



WHO Collaborating Centre



Patient reported outcome measures (PROMs) in HIV



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Competing or Conflicting Interests

None.

Background: problems & concerns for people living with HIV (PLWH)

- HIV considered “chronic” condition with potentially near-normal life expectancy
(Lohse et al. 2007)
- Health Related Quality of Life (HRQoL) on ART poorer than UK general population
(May et al. 2011; Miners et al. 2014)
- High symptom burden: physical, psychological, social and spiritual concerns and emerging physical complications (e.g. bone density, cardiovascular, renal, liver, malignancies)
(Simms et al. 2011; Harding et al. 2010; Harding et al. 2011)
- Contribution of physical and mental health to HRQoL is current “*critical challenge*” in HIV medicine
(Buscher et al. 2010)
- UK outpatient attendees perceive care does not address issues of physical, mental & social wellbeing that matter
(Harding et al. 2008)
- Physical and psychological symptoms are assoc. with sexual risk taking, viral rebound, poorer adherence, and poorer self-rating of health
(Sherr et al. 2008; Harding et al. 2010; Lampe et al. 2010; Harding et al. 2012)

UK most prevalent (physical) n=778

Symptom	7 day prev	Level of distress (% whole sample)				
		<i>Not at all</i>	<i>Little bit</i>	<i>Some-what</i>	<i>Quite a bit</i>	<i>Very much</i>
Lack energy	70.8%	10.8%	19.8%	12.3%	12.1%	10.8%
Drowsy/ tired	67.5%	10.7%	19.8%	9.8%	12.3%	10%
Difficulty sleeping	61.8%	13.5%	10.9%	9.5%	12.1%	10.9%
Difficulty concentrating	60.7%	16.6%	15.2%	10.3%	9.1%	5.5%
Diarrhoea	53.6%	17.6%	12.6%	7.5%	7.5%	5.4%
Sexual activity	53.5%	15.7%	8.1%	6.6%	7.1%	12.2%
Pain	53.2%	18.0%	12.0%	5.9%	8.6%	5.4%

(Harding
et al. BMJ
STI 2010)

UK most prevalent (psychological)

	7 day period prev	Intensity			
		<i>Rarely</i>	<i>Occasionally</i>	<i>Frequently</i>	<i>Constantly</i>
Worried	69.9%	8.4%	25.4%	21.5%	9.1%
Sad	66.3%	11.8%	26.9%	16.7%	6.2%
Feeling irritable	56.6%	10.4%	22.4%	16.3%	4.2%

(Harding et al. BMJ STI 2010)

Quality of Life EUROQol 5-D

	N	%
	Quality of life A – Mobility	
1: I have no problems walking about	538	71.9
2: I have some problems walking about	207	27.7
3: I am confined to bed	3	0.4
	Quality of life B – Self-care	
1: I have no problems with self-care	608	81.3
2: I have some problems with self care	136	18.2
3: I am unable to wash or dress myself	4	0.5
	Quality of life C – Usual activities	
1: I have no problems performing my usual activities	464	62.5
2: I have some problems with performing usual activities	257	34.6
3: I am unable to perform my usual activities	21	2.8

(Harding et al.
BMJ STI 2010)

Quality of Life EUROQol 5-D

	N	%
Quality of Life D- Pain/discomfort		
1: I have no pain or discomfort	413	55.7
2: I have moderate pain or discomfort	287	38.7
3: I have extreme pain or discomfort	42	5.7
Quality of Life E- Anxiety/ Depression		
1: I am not anxious or depressed	312	41.9
2: I am moderately anxious or depressed	355	47.7
3: I am extremely anxious or depressed	78	10.5

(Harding et al.
BMJ STI 2010)

EUROQoL VAS

Scale 0-100	N	%
	Quality of life F – General health	
0-25	21	2.8
26-50	181	24.4
51-75	239	32.2
76-100	300	40.5

(Harding et al
BMJ STI 2010)

Conceptual approaches: 'health' & 'quality of life'

- *“Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”* WHO 1948
- *“Health-related quality of life is an assessment of how the individual's well-being may be affected over time by a disease, disability or disorder”* CDC

Background: Patient Reported Outcome Measures (PROMs) in HIV

- Recognised need for person centred care for PLWH

(Engelhard et al. 2017; Boyd et al. 2014)

- HIV practitioners often miss patients' needs and symptoms, especially non-physical ones

(Justice et al. 2001)

- Routine use of PROMs helps identify problems/concerns & improves outcomes for patients

Greenhalgh et al. 2009; Boyce & Brown 2013)

- NHS policy drive for PROM use and PLWH & clinicians have requested a PROM

(Platt et al. 2014)

- PROMS are used in clinical trials, but not in routine HIV care

(Simpson et al. 2013)

