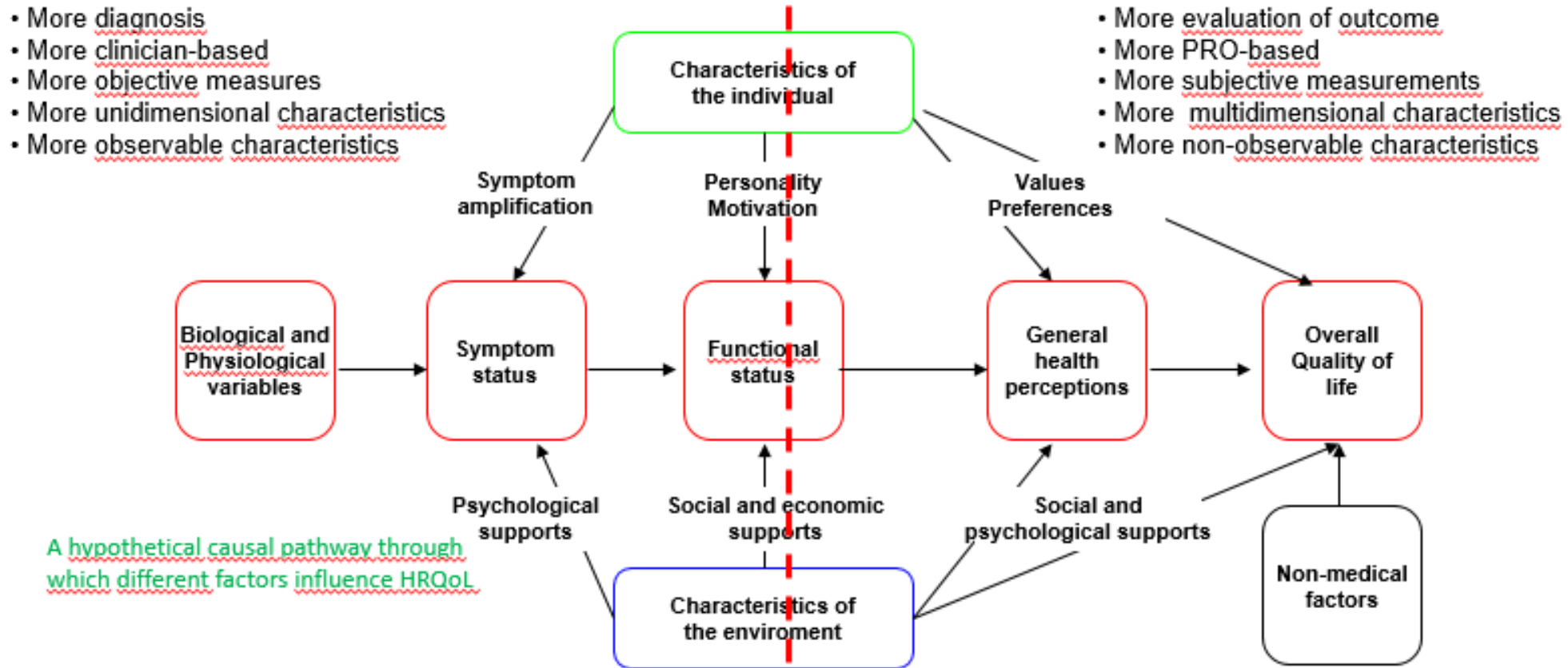
- A concept is robust and detailed
- A concept is often multi-dimensional

Construct: “A well defined and precisely demarcated subject of measurement”

Find out what do we want to measure (all of it or parts of it)?

- E.g. symptoms, functioning or quality of life

Conceptual model – Health related quality of life (HRQL)



Wilson, I.B. & Cleary, P.D. (1995). Linking clinical variables with health related quality of life *Journal of the American Medical Association*, 275, 59-65



Litterature

- What have other researchers found?
- How does other researchers work with the concept?
- Are there any existing theories or theoretical models concerning the concept?
- Any definitions?

Individual interview/ focus groups, expert panels, etc.

- Does the understanding of the concept differ among different groups (e.g. Researchers vs. patients, men vs. women etc.)?
- What does patients/professional say?

Example

Conceptualization, operationalization, and content validity of the EQOL-questionnaire measuring quality of life and participation for persons with disabilities



Louise Norman Jespersen*, Susan Ishøy Michelsen, Bjørn Evald Holstein, Tine Tjørnhøj-Thomsen and Pernille Due

Abstract

Background: Measurement of quality of life demands thoroughly developed and validated instruments. The development steps from theory to concepts and from empirical data to items are sparsely described in the literature of questionnaire development. Furthermore, there seems to be a need for an instrument measuring quality of life and participation in a population with diverse disabilities. The aim of this paper was to present and discuss the initial steps in the development of the Electronic Quality of Life questionnaire (EQOL).

