Pilot Program of Shared Assistance with Primary Care in Patients Living with HIV, and Satisfaction with The Healthcare Received

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Abstract

Background: There are few shared assistance programs with Primary Health Care (PHC) in PLWH. The aim was to develop a Pilot Program of shared HIV care in PLWH ensuring proper HIV control.

Methods:

Design: Prospective pilot project of a shared care intervention.

Setting: HIV specialized outpatient consultations for HIV infection at Son Espases University Hospital which serves 2000 patients.

Subjects: Patients who attended HIV specialized consultation between January 1st and June 30th, 2017.

Intervention: Basal questionnaire on health services used by patients. HIV Training Program on HIV in Primary Health Care (PHC). Pilot Program of shared assistance (PPAC) with PHC.

Main Outcomes: Maintenance of undetectable HIV viral load, antiretroviral therapy (ART) adherence, AIDS and non-AIDS events, loss of follow up, and satisfaction questionnaire.

Results: The basal questionnaire was filled out by 918 patients, with 108 (11.7%) patients reporting neither knowing nor having been visited by their GP. A total of 93 patients were included in the PPAC, with a mean age of 49.9 years (SD 11.7), and an average of 14.6 years since the HIV diagnosis. Eleven patients were followed up for less than six months and were excluded from the analysis. Median follow-up during the PPAC of the remaining 82 patients was 728 days (IQR 370-1070).

Sixteen patients dropped out of the PPAC (19.5%), three died, three were lost to follow up, one was withdrawn due to medical criteria, and nine withdrew voluntarily.

No patient presented any AIDS defining events, although eight patients presented non-AIDS events. All the patients had undetectable viral load (VL) and average ART adherence was 99.4% (SD1.4). The patient’s satisfaction score with PPAC was 8.64 (SD2.5).

Conclusion: It is possible to establish shared care programs with PHC in selected patients with HIV infection, thereby reducing hospital visits while maintaining good adherence and virological control and achieving high patient satisfaction.

Background

Human Immunodeficiency Virus infection is now a manageable chronic condition, since newer antiretroviral drugs (ART) allow a good virological and immunological control of patients, with near normal life expectancy for those who are diagnosed early (1, 2).
Historically, in high-income settings such as some countries in Europe, care for people living with HIV infection (PLWH) has been delivered by HIV specialist services in a hospital setting, basically to ensure correct administration and monitoring treatments. This model also initially benefitted specialists as it enabled development of HIV expertise and facilitated research opportunities. (3–5). This meant that patients had to follow rigorous controls that required frequent trips to the hospital and many people were not registered with a local GP (General Practitioner). In recent years, many HIV specialists have started to offer less frequent consultations or telephone and email-based services in stable patients (6).

In the current context of increasing prevalence of patients with HIV infection in high income settings, with older patients, and patients with chronic diseases related to HIV or not, such as lipid disturbance, osteoporosis, neurocognitive and psychiatric disorders, and cardiovascular disease, a model focused on specialized HIV care may not be optimal or sustainable, since in this area the GP shows his expertise( 7–8).

Shared care programs with Primary care for asthma and diabetes mellitus have been reported to improve quality of care and facilitate knowledge transfer. In 2012 the British HIV Association proposed a theoretical model of shared care in stable HIV patients with a single annual visit to the specialist (9).

Recent reviews show that there are very few articles on shared or transferred care from specialized to primary care in high-income countries/5).

The aim of this study was to better understand the wishes of PLWH regarding their care and to develop a Pilot model of shared HIV care, in stable PLWH, while ensuring proper HIV control.

**Material And Methods**

**Setting**

HIV specialized outpatient consultations for HIV infection at Son Espases University Hospital which serves 2000 patients in a universal tax-funded health care system. All residents have free and direct access to healthcare and PHC (Primary Health Care).

**Participants**

Patients who attended HIV specialized consultation at Son Espases University Hospital between January 1\textsuperscript{st} and June 30\textsuperscript{th}, 2017.

**Procedures**

1. **Basal questionnaire.** Patients conducted a questionnaire-based survey about PHC, number of visits to the PHC center, delays in established visits, and satisfaction with the GP and with the PHC using visual analogue scales ranging from 0 to 100%. Degree of satisfaction with hospital care was also assessed: medical consultation, specialized nurse, pharmacy care, accessibility to the hospital specialist, and time spent, monthly, to attend consultations and care at the hospital. They were additionally asked about their comorbidities and related treatments, their preferred location for blood tests (PHC or hospital),
the possibility of receiving the antiretroviral drugs anonymously at the PHC, and how they would value the possibility of having only one annual visit with their specialist.

