The Impact of Implementing a Financial Incentive Program for Viral Suppression on the Clinic Environment: Findings from a Qualitative Sub-study of HPTN 065

RESULTS

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BACKGROUND

The HPTN O65 (TLC-Plus) study assessed the feasibility and effectiveness of providing quarterly \$70 financial incentives (FI) in the form of gift cards to HIV-infected patients on antiretroviral therapy (ART) who were able to achieve or maintain viral suppression (VS). VS was defined as HIV RNA<400 copies/mL. Nineteen participating sites in the Bronx, NY (BNY) and Washington, DC (DC) were randomized to the FI intervention and 20 sites were randomized to standard of care (SOC). A total of 39,359 FI gift cards were dispensed to patients with VS over 2 years at FI intervention sites. This qualitative sub-study was conducted for the purpose of exploring individual patient, provider and staff attitudes and experiences with the FI intervention. This sub-study complements the parent study, which will analyze the efficacy of the FI intervention using aggregate site-level data.

METHODS

The following qualitative data were collected by trained interviewers from diverse demographic backgrounds:

- Semi-structured in-depth interviews with 75 patients (aged 14-72) from 14 sites randomized to the FI intervention (all patients received at least 1 FI)
- Key informant interviews with 12 site investigators (SIs) [6 BNY, 6 DC] from 15 sites randomized to the FI intervention
- Three focus group discussions (FGDs) [6 BNY, 6 DC] with 12 site staff members representing 10 sites randomized to the FI intervention

All interviews were conducted in English, audio-recorded and transcribed. Transcripts were coded for major themes and analyzed in NVivo 10.0. Sub-themes related to implementation challenges and facilitators, descriptions of implementation, and experiences in giving and receiving FI were extracted and



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CHALLENGES EXPERIENCED BY SI AND STAFF

Timing of FI Provision The FI intervention was designed to be integrated into standard clinical care schedules for HIV management, which often include quarterly blood draws to monitor CD4 cell count and viral load (VL). As such, patients could qualify to receive FI as often as every 3 months, though some patients required less frequent monitoring. Despite these efforts to minimize disruption of care schedules, SIs and staff reported that the allowance of quarterly VL tests for FI qualification did not always align with clinical care, sometimes shifted the patients' priority to the FI, and resulted in busier clinics as patients adhered to appointments or visited more frequently.

The study calls for its own needs in terms of CD4 and viral load draws. And meanwhile clinical care has sometimes different demands. Meaning that providers might not always see the need to send the CD4 and viral load on a given date. But the patient feels that if they don't have CD4 and viral load done on those dates, they don't get their incentive card. So there's some times it led to conflicts between the study and the clinical care.

— Site Investigator-02, BNY

SIs saw this increased engagement in care as a benefit, but acknowledged that it also increased demands on staff time and space and interfered with clinic flow.

We experienced significantly higher patient volume because patients were showing up for their visits and also were wanting to be rescheduled every three months, whereas otherwise they might have begged and pleaded for four month visits or six month visits or even not have scheduled right away when they left the clinic at a previous appointment. So it was a challenge for us to deal with a steadier volume.

— Site Investigator-O1, BNY

Implementation Logistics Implementation of the FI intervention required determining patient eligibility and qualification for FI based on study criteria and VL results, disbursing gift cards to patients, monitoring and tracking gift card inventory, ensuring safe storage of gift cards, and tracking FI disbursement in paper forms and an electronic database. Study procedures were designed to be as streamlined as possible, ongoing training and support were provided, and sites were given the latitude to develop their own process of gift card distribution and staffing, but some SIs and staff noted an increased administrative burden, particularly in large hospitals or clinics with a high volume of patients.

I think that there were issues around the gift cards and making sure we kept them straight and making sure nothing got stolen. That was a big stress among the providers, and that we kept track of them properly..the operational issues were not without attention and some degree of vigilance.. it was an extra layer of activity on an already burdened system with inadequate staff to do it.

— Site Investigator-11, DC

Entitlement Staff, more so than SIs, had difficulty dealing with patients who felt "entitled" to receiving FIs or who would become upset upon learning that they did not qualify for an FI. (See posters A-671-0004-00774 and A-671-0005-00765).

Confidentiality Concerns Some sites integrated the FI intervention procedures into their usual patient registration processes involving front desk staff. A few staff noted confidentiality concerns within these contexts related to discussing eligibility for FIs in semi-private areas such as clinic waiting rooms.