AIMS:

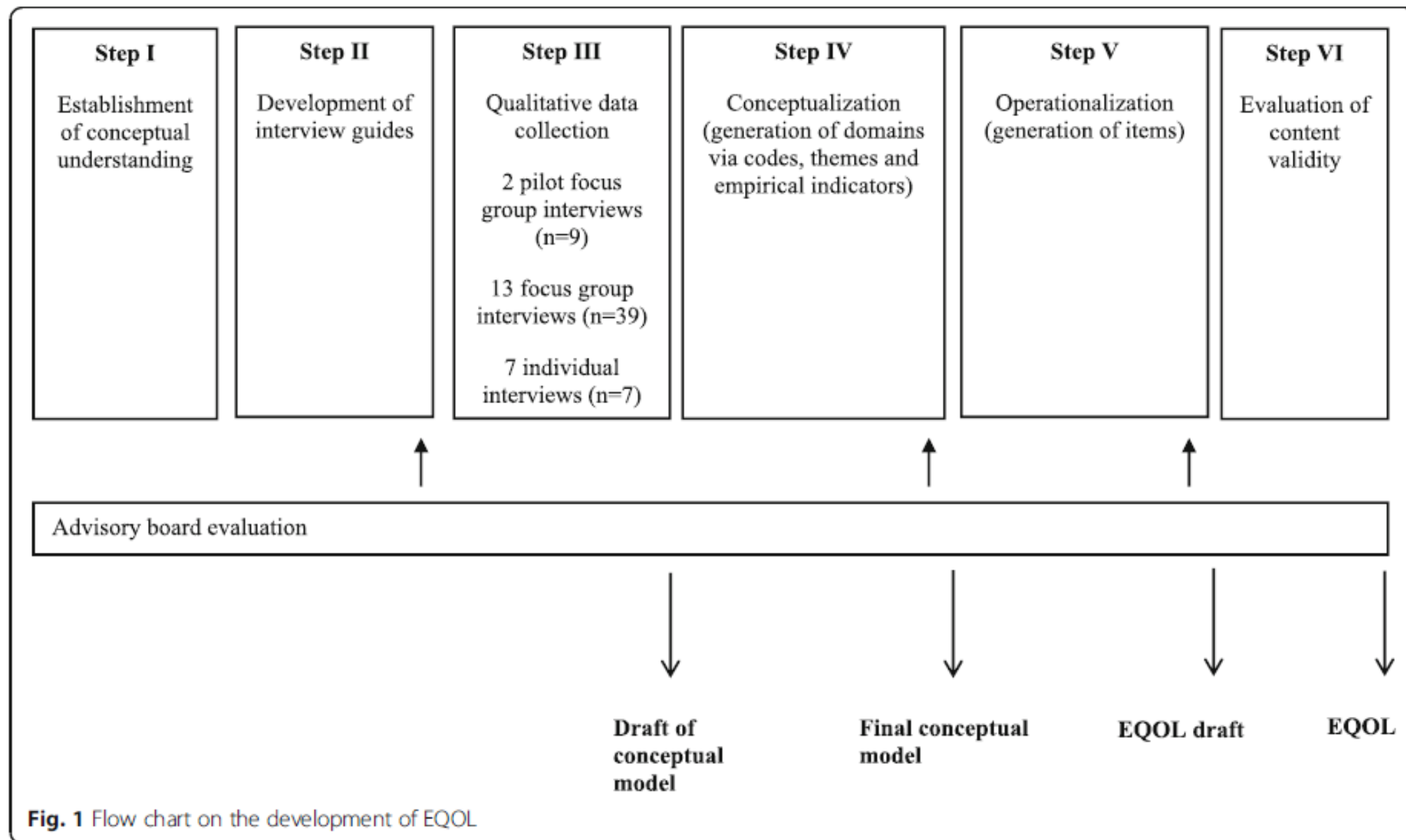
“To present and discuss the initial development of the Electronic Quality of Life (EQOL) questionnaire attempting to measure quality of life and participation across people with diverse disabilities”.

“Conceptualization of information derived from the qualitative interviews and operationalization of the ensuing domains into items”

“Another objective was to explore the content validity of the EQOL-measure”.

