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Information about medication in HIV-infected patients and its relation to adherence

An observational cross-sectional study

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Summary

QUESTIONS UNDER STUDY: In HIV-infected patients, comprehension of medication instructions is an essential condition for adherence to Highly Active Antiretroviral Therapy (HAART). In this study, we used a self-reported questionnaire to know which sources of medication information HIV-infected patients used and their impact on adherence. In secondary objectives, we determined profiles of non-adherent patients and specified the role of the pharmacist.

METHODS: A cross-sectional, observational study was conducted in one community pharmacy and one French university hospital pharmacy, in HAART-naïve or not patients, from April to June 2009.

RESULTS: During the 3-month study period, 233 HIV-infected patients were included. The majority of patients sought information about their HAART treatments from the hospital physician (79.8%), the community physician (74.2%), and patient information leaflets (73.8%). The community and hospital pharmacists were consulted by respectively 16.3% and 3.4% of patients. According to multivariate regression analysis, adherence seemed to be associated with the sources of information "community physician", "hospital physician", "internet", and the potential support of patient associations. A total of 65.7% of patients were considered to be adherent.

CONCLUSIONS: In our study, among sources used by HIV-infected outpatients, their physicians are the most helpful sources of information about HAART. Regarding practice implications, the key role of the pharmacist is underutilised, indicating the need for improved communication between the pharmacist and outpatients.

Key words: *sources of information; medication adherence; highly active antiretroviral therapy*

Introduction

The degree of patient adherence to Highly Active Antiretroviral Therapy (HAART) is recognised to be a key factor for long-term positive health outcomes [1]. Research indicates that consistently high levels of adherence are necessary for reliable viral suppression [2, 3] and prevention of resistance [4], disease progression [5], and death [6]. An adherence level to HAART, of 80–95% for each patient, has been considered necessary to ensure treatment success [2, 7], but 40–60% of patients do not achieve these levels [8]. Despite the HAART simplification strategies in recent years [9], HIV remains a disease with some predictive characteristics of poor adherence, including its chronic asymptomatic nature, and its rapidly changing treatment regimens associated with adverse effects, which can also require dietary restrictions [10, 11].

Health-related information helps patients cope with illness by increasing knowledge and reducing feelings of uncertainty [12]. In chronic illness, comprehension of medication instructions is an essential condition for adherence [13, 14]. In the field of HIV/AIDS, accurate and appropriate information is necessary to promote adherence, and to ensure that patients achieve the best treatment outcomes [15]. Currently, when seeking medical information, outpatients have a number of sources to choose from, including health-related websites, patient information leaflets, mass media sources such as newspapers, magazines and television, family and friends, and patient associations [16–20]. In the medical literature, positive collaboration between patient and physician has been widely explored, and is associated with better patient adherence [21]. The patient-pharmacist relationship has been less studied [22]. In France, drugs are available for patients in hospital pharmacies together with community pharmacies. In theory, pharmacists are well-positioned to play a primary role in improving adherence to HAART therapies, because they are access-

ible without appointment and outside of hospitalisation, unlike nurses or physicians, and because they have extensive training in HAART pharmaceuticals. In the Bultman et al. study [23], patient satisfaction and medication adherence were strongly influenced by the pharmacist's role in medication monitoring.

In this study, we wanted to know which sources of medication information HIV-infected patients used and their impact on adherence. In secondary objectives, we determined profiles of non-adherent patients and specified the role of the pharmacist.

Methods

Setting

We conducted a cross-sectional, observational study during three months, from April to June 2009, in one community pharmacy and one French university hospital pharmacy.

Study population

Subjects included were outpatients of community and university hospital pharmacies treated by HAART (naïve or not). Patients who were not able to read and understand French and those with cognitive impairment were excluded from the study. Each patient gave informed consent and participated only once in the study. The clinical data and medical history were extracted from software protected by the CNIL (National Committee on Data Protection).

Self-reported questionnaire development

The research group, composed of one infectious disease physician, one public health physician, two pharmacists and one statistician, created a self-report questionnaire divided into 7 items (table 1). The questions were formulated in a way that allowed for differentiation of (1) medication adherence measurement (items 1, 2 and 3), (2) predictors of adherence (items 1, 5 and 7), and (3) sources of medication information (items 4 and 6). The pharmacist's role was assessed by two items: item 6, which was a direct question, and the multi-choice item 4. Items 2 and 3 were extracted from the 8-item Morisky medication adherence scale [24].

