

Feasibility of an Electronic Patient-Reported Outcome System in People Living With HIV: Retrospective Analysis of a Mobile App-Based Pilot Study

Yusuke Yoshino, Yoshitaka Kimura, Yoshitaka Wakabayashi, Takatoshi Kitazawa

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Yusuke Yoshino^{1,2} MD, PhD; Yoshitaka Kimura¹ MD, PhD; Yoshitaka Wakabayashi² MD, PhD; Takatoshi Kitazawa² MD, PhD

¹Department of Microbiology School of Medicine Teikyo University Tokyo JP

²Infectious Disease Group Internal Medicine Teikyo University Hospital Tokyo JP

Corresponding Author:

Yusuke Yoshino MD, PhD
Department of Microbiology
School of Medicine
Teikyo University
2-11-1
Tokyo
JP

Abstract

Patient-reported outcomes (PROs) are used to enhance patient-centered care. We developed an electronic patient-reported outcome (ePRO) system as a cell phone application for home use and tested its feasibility and usefulness. Patients completed PROs via the application before appointments, with clinicians reviewing responses. A post-use questionnaire assessed clarity, response time, and clinician communication improvement. Most patients completed the questionnaire in under five minutes and reported high satisfaction. The ePRO helped identify new health issues, leading to further medical interventions. Overall, ePRO proved valuable for enhancing patient care among people living with HIV, improving clinical communication and medical records.

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Original Manuscript

Feasibility of an Electronic Patient-Reported Outcome System in People Living With HIV: Retrospective Analysis of a Mobile App-Based Pilot Study

Yusuke Yoshino^{1,2} M.D., Ph.D., yyoshino@med.teikyo-u.ac.jp

Yoshitaka Kimura¹ M.D., Ph.D., yo.kimura.july@med.teikyo-u.ac.jp

Yoshitaka Wakabayashi² M.D., Ph.D., wakabayashi-tky@med.teikyo-u.ac.jp

Takatoshi Kitazawa² M.D., Ph.D., tkitazaw@med.teikyo-u.ac.jp

¹ Department of Microbiology and Immunology, Teikyo University School of Medicine

² Teikyo University Hospital, Department of Internal Medicine, Infectious Disease Group

Correspondence

Yusuke Yoshino, M.D., Ph.D.

Department of Microbiology and Immunology, Teikyo University School of Medicine

2-11-1 Kaga, Itabashi-ku, Tokyo 173-8606, Japan

Telephone: +81-3-3964-1211 (Ext 7731)

Fax: +81-3-3579-6310

E-mail: yyoshino@med.teikyo-u.ac.jp

Abstract

Background:

Advances in antiretroviral therapy have transformed HIV into a manageable chronic condition, allowing people living with HIV (PLWH) to live longer. However, with aging, PLWH face increased risks of lifestyle-related diseases and unaddressed psychosocial issues, including stigma, discrimination, and mental health concerns. Patient-reported outcomes (PROs) are essential tools in

person-centered care and have demonstrated clinical utility in oncology and rheumatology, yet remain underutilized in infectious disease settings. Recently, the European AIDS Clinical Society has recommended electronic PRO (ePRO) systems to support HIV care. This study aimed to evaluate the feasibility and clinical utility of a smartphone-based ePRO system specifically developed for PLWH in Japan.

Methods:

A retrospective study was conducted among PLWH who attended the HIV outpatient clinic at Teikyo University Hospital between July and September 2022. Participants who consented to use the ePRO system installed a smartphone application and completed the HIV Symptom Index prior to their clinic visit. Physicians reviewed the responses during consultations. Following the visits, patients completed a usability survey addressing clarity, response time, satisfaction, communication quality, and intention for future use. Medical records were reviewed to determine whether any new symptoms, findings, or medical actions had been added that had not been documented in the previous two years.