“The intention was to allow for comparison between people with and without disabilities on the aspects of quality of life that were found to be relevant to people with disabilities”.





Results: We identified six domains (*function and health, environment (physical and social), social network, wellbeing, occupation, and managing strategies*) based on themes derived from the qualitative interviews and on conceptual discussions within the author group. These domains were incorporated in a conceptual model and items were generated to measure the content of each domain. Participants expressed satisfaction with EQOL but most participants felt that there were too many items.

Conceptual model

The six domains: *function and health, environment (physical and social), social network, wellbeing, occupation, and managing strategies* were incorporated in a conceptual model (Fig. 5) covering the domains and empirical indicators which participants across age and diagnoses perceived as important to their quality of life and participation. The vertical dimension illustrates quality of life and the horizontal dimension illustrates participation. The intersection between the two dimensions indicates a conceptual overlap between the content of the domains. Domains that are placed partly outside the dimensions illustrate that the domain also includes more objective aspects of the concepts (for example whether or not you take medications). The box to the top right shows the included background information.

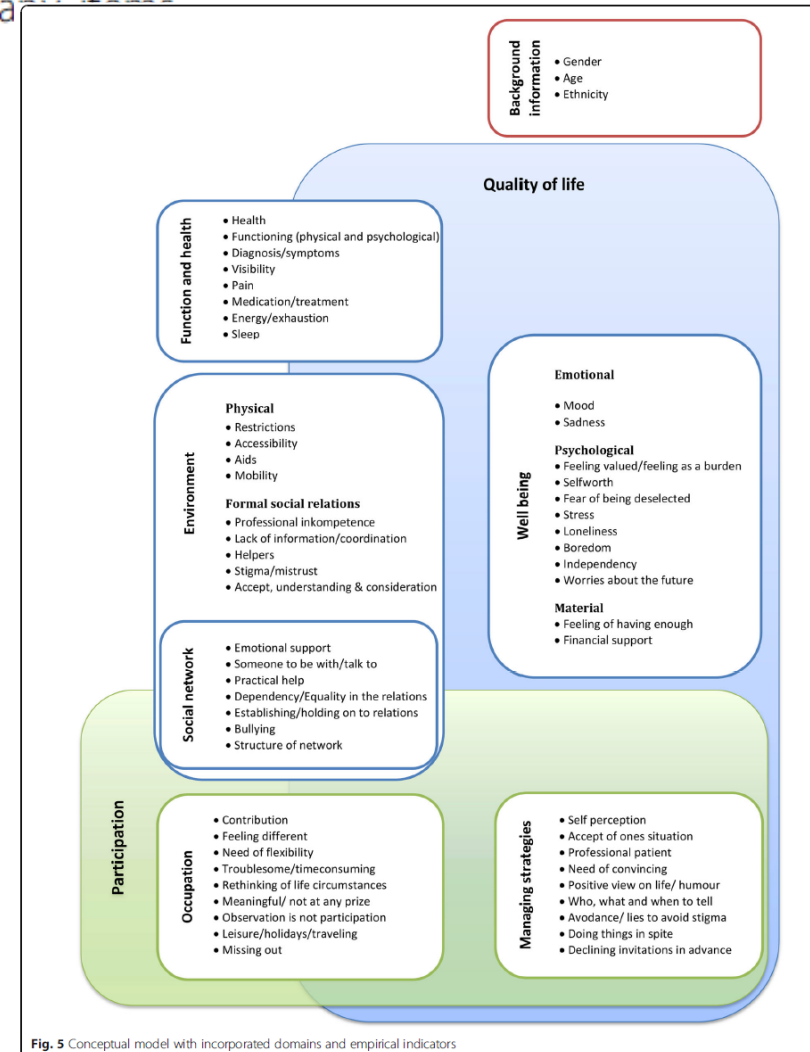
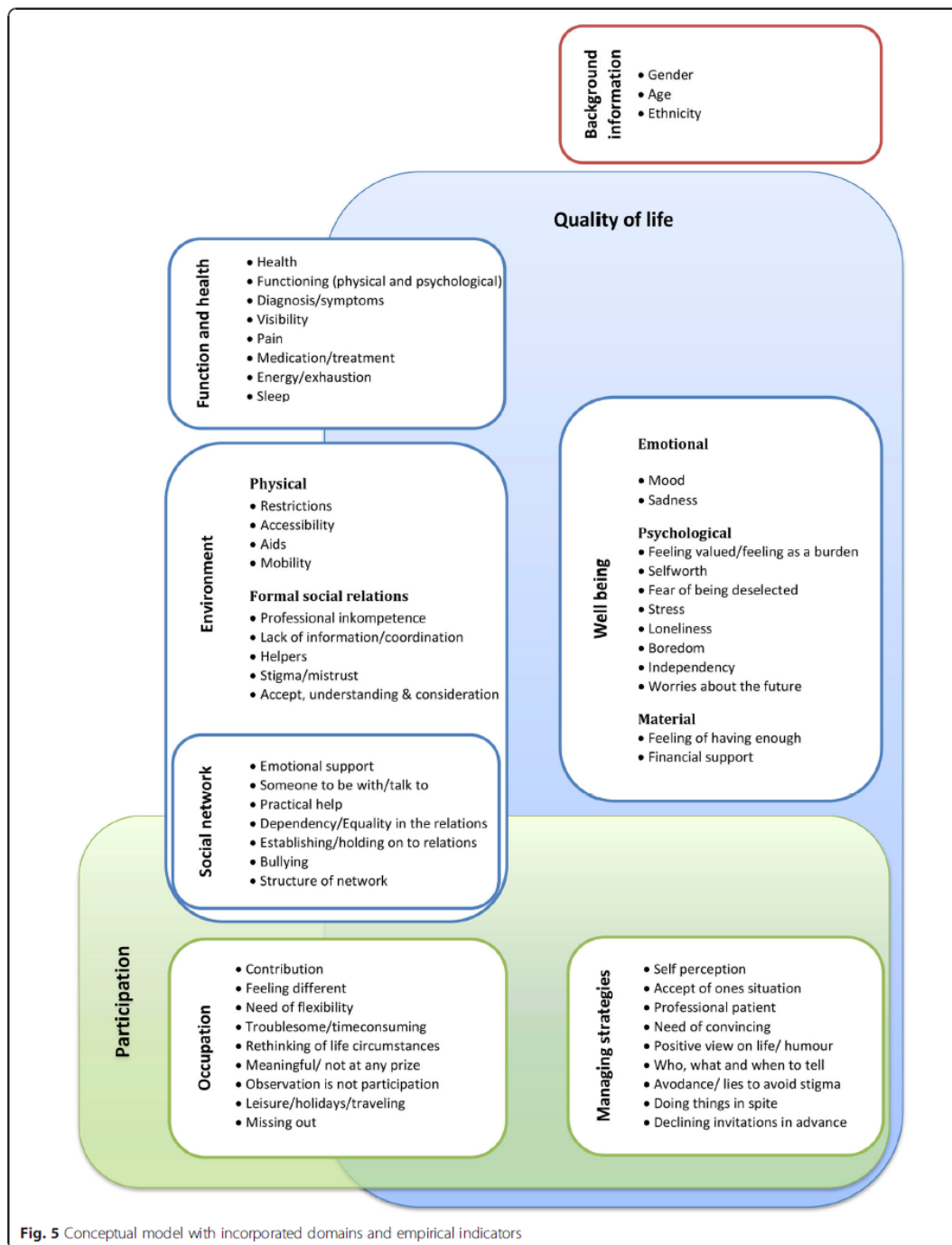
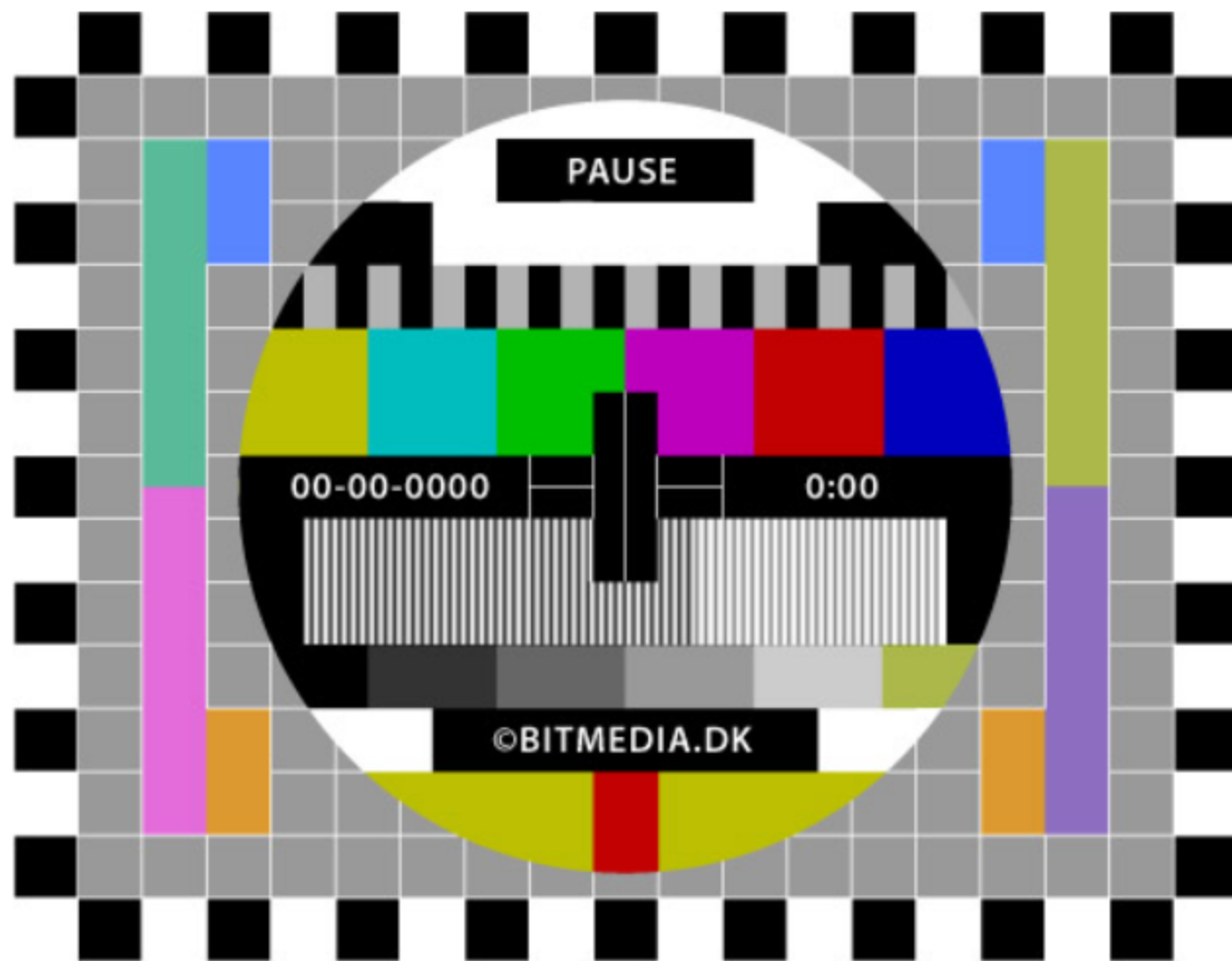


