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Are we seeing the whole picture?  
Capturing the impact of treatments and  
interventions on HRQoL in clinical  
settings.

Rosie Duncan

Elizabeth Lumley

Simon Palfreyman

Patrick Phillips



**Sheffield  
Hallam  
University**

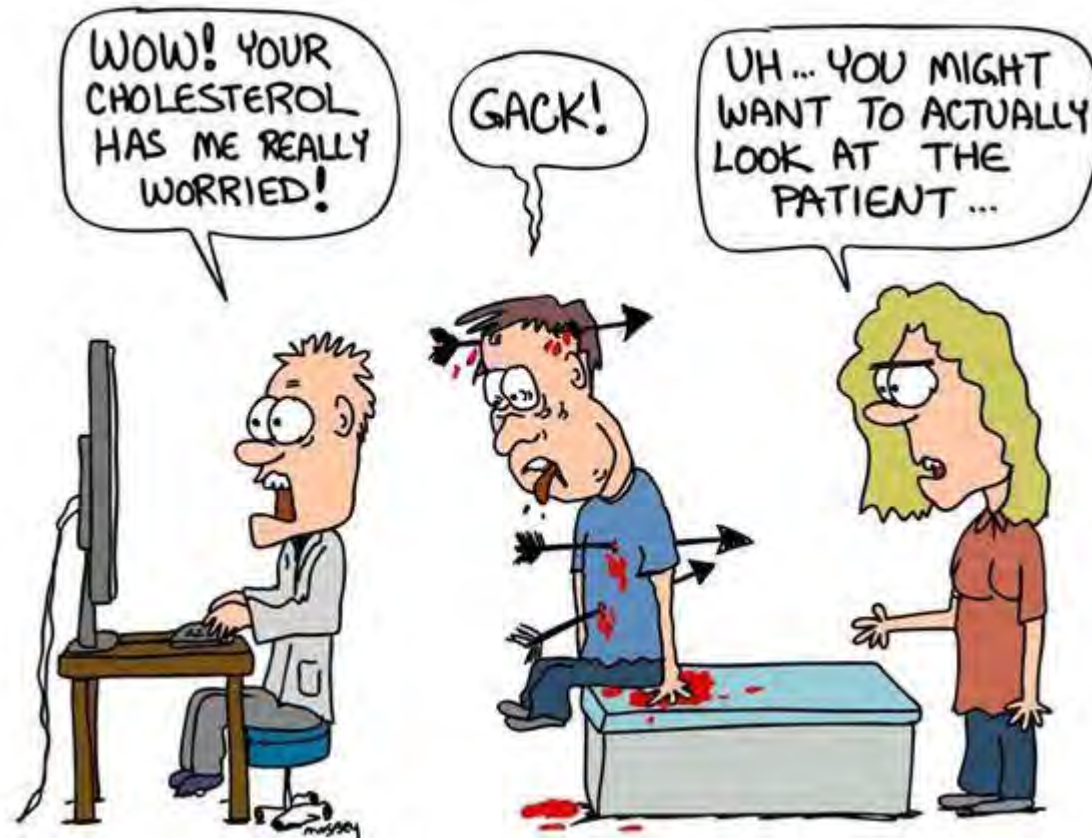
# Thank You to Our Co-authors and Funders



- Angela Tod
- Helen Buckley Woods
- Ahmed Aber
- Georgina Jones
- Stephen Radley
- Jonathan Michaels

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# Seeing the whole picture!



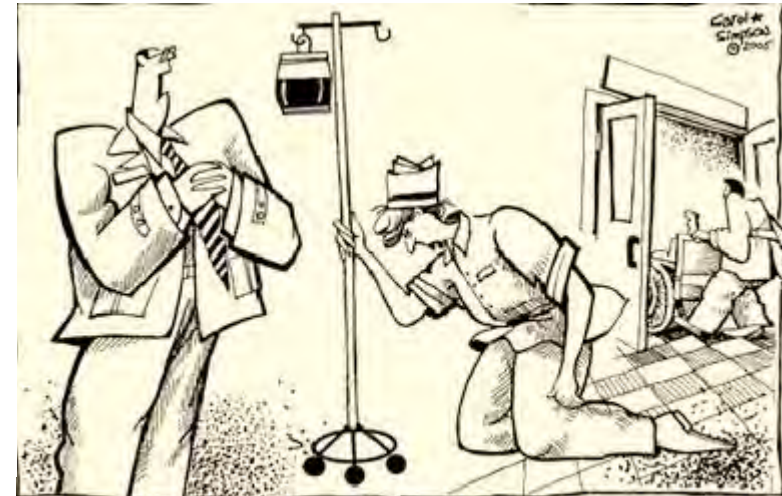
# Linking Patients and Outcomes



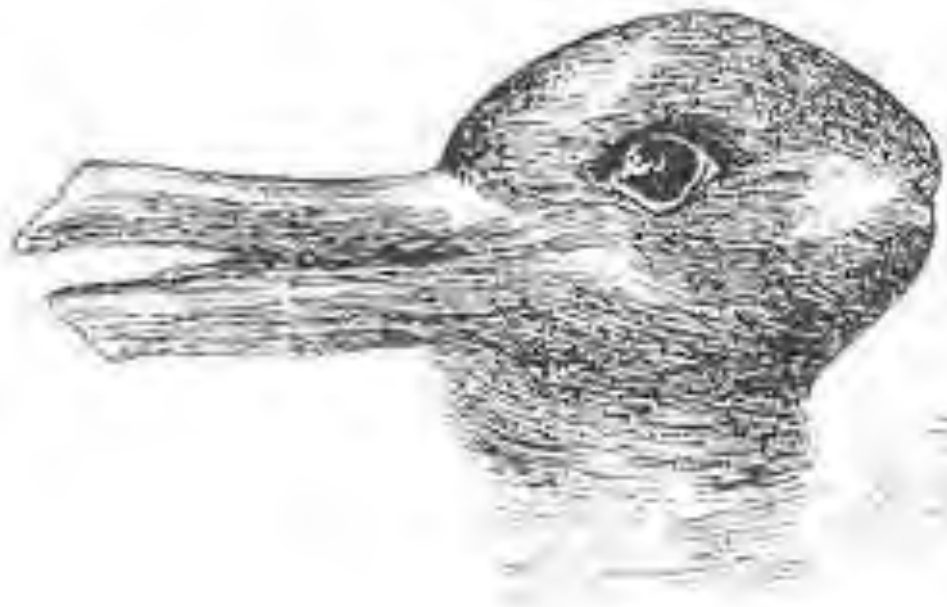
# Measuring the Impact



"THE NEW PRODUCTIVITY GOALS ARE HERE."



"You're in a hospital, Nurse Hill. If you collapse from exhaustion, the emergency room is just down the hall."



**THE  
WHOLE  
PICTURE**



- Capturing Health Related Quality of Life in Clinical Care.
  - Simon (Me)
- Using Qualitative Data Techniques to Capture Health Related Quality of Life.
  - Lizzie
- Capturing Health Related Quality of Life in Marginalised Groups.
  - Rosie
- Development of an Electronic Personal Assessment Questionnaire: The ePAQ-VAS.
  - Pat

# The Challenges of Capturing Health Related Quality of Life in Clinical Care.

Simon Palfreyman  
Assistant Professor.  
University of Alberta



# Outline

- Patient Reported Outcomes
  - What are they?
  - What do they measure?
  - What to include?
  - Whose PROM?
  - Which PROM?
- Reality vs Practice

# What are PROMS?

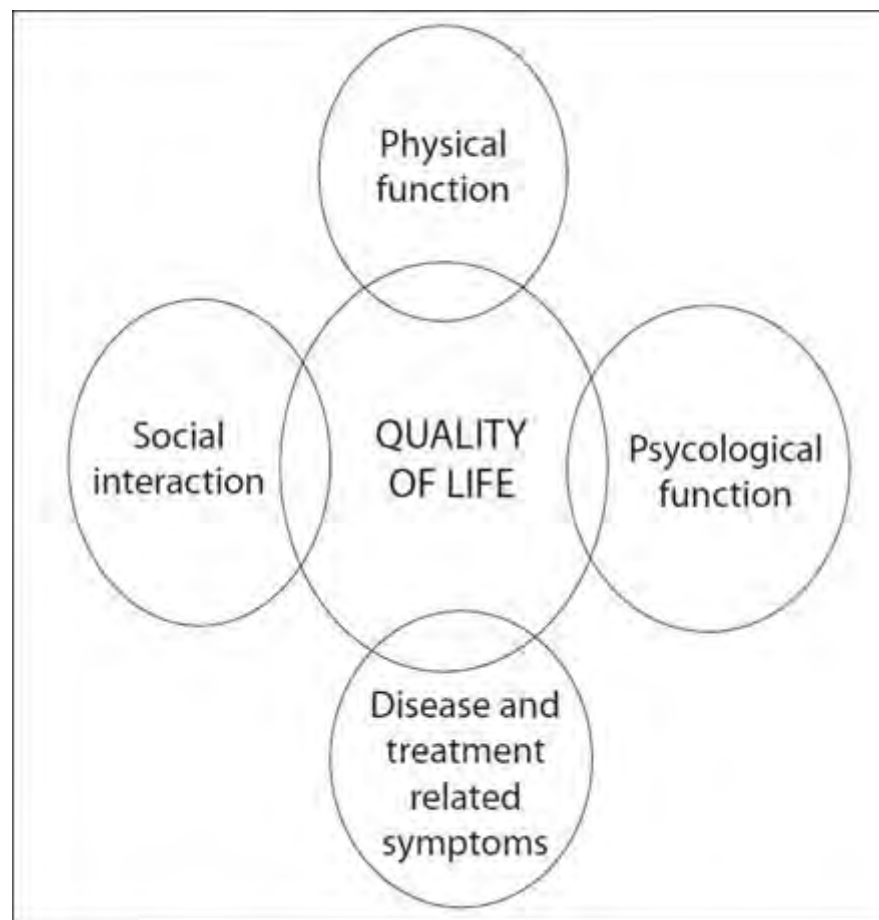
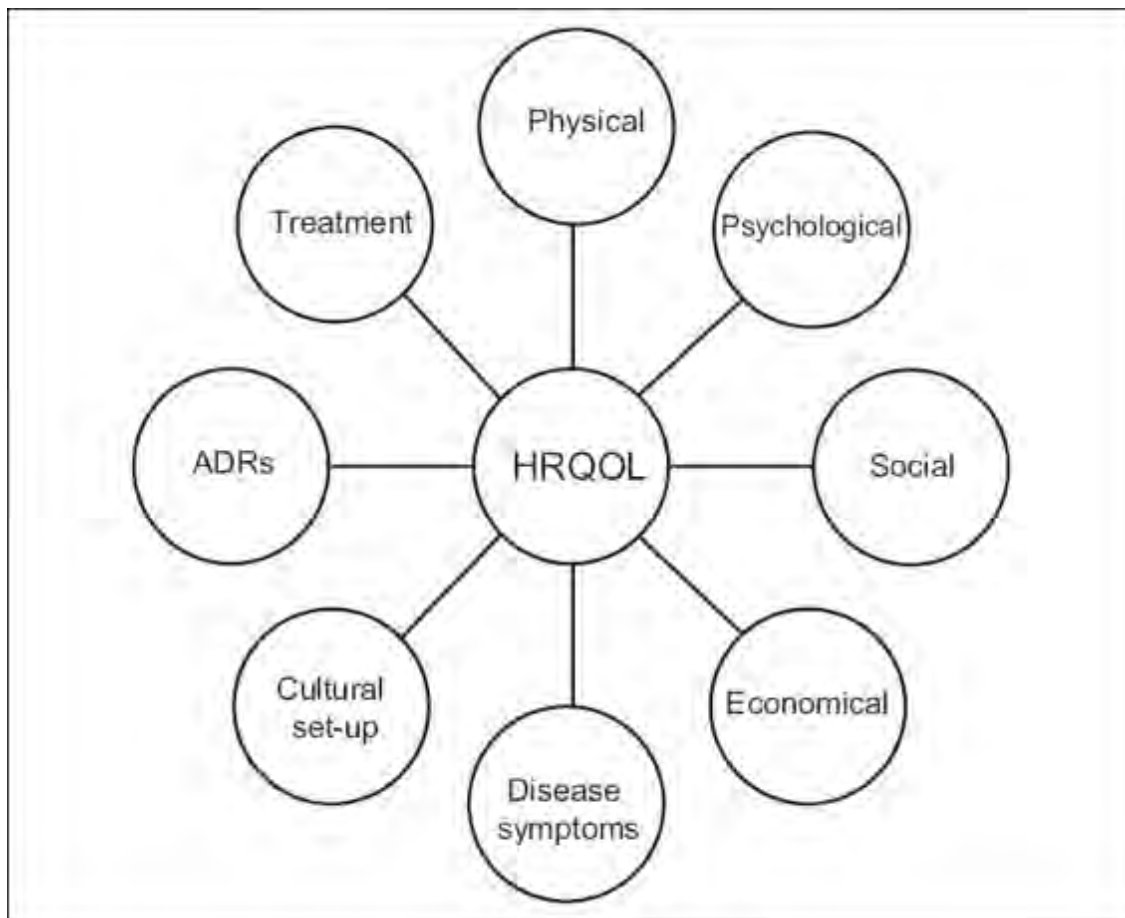