- HIV PROMs available for single dimension outcomes (eg. depression, stigma, adherence)

(Simpson et al 2013)

- No brief, person-centred PROM that reflects the range of outcomes relevant for PLWH to drive and evaluate care

(PROM Group 2010)

Aims

- Determine the priorities of adults living with HIV in terms of measurement of outcomes from their NHS care
- Develop a patient-reported outcome measure (PROM)
- Establish how the novel PROM should be implemented to improve the person-centredness of healthcare and maximise benefit for PLWH, clinicians and commissioners

Design

Observational qualitative study following the COSMIN taxonomy and guidance for relevance, comprehensiveness and comprehension of PROMs, and Rothrock guidance on the development of a valid PROM

(Mokkink et al. 2010; Terwee et al. 2018; Rothrock et al. 2011)

Methods

Gather Input

Qualitative interviews with key stakeholders to establish face & content validity

- PLWH (n=28)
- HIV Professionals (n=21)
- HIV Commissioners (n=8)

Conceptual model and item generation

Analysed using thematic & framework analysis comparing within & across groups

Existing literature & interview finding were used to:

- define the concepts (priorities or concerns) for PLWH
- inform a conceptual model (key domains for inclusion within HIV PROM)
- inform item generation (individual items within each domain)

Item generation meeting where items were selected & refined

- PLWH (n=4)
- health services researchers (n=4)
- HIV professionals (n=5)

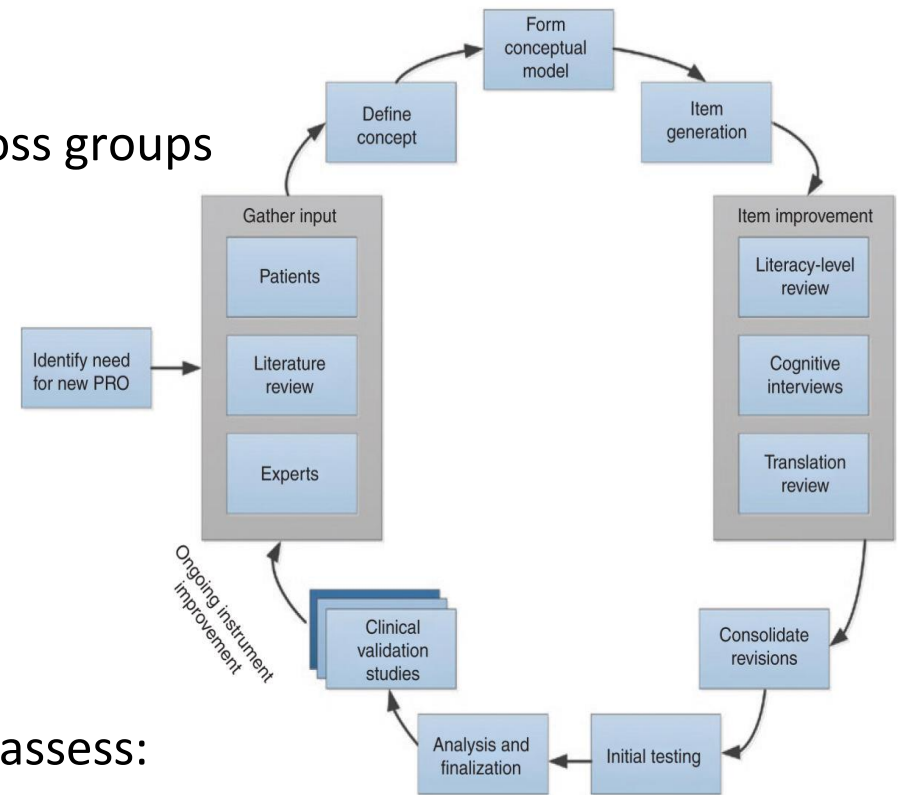
Second round of revisions to refine items

Item improvement

Cognitive interviews with maximum variation sample of PLWH (n=6) to assess:

- acceptability and accessibility of the format and structure
- interpretation of items
- how responses are formulated
- whether any key concepts have been missed

PROM refined further informed by findings from cognitive interviews



(Rothrock et al. 2011)

Phases

Phase 1: In depth qualitative interviews with key stakeholders to inform PROM content

Phase 2: Generate pool of potential PROM items

Phase 3: Cognitive interviews and finalise PROM

Phase 4: Validation of PROM

Results: sample characteristics

PLWH (n=28)

- Male (n=14), female (n=14)
- Gay (n=10), Hetero. (n=17), Bisexual (n=1)
- White British (n=12), White Irish (n=8), Black African, Black Caribbean or Black British (n=8)
- Single (n=14), in relationship (n=14)
- Median age 45.5 (range 23-81)
- Diagnosis <5 years ago (n=7), 6-15 yrs (n=5), 16-20 yrs (n=9), over 20 yrs (n=7)
- Comorbidities: none (n=3), 1-2 (n=12), 3 or more (n=13)
- Median duration 53.5m (range 13-111)