Fig. 5 Conceptual model with incorporated domains and empirical indicators

QoL and participation

Jespersen et al. Health and Quality of Life Outcomes
(2018) 16:199; [https://doi.org/10.1186/s12955-018-1024-](https://doi.org/10.1186/s12955-018-1024-6)





Exercise conceptualisation

Perceived Stress Scale

A more precise measure of personal stress can be determined by using a variety of instruments that have been designed to help measure individual stress levels. The first of these is called the **Perceived Stress Scale**.

The Perceived Stress Scale (PSS) is a classic stress assessment instrument. The tool, while originally developed in 1983, remains a popular choice for helping us understand how different situations affect our feelings and our perceived stress. The questions in this scale ask about your feelings and thoughts during the last month. In each case, you will be asked to indicate how often you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer fairly quickly. That is, don't try to count up the number of times you felt a particular way; rather indicate the alternative that seems like a reasonable estimate.

For each question choose from the following alternatives:
0 - never 1 - almost never 2 - sometimes 3 - fairly often 4 - very often

1. In the last month, how often have you been upset because of something that happened unexpectedly?

2. In the last month, how often have you felt that you were unable to control the important things in your life?

3. In the last month, how often have you felt nervous and stressed?

4. In the last month, how often have you felt confident about your ability to handle your personal problems?

5. In the last month, how often have you felt that things were going your way?

6. In the last month, how often have you found that you could not cope with all the things that you had to do?

7. In the last month, how often have you been able to control irritations in your life?

8. In the last month, how often have you felt that you were on top of things?

9. In the last month, how often have you been angered because of things that happened that were outside of your control?

10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

The **PSS-10** is a short questionnaire consisting of 10 items that measures perceived stress over the past four weeks.

The questions are designed to capture how unpredictable, uncontrollable, and overwhelming participants perceive their lives to be

A. Identify the Constructs and Subdimensions in PSS-10

B. Map Dimensions vs. Questions

C. Discuss how the items operationalize the overall theoretical construct

D. Identify Potential Gaps – are there aspects of stress that are not directly measured?