2. Training Program with Primary care on HIV infection

A training program of shared HIV care with Primary care was started in 2017 in three PHC centers, and later extended in 2018 to four more. This program was carried out intensively over one morning with special emphasis on the most widely used antiretroviral drugs, assessment of pharmacological interactions, description of the main comorbidities associated with HIV, and the need to develop preventive smoking cessation programs, and vaccinations against influenza and hepatitis B and A viruses. Emphasis was also placed on the early diagnosis of HIV infection, and warning signs that should lead to suspicion of loss of control of HIV infection, etc.

3. Prospective descriptive observational study

We invited PLWH with regular follow up and who met the inclusion criteria to participate in a Pilot Program of Shared Assistance with Primary Care (PPAC).

Inclusion criteria: Patient belonged to one of the Health Centers attached to the program. Follow up in HIV hospital consultations for at least two or more years with good virological control (defined by viral loads <50 cop/mL in the last year of follow-up), stable antiretroviral therapy (ART), adherence greater than 90%, with nadir CD4 lymphocytes greater than 200 and current CD4 lymphocytes > 350 cells/ul and without active drug addictions. In this project, included patients had an annual HIV specialist visit and a GP consultation between successive specialized visit, in the 6th month. Phlebotomies for laboratory test were performed in their PHC, and ART collection was performed every four months in the hospital. Before entering the PPAC, patients signed a written informed consent form, as well answering a basal questionnaire, which was attained from all participants. The evaluation of PPAC was carried out prospectively with the following predefined objective variables: maintenance of undetectable HIV viral load, adherence measured by refill in the antiretroviral drugs collection, hospital admission or death, opportunistic infections, non-AIDS events during the follow-up time, loss of follow-up, and evolution of tobacco use.

Patients who completed the PPCA for two years of follow up underwent a satisfaction questionnaire. Patients were followed until June 2020. Patients with less than six months of follow up were excluded from the analysis.

Statistics

Categorical variables were expressed as numbers and percentages, and continuous variables as mean and standard deviation (SD), or median and interquartile range (IQR) values.

The study was approved by the local Ethics Committee (Comité Ético de Investigación Clínica Illes Balears) and was performed in compliance with the Declaration of Helsinki. Informed consent forms were
Results

Degree Of Patient Satisfaction Concerning Phc And Specialized Care

Between January 1st and June 30th 2017, 918 patients filled out the basal questionnaire, from 71 different Health Centers. Of these, 73.7% were male and 26.3% female, with a mean age of 49.3 (SD 10.4) and a median follow-up in specialized HIV clinics of 15 years (IQR 25–75). The results obtained are shown in Table 1: 108 (11.76%) patients reported neither knowing nor having been visited by their GP, while 378 (41.17%) patients reported at least one associated comorbidity (Table 1).
Table 1
Initial health satisfaction questionnaire received at the PHC and at the hospital.

| Variables                                           | N: 918 |
|-----------------------------------------------------|--------|
| Age (Mean-SD)                                       | 49.3 (10.4) |
| Sex (Male%)                                        | 73.7%  |
| Mean years follow up in HIV clinic (SD)             | 13.7 (8.1) |
| PHC visits frequency N (%)                          |        |
| - 0–1 time per year                                 | 259 (28.2%) |
| - 2–6 times a year                                  | 480 (52.3 %) |
| - 6–12 times a year                                 | 55 (6%)  |
| - > 12 times a year                                 | 51 (5.6%)  |
| - Unknown                                           | 73 (8%)  |
| Delay in PHC attendance N (%)                       |        |
| - 0–1 day                                           | 150 (23.2) |
| - 2 days                                            | 139 (20.7) |
| - 3 days                                            | 90 (13.9)  |
| - 4 days                                            | 64 (9.9)   |
| - 5 days                                            | 34 (5.2)   |
| - > 5 days                                          | 173 (16.8) |
| Satisfaction with the PHC Center 0–10 points (mean-SD) | 7.88 (2) |
| Satisfaction with the General Practitioner 0–10 points (mean-SD) | 8.49 (3.6) |
| Specialized Care visits frequency (%)               |        |
| -1-2 times a year                                   | 217 (23.6%) |
| - 3–4 times a year                                  | 554 (60.3%) |
| ->4 times a year                                    | 107 (11.7%) |
| -Unknown                                            | 40 (4.4%)  |
| Satisfaction with the infectious diseases specialist 0–10 points. Mean (SD) | 9.51 (1.09) |
| Satisfaction with the hospital nurse. Mean SD        | 9.19 (1.53) |
| Satisfaction with Pharmacy Department. Mean SD       | 9.05 (1.5)  |
### Variables