# Patient Reported Outcome Measure

- Directly asking the patient about impact of treatment/ interventions.
- Questionnaire based tools.
- Use to measure:
  - Health
  - Quality of life
  - Health Related Quality of Life
  - Well-being
  - Satisfaction
  - Symptoms
  - Experience



# Health Related Quality of Life (HRQoL)



# Patient Reported Outcome Measures (PROs or PROMs)

- Can be use to:
  - Inform treatments
  - Evaluate interventions
  - Improve quality
  - Research
  - Plan care

# Key Principles of Using PROMs

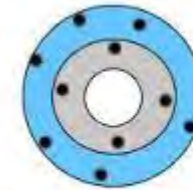
- Can measure impact at level of individual, group or population
- Changes in health states at different time points
- Measure of outcome.
  - Treatment
  - Intervention
- Economic evaluation
  - QALYs

# Why oh Why?

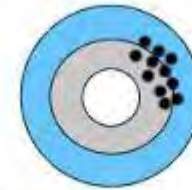
- Directly obtaining information from the patient
  - Patient centered care
  - Patients may have different priorities
- Clinicians are poor at estimating impacts of treatments
  - Pain
  - Benefit
- Clinical outcomes might be different to the patient's outcomes
- Improves satisfaction?
  - It's nice to be involved in your care?

# PROMS, PROMS AND MORE PROMS

- Does it measure what it's supposed to?
  - Evidence of reliability, validity and responsiveness
    - Specific patients, populations and diseases
- Also, need to consider:
  - Acceptability
  - Response and completion rates
  - Mode of administration
  - Feasibility
- Plus, PROMS Vary in terms of:
  - Development
  - Rigour
  - Conceptual model



Not reliable or valid



Reliable but not valid



Both reliable and valid



# Choosing the Wrong PROM

- May not identify significant impacts.
- False picture of impacts and outcomes

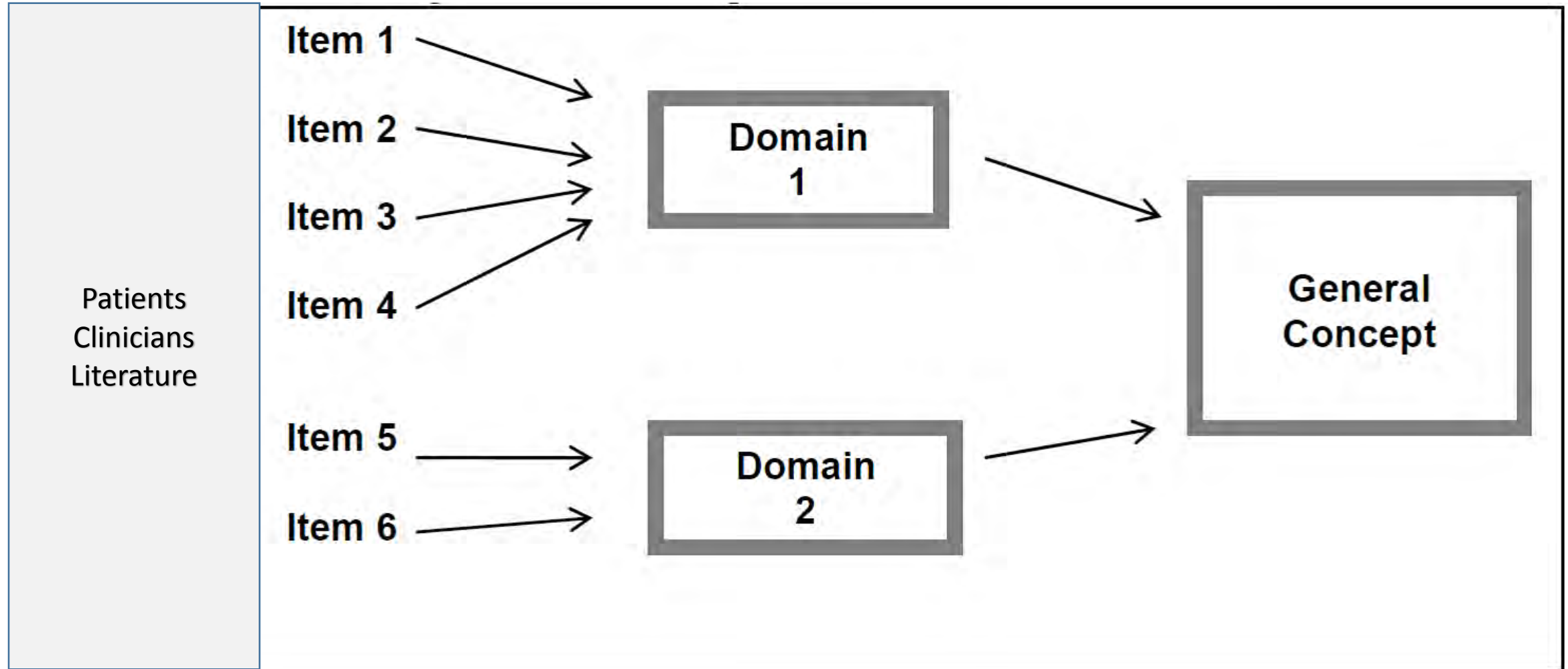
# INTERPRETING PROM DATA

- Minimally important difference (MID)
- Known group variability
- Effect size
- Significance – clinical vs statistical
- Comparison with reference groups and populations

# Types of PROM

- Generic
  - Across populations and health diseases
  - Allow comparisons between conditions
- Disease or Condition-specific
  - Specific to condition or disease
  - May be more relevant
- Preference-based
  - Have “utility” (preference weights) on 0 to 1 scale
  - Can be use to produce QALYs

# PROM DEVELOPMENT PROCESS



# Example of Generic – EQ5D-5L

## EQ-5D-5L

<b>MOBILITY</b>	
I have no problems in walking about	<input type="radio"/>
I have slight problems in walking about	<input type="radio"/>
I have moderate problems in walking about	<input type="radio"/>
I have severe problems in walking about	<input type="radio"/>
I am unable to walk about	<input type="radio"/>
<b>SELF-CARE</b>	
I have no problems washing or dressing myself	<input type="radio"/>
I have slight problems washing or dressing myself	<input type="radio"/>
I have moderate problems washing or dressing myself	<input type="radio"/>
I have severe problems washing or dressing myself	<input type="radio"/>
I am unable to wash or dress myself	<input type="radio"/>
<b>USUAL ACTIVITIES</b> (e.g. work, study, housework, family or leisure activities)	
I have no problems doing my usual activities	<input type="radio"/>
I have slight problems doing my usual activities	<input type="radio"/>
I have moderate problems doing my usual activities	<input type="radio"/>
I have severe problems doing my usual activities	<input type="radio"/>
I am unable to do my usual activities	<input type="radio"/>
<b>PAIN / DISCOMFORT</b>	
I have no pain or discomfort	<input type="radio"/>
I have slight pain or discomfort	<input type="radio"/>
I have moderate pain or discomfort	<input type="radio"/>
I have severe pain or discomfort	<input type="radio"/>
I have extreme pain or discomfort	<input type="radio"/>
<b>ANXIETY / DEPRESSION</b>	
I am not anxious or depressed	<input type="radio"/>
I am slightly anxious or depressed	<input type="radio"/>
I am moderately anxious or depressed	<input type="radio"/>
I am severely anxious or depressed	<input type="radio"/>
I am extremely anxious or depressed	<input type="radio"/>

# Example of Condition-specific

Table 1.

