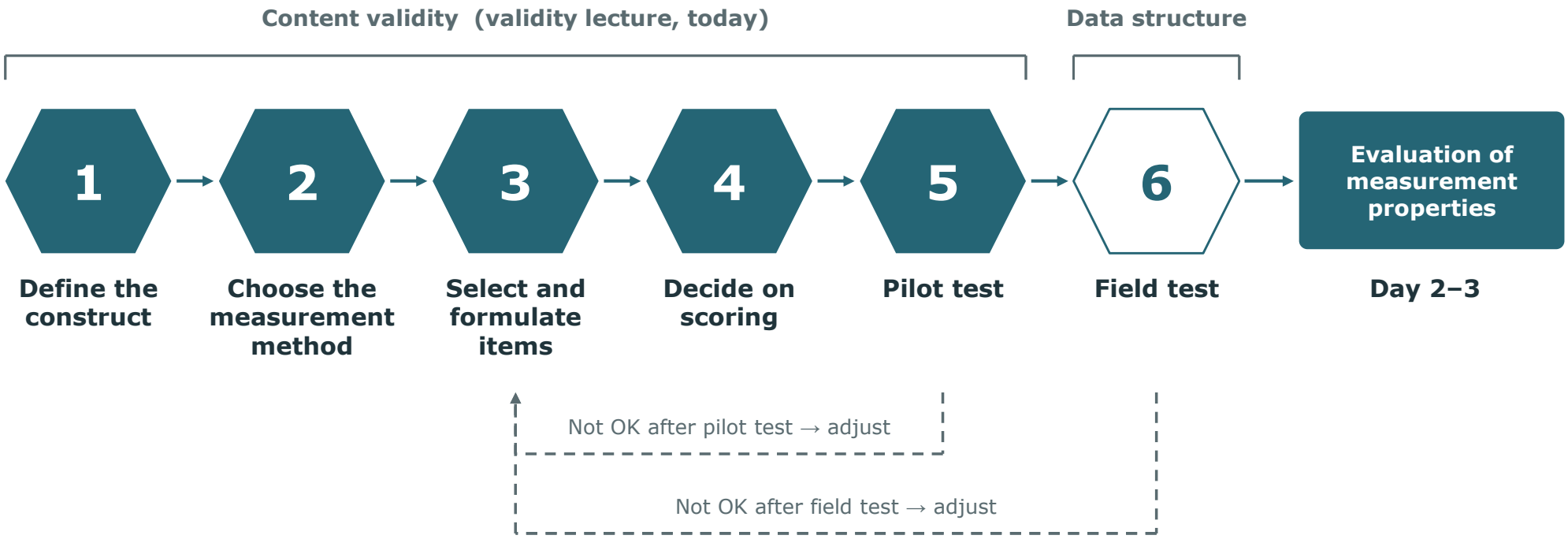
Development of a new questionnaire

The six steps
Advanced course in questionnaire technique and clinimetrics
Eva Ørnbøl

Six steps from idea to instrument



Step 1 · Define and elaborate the construct

1

Everything later depends on this step – be explicit before writing a single item

What?

The construct

- Theory or conceptual model
- Domains and sub-domains
- What is deliberately NOT included

Who?

Target population

- Diagnosis, severity, age
- Setting and language
- Who will complete it

Why?

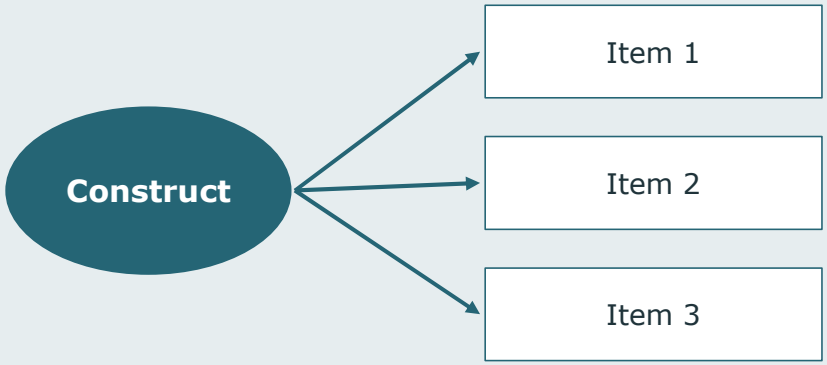
Purpose of measurement

- Discriminative: between persons
- Evaluative: change over time
- Predictive: future outcome

Purpose matters statistically: an evaluative instrument needs items that are responsive to change; a discriminative one needs items that spread persons out.

