

Fewer side effects, better treatment. The PROMise of patient-reported outcomes: The role of the community in the development and implementation of PROMs.

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Purpose:

To describe the current use of patient-reported outcome measures (PROMs) in HIV research and development and to inform an advocacy agenda to guide the use and development of PROMs, highlighting the role of communities living with or affected by HIV in this agenda.

Literature Review:

PROMs—or patient-reported outcomes measures—provide understanding into how people feel about their health and wellbeing. PROMs can be used to check on a person's outlook into their quality of life or they can prompt responses to their experiences with their treatment or health services. PROMs that measure people's quality of life provide important information regarding their experience with HIV treatment over time, including how other non-HIV-related issues impact their daily lives, covering issues such as stigma, depression, anxiety, sleep disturbances, and other problems. Chronic treatment for HIV is safe and effective but the question remains whether or not better drugs can address some of the outstanding issues that people living with HIV face on a daily basis. PROMs might be useful to help distinguish new medicines in the future and this research looked into whether or not this would be possible.

Survey Results:

EATG distributed a survey in November and December 2020 in English and Russian. A diverse group of 96 people living with HIV on treatment from 26 countries responded. The survey asked two main questions: (1) what disturbances (side effects) you currently experience with treatment and (2) what kind of improvements you would like to see in treatment in the future. Key takeaway/conclusion: Among the large range of side effects that need to be improved and the lack of clear preference for one type of future treatment improvement, it will be difficult for PROMs to drive future medicines development in one particular direction. However, PROMs can help to identify the range of possibilities for improving treatment in the future.

Stakeholder Input:

EATG spoke to several groups of stakeholders, including Academic Advisors to this project, Clinicians, Pharmaceutical Companies and Health Technology Assessment agencies (HTAs). While many important nuances exist within and across groups, the following main points were found:

- PROMs might become useful primary endpoints for medicines research and development trials in the future but, for the time being, PROMs are used primarily as secondary or exploratory endpoints.
- Challenges in using PROMs include the short timelines of medicines research and development trials, the homogeneity of trial participants and the difficulty to attribute some patient reported outcomes to a specific treatment arm of a trial.
- PROMs need to be linked to clinical outcomes in order to become meaningful to decision makers, including regulatory bodies and HTAs.

Role of People Living with HIV:

People living with HIV should be involved in all aspects of PROMs development from identification of a conceptual model, to development of the design of the measurement tool (including validation), to implementation of the PROM and analysis of the results. "Nothing about us without us" is the mantra for GIPA and this should also be applied to HIV-specific PROM development.

Involvement in PROMs

Driving Force
Co-creator
Adviser
Reviewer
Information

Greater Involvement of People Living with HIV

Decision Makers
Experts
Implementers
Speakers
Contributors
Target Audiences

Recommendations:

People living with HIV:

- Organisations working on behalf of people living with HIV should build capacity for people to understand the importance of PROMs and to advocate that people living with HIV be involved in all aspects of PROMs development and implementation.
- More work needs to be done to identify the outstanding needs of people living with HIV with respect to their treatment, health and wellbeing and to link these with future medicine development.

Pharmaceutical companies:

- Ensure that only relevant PROMs are included in their research and development and that, when used, PROMs should be developed and implemented in collaboration with people living with HIV.
- Work should be done to identify PROMs that are sensitive to short trial timelines and relevant to the outcomes that are important to people living with HIV.
- Continue to work with clinicians and people living with HIV to identify ways that PROMs can influence practice guidance after-market authorisation.

Researchers and Clinicians:

- Continue research into PROMs that are relevant for clinical research as well as clinical practice, looking for PROMs that are sensitive to shorter timeframes and allow for better attribution to treatment arms.
- Find ways to use PROMs to connect psychosocial and emotional issues that people living with HIV experience to the continuum of care in order to show the value of addressing the people's overall health and wellbeing, as well as their virological outcome.
- Find innovative ways to collect and analyse data in order to develop algorithms to inform clinical care and the development of new medicines.

Regulatory bodies and HTAs:

- Regulatory bodies should develop better guidance that addresses labelling as a result of the use of PROMs in HIV research and development.
- Enter into dialogue with people living with HIV and pharmaceutical companies to understand people's long-term needs and how these relate to the development of products that will ultimately improve clinical results and save money.