The SPVU-5D

Attribute	Level	Description
Pain	1	I have pain none of the time
	2	I have pain a little or some of the time
	3	I have pain most of the time
	4	I have pain all of the time
Mobility	1	I do not have problems with mobility at any time
	2	I occasionally or very occasionally have problems with my mobility
	3	I have problems with my mobility most of the time
	4	I have problems with my mobility all of the time
Mood	1	I am not down or depressed any of the time
	2	I am down and depressed a bit of the time
	3	I am down or depressed some of the time
	4	I am down or depressed most of the time
	5	I am down or depressed all of the time
Smell	1	There is no smell from my ulcer/ I do not have an ulcer
	2	I notice the smell from my ulcer a little bit or some of the time
	3	I notice the smell from my ulcer most or all of the time
Social activities	1	I have no limitations with my social activities
	2	I very occasionally or occasionally have limitations with my social activities
	3	I nearly always or always have limitations with my social activities

# Challenges ?????

- Content and Coverage
- Relevance
  - Negative attitudes clinicians
- Administration
  - Workload
  - Technology
- Representativeness
- Resources



# Whose PROM?

- Representative
- Top down approach
- Exclusion of groups
  - Cultural
  - Gender
  - Ethnic
  - Socio-demographic
  - Cognitive impairment
  - Physical impairment



# PROMS in the NHS

Varicose Veins	Aberdeen Varicose Vein Questionnaire	EQ5-D
Knee replacement	Oxford Knee Score	EQ5-D
Hip replacement	Oxford Hip Score	EQ5-D
Hernia repair	-	EQ5-D

- Began in 2009
- Plans to broaden to other conditions: cancer, cataract, diabetes, stroke.....
- Quality Improvement
- Used by CQC to monitor Trusts
- Best Practice Tariff – Hip and Knee Replacement
  - Providers paid according to performance
    - 2014/15
    - Potential 10% decrement to funding

# CHALLENGES: PROMS IN CLINICAL PRACTICE

- Patient burden
- Patient resistance
- Clinician resistance
- Inclusiveness
- Breadth vs Depth
- Implementation
  - Infrastructure
  - Relevance
  - Top down



# Conclusion

- PROMs are here to stay
- Potential benefits
  - Patient centred
  - Improved service

BUT:

- Issues in PROM development
  - Inclusiveness
  - Representativeness
- Issues related to implementation
  - Top down
  - Clinician and patient resistance?





# Examining the relevance of PROMs to patients: A review of qualitative data capturing which HRQoL domains are important to patients.

Presenter: Elizabeth Lumley Research Associate

# Background

- Part of NIHR Programme Grant (RP-PG-1210-12009).
- Relates to other work including the identification and evaluation of existing Patient Reported Outcome Measures (PROMs) for vascular conditions.
- Integral part of the development of a new PROM, an electronic patient questionnaire for vascular patients (ePAQ-VAS).

# Patient Reported Outcome Measures (PROMs)

- PROMs allow measurement of outcomes elicited from patients.
- PROMs should include domains that are relevant to patients.
- FDA (2009) advises that measures show evidence that their items have been generated through taking into account the experiences and perspective of the patient group.



# Construction of PROMs



- Accepted guidance suggests that PROMs should be developed using patient generated information (FDA 2009).
- This is best generated using qualitative research methods that offer greater insight into the experiences of patients.
- The reality is often development of PROMs based on clinical or researcher 'expertise.'



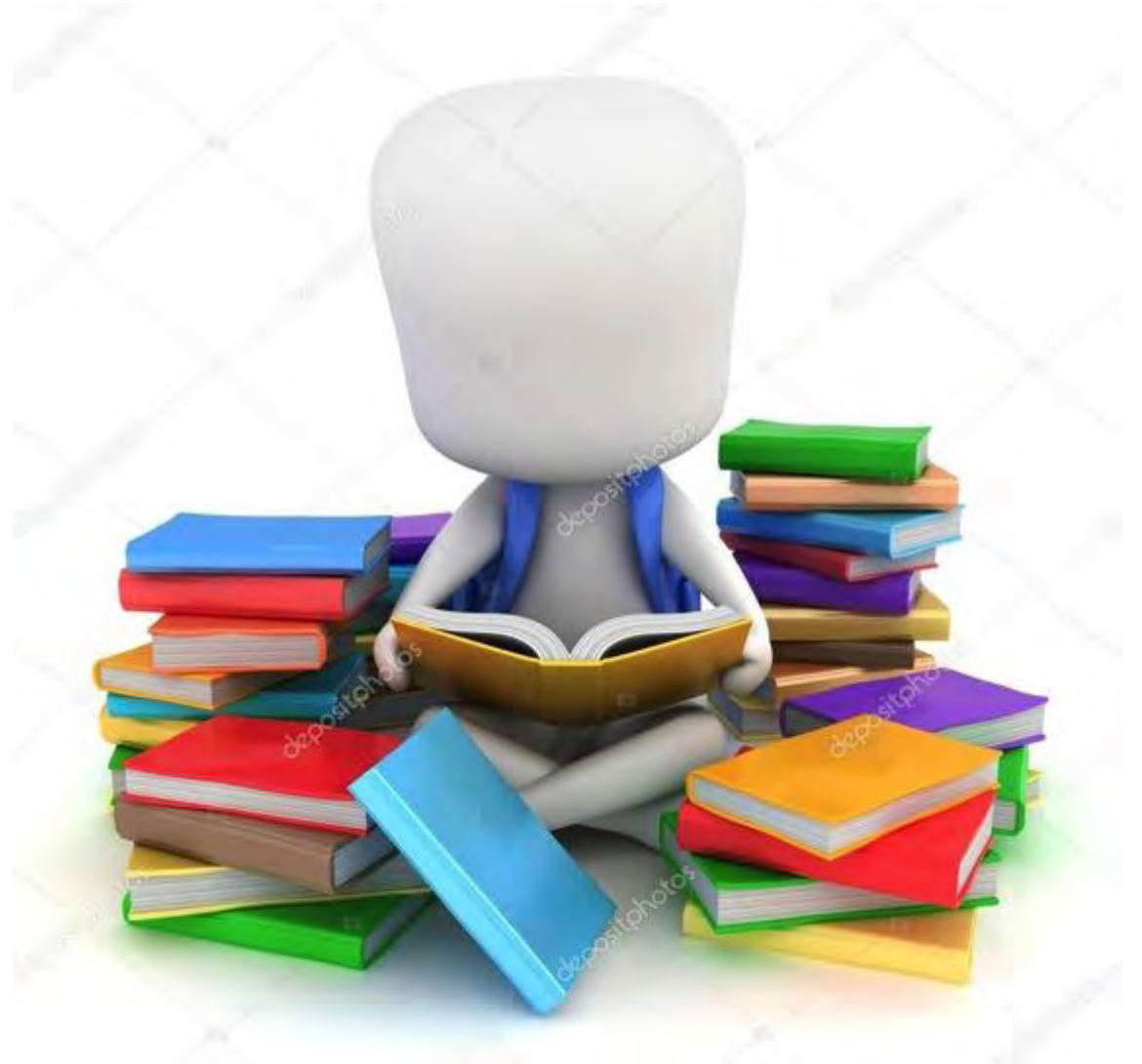
# Qualitative Research

- Qualitative research explores people's subjective understanding of their everyday lives (Pope and Mays 2006).
- They can also be used to compliment other data sources thus enhancing any findings.



# Using Qualitative Research

- Conduct primary studies using interviews or focus groups with patients.
- Undertake reviews of existing qualitative research and synthesise the findings.

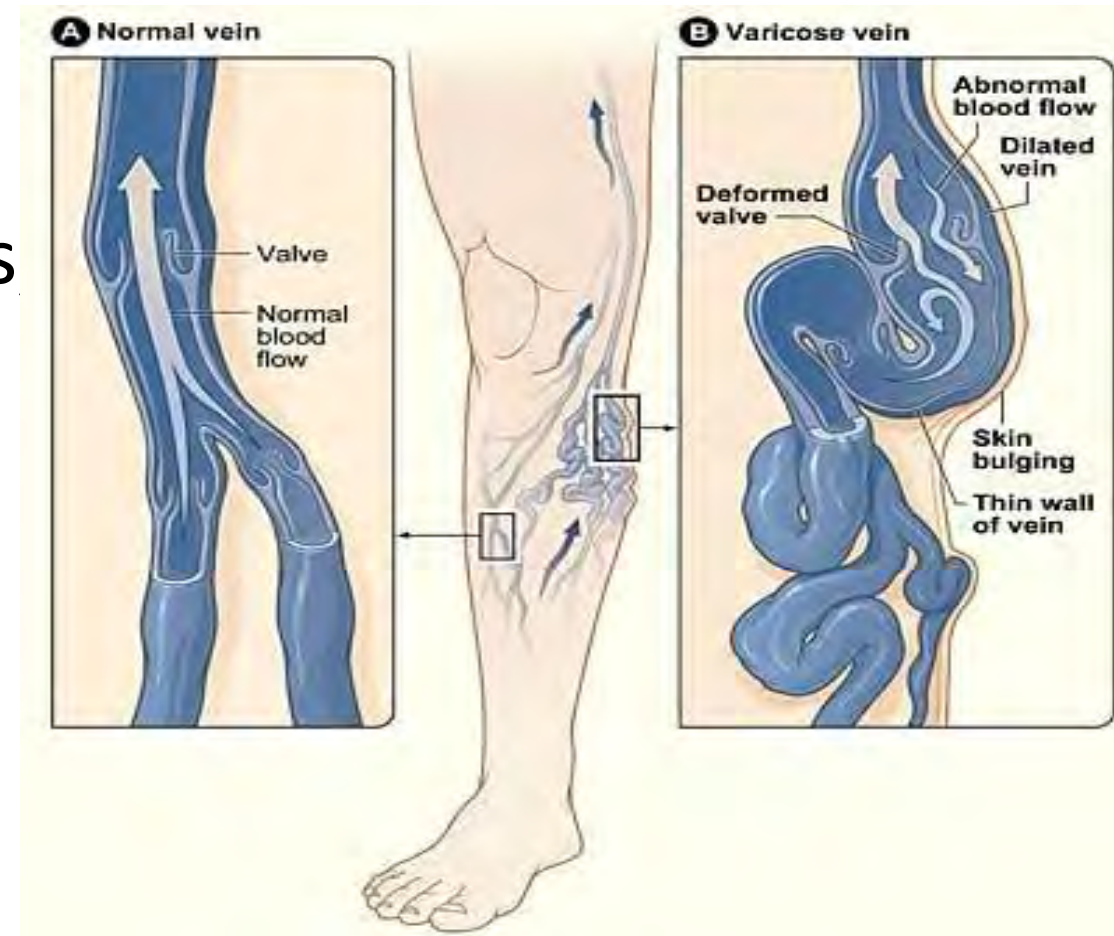


# Aim of Evidence Synthesis

- Primary aim of this qualitative evidence synthesis was to examine the symptoms and HRQoL domains that are important from the perspective of a patient with varicose veins (VV).
- Secondary aim was to compare the findings to existing PROMs domains that are currently used with VV patients.

# Varicose Veins (VV)

- Relatively common affecting at least a third of the UK population.
- Wide range of reported symptoms and severity can differ.
- Treatment can vary from compression hosiery through to invasive procedures.
- HRQoL issues may be deciding factors in treatment decisions.



# PROMs in the NHS

- Since 2009 NHS providers have been required to collect PROMs for four surgical procedures, including VV treatments.
- PROM completion rates for VV patients are much lower than for other required PROMs.
- 2013/14 completion rate was 40.5% compared to 86% and 94% for hip and knee surgeries respectively.



## VV PROMs Used in NHS

- Patients complete the condition specific Aberdeen Varicose Vein Questionnaire (AVVQ).
- Also complete two generic measures – the EQ-5D Index and the EQ- Visual Analogue Scale (EQ VAS).

# Systematic Review of VV PROMs

- A systematic review (Aber et al 2017) to identify validated PROMS for VV patients and assess the psychometric properties.
- One generic (SF-36) and three disease specific PROMs were identified (AVVQ, VVSymQ, SQOR-V).
- The SF-36 and AVVQ were found to be the most appropriate generic and condition-specific PROMs for patients with VV.