Before the study, a questionnaire was piloted with a small sample of patients (n = 10) to ensure patient understanding of the wording of the questionnaire. These patients were excluded from the present study. In the community and hospital pharmacies, the self-reported questionnaires were offered to outpatients by a pharmacist.

Data collection

Socio-demographic information, including gender, age, marital status, profession, and duration of HIV diagnosis were collected through the self-administered questionnaire. Medical records were reviewed for CD4 cell count and baseline viral load. HAART regimens were collected from computer-entered prescriptions.

Statistical analysis

A patient was considered adherent according to the first three items that is if he/she answered he/she always takes his/her medication ("In which circumstances did you not taken your HIV-medication?" "It never happens to me, I always take my medication"), and he/she never stopped taking his/her medicine when he/she felt better or worse ("When you feel better, do you sometimes stop taking your medicine?" "No", and "Sometimes if you feel worse when you take the medicine, do you stop taking it?" "No"). In all other cases (answers converging to nonadherence or divergent answers), the patient was considered to be non-adherent. A sensitivity analysis was performed using a less restrictive definition for adherence: a patient was considered adherent if he/she never stopped taking his/her medicine when he/she felt better or worse (items 2 and 3).

We presented the proportion of adherent patients. The 95% Confidence Intervals (CIs) were estimated using the exact binomial distribution.

We analysed potential predictors of adherence (sex, age, marital status, dispensing site and length of HAART treatment, CD4 cell count and baseline viral load, side effect and patient tolerance) in univariate analyses, using Wilcoxon's test or Fisher's exact test as appropriate. We also

Table 1: Self-reported questionnaire on taking medication and sources of information.

① **Under what circumstances, did you not take your HIV-medication?**
Several answers are possible
- ❑ I was not home and I did not have my medication with me
- ❑ I was busy doing something else
- ❑ There have been changes in my routine
- ❑ I felt asleep when taking my medication
- ❑ I had too many tablets or capsules to take
- ❑ I felt that the treatment was dangerous or toxic
- ❑ I did not want to be seen taking my medication
- ❑ This never happens, I always take my medication
- ❑ Other: .....

② **When you feel better, do you sometimes stop taking your medicine?**
❑ Yes ❑ No

③ **Sometimes if you feel worse when you take the medicine, do you stop taking it?**
❑ Yes ❑ No

④ **When you have a question about your HIV-medication, where do you look for information?**
Several answers are possible
- ❑ Community physician
- ❑ Hospital physician
- ❑ Community pharmacist
- ❑ Hospital pharmacist
- ❑ Social workers
- ❑ Patient associations
- ❑ Internet
- ❑ Newspapers
- ❑ Patient information leaflet
- ❑ Family

⑤ **Have you experienced any side effects?**
❑ Yes ❑ No

⑥ **Has your pharmacist informed you about your HIV-medication?**
❑ Yes ❑ No

⑦ **Are you supported by patient associations?**
❑ Yes ❑ No

examined if the sources of treatment information (multichoice item 4) were linked to adherence using the same tests. To avoid multiple tests, we considered only sources that were not highly correlated (correlation coefficient r <0.50 using the sources of information as dichotomous variables). Candidate variables for the multivariate logistic regression analysis were variables with p <0.20 in univariate analysis and with less than 20% missing data (age, marital status, CD4 cell count and baseline viral load were excluded). The final model was achieved using a backward selection (non significant variables were removed sequentially). P <0.05 was considered statistically significant.

The statistical software SAS (release 9.1; SAS Institute Inc., Cary, NC, USA) and R (release 2.8.1; 2008 The R Foundation for Statistical Computing) were used for all analyses.

Results

Patients

During the 3-month study period, 233 HIV-infected patients were included. The patients were 62.2% male (145/233), and the median age was 43 (min-max: 36–51 years). 77.3% (180/233) of the patients included received their HAART medication at hospital pharmacy, and 76.4% (178/233) of them had been treated for more than 5 years (table 2).