| Time spent quarterly in the hospital for HIV monitoring          | N: 918 |
|---------------------------------------------------------------|--------|
| <2hrs.                                                        | 44.9%  |
| 2-4 hrs.                                                      | 35.5%  |
| 5-10 hrs.                                                     | 8.8%   |
| >10 hrs.                                                      | 1.3%   |
| Unknown                                                       | 9.9%   |

### Comorbidities

| Condition                      | Number (Percentage) |
|-------------------------------|---------------------|
| HTA                           | 188 (20.5%)         |
| Diabetes mellitus             | 79 (8.6%)           |
| Hypercholesterolemia          | 315 (34.3%)         |
| Heart Disease                 | 45 (4.9%)           |

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**Pilot Shared Care Program**

Nurses and GPs from the seven participating PHC included in the PPAC received intensive training sessions on HIV and the structure of PPAC.

A total of 93 patients were included in the PPAC, whose main characteristics are described in Table 2. Their mean age was 49.9 years (SD 11.7), predominantly men 89.2%, with an average of 14.6 years since the HIV diagnosis. Previous AIDS was documented in 15 (16.1%), and the median nadir CD4 count was 288 cells/µL.
|                                | N: 93          |
|--------------------------------|---------------|
| Age (Mean-SD)                  | 49.9 (11.7)   |
| Sex (Male %) (N[%])            | 83 (89.2)     |
| HIV exposure categories (N[%]) |               |
| - MSM                          | 50 (53.8)     |
| - Heterosexual                 | 20 (21.5)     |
| - IDU                          | 17 (18.3)     |
| - Other                        | 6 (6.5)       |
| Country or region of origin (N[%]) |           |
| - Spain                        | 80 (86)       |
| - South America                | 9 (9.7)       |
| - Western Europe               | 3 (3.2)       |
| - North Africa                 | 1 (1.1)       |
| Educational level (N[%])       |               |
| - Primary education            | 24 (25.8)     |
| - Secondary Baccalaureate      | 48 (51.6)     |
| - University studies           | 20 (21.5)     |
| - Unknown                      | 1             |
| Primary Health Care Center (N [%]) |         |
| - 1                            | 13 (14.7)     |
| - 2                            | 20 (22.7)     |
| - 3                            | 25 (28.4)     |
| - 4                            | 5 (5.7)       |
| - 5                            | 7 (7.9)       |
| - 6                            | 14 (18.2)     |
| - 7                            | 4 (4.54)      |
| Time on HIV infection (years). Mean-SD | 14.6 (8.7)   |
| AIDS defining illness         | 15 (16.1%)    |
|                             | N:93          |
|-----------------------------|---------------|
| Viral load 200 copies/mL (N [%]) | 93 (100)     |
| CD4 nadir cells/ul Median IQR | 288 (169–403) |
| CD4 lymphocytes (cells/ul) Median IQR | 775 (573–1032) |
| Current smoker (N [%])     | 35 (37.6)     |

Eleven patients were followed up for less than six months, so they were excluded from the analysis. Median follow-up during the PPAC of the remaining 82 was 728 days (IQR 370–1070). Table 3
Table 3
Follow up of the patients included in the PPAC

