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A novel patient reported outcome measure for people living with HIV: development, face and content validity and stakeholder views on implementation

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Competing Interests

• No competing interests to declare
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 outpt. 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)
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)
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

“I think, living with HIV is a bit hard and tricky. Sometimes, you just feel down, you feel lethargic, tired. The aches and pains in your body, physical... Yes, so it's all physical, mental... Most of the people I talk to kind of feel the same. Especially with lethargy and tiredness, low mood... Yes, I know everyone gets stressed and depressed, but if you are on the medication, it's a different feeling that you're feeling in your body... Sometimes, it's the time. If you take them late, which means in the day time, you still have the hangover effect. That's the difficult bit. You just move, but you still have the kind of hangover... Sometimes, for me, I get foggy and forgetful, muddled. Like, I was going to college. I stopped going to college because I could hear the teacher talking, but I couldn't process what she was saying or what was going on. It was just useless for me to keep going to college.” PLWH: 5
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

“Undoubtedly HIV has an impact on the psychological status of the individual. And so many people will require a greater level of support than others. So yes, it is a key early indicator, and it could help the clinicians identify the need in the patients, but it could also help the commissioner identify the need of either developing pathways between clinical care and psychological and mental health care...The single tool needs to be voiced in a way that it is relevant for people at different stages of their disease pathway. So it needs to be sensitive enough and... It is complex. It is not “flexible”, the word I am trying to find, but it needs to, it needs to relate to people at different stages.”

HIV Commissioner: 3
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’

HIV Professional: 7: “I suppose it might make the **consultation longer**, because it might bring up **things that haven’t been discussed before**, but hopefully that will be **worth investing that time**. If there are **things that are out of our hands**, that would be frustrating. I wouldn’t want to **give false hope** that you can tell us these things and we can cure or whatever.”

Interviewer: “Yes, opening a can of worms?”

HIV Professional: 7: “Yes. Yes, but **it’s better to open it, have a look inside and check it and see what you can do.**”

HIV Professional: 7
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*

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• PROM was refined following cognitive interviews PLWH (n=6)
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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Positive Outcomes Project Steering Group:

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References

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