Sources of information about HAART treatment

The sources of information reported by patients about their HAART treatment according to their adherence or non-adherence are presented in table 2. Amongst all patients, more than 70% of patients sought information about their HAART treatments from their physicians (hospital or community physician), and patient information leaflets. Patient associations, internet and newspapers have been consulted by 33.9%, 29.6% and 26.6% respectively. Medication information was requested by 16.3% of outpatients from their community pharmacists and by 3.4% from their hospital pharmacist.

Most sources of information were highly correlated (reported/not reported simultaneously):

"community physician" and "patient information leaflet" (r = 0.68), "internet" and "newspapers" (r = 0.59), and "patient associations" and "newspapers" (r = 0.55). The correlation coefficient between "internet" and "patient associations" was 0.43 whereas correlation coefficients between other sources of information were lower than 0.40.

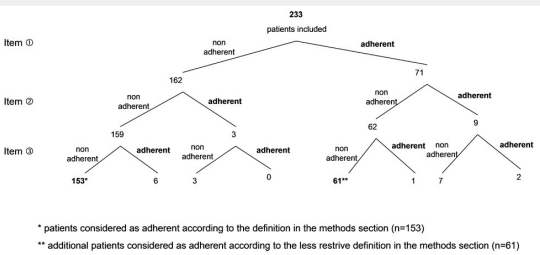

Figure 1

Responses given by the patients to the first three items of the questionnaire.

Adherence rates

Responses given by the patients to the first three items of the questionnaire are described in figure 1. A total of 65.7% patients (95% CI: 59.2% to 71.7%, 153/233) were considered to be adherent according to their answers to the first three items (see definition in statistical analysis section). The reasons for non-adherence to treatment were reported by 71 patients (out of 80 non-adherent patients) and are presented in table 3. The main reasons were: feeling uncomfortable taking medication in front of other people (39.4%), and absence of their medication due to absence from home (28.2%).

Among the 80 non-adherent patients, 61 gave a circumstance in which they did not take their HIV-medication (item 1) but answered they never stopped taking their medicine when they felt better or worse (items 2 and 3). Thus, according to a less restrictive definition for adherence (considering only items 2 and 3), 91.8% patients (95% CI: 87.6% to 95.0%, 214/233) were adherent.

Predictors of adherence

The sources of information from newspapers, patient information leaflets and social workers were not studied since the prior two were highly correlated with internet and community physicians respectively and the last one was never reported by patients (see paragraph on sources of information about HAART treatment). In univariate analysis, community pharmacy dispensing, number of sources of information, potential support of patient associations, presence of side effects and the sources of information "community physician", "hospital physician", and "internet" were significantly associated with adherence to treatment; male sex and the source of information "patient associations" were at the limit of significance (respectively p = 0.07 and p = 0.09). Age, marital status, length of HAART treatment, CD4 cell count, baseline viral load, and the sources of information "community pharmacist", "hospital pharmacist" and "family" did not influence adherence (p >0.20).

In the multivariate logistic regression model (table 4), the sources of information "community physician", "hospital physician", "internet", and the potential support of patient associations remained significant. Patients with "hospital physician" as source of information were almost six times more likely to be adherent than patients without (OR = 5.8 [95% CI: 2.3 to 14.2], p <0.001), patients with "community physician" as source of information were four times more likely to be adherent than patients without (OR = 4.5 [95% CI: 2.1 to 9.7], p <0.001), patients with potential support were four times more likely to be adherent than those without support (OR = 4.5 [95% CI: 2.1 to 9.4], p <0.001), and patients with "internet" as source of information were almost three times more likely to be adherent than patients without this source of information (OR = 2.7 [95% CI: 1.1 to 6.5], p = 0.028).

Discussion

In our study, among sources used by HIV-infected outpatients, their physicians are the most helpful sources of information about HAART. Patients who reported both newspapers, internet, and patient associations together were the most adherent. In our study, the hospital pharmacist didn't play a key role in informing HIV-infected outpatients; the community pharmacist had a limited role.

To date, there has been little research on HIV-positive patients' use of information concerning HAART. In our study, we have identified patterns of patient behaviours in seeking medication information with highly correlated sources. The

Table 2: Characteristics of patients and HAART treatment.

