Everyone Should Be Invited to the PROM: Diversifying Patient Reported Outcome Measures for LGBTQ+ Inclusion

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Introduction

> Patient characteristics such as biological sex, race, ethnicity, and age are increasingly recognized as important to consider in clinical research, including by regulatory agencies such as the US FDA.[1]
> However, there appears to be little evidence of explicit consideration of **LGBTQ+** (here defined as lesbian, gay, bisexual, transgender, queer/questioning and individuals who identify with this community) perspectives in clinical research.
> Patient Reported Outcome (PRO) measure selection and development is a key area of study design where patient characteristics must be considered.
> PRO measures must be appropriate for their context of use and to achieve this, item language and concepts assessed must be inclusive of all individuals who may complete such measures.

Objectives

> The objectives of this poster are to evoke initial discussion on:
- Some implications of excluding **LGBTQ+** perspectives from PRO measure selection and development,
- Strategies for incorporating **LGBTQ+** perspectives,
- Challenges to engaging the **LGBTQ+** community in Health-Related Quality of Life (HRQoL) research.

Implications of excluding LGBTQ+ perspectives from PRO measure selection and development

> **Excluding LGBTQ+ community perspectives can negatively impact the validity of PRO measures, for example:**

✗ Heteronormative or cis-gendered assumptions being embedded into item wording, especially items that assess HRQoL concepts such as impacted sexual functioning and relationships, body image, and family relationships/dynamics.

> **Including PRO measures in clinical research with inappropriate wording and/or response options could result in missing, inaccurate or incomplete data, for example:**

✗ Not using inclusive item wording and/or appropriate response options (e.g. 'not applicable') to ensure that the item can be completed by all respondents regardless of their physical/social/sexual circumstances; thus, resulting in these individuals being unable to answer items appropriately or accurately.

✗ Items not assessing or fully assessing concepts that are relevant or important to **LGBTQ+** patient experience; thus, resulting in data that is incomplete or does not provide an accurate presentation of the subjective disease experience.

> **Excluding LGBTQ+ perspectives from this area of research has the wider implication of perpetuating LGBTQ+ community exclusion from healthcare and healthcare research more generally.** Furthermore, disparities in health outcomes is increasingly being documented. This historical context and persisting barriers to **LGBTQ+** patient participation in research and their wider implications must be acknowledged in any inclusion strategies.

Strategies for LGBTQ+ inclusion in PRO measure selection and development

✓ **Study design**
- Directly involve members of **LGBTQ+** community in decision making around study design and as researchers when selecting/developing PRO measures to ensure **LGBTQ+** perspectives are considered.
- Develop patient-facing research materials that are appropriate and serve to reduce the barriers to **LGBTQ+** participation in research by avoiding heteronormative or cis-gendered assumptions and using additive language (e.g. 'men and people with a prostate'). *Always carefully consider potential unintended consequences.*

✓ **Data collection**
- Include **LGBTQ+** individuals as study participants in interview studies supporting PRO measure selection/development, especially where the disease experience may differ from that of cis-gendered or heterosexual individuals, but also when the disease experience is not expected to differ.
- When possible and appropriate, explicitly capture and report **LGBTQ+** factors in sample characteristics (recognizing that **LGBTQ+** status disclosure can be a barrier to research participation).

✓ **Instrument evaluation & item development**
- Assess instruments for their appropriateness in diverse populations. Take care when drafting item wording to avoid embedding heteronormative or cis-gendered assumptions.

✓ **Researchers**
- Educate researchers and stakeholders on **LGBTQ+** inclusion utilising resources from advocate groups.

Next steps

> This is intended to prompt discussion on the importance of including **LGBTQ+** individuals in clinical research, focusing specifically on PRO selection and development as one aspect of clinical research design.
> Only through such discussions can recommendations be developed to guide researchers on how best to engage marginalized groups, such as the **LGBTQ+** community in HRQoL research.
> The **LGBTQ+** community and all marginalised groups warrant discussions and tailored considerations around PRO development and selection, and other aspects of clinical research design (e.g. clinical trials).

Key reference

1.US Food and Drug Administration. Enhancing the diversity of clinical trial populations-eligibility criteria, enrollment practices, and trial designs guidance for industry. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial. Published 2020.

Virtual ISPOR Europe, 30th November – 3rd December 2021