|                                | N:82                                                                 |
|--------------------------------|----------------------------------------------------------------------|
| Median follow up on PPAC       | 728 days (IQR 370–1070).                                             |
| Follow up                      |                                                                       |
| - They are still in PPAC       | 66                                                                   |
| - Died                         | 3                                                                    |
| - Loss of follow up            | 3                                                                    |
| - Voluntary withdrawal         | 1                                                                    |
| - Medical criteria             | 9                                                                    |
| Viral load < 200 cop/mL N (%)  | 82 (100)                                                             |
| Lymphocytes CD4 (Median and IQR) |                                                                  |
| - Baseline                     | 775 (603–1039)                                                       |
| - 18 m follow up               | 864 ((675–1163)                                                     |
| ART adherence (mean (SD)       | 99.4 (.4)                                                            |
| Hospital admission N           |                                                                       |
| - One admission                | 5                                                                    |
| - Two admission                | 2                                                                    |
| AIDS events                    | 0                                                                    |
| Non-AIDS tumor events          | 3                                                                    |
| Other non-AIDS associated events | 5                                                                  |
| Tobacco use                    |                                                                       |
| - Baseline                     | 34 (41.5)                                                            |
| - Current smoker n (%)         | 34 (41.5)                                                            |
| - Cholesterol levels. Mean (SD)|                                                                       |
| - Baseline                     | 188 (30.9)                                                           |
| - 18 m follow up               | 185.3 (28.8)                                                         |

Sixteen patients dropped out of the PPAC (19.5%), three died due to non-AIDS events, three were lost to follow up due to home relocation, one was withdrawn due to medical criteria (relapse in alcohol use), and nine withdrew of their own volition.
No patient presented any AIDS defining events. One patient had bacterial pneumonia and another patient had oral thrush. Three patients were diagnosed with non-AIDS neoplasms (pancreas, hepatocarcinoma, and breast). Five patients had cardiovascular events (1 AMI, 1 acute ischemic stroke, 2 heart failure, 1 atrial fibrillation) while one patient presented kidney failure.

All patients had undetectable VL during follow-up and average ART adherence was 99.4 % (SD 1.4). No reduction in smoking habits was observed.

**Patient Satisfaction With The Ppac**

A satisfaction questionnaire was conducted in 63 patients at two years of follow up. Satisfaction with the PPAC was high with an average score of 8.64 (SD 2.5): 8.6 (SD2.2) for the PHC centers, 8.9 (SD2.2) for GPs, 9.6 (SD 1.2) for specialist doctors, 9.5 (SD 0.96) for hospital nurses, and 9.27 (1.4) for the hospital Pharmacy. Six patients scored the PPAC below five. The main problems reported by the patients during the PPAC were frequent GP changes, lack of knowledge of the GP about HIV infection, delays and confidentiality problems in laboratory extractions in the PHC center, and saturation and waiting in the hospital pharmacy.

Some of the improvements proposed by patients are related to the delivery of ART at PHC centers and being able to access their health records and laboratory results on the Internet.

**Discussion**

Our study shows that it is possible to establish shared care programs with Primary Care in selected PLWH, while maintaining good adherence and virological control, reducing patient journeys, and achieving a good degree of satisfaction.

From the initial questionnaire, it is striking that 108 patients (12%) reported not knowing their GP and that 28% hadn’t been to their PHC during the previous year. To date, in Europe and in many high-income countries, care for patients with HIV infection has been carried out mainly in hospitals, so it comes as no surprise that a percentage of patients are not aware of or do not use PHC (10). We agree with the British HIV association, that recommends that every patient with HIV infection must remain under the care of a suitable specialist service but must also be strongly encouraged to register with a GP (9).

In general, satisfaction with medical care was very good, despite being slightly higher within specialized care. In our center, specialized care has been carried out in the last few years by the same doctors who are experts in infectious diseases-HIV infection and by hospital pharmacists. Meanwhile, in the Primary Care setting, changes of GP and lack of means are not uncommon. What is striking is both the high percentage of patients with comorbidities in a population with a mean age under 50 years and the fact that during the 2-year follow-up of the PPAC, 10% were diagnosed with cardiovascular events or unrelated neoplasms.
If we want to improve the care of PLWH, it is necessary to implement management strategies and organizational models that have demonstrated their effectiveness in other chronic diseases, which includes improving coordination with Primary care (11–12). Patient transfer or share for chronic conditions has received surprisingly little attention from researchers, with some authors suggesting more research is urgently required regarding reasons for and outcomes of transfers, transfer processes, and interventions to optimize transfers for different chronic conditions (13).

Many studies on Primary care of PLWH in developed countries have been carried out in Canada and in the United States, where an attempt has been made to implement the Chronic Care Model (CCM) in some places, observing that it enables significant improvement of certain quality indicators such as vaccination against pneumococcus, screening for syphilis or TB, adherence to ART, and percentage of patients with undetectable VL (14).