Results:

A total of 27 PLWH (median age 46 years, 100% male) used the ePRO app, and 25 (93%) completed the post-use questionnaire. Of these, 19 (76%) completed the symptom index within 5 minutes, while one participant took more than 15 minutes. Regarding usability, 76% reported being satisfied or very satisfied, and 76% found the system useful in improving communication with their provider. Additionally, 76% expressed willingness to use the system again, while five indicated interest only if improvements were made. Medical record analysis revealed that 17 patients (63%) had new clinical information documented, including mental health symptoms (n=7), skin problems (n=7), and new diagnoses or treatment changes in 6 cases. Over 40% of patients reported issues such as anxiety, insomnia, dermatologic symptoms, or concerns related to body image.

Conclusions:

This pilot study demonstrated that a smartphone-based ePRO system for PLWH is feasible and well accepted in real-world clinical practice. It facilitated early detection of psychosocial and physical issues that may otherwise be overlooked in routine care and improved patient-provider communication. The findings support the integration of ePRO systems into HIV care and underscore the need for further refinement of the app and prospective studies to assess long-term impact on patient outcomes and quality of care.

Keywords: Patient Reported Outcome, Cell phone application, Quality of life, Feasibility test

Introduction

Advances in human immunodeficiency virus (HIV) treatment have transformed HIV from an incurable to a survivable disease, requiring continuous use of therapeutic drugs to suppress the growth of the virus in the human body. However, while people living with HIV (PLWH) survive longer compared to decades ago, the risk of life-style diseases such as diabetes tend to increase when they age [1]. Additionally, social problems such as previous studies also showed that stigma and discrimination towards them had remained, which could lead psychological concerns [2]. Therefore, there is a growing demand for patient-centered medicine that transcends suppressing viral proliferation in the body. Patient-reported outcomes (PROs) are gaining attention as tools for person-centered care.

PROs are information obtained from patients' direct responses to a questionnaire. The validity of the questions has been evaluated in various studies, and PROs can measure many indicators, such as symptoms, functioning, health status, and quality of life (QOL) [3]. PROs can be of two types: disease-specific and those that can be reported by all patients regardless of the disease. Medical practitioners can select the appropriate PROs and use them for medical care and other purposes, such

as clinical studies.

PROs have been incorporated into clinical practice, especially for diseases that affect the patient's long-term QOL, and recently attracted attention in the field of malignancy. Some studies have revealed a gap between patients and providers regarding adverse reactions to the treatment of malignant tumors. It is widely recognized that evaluation centered on patients' opinions and thoughts is important for improving the health-related QOL (HRQOL) of patients with malignant tumors [4]. In the field of collagen disease, PROs are widely used for evaluating "pain," and consequently, they contribute to improving the quality of medical care and patients' HRQOL. Thus, PROs can be considered tools that improve the quality of medical care and support the practice of patient-centered medicine.

The usefulness of PROs has rarely been evaluated in the field of infectious diseases, especially acute ones, because many infectious diseases are acute and improve with short-term treatment. We investigated the potential of PROs in the field of infectious diseases using one of the PROs, which could measure the status of QOL, in cases of community-acquired influenza virus infection [5]. We evaluated changes in QOL after treatment of influenza virus infection with antiviral drugs. Mental QOL exacerbated during the course of the treatment. Furthermore, physical QOL remained relatively higher among vaccinated patients with influenza than among non-vaccinated patients with influenza [6].

These results led us to conclude that PROs may be useful in the treatment of PLWH for HIV infection, which has progressed to a point where it can be considered a chronic disease in recent years. In Europe and the U.S., PROs have been used in the field of HIV infection to evaluate treatment efficacy and adverse reactions in tertiary trials of therapeutic agents, and some experts

have confirmed that PROs improve HRQOL in PLWH based on their application in actual clinical practice.

An electronic patient-reported outcome (ePRO) system has recently been developed that allows patients' status to be determined in real time through questions that can be answered on a tablet or computer in an outpatient setting. This ePRO system has been recommended for use in the European AIDS Clinical Society guidelines 2023 [7]. Therefore, in 2022, we asked the Integrity Healthcare Corporation, with support from Gilead Sciences Inc., to develop an ePRO system as a cell phone application that could be answered at home. In this paper, we present the results of testing the feasibility of our prototype cell phone application, ePRO, and demonstrate its usefulness.