# Appropriate VV PROMs



“I know nothing about the subject,  
but I’m happy to give you my expert opinion.”



# Review of Published Qualitative Studies

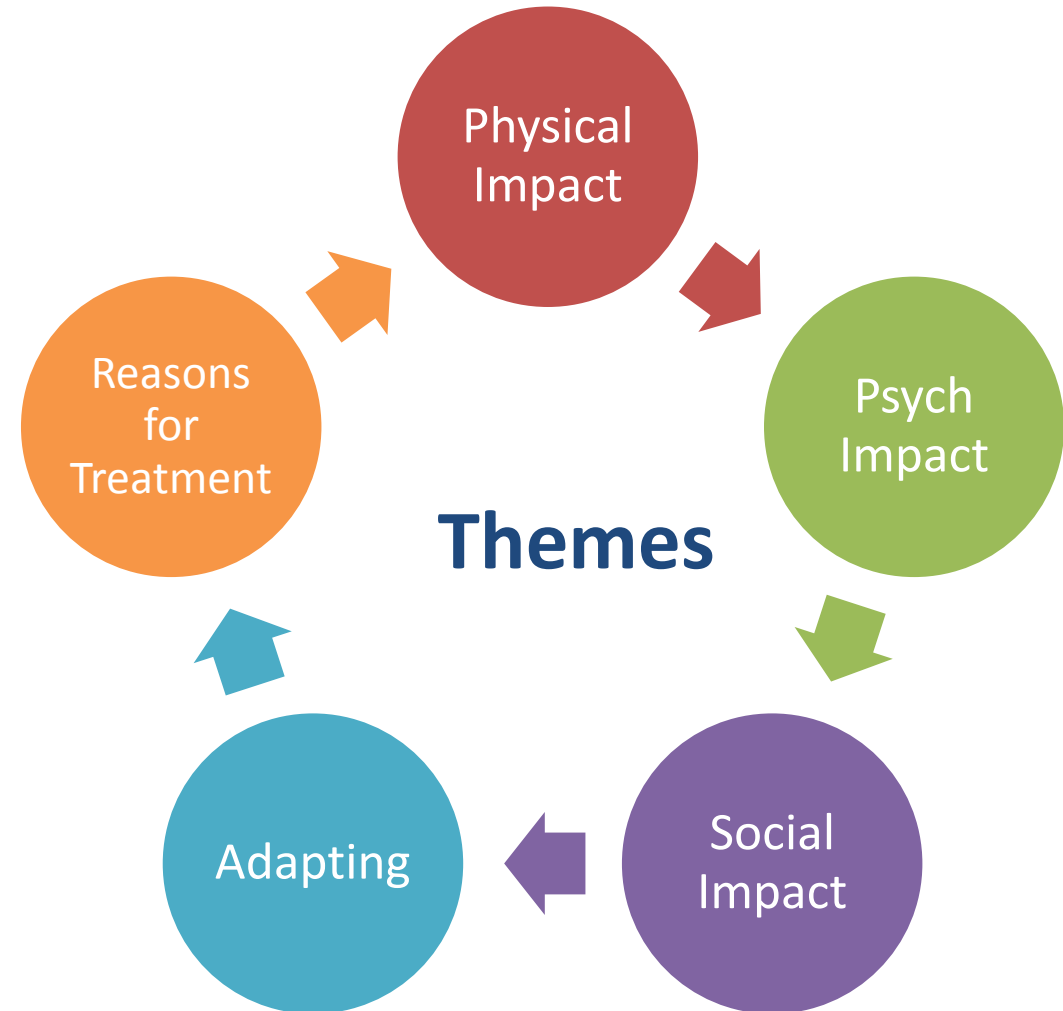
- Eight electronic databases were searched to identify qualitative research published in English of the experiences of adults with VV.
- A total of 1804 citations were identified; after screening only three studies met the inclusion criteria.
- Three included studies – Palfreyman et al 2004, Hudson et al 2015, Franz & Wann-Hansson 2015.

# Discussion & Synthesis of Emergent Themes

- Findings of review are discussed with reference to domains or items used in PROMs that have undergone some sort of validation in a VV population.
- This was done as PROMs are regularly used to support clinical decision making.

# Findings of the Review

- Five overarching themes were described in the studies; physical impact, psychological impact, social impact, adapting to VV and reasons for seeking treatment.



# Themes Identified

	Palfreyman et al 2004	Hudson et al 2015	Franz & Wann-Hansson 2015
<b>1. Physical Impact</b>	✓	✓	✓
<i>Symptoms</i>	✓	✓	✓
<i>Heaviness</i>	✓	✓	✓
<i>Itching</i>	✓	✓	✓
<i>Pain</i>	✓	✓	✓
<i>Swelling</i>	X	✓	✓
<i>Other Symptoms (phlebitis, tiredness)</i>	✓	✓	✓
<i>Sleep</i>	✓	X	✓
<i>Management of symptoms</i>	✓	✓	✓
<i>Coping Strategies</i>	✓	✓	✓
<i>Compression</i>	✓	X	✓
<i>Analgesia</i>	✓	X	X
<i>Elevation</i>	✓	✓	✓
<i>Physical Function</i>	✓	✓	✓
<i>Limitations</i>	✓	✓	✓
<i>Work</i>	✓	X	✓
<b>2. Psychological Impact</b>	✓	✓	✓
<i>Worry/Anxiety</i>	✓	✓	✓
<i>Future Health Problems</i>	✓	✓	✓
<i>Deterioration</i>	✓	✓	✓
<i>Appearance</i>	✓	✓	✓
<i>Personal Feelings (embarrassment, self-conscious, disgust)</i>	✓	✓	✓
<i>Reactions of Others</i>	✓	✓	✓
<i>Self-Image/Self-esteem</i>	X	✓	X
<b>3. Social Impact</b>	✓	✓	✓
<i>Restrictions</i>	✓	✓	✓
<i>Relationships</i>	✓	✓	✓
<b>4. Reasons for Seeking Treatment</b>	✓	✓	X
<b>5. Adapting to VV</b>	✓	✓	✓
<i>Life Adaptations</i>	✓	✓	✓
<i>Clothing Adaptations</i>	✓	✓	✓

# Physical Impact

- Diversity and impact of the symptoms reported across the papers demonstrated there is no definitive list, and not all symptoms affect people in the same way.
- Implications for the use of PROMs as specific symptoms, such as swelling, may not be included in generic PROMs.

*“The last few days I literally crawled through the door and had to sit down with my feet up high to get the blood and swelling down.”*

**(Patient 14 – Hudson et al 2015)**



# Psychological Impact

- Strong psychological impact identified in this review.
- Cosmetic appearance was a significant finding.
- Only one VV specific PROM includes items relevant to psychological, emotional & or mental impact.



# Social Impact

- All papers identified an impact on social function – often led to social isolation.
- Link to psychological impact as social isolation led to low mood.
- Social activities are included in the SF-36, AVVQ and the SQOR-V.

*“I don’t feel comfortable I feel like a lot of people stare at them or feel repulsed by them.”*

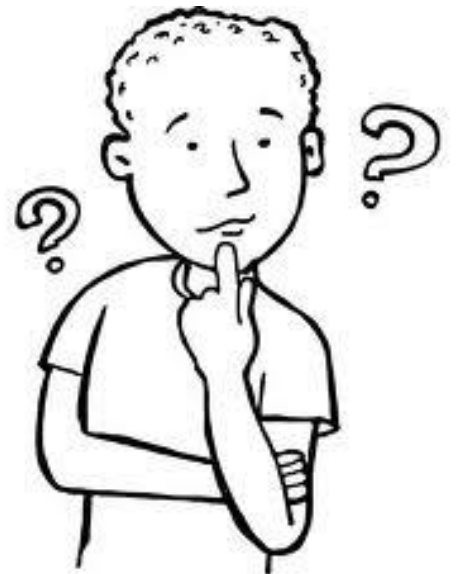
**(Participant 11 – Palfreyman et al 2004)**



# Reasons for Seeking Treatment

- Symptom relief rather than cosmetic appearance was the primary reason.
- Improvement in symptoms may be an unmet expectation.
- Patients may be unaware of risk of failure.

*“More than anything is that it won’t be as it is now, so that the pain factor, the heaviness, everything that goes with it hopefully will have gone.”*  
(Participant 14 – Palfreyman et al 2004)





# Adaptations



A change in the way of life that allows people to survive in a particular environment.

# Adaptation

## Life Adaptation

*“Well, I have been thinking about the work situation...if it is possible to perhaps change the length of the period and the length of working hours during the day....”*

Informant 9 – Franz and Wann-Hansson 2015

*‘When it came to interests involving physical activity and exercise, the informants tried to find alternative activities that they could do despite their leg problems.’*

– Franz and Wann-Hansson 2015

## Clothing Adaptation

*‘Many participants reported shame regarding their legs and took measures to avoid exposing them in public, often at cost to their comfort.’ – Hudson et al 2015*

*‘Those who had been living with VV symptoms for a long time had different methods to conceal their unattractive legs. For example, covering the legs with long pants or a sarong in the summer was one way of hiding them.’ – Franz and Wann-Hansson 2015*

*‘In addition to the impact on their activities, the cosmetic appearance of their legs also influenced the type of clothing worn by participants.’ – Palfreyman et al 2004*

# Discussion

“HRQoL, patient-assessed symptoms (including pain, discomfort, body-image concerns, swelling, aching and heaviness), and progression.....were considered to be the most important outcomes to identify who would benefit from a referral to a vascular service”

NICE 2013

**NICE** National Institute for  
Health and Care Excellence

# Conclusion

- The use of PROMS to gather information is well established in the NHS but those currently used may not capture the full impact.
- Qualitative research methods allow an in-depth understanding of the range and severity of symptoms experienced by patients, and the impact these may have.
- Dimensions of PROMs should be based on patient experiences, best generated using qualitative research methods.