We approach [patients] at the check-out desk. So you really don't want to use any language that is going to say they have HIV outright. So you're trying to use roundabout language to say, 'you're getting this gift card for taking care of yourself, adhering to your medication, and this is for looking at your result of your good blood work.' You're not really saying anything specifically but you want to be straight up and just tell them this, but you can't really.

— Staff, FGD-O3, DC

IMPLEMENTATION FACILITATORS

Systems and Processes While SIs and staff described challenges related to implementing the FI intervention, they also described a learning curve as processes were developed to improve logistics, clinic flow, and FI and patient tracking.

The way the cards were distributed to the patients changed over time, because first [the study coordinator] was just putting them all on my desk, and I'd be left carrying those cards from patient to patient.. because I was seeing several patients at once and they were not always HIV positive, I didn't want to carry a stack of credit cards with me into room after room. And what he started to do was just to clip the credit cards to the chart of the patient that was supposed to be getting it. That way when I picked up the chart I picked it up specifically for that patient and would bring it in. So, the way in which we got the cards to patients evolved over time. By the end of it, it was just going off seamlessly.

— Site Investigator-12, DC

Positive Patient Interactions SIs and staff generally expressed positive opinions of the FI intervention and indicated that the positive patient interactions they experienced due to the FIs helped to overcome implementation challenges or resistance to the program. (See poster A-671-0005-00765)

FI Program Support, Education, and Collaboration SIs and staff also described processes by which they sought to increase awareness of and buy-in for the FI intervention among other providers and staff, which facilitated integration of the FI program into standard of care procedures.

The doctor didn't want to schedule things around the gift card distribution.

But eventually when they realized how the program works and everything I think they were more careful in telling their patients, 'well find out when you can get your next gift card and then make your appointment at the front.' We definitely had a lot of support from the clerks that were out front also, often they knew the patients. So that also definitely helped with patients that gave trouble.. And we worked with the nurses too.. when they were talking to patients, doing patient education they would bring up the program.

— Staff, FGD-O2, BNY

Dedicated and Trained Staff Most SIs attributed smooth implementation to having well-trained and dedicated study staff.

I think that we were very fortunate to have the young ladies that we had work on our study here. And they did a great job. And I think they learned very much how to work with the flow of the clinic, work with the providers, and work with the patients so that it really became much smoother over time.

— Site Investigator-02, BNY

PATIENT PERSPECTIVE

While SIs and staff were keenly aware of the changes necessary to adapt to and integrate the FI intervention into their care process, the majority of patients, when asked, noticed no effect on their clinic experience due to the FI program beyond the added benefit of receiving the gift card.

- I don't think [the FI program] has [changed my experience], because, like I said, I never anticipated this program, and I never expected it to continue at long as it did. And now I am understanding that it has dissolved, it doesn't change the fact that since I've been here, the services have been very good. It hasn't been perfect, nobody is. But it's been good, it's convenient, it's right across the street from where I live, I'm in and out, I've come to know staff, and the staff knows me.

 So I'm comfortable here. Patient, non-Hispanic mixed race male, 49 years old, BNY
- [The FI program] made the visit a little bit more .. I would say happier.. Every three months when I would come in, I knew that, for the most part, I was going to get a gift card based on my lab results, because I know my history, my health history, and I know that everything's pretty much on point.

 Patient, non-Hispanic black male, 34 years old, DC

CONCLUSION

Implementing the FI intervention posed some challenges for providers and staff; primarily:

- Integrating the quarterly FI schedule into the standard clinical care schedule for HIV management.
- Increased patient volume, as well as demands on staff time and space.
- Adapting to logistical and administrative processes required for managing the FI program.
- Dealing with difficult or demanding patients.
- Ensuring the confidentiality of patients while explaining the FI program to them.

However, SIs and staff noted several strategies used to mitigate implementation challenges; notably:

- Developing systems and processes over time to improve logistics, clinic flow, and patient tracking.
- Recognizing the positive benefits afforded to patients by the FI program and experiencing positive patient interactions.
- Educating patients and other providers and staff about the FI program and its requirements.
- Relying on trained and dedicated study staff to lead FI program implementation.

The positive experiences and strategies used to overcome challenges facilitated eventual smooth implementation of the FI intervention without patients' perceiving any negative effects on their clinical care experiences. While the efficacy of the FI intervention remains to be determined through the assessment of the primary HPTN O65 study data, these qualitative results provide encouraging evidence as to the feasibility of implementing a large scale FI program in a clinical setting.

Additional findings from this sub-study are presented in the following three posters: A-671-0004-00749; A-671-0005-00765; A-671-0004-00774.

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