An overview of patient-reported outcome measures

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Patient-reported outcomes, an overview

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Conflict of Interest

Speaking fees from MSD, Gilead, ViiV

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GREAT NEWS, YOU ARE “UNDETECTABLE”, YOU’RE RESPONDING WELL TO THE ANTIRETROVIRAL THERAPY THAT WE PRESCRIBED.

BUT THIS DIAGNOSIS HAS AFFECTED MY WHOLE LIFE.

I AM HAVING TROUBLE SLEEPING...

I FEEL TIRED, I KEEP GETTING THESE HEADACHES...
*What is the matter with you?*

*v**ersus*

*What matters to you?*

Patient-reported outcome measures (PROMs) are tools which help us determine what matters to individuals in care.
Patient-reported outcomes (PRO)

« any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else »

- Food and Drug Administration (FDA)

Patient-reported outcome measure (PROM)

• Standardized questionnaires or instruments designed to assess patient-reported outcomes

• Completed by the patient

• Provide valuable information about the patient's experience of their condition (e.g. symptoms, functioning, quality of life, and other aspects of their health)

• Used to
  • improve patient-physician communication
  • monitor patient outcomes
  • guide clinical decision-making
  • enhance patient-centered research and care

Devlin NJ, Appleby J. Getting the most out of PROMs: Putting health outcomes at the heart of NHS decision-making. The King's Fund; 2010.
An origins story...

1920: Assess symptoms in tuberculosis patients (St. George's Respiratory Questionnaire and the Tuberculosis Symptoms Index)

1950: RAND-36 Health Survey, a precursor to the widely used Short Form-36 (SF-36) questionnaire, was developed.

1980/90: PROMs explosion!

2000: PROMs used in clinical trials and healthcare quality improvement initiatives.
Development of guidelines for the selection, administration, and interpretation of PROMs in clinical research and practice.
Types of PROMs & applications

• Generic versus (disease) specific?
  • broad aspects of quality of life, health status versus unique concerns specific to a disease/condition
  • applicable to all populations versus to a specific disease/condition, sensitive to changes
  • specificity, depth
  • not mutually-exclusive

• Applications: clinical trial, clinical practice, quality improvement
What makes a good PROM?

- Relevance
- Reliability
- Validity
- Responsiveness
- Interpretability
- Feasibility / Acceptability
- Equitable/Inclusive

PROMs for HIV?

• **Good news**, we have options!
  • 117 HIV-specific PROMs identified *Engler, Lessard et al. 2017*
  • 9 generic and 7 HIV-specific *health-related quality* of life PROMs *Cooper et al., 2017*
  • Newer instruments reflecting needs and priorities of people with HIV in the treat-all-era (e.g. Positive Voices (UK)) *Harding et al. 2021*
  • Conducive environment: instruments, advances in measurement, technology, stakeholder motivation

• **Bad News**
  • Absence of a “gold standard” in terms of PROMs for quality of life
  • Choice of the scale is a function of specific research question and end use
  • Poor practices (selection, reporting, etc.)
  • Relevance?
Final thoughts

• Why were they developed?
• When were they developed?
• What is clinically meaningful change in people living with HIV who are maintained on treatment?
  • Should we be thinking about “clinically meaningful change” differently now that HIV is a chronic condition?
• How do we validate new instruments in populations where fewer and fewer people are expected to experience advanced disease (AIDS) yet still consider them “disease-specific”?
• Do we still need HIV-specific instruments?
Thank you for your attention