HIV Professionals (n=21)

- Doctors (n=7 - consultants, registrars, clinical fellow)
- Nurses (n=7 - clinic, community, research)
- AHSPs (n=7 - welfare officer, psychologist, physiotherapist, phlebotomist, dietitian, pharmacist x 2)
- Male (n=8), female (n=13)
- Median duration 55m (range 13-84)

Commissioners (n=8)

- NHS (n=4) & Local Authority (n=4)
- Male (n=3), female (n=5)
- London (n=4), out of London (n=4)
- Prevalence: very high (n=2), high/very high (n=3), low-very high (n=3)
- Median duration 57m (range 38-69)

Results: findings

- Participants described **diverse** but **interrelated** problems and concerns
- Priority areas for inclusion within the PROM emerged under six domains:
 - **Physical**
 - **Cognitive**
 - **Psychological**
 - **Welfare**
 - **Social**
 - **Information needs**
- Participants requested inclusion of:
 - **global assessment** of wellbeing
 - **freetext** opportunities

Results: benefits of HIV PROM

For PLWH:

- Enable **patient centeredness** and **empower** PLWH
- Help PLWH **raise concerns**, and **feel heard** and **valued**, and **share sensitive information**
- Help PLWHIV to build **resilience** and **self confidence**
- Encourage **referrals** for additional **support**
- Reduce **assumptions**, establish an **individual baseline** and monitor **changes over time**
- Help get to know **new patients**
- Go **beyond adherence and viral load**

For services:

- Tailor service to **specific needs** of population
- Understand **changing picture** of HIV
- Improve **efficiency** and reduce inappropriate service use
- **Reassure** and **build confidence** in clinicians
- **Justify** current spending

Results: challenges of HIV PROM

- **Heterogeneity** of HIV population
- Heterogeneity of need depending on **time since diagnosis**
- **Literacy**
- Utility for those who struggle to **engage** Highlighting symptoms **may cause anxiety**
- Asking about areas that we **cannot help with**
- Data **must be used** – not 'tick box exercise'

Phases

Phase 1: In depth qualitative interviews with key stakeholders to inform PROM content

Phase 2: Generate pool of potential PROM items

Phase 3: Cognitive interviews and finalise PROM

Phase 4: Validation of PROM

Phase 2: PROM Item Generation

- Framework analysis of data
- Findings reviewed at item generation meeting
 - people living with HIV, clinicians, academics with expertise in psychometrics
- Item selection with reference to the UK literature on needs and experiences of HIV care
- The process ensures pool of items represents the expressed priority patient-reported outcomes of PLWHIV, their clinicians, and those outcomes deemed most important to commissioners
- PROM content, design and length informed by interviews

Positive Outcomes HIV PROM

- 23 item person-centred PROM developed
- Items across the 6 domains of need described by PLWH:
 - Physical, Cognitive, Psychological, Welfare, Social, and Information needs
- Includes single item for **global assessment** of wellbeing
- Includes a **freetext** option to list main problems and concerns
- Example question:

5. Over the past 4 weeks, how much have you been affected by **stomach or bowel problems**? *This could include sickness, diarrhoea, bloating, feeling sick or other stomach or bowel problems*

Not at all	Slightly	Moderately	Severely	Overwhelmingly
<input type="checkbox"/> ⁰	<input type="checkbox"/> ¹	<input type="checkbox"/> ²	<input type="checkbox"/> ³	<input type="checkbox"/> ⁴

Phases:

Phase 1: In depth qualitative interviews with key stakeholders to inform PROM content

Phase 2: Generate pool of potential PROM items

Phase 3: Cognitive interviews and finalise PROM

Phase 4: Validation of PROM

Cognitive interviews (n=6)

Cognitive interviews undertaken (think aloud and verbal probing) with maximum variation sample of PLWH (n=6) to assess:

- acceptability and accessibility of the format and structure
- interpretation of items
- how responses are formulated
- whether any key concepts have been missed

E.g. Question asking about:

- 'social support' changed to 'support from people around you'
- 'immigration' changed to 'immigration status'

Following the cognitive interviews the PROM content and structure was finalised.

Summary

- PLWH and HIV Professionals have requested an **HIV specific PROM** that reflects the **range of outcomes for PLWH**
- Participants welcomed the development of a new HIV PROM to **drive, evaluate and improve care**
- A novel HIV specific person-centred PROM was developed from interviews with key stakeholders for **face and content validity**
- Development was informed by **Cosmin** taxonomy and guidance and followed **Rothrock** guidance on development of PROMs
- Next steps - further validation through project EmERGE

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