Characteristics	All patients (N = 233)		Adherent* (N = 153)		Non adherent* (N = 80)		pvalue †
Patients							
Male, n (%)	145	(62.2)	102	(66.7%)	43	(53.7%)	0.065
Age, median (IQR)	43	(36–51)	43	(34–51)	42	(37–51)	0.76
Marital status, n (%)							0.43
Single	74	(31.8%)	50	(32.7%)	24	(30.0%)	
Married	47	(20.2%)	29	(18.9%)	18	(22.5%)	
Other	60	(25.8%)	34	(22.2%)	26	(32.5%)	
HAART treatment							
Dispensing, n (%)							<0.001
Hospital pharmacy	180	(77.3%)	107	(69.9%)	73	(91.2%)	
Community	51	(21.9%)	44	(28.8%)	7	(8.7%)	
Duration, n (%)							0.55
<1 year	3	(1.3%)	3	(2.0%)	0	(0.0%)	
1 to 5 years	46	(19.7%)	31	(20.3%)	15	(18.7%)	
>5 years	178	(76.4%)	113	(73.9%)	65	(81.2%)	
Medical records							
CD4 cell count (ml^3), median (IQR)	559	(398–730)	548	(396–700)	581	(407–776)	0.85
Baseline viral load (no. copies/ml) , median (IQR)	40	(20–40)	40	(20–40)	40	(20–40)	0.49
Sources of information‡							
Hospital physician	186	(79.8)	142	(92.8)	44	(55.0)	<0.001
Community physician	173	(74.2)	126	(82.4)	47	(58.8)	<0.001
Patient information leaflet ¶	172	(73.8)	127	(83.0)	45	(56.3)	
Patient associations	79	(33.9)	58	(37.9)	21	(26.3)	0.082
Internet	69	(29.6)	60	(39.2)	9	(11.3)	<0.001
Newspapers §	62	(26.6)	52	(34.0)	10	(12.5)	
Community pharmacist	38	(16.3)	25	(16.3)	13	(16.3)	0.99
Family	25	(10.7)	18	(11.8)	7	(8.8)	0.66
Hospital pharmacist	8	(3.4)	4	(2.6)	4	(5.0)	0.45
Social workers	0	(0.0)	0	(0.0)	0	(0.0)	ND
number of sources of information, mean (SD)	3.5	(1.8)	4.0	(1.8)	2.5	(1.5)	<0.001
Discomfort and support							
Side Effects	100	(42.9)	75	(49.0)	25	(31.2)	0.012
Support by patient associations	129	(55.4)	106	(69.3)	23	(28.8)	<0.001

IQR = Interquartile Range, SD = Standard Deviation, ND = Not Defined

Characteristics with more than 20% missing data (number of missing data): Age (82), Marital status (52), CD4 cell count (51), Baseline viral load (49).

* See Methods for definition.

† according to Wilcoxon's test or Fisher's exact test as appropriate

‡ Total percentages for all sources of information exceed 100%, since answers were not exclusive (item4).

§ To avoid multiple tests, this comparison was not tested. The source of information "newspapers" was highly correlated with "internet" (pr = 0.59)

¶ To avoid multiple tests, this comparison was not tested. The source of information "patient information leaflet" was highly correlated with "community physician" (r = 0.68)

Table 3: Reasons for non-adherence to treatment.

Reason, n (%)*	N = 71†	
Did not want to be seen during administration	29	(39.4)
Not at home and did not have medication	20	(28.2)
Fell asleep when taking medication	14	(19.7)
Change in the daily routines	11	(15.5)
Under the impression that the medication was dangerous or toxic	10	(14.1)
Busy doing something else	5	(7.0)
Other	5	(7.0)
Too many pills or capsules to take	0	(0.0)

* Total percentages exceed 100% since answers were not exclusive

† 80 patients were considered non-adherent according to their answers to the first three items (see Methods for definition) but 9 did not give reasons, since they answered to item 1 ("In which circumstances do you forget your medicine?") "It never happens to me, I always take my medicine".

