

## **1. Construct Definition -**

PRO development should be underpinned by theory (have a strong conceptual base) and consideration of the target population (i.e. people with PUs)

- Literature review-generated broad HRQL domains/important PU-specific PROs identified
- Clinical expert opinion-produced a working conceptual framework
- Qualitative interviews (n=30) with people with PUs - revised conceptual framework
- Clinical and methodological expert review = produced a conceptual framework of HRQL outcomes

## **2. Establish need for a new measure -**

map content from existing instruments to conceptual framework

- Literature review of PU and other chronic wound measures-no PU instrument available
- Content from existing instruments did not comprehensively represent PU-specific conceptual domains

## **3. Item Generation**

- Qualitative interview transcripts reviewed (30)-patient words taken for items
- Operationalisation-content analysed and revised, producing 117 items into 13 scales
- Clinical and methodological expert review = produced a preliminary instrument

## **4. Pre-testing**

- Semi-structured cognitive interviews with people with PUs (n=35)-identified problems with item content (ambiguous, confusing), layout and administration
- Revised instrument based on patient recommendations
- Clinical and methodological expert review = produced a first draft PU-QOL instrument

## **5a. Field Test 1- 5b. Mode of Administration Study**

- Item analysis and scale construction (n=227)
- Rasch analysis followed by traditional psychometric tests for reliability and validity
- Sub-sample (n=75) randomised to self-complete or administered groups and differential item functioning performed to determine the best administration mode for this population
- Clinical and methodological expert review-considered analyses in combination and clinical relevance-modified first draft PU-QOL

## **6. Field Test 2**

- Final psychometric analysis (n=229)
- Rasch analysis followed by traditional psychometric tests for reliability and validity
- Clinical and methodological expert review = produced final version PU-QOL