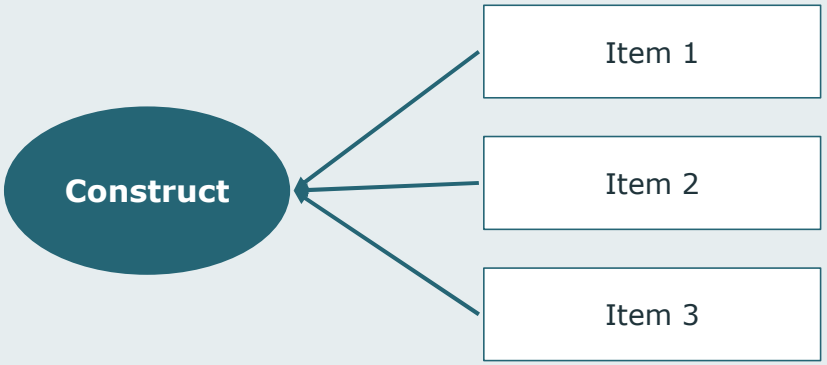
Step 1 · Reflective or formative model?

Reflective – items reflect the construct



e.g. fatigue (feeling tired, exhausted, lacking energy): items should correlate; interchangeable

Formative – items form the construct



e.g. stress from life events (cancer, death of partner, job loss): items need not correlate; each is essential

Consequence: the field test differs by model (Day 2). Formative: item importance (impact score). Reflective: item distributions, dimensionality (EFA), internal consistency (α), targeting (IRT).

Steps 2 and 3 · Method and items

2 Choose the measurement method

- Patient-reported, clinician-rated or performance-based
- Mode: paper, web, interview – mode affects responses
- Search systematically for existing instruments first: adapt rather than build if possible

3 Select and formulate items

- Sources: literature, existing instruments, experts – and above all the target population (interviews, focus groups)
- One idea per item, plain language, no double negatives
- Specify the recall period
- Generate more items than needed – reduction comes later

Step 4 · Scoring – items and scales

4

Decide how responses become numbers – and how numbers become a score

Item scores

- Response format: dichotomous, Likert, NRS, VAS
- Number and labelling of categories
- Same direction for all items, or reverse scoring
- Avoid a neutral middle category only if justified

Scale and index scores

- Reflective: (unweighted) sum or mean per unidimensional (sub)scale
- Formative: index, possibly weighted by importance
- Total score vs. subscale scores
- Rule for missing items

Steps 5 and 6 · Pilot test versus field test

5 Pilot test

Sample	Small, from the target population
Method	Cognitive interviews, think-aloud
Asks	Is it understood, relevant, complete? Time and burden?
Nature	Qualitative

6 Field test

Sample	N ≥ 100; factor analysis 4–10 per item (min. 100); IRT > 500
Method	Administer the full draft
Asks	Formative: item importance. Reflective: distributions, missing, floor/ceiling, EFA, α, targeting
Nature	Quantitative – item reduction

Field testing: what is covered where

Field-test element	Typical tool	Where
Item importance (formative models)	Impact score	**Day 2**
Item scores, distributions, missing	Skewness, kurtosis, % missing	**Day 2**
Dimensionality	Exploratory factor analysis	**Day 1**
Internal consistency	Cronbach's α, item-rest correlations	**Day 2**
Floor and ceiling effects	% at minimum / maximum score	**Day 2**
Item difficulty and targeting	IRT, Rasch	**Day 3**

Take-home

Define construct, population and purpose before writing items

Decide early: reflective or formative – it determines the statistics

Involve the target population in item generation and pilot testing

Pilot and field test both loop back – field testing (Day 2) prepares for the measurement properties