physician-patient collaboration has been widely explored in the medical literature [25, 26]. The goal of this collaboration is that the patient's self-knowledge needs are combined with the medical knowledge of the physician, in order to find the best possible treatment regimen for that individual patient [27]. Despite these numerous sources of information, the relationships between patients and healthcare professionals are still significant in their perception of the disease. Additionally, patient information leaflets were widely consulted by participants. These documents were written by healthcare professionals especially to inform about the drug and prevent its misuse [28]. The internet was not classified among the prominent sources. This result is all the more surprising because the populations were young (median ages: 43 [36–51] years). Conversely, in 2002, Kalichman et al. [29, 30] found that 64% of persons with home access to Internet had searched for HAART information online.

In our study, the self-reported rate of adherence was 65.7% and the main reasons for non-adherence reported by outpatients were: feeling uncomfortable taking medication in front of other people and absence of their medication when they were away from home. The self-reported rates of non-adherence were similar to those published in the scientific literature for patients receiving treatment for chronic conditions. Recent studies of patients with HIV/AIDS have reported low adherence rates [31]. There is no ideal rate of adherence, but in HIV infection, it is accepted that each patient achieve more than 95 percent adherence to HAART [32] in order to suppress viral replication and avoid the emergence of resistance. Non-adherence to HAART can have important public health implications. Understanding treatment, anticipation of side effects, and information about therapeutic objectives could be measures for improving adherence to HAART [31]. Knowing the reasons for non-adherence to HAART is essential in elaborating educational programs and training healthcare professionals to properly advise patients. In our study, the most common reasons patients reported for skipping HAART medications included the difficulty of integrating treatment schedules into their daily activities, and worries about HIV disclosure. The same results were reported in the National Institutes of Health guidelines about antiretroviral therapy [33] which note the ability of patients to fit the medication into their daily routines and feel comfortable taking medication in front of other people were identified as psychosocial predictors of good adherence. These predictors of adherence underline the importance of tailoring the regimen to the patient's lifestyle [34].

A multicentre qualitative survey on HIV positive adolescents' perceptions of their disease [35], published in 2010, confirms the results of the present study. Indeed, this work has shown that the majority of the adolescents do not reveal their HIV condition to their friends and consequently take their medication secretly. In the same study, the results suggest that adherence was linked with the kind of relationship established between the patient and physician, from a fairly paternalistic type to a more collaborative one.

Our results show that, although the majority of the outpatients received their HAART at the hospital pharmacy (77.3%), only 3.4% indicated they consulted their hospital pharmacist for information about HAART. In the context of HIV, all members of the healthcare team are responsible for ensuring that patients understand their treatment. The ultimate responsibility for this understanding lies with the pharmacist [36]. The hypothesis which explains the present results, and which was often formulated by the outpatients during the study, is that the hospital pharmacists' knowledge and expertise are not well known by the patients. The main role of pharmacists is to dispense medications. They must also ensure the proper use of drugs by validating medical prescriptions and providing patient counseling. However, pharmacists may be a source of information about drug usage, such as interactions, drug benefits or side effects, and as a support about medication [22]. The results of the present study confirm that, in our teaching hospital, hospital pharmacists still have a way to go before being perceived as professionals who fully meet patients' healthcare needs [22]. Paradoxically, many studies have reported hospital pharmacist interventions to improve HAART adherence. Like other healthcare professionals, the hospital pharmacist has also participated in patient education and counselling [37]. The pharmacist's role as partner and active participant in patient care is relatively new, and still evolving [22].

The main limitation in our study is the measure of non-adherence. We have chosen the principal method employed, and the easiest to use in clinical practice: the self-reported questionnaire. There is no standard method for measuring non-adherence, and we did not confirm the validity of pa-

Table 4: Multivariable analysis of adherence to treatment.

