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Engaging stakeholders into an electronic patient-reported outcome development study: On making an HIV-specific e-PRO patient-centered

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Abstract

Background: The use of patient-reported outcome (PRO) measures in care and research is proposed to foster patient-centered care but this outcome may depend on stakeholder engagement in their development and implementation. Hence, we subsequently engaged HIV patients and clinicians into a study aimed at creating a new electronic PRO (e-PRO) for monitoring barriers to antiretroviral therapy adherence in HIV care. As detailed examples of such engagement are lacking, we describe our rationale, methods and first results of these engagement initiatives.

Methods: We established a 10-member patient committee. Periodic focus groups engaged HIV clinicians. Focus groups were conducted with both groups to assess needs for the e-PRO: 3 mainly with patient committee members ($n=12$) and 5 with clinicians ($n=31$). Content on the e-PRO's targeted concept (adherence barriers) was analysed with Grounded Theory (patients) and with typological analysis (clinicians).

Results: Patients' discussions reflected three temporal categories (imprinting, domino effects, future-shadowing) and one overarching theme (weathering) in the experience of adherence and its many barriers. Latent within HIV clinicians' discussions was a typology of patients organized by distinct barriers to adherence, life conditions, and attitudes to care.

Discussion: Results emphasize the lived experience of managing barriers and its complexity. They suggest the new e-PRO should accommodate patient diversity, contextualize scores longitudinally, and address the personal significance of individual barriers (e.g., distressfulness)

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beyond their mere presence. These initial results and the opportunities presented by our long-term engagement initiatives should ensure the production of a useful and used patient-centered e-PRO.

Introduction

Infection with the human immunodeficiency virus (HIV) is now recognized as a chronic condition, given the availability of many potent antiretroviral drug regimens that can efficiently suppress the virus, stabilizing biological markers of infectiousness and immune function (e.g., sustaining an undetectable HIV viral load and a high CD4 T cell count), and reducing the risks of disease progression and secondary transmission [1]. Nevertheless, challenges remain. Taking antiretroviral therapy (ART) for HIV as prescribed (adherence) is essential to its efficacy but many on ART experience difficulties with adherence [2]. The proportion of people with HIV on ART with detectable viral loads is not insignificant, nationally estimated at 10% in the United Kingdom [3] and 20% in the United States [1], which might approximate the situation in Canada [4]. Barriers to adherence are numerous, complex and vary from patient to patient and over time [5]. Examples include features of the treatment regimen, beliefs about medication, lifestyle, patient-provider relationship, and socio-economic factors [5]. In practice, studies demonstrate that many clinicians incorrectly estimate HIV patients' adherence and that barriers to ART adherence can be inadequately addressed during consultations [6-9]. Adherence to ART is difficult to assess, for many reasons, and, in current HIV clinical practice, biomedical markers (e.g., viral load and CD4 cell count) are often used as proxies for adherence and therapeutic success [10]. However, these markers have limitations for capturing not only adherence but the effects of non-adherence and treatment on patients. For example, among virally suppressed patients, suboptimal adherence is a predictor of viral rebound [11] and associated with higher inflammation [12] which argues for attending to ART adherence, irrespective of a patient's viral load. Biomedical markers also supply no information on patients' subjective experience of ART-taking. Such input from patients is highly relevant to meeting key recommendations within clinical care guidelines for HIV [13], such as to tailor ART "for the individual patient," to help ensure a patient's "quality of survival", and to identify "those with adherence-related challenges" and "reasons for nonadherence." Another disadvantage of biomedical markers is that they offer little opportunity for preventive action.

A more patient-centered orientation to HIV care and research could help address these issues, according greater attention to patients' values, preferences and needs. The integration of a new monitoring tool based on patients' perceived ART adherence barriers into routine HIV care as an adjunct marker of therapeutic success and of patients' experience of ART could help address the above limitations and contribute to ensuring that potential adherence problems are identified and addressed in a timely fashion, before they impact biomedical markers. Doing so could not only help signal when an ART regimen is a poor match for a given patient, for instance, but may also help identify and lead to the care of co-morbidities associated with non-adherence to ART, such as depression and substance abuse [13].

In individual clinical encounters, patient-reported outcome (PRO) measures are deemed useful for screening for previously undetected problems, monitoring how treatments are working for patients, and encouraging more patient-centered care [14]. Currently, while PROs are used in HIV research, they are little applied and investigated as a component of HIV clinical practice [15] and thus seem to be an underused resource in this regard. While HIV-specific PROs assess a wide variety of constructs, a review we completed indicates that none comprehensively addresses reasons for non-adherence among patients [16]. Hence, in response to the above concerns, we sought to create such a tool for electronic administration. Having patients complete the PRO electronically carries many advantages. These include the fact that electronic PROs avoid data entry errors, provide immediate access to data, allow for trigger alerts or notifications, decrease missing data when compared to paper-based PRO administration, and increase patients' ease to provide sensitive information [17]. Electronic administration also allows for adaptations to patients with special needs, such as poor literacy, and increases options for rapidly presenting results in a form that is useful and user-friendly to providers and patients. Furthermore, as a health monitoring tool, electronic administration of the PRO is consistent with the move of Canada and other countries towards electronic health records. The PRO's digital application could be designed to contribute information for a patient's personal health record and/or integration within a patient's existing institution-specific electronic medical record. Hence, the efficiency of the PRO data's storage, sharing, retrieval and use for health-related purposes could be enhanced.

Our study, which is in its early stages, is based on an exploratory mixed methods (qualitative and quantitative) design– instrument development variant [18] and involves the participation of 10 clinical sites located across Canada and France (The I-Score Study, clinicaltrials.gov identifier: NCT02586584). While our PRO is intended for use in HIV practice in the Canadian and European clinical settings represented, our methods were originally selected to meet the US Government's recommendations to industry for PRO development by the Food and Drug Administration [19]. The objective of this paper is not, however, to fully detail the methods of this study. It is rather to present why and how we later supplemented them with stakeholder engagement activities for greater patient-centeredness, given potential

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