# Pub Stops of Sheffield



# Including people with learning disabilities in quality of life measurement: a methodological discussion

Presenter: Rosie Duncan

Student of Applied Nursing (Learning Disability) and Social Work

Sheffield Hallam University

# What is a learning disability?

- A social construct
- Department of Health (2001) valuing people whitepaper set out a learning disability as;
  - a significantly reduced ability to understand new or complex information and to learn new skills,
  - a reduced ability to cope independently,
  - an impairment that started before adulthood, with a lasting effect on development

# Further categories

People with a learning disability are thought to have an IQ of 70 and below:

- 50 -70 mild learning disability
- 35 - 50 moderate learning disability
- 20 - 35 severe learning disability
- Below 20 profound learning disability



# Some figures...

- There are approximately **1.5million** people in the UK considered to have a learning disability (Hatton et al, 2014). That's **2%** of the population. In a service seeing **100 people a day that is 2 people.**
- **1 in 5** people in the UK have low literacy levels

# What is Quality of Life (QoL)?



Eight core QOL domains identified (Schalock et al 2002, as cited in Townsend-White, 2008)

# Measuring QoL

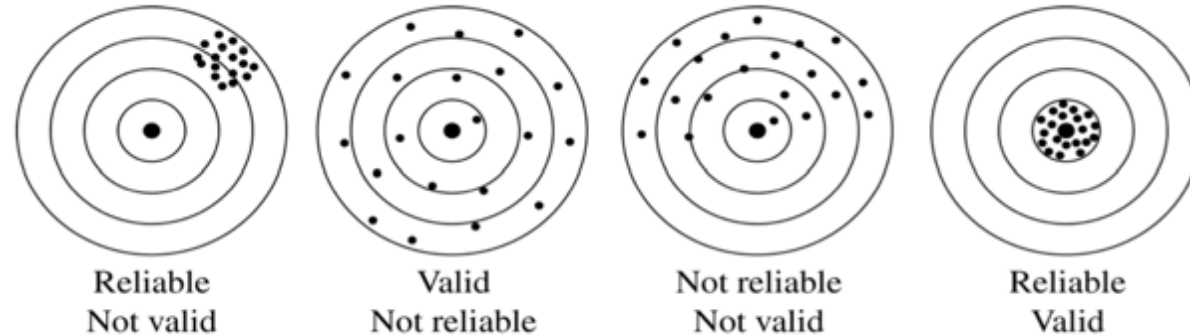
- QoL is a key goal of service provision, aside from mortality and morbidity
- Measuring QoL is useful for assessing the outcomes of a service, aiding service development and informing evidence-based policy
- It is a complex social construct with many different theories of how it should be measured/ assessed
- Objective and subjective



# General critique of QoL measures

- The validity of the quality of life construct
- It is arguably not a useful measure of service outcomes as **subjective QoL** might be a personal trait rather than change as a result of circumstance (Hatton & Ager, 2002)

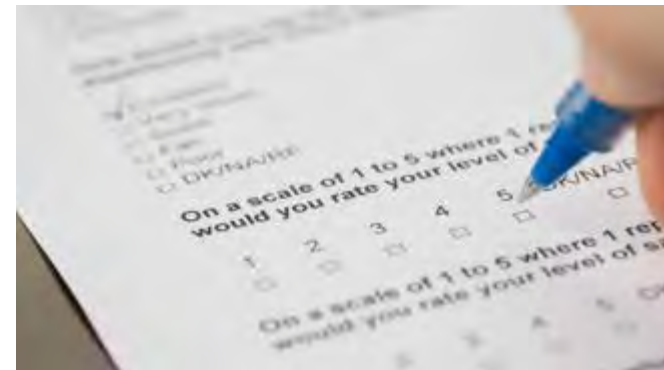
# Critique of QoL measurement



- Reliability and validity of **responses**
- Reliability and validity of **proxy responses** particularly relating to the more subjective aspects of QoL (Perry et al, 2000)
- Standardised measures might miss important **aspects of quality** of life for people with a learning disability
- Another way of professionals excluding the '**voice**' of people with a learning disability

# Patient Reported Outcome Measures (PROMs)

- Self-reported questionnaires either paper or electronic asking information on people's **symptoms, condition and the impact on QoL**
- They can be **condition specific** (AVVQ) or **generic** (e.g. EQ-5D)
- PROMs usually take a number of **years** to develop with patients, clinicians and researchers
- **Few include** people with learning disabilities or low literacy levels are included in the development and design of PROMs



# Legislation

- **The Equality Act (2010)** outlines that reasonable adjustments should be made to include people in services
- From **1<sup>st</sup> August 2016** the NHS introduced an **accessible information standard** that legally requires all NHS organisations to ensure that people with a “disability, impairment or sensory loss” are provided with information they can easily read, understand and are supported to communicate effectively with health and social care services (NHS England, 2015)
- Measuring outcomes for people with learning disabilities needs to be done across all services, not only specialist learning disability services; however, there is little routine guidance on including people with learning disabilities or low literacy levels in outcome measurements across services (Jaydeokar, 2015)



# Including people with learning disabilities in PROMs

Health-care improvement Scotland (2012) with the University of Glasgow and the University of Dundee consulted service users with learning disabilities on how to make PROMs more accessible.





# Their key recommendations

- To have an option of completing the PROMs with the **assistance** of a family member, carer or health professional to read the questions
- Ensuring the PROMs are in an **easy read** format. This became a requirement for all NHS organisations in August 2016
- Providing a **choice** of where to complete the measure
- Providing a **quiet space** to complete the measure if in clinic



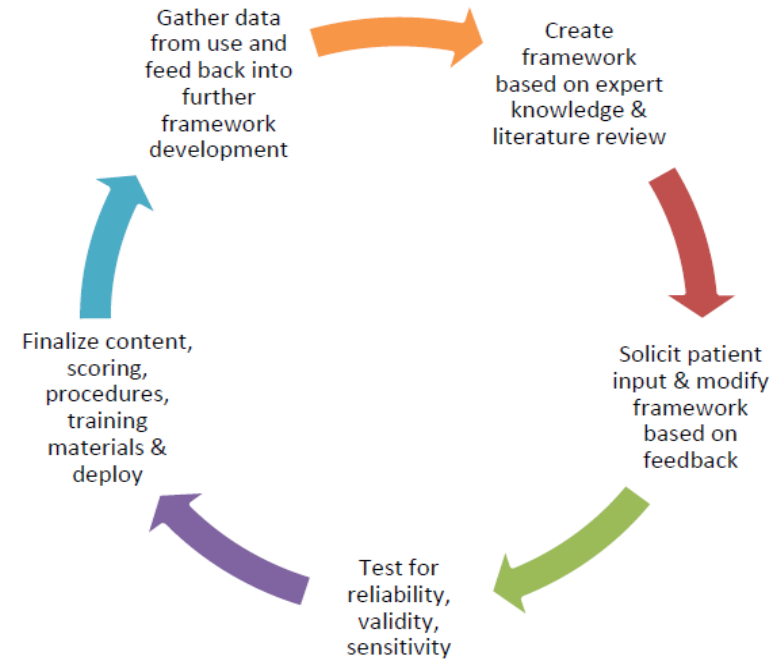
# Barriers and solutions for implementation in practice

- Finding quiet space in a clinic where space might be limited needs to be thought through before implementation
- Technology and ability to complete the measure at home
- Understanding and attitudes of staff to assisting people with learning disabilities



# Further consideration is needed

- Planning for making PROMs accessible takes time and needs to be done during the development stage
- Involving people with a learning disability in the development stages through PPI
- Consent
- Proxy issues, flexibility





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# Development of an electronic personal assessment questionnaire to capture the impact of living with a vascular condition (ePAQ-VAS).



## ePAQ-VAS

Sheffield Teaching Hospitals   
NHS Foundation Trust

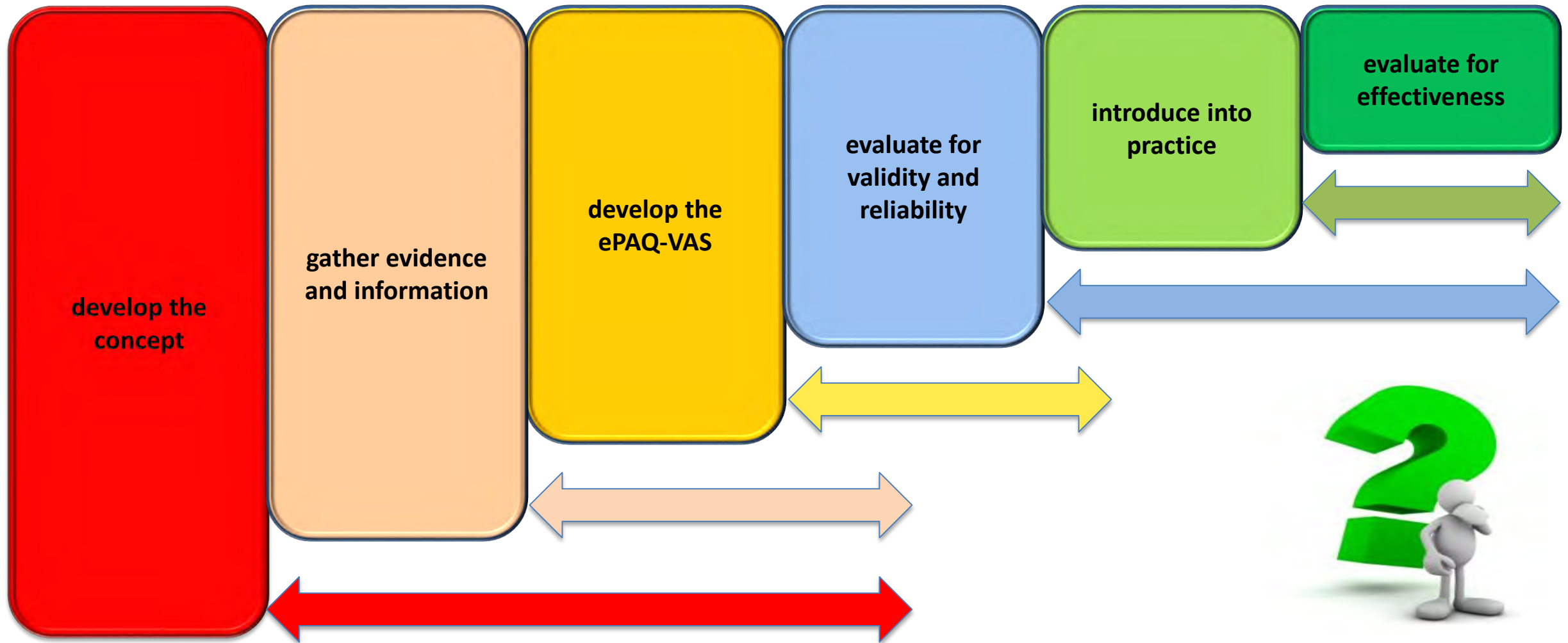
Presenter: Patrick Phillips - Research Associate

# Process

- Development of an electronic questionnaire for use by people with vascular conditions
  - completion in the home or healthcare setting
  - online via P.C, laptop, tablet or mobile device
  - Prior to consultation
- The design, development, commissioning and evaluation of patient focussed vascular services - NIHR RP PG 1210-12009
- Start date June 2013
- Planned end date May 2018

Presentation aim - overview of the process

**Doctors, nurses, psychologists, information specialists, systematic reviewers, statisticians, software engineers, administrators and patients**





# The Concept – electronic personal assessment questionnaire - Why?

But

- Electronic questionnaire
  - ✓ Technology is available
  - ✓ Devices allow completion in a range of settings
  - ✓ Electronic storage
  - ✓ instantaneous data analysis
  - ✓ Accessible and Instantaneous report
  - ✓ Enables comparisons
  - ✓ research and audit
    - ✓ consent for use (incorporated in e-PROM)
  - ✓ Efficiency
  - ✓ completion rates??