N = 231 patients*	**Full Model†**		**Final Model‡**	
	OR [95%CI]	**pvalue**	**OR [95%CI]**	**pvalue**
Male (versus female)	2.4 [1.1–5.6]	0.037		
HAART treatment dispensing at community (vs hospital pharmacy)	1.7 [0.5–5.8]	0.43		
Information by community physician (versus no)	7.3 [1.9–28.3]	0.004	4.5 [2.1–9.7]	<0.001
Information by hospital physician (versus no)	5.4 [1.5–20.0]	0.012	5.8 [2.3–14.2]	<0.001
Information by patient associations (versus no)	1.5 [0.4–5.7]	0.54		
Information by Internet (versus no)	2.2 [0.7–7.3]	0.182	2.7 [1.1–6.5]	0.028
number of sources of information (for one-source increase)	0.9 [0.5–1.4]	0.59		
Side Effects (versus no)	1.0 [0.5–2.3]	0.97		
Support by patient associations (versus no)	5.5 [2.5–12.0]	<0.001	4.5 [2.1–9.4]	<0.001

OR = Adjusted Odds Ratio of adherence to treatment (versus non adherence)

* Two missing data on site of HAART treatment dispensing.

† Including variables with p <0.20 in univariate analysis and with less than 20% missing data (age, marital status, CD4 cell count and baseline viral load were not included).

‡ After removing non significant variables sequentially (backward selection).

tients' responses to the questionnaire with an objective adherence measure. The non-validation of the adherence questionnaires is common in scientific literature, but could question the predictive factors identified. Another limitation of the self-reported questionnaire is can there be a chance of recall bias which could in turn affect the measurements. In addition, results from the multivariate analysis must be considered carefully, since variables with a lot of missing data were not included in the logistic regression model. A potential limitation could be that this study was conducted in a single hospital. The other centres might have different models to counsel HIV-infected patients with their medication and hospital pharmacists might have different missions. Another limitation is that the frequency with which each source was accessed was not measured. Our study does not take into account this possibility and a person who uses a source of information once has been classified in the same way as someone who uses it frequently, to get medication information.

Regarding practice implications, pharmacists are medication experts, and could be a competent supplement to the physician in informing patients about their medication. Based on the findings of this study, there is evidence indicating the need for improved communication between the hospital pharmacist and outpatients. Pharmacistscan aid adherence by playing a key educational role, counseling patients on the importance of medication adherence and providing specific guidance on the proper use of medication, including information on any adverse effects and drug-drug interaction that may be expected.

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Figures (large format)

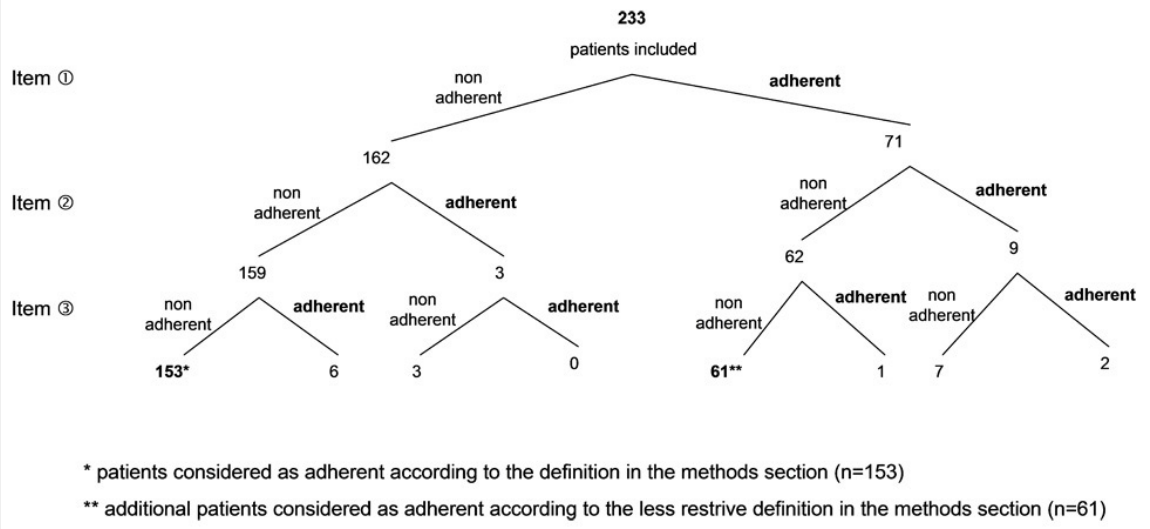

Figure 1

Responses given by the patients to the first three items of the questionnaire.