Methods

The results of a post-use questionnaire and the impact of the ePRO on actual clinical practice were evaluated retrospectively in outpatients who visited the Teikyo University Hospital, Tokyo, JAPAN between July and September 2022, agreed to use the ePRO, and used the ePRO during their actual visits. First, the participants were asked to install the newly developed cell phone application on their phones. Consent to use the application was obtained from all participants. Next, they responded to the PRO through the application in the week leading up to their next visit. During the visit, the clinician reviewed the PRO results and treated the participants. All PLWH who visited the clinic during the observation period were introduced to the app, and the results of those who agreed to use it on the same day were included in the analysis.

After the clinic visit, the PROs answered via the application were evaluated through a survey of questions concerning the clarity of content, time to answer, satisfaction with use, change in quality of communication with the clinician, and desire to use PROs in the future. Regarding satisfaction with

use, participants were asked to rate the following question on a five-point scale (very satisfied, satisfied, neutral, somewhat dissatisfied, dissatisfied): "How was your experience with the consultation after answering the HIV-SI via the app and sharing the results with your doctor in advance?" In addition, the contents of the medical records described during the consultation when the PRO was used were checked to see if there were any new symptoms or findings described that had not existed within the past two years, or if any new medical procedures had been added. The ePRO results were also summarized.

The ePRO employed the HIV symptom index as the content of its questions [8]. Specifically, 20 items, including those on physical findings, psychological problems, sexual activity, and body image, were rated on a five-point scale [(1) I did not have this symptom, (2) I was not bothered, (3) I was a little bothered, (4) I was indeed bothered, and (5) I was bothered a lot]. The content of the responses to the questions was available to the responsible physician immediately after the PLWH posted them on the Internet.

The number of participants (n) and corresponding percentages (%) are reported throughout the manuscript

Ethical considerations

This study was conducted in accordance with the Declaration of Helsinki and approved by the Teikyo University Ethics Committee (No. 23–009). Due to the retrospective nature of the study and the use of anonymized data, the requirement for written informed consent was waived. Instead, an opt-out method was used to inform patients about the study via the institution's website, providing them with the opportunity to decline participation. All data were fully anonymized prior to analysis, and no information that could identify individual participants was included. No financial

compensation or other incentives were provided to participants.

Results

Twenty-seven patients used the cell phone application in clinical practice. All patients were male, with a median age of 46 years. All patients had been on anti-retroviral treatment, had maintained a cluster of differentiation (CD) 4 positive lymphocyte count of more than 200/ μ L for the past six months, and had a viral load of less than 200 copies.

Twenty-five patients returned the post-use questionnaire. Nineteen of the 25 respondents (76%) answered that the time from the start of the application to the end of answering questions was 5 min, 5 person answered that it took approximately 5 to 10 minutes to answer the questions and only one person answered that it took more than 15 min. Regarding satisfaction with the use of the system, 19 patients (76%) were very satisfied or satisfied, five were neither satisfied nor dissatisfied, and one was somewhat dissatisfied. Regarding the degree to which the questionnaire helped with communication, 19 patients (76%) responded that it was very or mostly useful and six responded that it was neither useful nor useless. Regarding the intention to use the system in the future, 19 patients (76%) indicated that they would like to use it in the future, five indicated that they would like to use it if improvements were made or additional functions were added, and one indicated that they did not want to use it.

The results of the medical record review showed that 17 of the 27 patients (63%) had new information added to the medical records that had not been included in the previous two years. Of these, seven patients had mental health-related symptoms and seven reported skin problems. In addition, for six patients, the use of PRO led to additional medical treatment or other actions that had not been taken in the previous two years. A consultation with a dermatologist was reported by three

patients. In one patient, a complaint of respiratory symptoms led to the diagnosis of chronic obstructive pulmonary disease.