- Motivation to engage
- Computer literacy
- Visual impairment
- Learning disabilities
- Language



- ePAQ – Gynaecology pelvic floor – since 2003
  - ePAQ – pre-operative assessment
- Increased usage and evidence of benefits of e-PROMS

# The concept –vascular conditions

## - why?

### ■ Diverse conditions

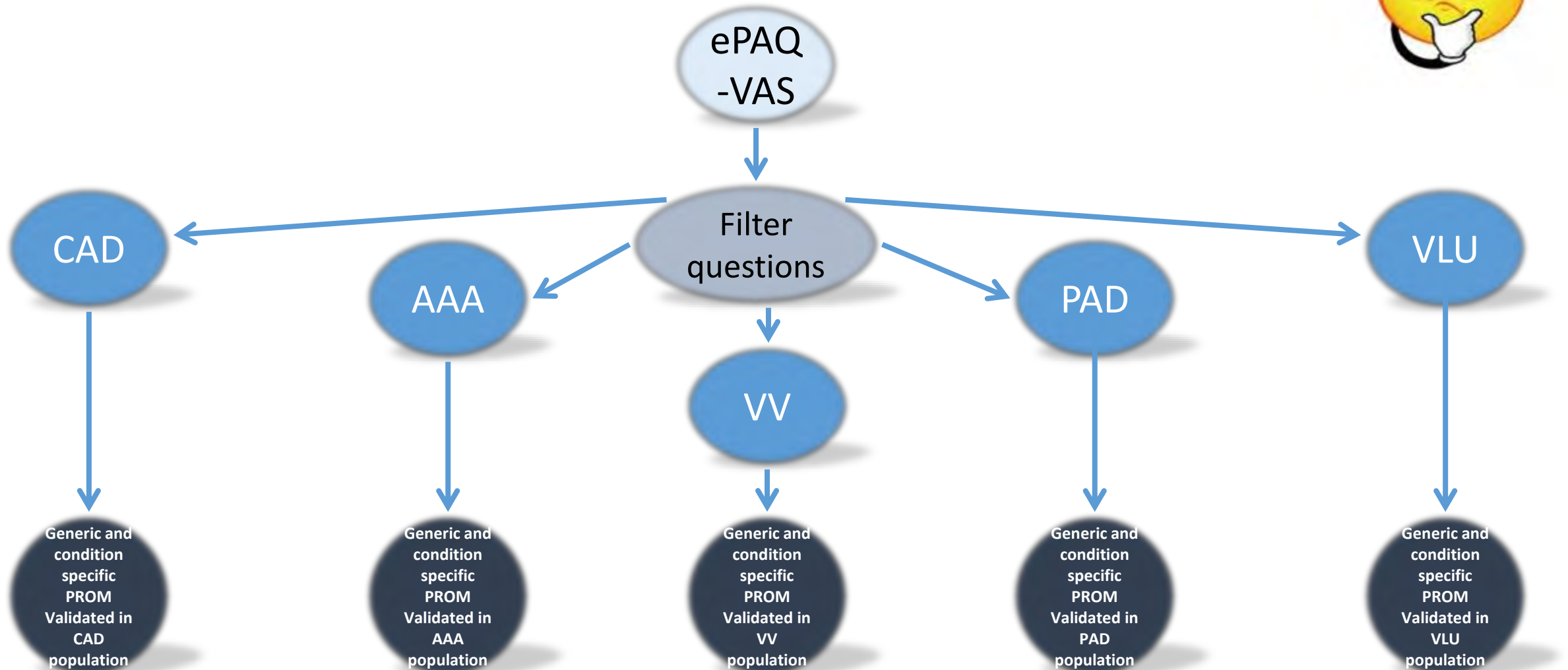
- Abdominal aortic aneurysm (AAA)
  - Carotid artery disease (CAD)
  - Peripheral artery disease (PAD)
  - Venous leg ulcer (VLU)
  - Varicose veins (VV)
- Urgency
  - Treatment options
  - Symptoms



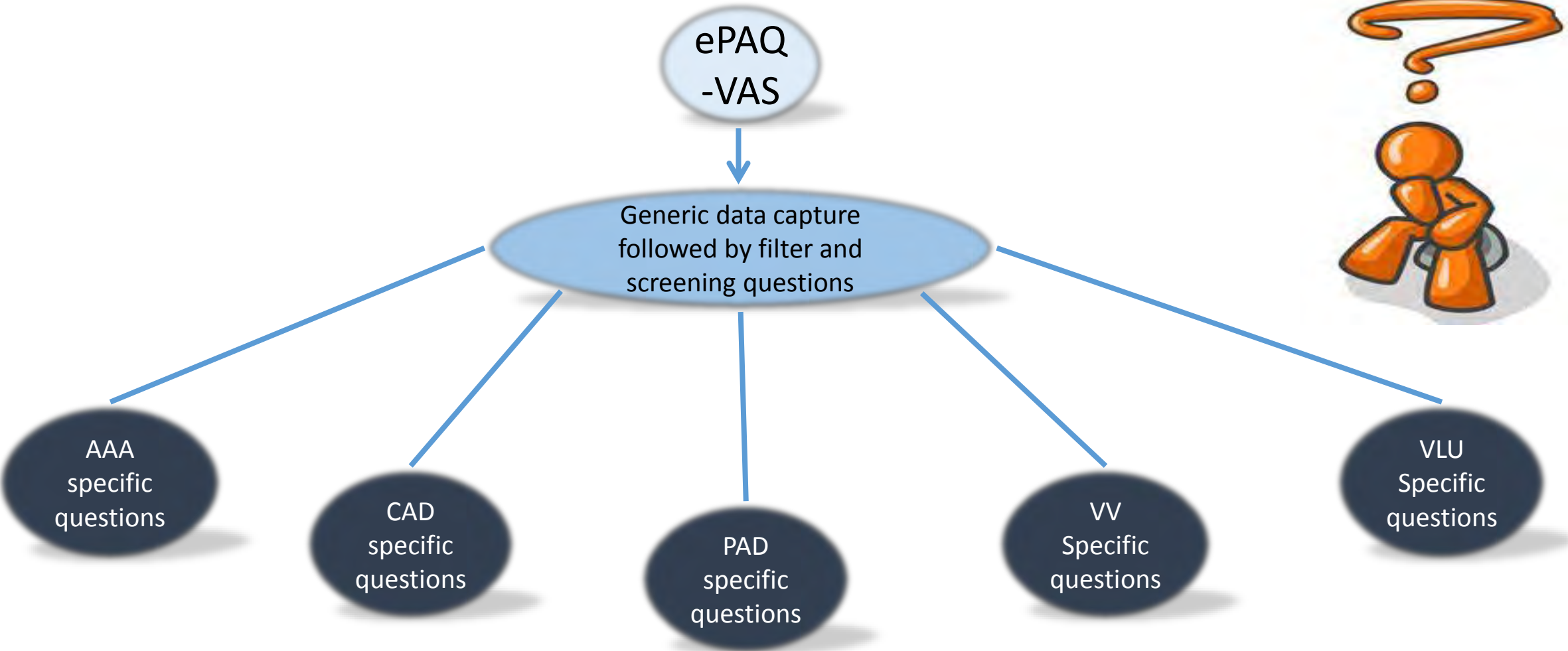
- Vascular disease is systemic
- Common themes



# Possible ePAQ models



# Possible ePAQ models





## ePAQ – VAS

methodological and practical aspirations

- Content validity
- Criterion validity
- Test re-test reliability
- Responsiveness
- Acceptability
- Useable
- Relevant
- Improves quality
- Enhanced communication
- Joint decision making

# Process

AAA

- Systematic reviews of existing AAA PROMS
- Systematic review of qualitative research
- Primary qualitative research

CAD

- Systematic reviews of existing CAD PROMS
- Systematic review of qualitative research
- Primary qualitative research

PAD

- Systematic reviews of existing PAD PROMS
- Systematic review of qualitative research
- Primary qualitative research

VLU

- Systematic reviews of existing VLU PROMS
- Systematic review of qualitative research
- Primary qualitative research

VV

- Systematic reviews of existing VV PROMS
- Systematic review of qualitative research
- Primary qualitative research

Provisional Electronic Patient Questionnaire - ePAQ-VAS (version 1)

Interviews and focus group with vascular patients; Consensus exercise with clinicians

Provisional Electronic Patient Questionnaire - ePAQ-VAS (version 2)

Item reduction and assessment of psychometric properties

Provisional Electronic Patient Questionnaire - ePAQ-VAS (version 3)

# Qualitative study (interviews)



- **AAA - 13 participants**
  - ◆ No physical symptoms, a small number of participants reported abdominal pain and pain in their legs. Uncertainty, anxiety and fear of rupture and death appeared to impact most greatly on people's QoL.
- **CAD - 9 participants**
  - ◆ This condition seemed to have had the least impact on physical and social function, although psychologically it created a sense of worry and anxiety for some participants. The main reported outcome was fear of having a major stroke.
- **PAD – 14 participants**
  - ◆ Pain and mobility were the most commonly reported themes. The extent to which they impacted on QoL was associated with the severity, age expectations and social support. Fear of the symptoms worsening and amputation was evident.
- **VV - 10 participants**
  - ◆ VV do not appear to have had a major impact on overall QoL for the majority of the participants. Pain was the most common issue. The perceived unpleasant appearance of the VV seemed to have the greatest psychological impact. Many of the participants had had their VV for very long periods of time, often just “putting up with it” for numerous years before seeking help.
- **VLU – 11 participants**
  - ◆ The impact of VLU on QoL differed within the group. For some there were no major issues and having a VLU was accepted as part of their current life, with the hope that it would heal eventually. For others there was a far more significant effect. Pain was quite severe for some participants leading to a significantly reduced QoL. VLU appeared to have a significant psychological impact causing a high degree of distress for some

# Qualitative reviews



- **AAA**  
315 citations (3 studies included)
  - Themes included anxiety and *lack* of physical symptoms
- **CAD**  
964 citations (3 studies included)
  - Themes included symptoms, psychological and social impact, risk and service experience
- **PAD**  
973 citations (9 studies included)
  - Themes included Pain, compromised physical function and impact on social life
- **VV**  
1804 citations (3 studies included)
  - The key theme to emerge was adaptation, as patients attempted to adapt to the physical, psychological and social impact of varicose veins.
- **VLU**  
1804 citations (13 studies included)
  - Themes included ulcer and treatment related pain, odour and exudate which affected sleep, mobility and mood.