Our Pilot Project, which initially consisted of training sessions at the PHC Centers, establishing easy communication channels with the PHC, and later sharing the care of well-controlled selected patients with multiple pathologies, enabled the gradual approach of patients to the Health Centers. We believe it is not only a good way to coordinate the care of these patients but also to improve early diagnosis of HIV infection and other sexually transmitted infections (STIs) in the Primary care setting.

The strength of this observational study is its prospective nature with a follow-up of over two years and pre-established outcome variables. In this model, 72 patients remained in the program (87%), with good adherence and virological control and with a very good acceptance of the program. Nine patients requested exit from the program and one patient was not eligible for follow-up due to relapse in alcohol consumption.

There are very few previous studies carried out in developed countries with the aim of promoting shared care of PLWH. Further, some of them achieved poor recruitment, although this was in situations where HIV infection was still symptomatic in many patients (3). Others such as Page’s, in Switzerland, showed no difference either in adherence to ART, or in virological control by level of care, with satisfaction being higher in those seen in Primary Care (9). Other studies evaluating the follow-up of PLWH in PHC have tried to determine the variables related to losses to follow-up (15), and the characteristics of the patients seen and the services offered by providers (16, 17), or attempted to evaluate some interventions to improve depressive symptoms and quality of life, or to understand the chronic nature of HIV (4)(18–19).

In order to improve the acceptance of PLWH being followed in the primary care setting, we must try to overcome some of the barriers that patients describe. One of these is some GPs’ lack of knowledge about HIV infection, the lack of confidentiality in some PHC care such as blood sample extractions, or the saturation of some services. The providers’ linkage-making behaviors will be influenced by their knowledge (HIV- and linkage-related training) and their opinions and attitudes toward Interprofessional collaboration (20). In our country, family residents do not receive proper training on HIV infection or infectious disease, as infectious diseases are not recognized as a specialty. We demonstrate that HIV education programs in Health Centers are feasible. In addition, as a result of this program, some services
have been brought closer to patients, such as blood testing and specific HIV tests, which can be done in PHC.

Various studies carried out in the US and Great Britain show that some PLWH may prefer accessing specialist services as it provides anonymity and there still exists some stigma around an HIV test being in medical records (21). This can be especially important and must be taken into account in regional contexts such as our hospital, located on a small island. Finally, the patient’s choice must be respected. Other services for improvement proposed by patients, but not yet available in our environment, would be the ARV approach, and on-line access to their health record and analytical results. These services, as well as the possibility of telephone consultations, tele-assistance, and on-line clinical sessions with PC, have demonstrated their importance in situations such as the current COVID pandemic.

The main limitations of the study are the small number of patients included in the pilot Project (since February 2020, with the COVID pandemic no new patients have been enrolled in the PPAC). This program was carried out in a developed country where access to health care is universally granted and it only included selected patients with good previous follow-up who agreed to enter the program. Therefore, the applicability might not be extrapolated to other countries or settings.

**CONCLUSIONS** It is possible to establish shared care programs with Primary Care in selected patients with HIV infection, thereby reducing hospital visits, while maintaining good adherence and virological control and achieving high patient satisfaction. To improve the continuity of the program, it is important to better the aspects suggested by the patients: greater knowledge of HIV, less replacement of GPs, and greater confidentiality in blood draws.

**Abbreviations**

ART. (Antiretroviral drugs)

PLWH. (People living with HIV)

GP. (General Practitioner)

PHC. (Primary Health Center)

PPAC. (Pilot Program of Shared assistance with Primary Care)

VL. (Viral Load)

CCM. (Chronic care model).

TB. (Tuberculosis)

**Declarations**
Ethics approval. The study was approved by the local Ethics Committee (Comité Ético de Investigación Clínica Illes Balears) and was performed in compliance with the Declaration of Helsinki. Written informed consent forms were obtained from all participants.

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Authors contribution: MR, AF, ASP and HHV had full access to the data in the study and takes responsibility for the integrity and accuracy of the findings presented. MR, FJF, AP, JM contributed to study design, analysis plan, interpretation, writing and editing of the report, and were responsible for data analysis. MLMPMP, FJF, AAC, MGG have participated as clinicians who follow patients in consultations and in reviewing the manuscript.

JP, MALL, MCG and MTC have contributed as organizers of the educational workshops and as family doctors who follow the patients included in the PPAC. AG is the pharmacist that contributed to the follow-up of the patients included in PPAC from the pharmacy office and in the revision of the manuscript.

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