Regarding the content of the ePRO, more than 40% of the patients responded that they had some symptoms in the following categories: nervousness or anxiety, difficulty sleeping or shallow sleep, skin problems due to rash, dryness or itching, and changes in appearance due to fat gain or weight gain.

Discussion

This study demonstrated the feasibility and clinical utility of a newly developed electronic patient-reported outcome (ePRO) smartphone application for people living with HIV (PLWH). The system was well accepted by users, with the majority completing the questionnaire in under 5 minutes and reporting high satisfaction. The ePRO facilitated improved communication between patients and clinicians and led to the documentation of new clinical information in nearly two-thirds of the participants. These findings support the initial hypothesis that an ePRO system tailored for PLWH can enhance patient-centered care and aid in the identification of unrecognized clinical issues.

The short completion time and favorable user responses suggest that the app's design—featuring a reduced number of questions and simplified interface—contributed to its high acceptability. This aligns with prior studies emphasizing the importance of minimizing patient burden when implementing PRO tools in chronic disease management [3]. The enhanced documentation of mental and dermatological symptoms highlights how ePROs can uncover patient concerns that may be underreported during standard consultations. These findings are consistent with existing literature indicating that PROs improve health-related quality of life (HRQOL) by capturing subjective symptoms more effectively [9].

Of particular note is the identification of mental health issues, which are known to be prevalent

among PLWH but often go undiagnosed due to their subjective nature and the limited psychiatric training of many HIV care providers. Similarly, skin-related concerns—such as rashes or changes in appearance—are frequently underrecognized in routine care. The integration of ePROs appears to bridge this gap by allowing patients to express symptoms that may not surface through clinician-led interviews. Compared with prior studies using paper or tablet-based PROs, the use of a smartphone application offers increased accessibility and convenience, enabling real-time symptom reporting regardless of location. As smartphone penetration continues to rise globally, especially among younger generations, app-based ePROs hold promise for broader implementation in HIV care and beyond.

This study has several limitations. First, the sample size was small and limited to a single center, which may affect the generalizability of the findings. Second, the study design was retrospective and did not include a control group, precluding causal inferences. Third, only a single type of PRO (HIV Symptom Index) was used, and the applicability of other PRO tools remains to be explored. Additionally, while most participants expressed satisfaction, some noted the need for improvements, suggesting that app content and design could be further optimized. Finally, the duration of observation was short, and the long-term utility and sustainability of the system require further investigation.

The results of this study underscore the feasibility and clinical relevance of incorporating smartphone-based ePRO systems into HIV outpatient care. By enabling the identification of otherwise undocumented symptoms and improving communication between patients and providers, ePROs may contribute to more holistic and person-centered care models. These findings support the integration of digital health tools in HIV management and highlight the potential for ePROs to address unmet needs in clinical communication and symptom assessment. Future research should focus on refining the application, expanding its use to diverse patient populations, and evaluating long-term outcomes associated with routine ePRO implementation.

List of abbreviations

HIV: Human immunodeficiency virus

PLWH: People living with HIV

PRO: Patient-reported outcome

QOL: Quality of life

HRQOL: Health-related quality of life

ePRO: Electronic PRO

Declarations***Ethics approval and consent to participate***

This study was reviewed and approved by the Teikyo University Ethics Committee (No. 23–009).

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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No funding was received to assist with the preparation of this manuscript.

Authors' contributions

YY conceived the study design, collected and compiled the data, and drafted the manuscript. TK and YW were responsible for data collection. YK compiled the data. All authors have read and approved the final manuscript.

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Availability of data and materials

Raw data were generated at Teikyo University School of Medicine. The analyzed during the current study are available from the corresponding author on reasonable request.

Authors' information

YY is affiliated with the Japan AIDS Society and serves as a member of the International Cooperation Committee. YY also plays a pivotal role in introducing the use of patient-reported outcomes in Japan by drawing from experiences abroad.

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