# Review of PROMS

- **AAA**
  - 1267 citations – 3 studies – 4 PROMS
- **CAD**
  - 1670 citations – 5 studies – 6 PROMS
- **PAD**
  - 6981 citations – 14 studies – 13 PROMS
- **VV**
  - 3641 citations – 9 studies – 4 PROMS
- **VLU**
  - 3647 citations – 10 studies – 10 PROMS



# Psychometric evaluation

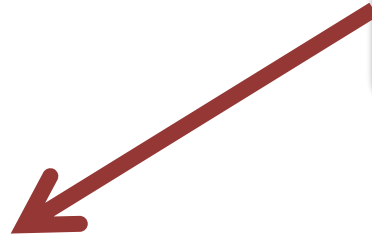
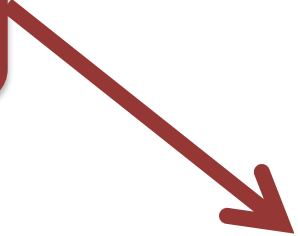
- Conducted using the COSMIN checklist (Terwee et al 2012)
  - Varicose veins - evidence of construct and criterion validity as well as the responsiveness, with good internal consistency (Cronbach  $\alpha = 0.72$ ) and a reasonable test retest reliability (intra-class correlation coefficient = 0.59) were found for AVVQ. SF-36 was considered to have satisfactory responsiveness and internal consistency (Cronbach  $\alpha = 0.80$ )
  - AAA, CAD, PAD, VLU – limited evidence of rigorous psychometric evaluation of identified PROMs

Qualitative review  
(31 studies)

Qualitative interviews (57  
participants)

Review of PROMS  
(41 studies)

Within condition  
interpretation, translation,  
comparison and triangulation  
of themes



# AAA PROM items triangulated with the qualitative synthesis themes

Qualitative themes	AUSVIQOL	SF-36	Aneurysm-DQoL & Aneurysm-SRQ
<b>Physical symptoms</b>			
Feeling no physical symptoms	.	.	+
Pain	-/+	-/+	+
Gastrointestinal upset	.	.	+
Numbness	.	.	+
Swelling	.	.	+
Bruising	.	.	+
Weakness	.	.	+
Heaviness	.	.	+
Sleep	-/+	.	+
Lethargy, fatigue	.	+	+
Weight loss	.	.	+
Appetite	.	.	+
Comorbidities	.	.	-/+
<b>Psychological outcomes</b>			
Concern over bodily symptoms	.	.	+
Concern over changes to the size of the aneurysm	.	.	.
Age related health expectations	+	+	+
Ability to forget about the condition	.	.	.
Cognitive function	-/+	.	+
Anxiety	.	.	+
Depression, fatalism, helplessness	.	+	+
Fear of rupture and death	.	.	.
Control	.	.	.

Qualitative themes	AUSVIQOL	SF-36	Aneurysm-DQoL & Aneurysm-SRQ
<b>Social outcomes</b>			
Effect on family <sup>24,29</sup>	.	+	+
<b>Functional outcomes</b>			
Effect on day to day life	+	+	+
Sexual Function <sup>24</sup>	.	.	+
Lifting heavy objects	.	+	-/+
Ability to travel	.	.	+
Financial implications	.	.	+

Key:

. silence

– dissonance

-/+ partial agreement

+ agreement

N.B. Aneurysm-DQoL & Aneurysm-SRQ are reported together as they were developed by the same authors.

four overarching themes were identified from the four studies included in the qualitative synthesis: physical symptoms, functional outcomes, psychological outcomes, and social outcomes

Qualitative review  
(31 studies)

Qualitative interviews (57  
participants)

Review of PROMS  
(41 studies)

Within condition  
interpretation, translation,  
comparison and triangulation  
of themes

Across condition  
interpretation, translation,  
comparison and triangulation  
of themes



## Qualitative study - map of symptoms and quality of life concepts reported across the five vascular conditions

	PAD	AAA	CAD	VV	VLU
<b>Symptoms</b>					
No symptoms		x	x		
Pain	x	x	x	x	x
Neck pain			x		
Leg pain	x	x	x	x	x
Abdominal pain	x	x			
Arm pain	x				
Cramp/ aching	x	x		x	x
Burning sensation					x
Pain severity	x	x	x	x	x
Pain on walking	x	x		x	x
Pain at rest	x			x	
Pain when standing				x	x
Mobility	x	x	x	x	x
Distance	x	x		x	x
Speed	x	x			
Stairs/ slopes	x	x			
Non-healing wounds	x				x
Co-morbidities	x	x	x		x
Progression of symptoms	x	x		x	x
Sleep	x		x	x	x
Swelling			x	x	
Loss of balance			x		
Confusion			x		

	PAD	AAA	CAD	VV	VLU
<b>Impact on physical functioning</b>					
Hobbies	x			x	x
Exercise	x	x		x	x
Daily activities	x				x
<b>Social impact</b>					
Travel	x	x	x		
Social activities	x	x		x	x
Social support	x	x	x		
<b>Psychological impact</b>					
Anxiety	x	x	x	x	x
Depression	x	x			x
Feelings of loss	x			x	x
Health expectations	x	x	x	x	x
Unightly appearance				x	
Feeling self-conscious	x			x	x
Fear of worsening symptoms	x	x	x	x	x
Fear of rupture death		x			
Fear of amputation				x	x
Fear of stroke			x		
<b>Financial impact</b>					
Income	x	x			x
Time off work				x	x
<b>Lifestyle</b>					
Smoking	x	x	x	x	x
Exercise	x	x	x	x	
Diet	x	x	x		x
Weight				x	x

Qualitative review  
(31 studies)

Qualitative interviews (57  
participants)

Review of PROMS  
(41 studies)

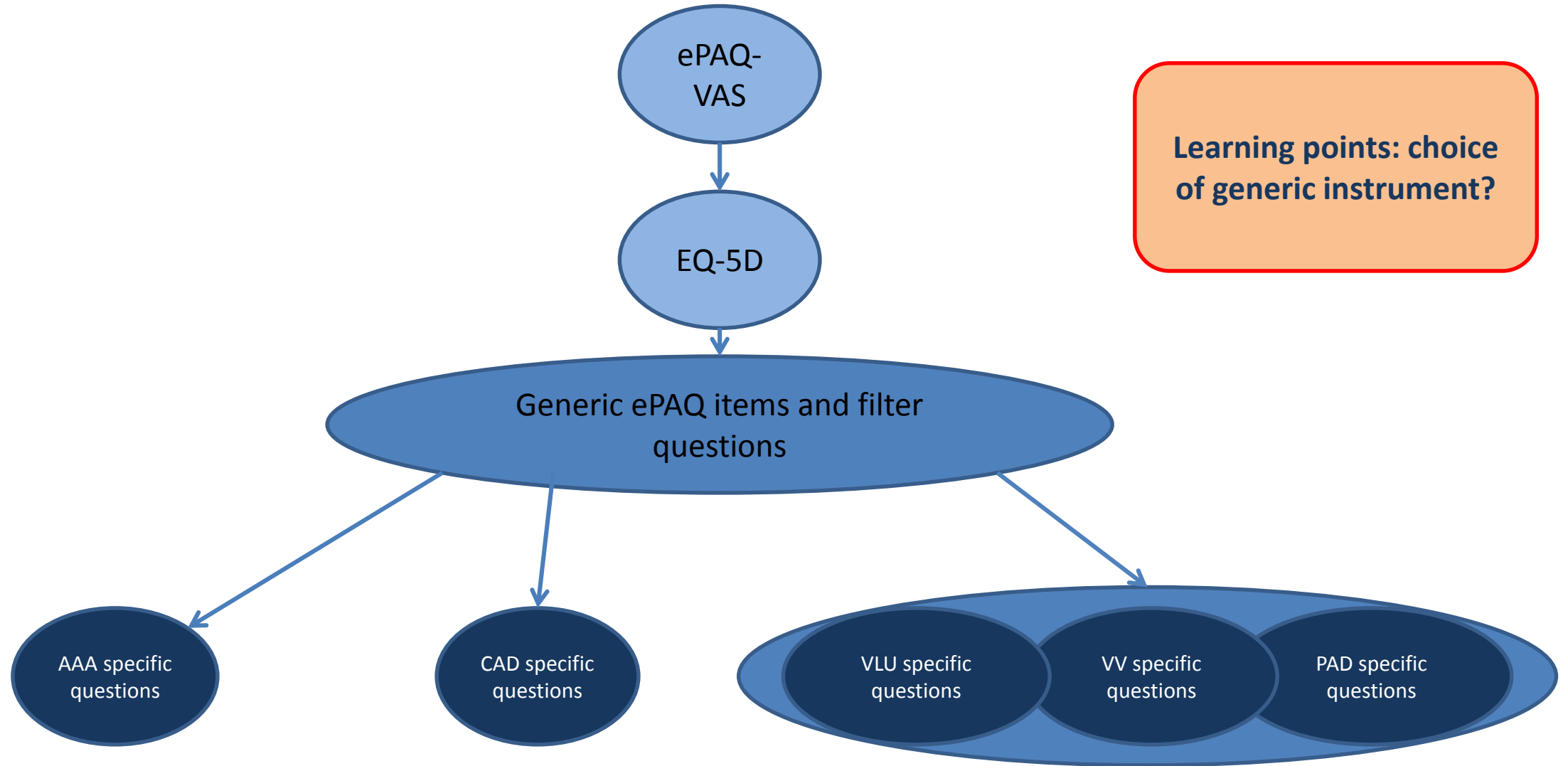
Within condition  
interpretation, translation,  
comparison and triangulation  
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Across condition  
interpretation, translation,  
comparison and triangulation  
of themes

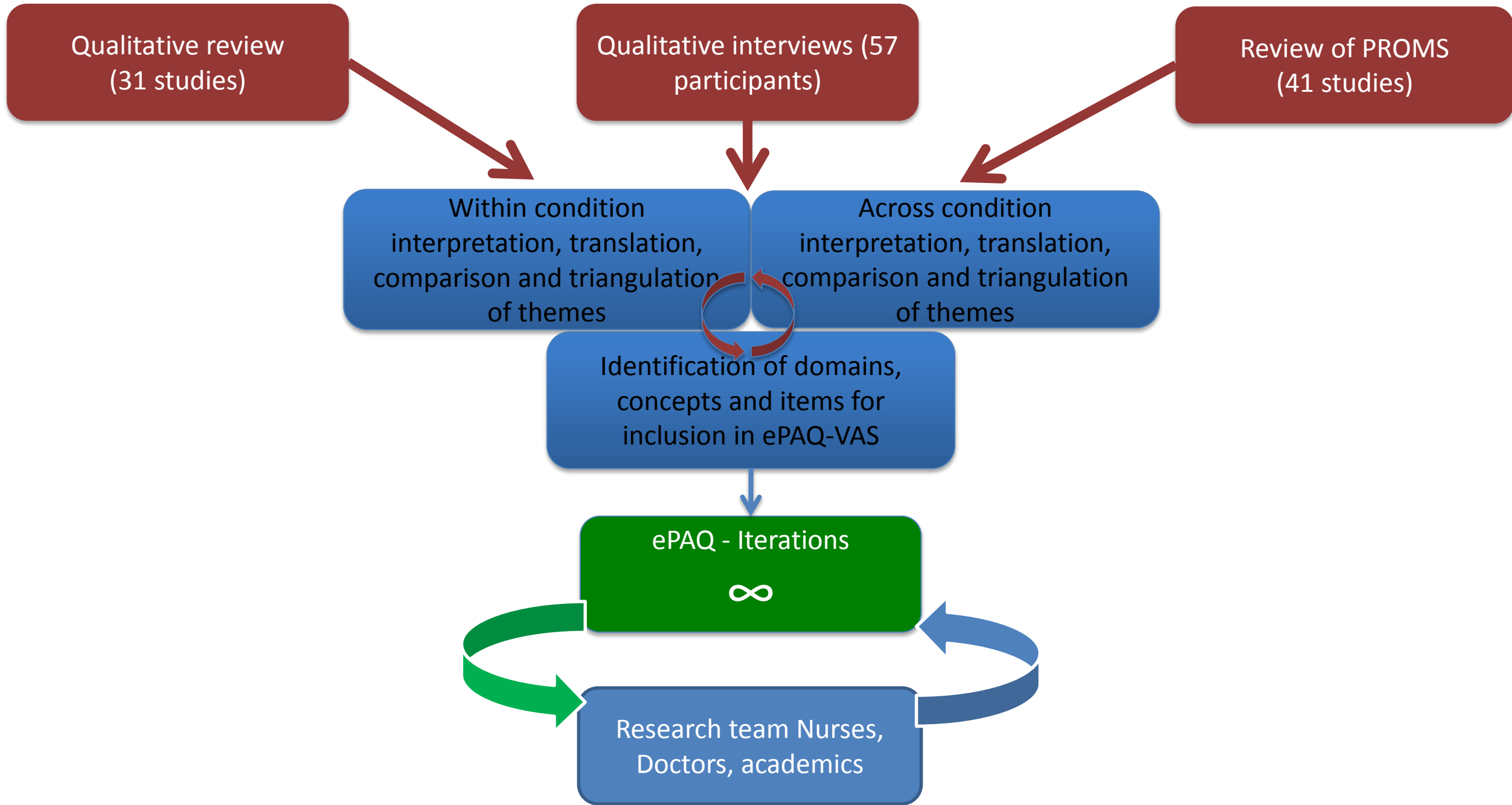
Identification of domains,  
concepts and items for  
inclusion in ePAQ-VAS

**Learning points:  
methods used to synthesise  
qualitative studies and  
reviews**

# Final ePAQ model

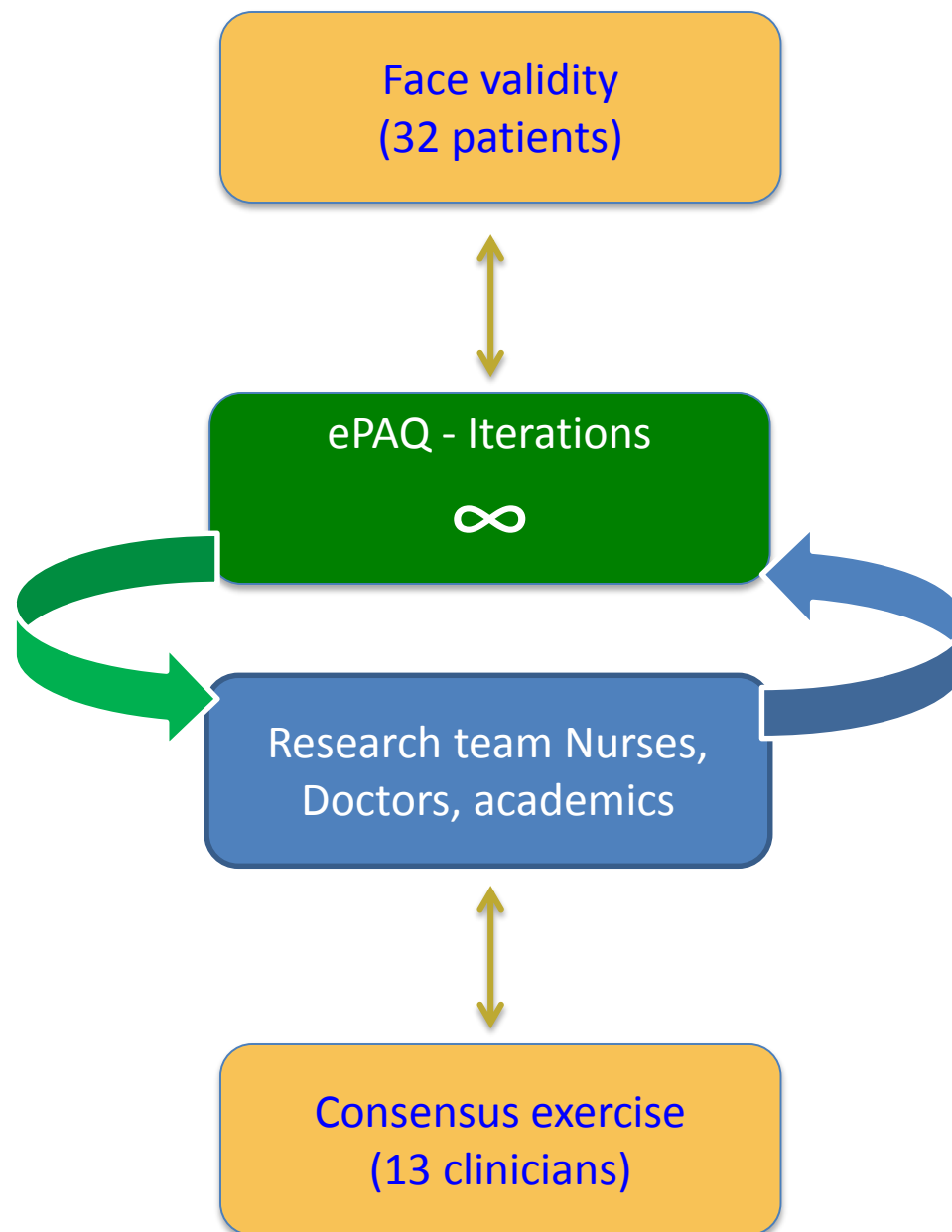






## Consensus exercise

- Investigation of relevance of included items
- to look at the presentation of the information gathered
- 13 participants - vascular surgeons and specialist vascular nurses



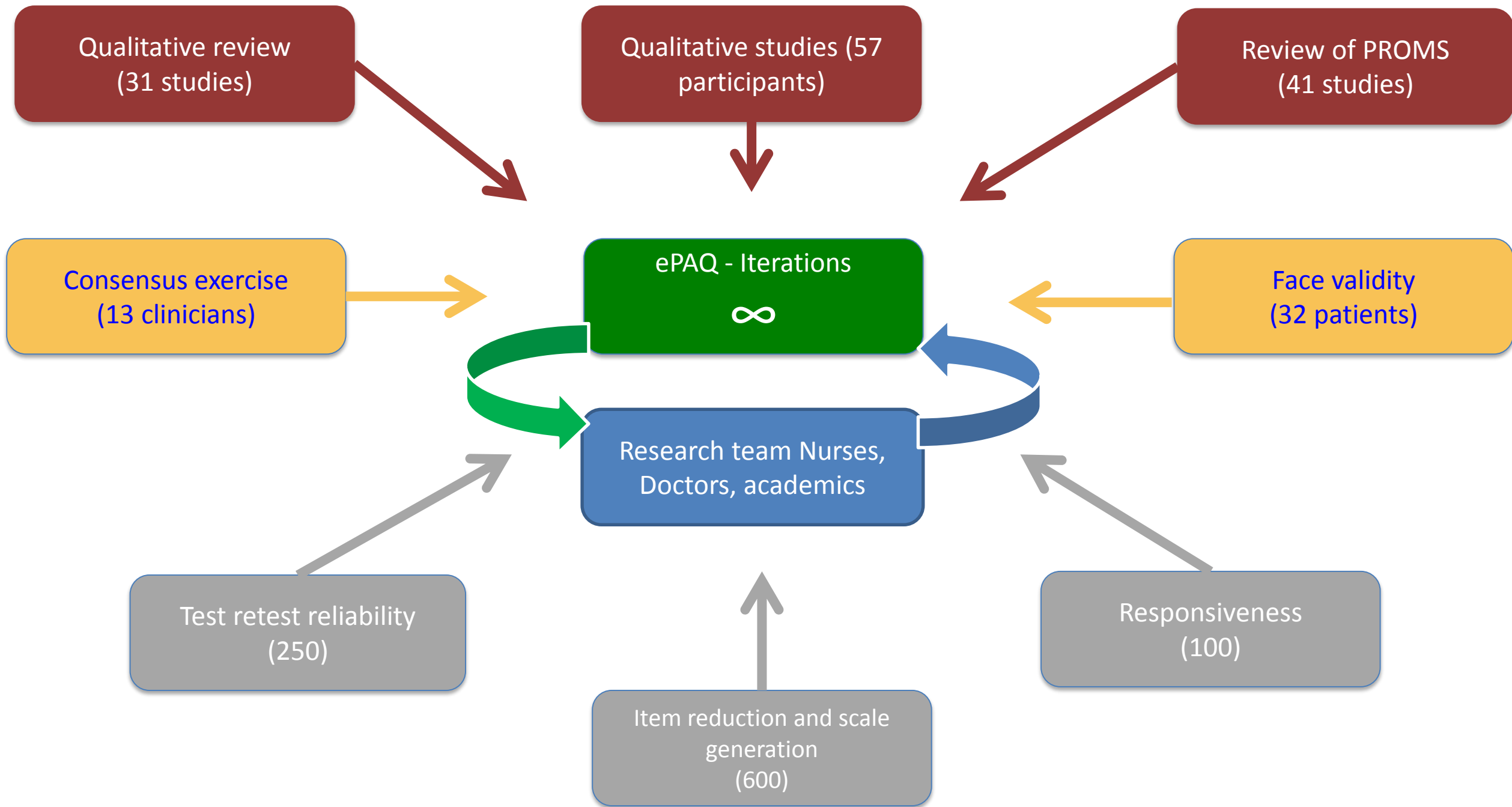
## Interviews/ focus groups

- to investigate:
  - Emotional response
  - Clarity
  - Relevance
- 20 interviews planned across five conditions
- Focus group planned to include up to 12 participants

# Next steps

- Roll out ePAQ-VAS into practice settings
- ePAQ access code delivered with outpatient appointment letter
- Participant logs on at home or in clinic and completes ePAQ-VAS prior to appointment
- Report available in clinic
- Requires involvement of NHS clerical, I.T. and clinical staff
- Psychometric evaluation
  - Factor analysis
  - Item reduction
  - Test retest
  - Responsiveness
  - Criterion validity





# Challenges

- Implementation
  - Engagement of clerical staff, information technology and clinical staff
  - Inter organisational working – university, NHS, private industry
  - Ensuring Accessibility
  - Acceptability



# Conclusion

- ❖ “To banish imperfection is to destroy expression, to check exertion, to paralyze vitality.” (John Ruskin)
- ❖ “Quality is never an accident; it is always the result of intelligent effort.” (John Ruskin)
- ❖ “Have no fear of perfection - you'll never reach it.” (Salvador Dali)

