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Long-acting injectable antiretrovirals for HIV treatment in the ICONA cohort: physicians' and nurses' points of view

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Background: Implementation level of long-acting injectable agents cabotegravir/rilpivirine (LAI CAB/RPV) for human immunodeficiency virus (HIV) treatment in Italy is still not known. The aim of this study is to identify the status of implementation of LAI CAB-RPV and its barriers.

Materials and methods: A cross-sectional online survey was conducted among infectious diseases (ID) physicians and nurses belonging to the ICONA network in Italy. Three validate 4-items measures were used: Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM) and Feasibility of Intervention Measure (FIM).

Results: Out of 61 ICONA centres, 38 (62%) completed the survey: 57.9% were academic centres, 42.1% were hospital-based. In total, 104 respondents were ID physicians (57.4%), 77 were nurses (42.5%); 4.5% of all PWH followed at the 38 centres started LAI CAB/RPV at time of study. Centres taking care of >1000 PWH reported 95% application of procedures for LA implementation, higher than other centres ($P = 0.009$). Mean score of AIM was (16.0, standard deviation, SD, 3.3), of IAM (16.0, SD 3.0) and FIM (16.0, SD 2.9). A linear correlation was found between AIM and the number of people with HIV who started LAI CAB/RPV (25–50 versus <25, coefficient of correlation [b] 2.57, 95%CI 0.91–4.60, $P = 0.004$), academic versus hospital-based centres (b −1.59, 95%CI −2.76–0.110044, $P = 0.007$) and the absence of preliminary systematic assessment of staff (b −1.98, 95%CI −3.31–0.65, $P = 0.004$). Implementation barriers were not significantly different according to the number of PWH/centre.

Conclusions: LAI CAB/RPV implementation was low, with a great variability according to centre size. Tailored and centre-specific interventions to address barriers and to optimize the LA treatment implementation should be designed.

Introduction

Intramuscular injection of long-acting cabotegravir and rilpivirine (LAI_CAB/RPV) is the only approved LA combination antiretroviral therapy (cART) for treatment of people with human immunodeficiency virus (HIV) (PWH) with a confirmed virological suppression.[1–4] The regimen was approved by the European Medical Agency in October 2020 and recognized by all the international guidelines as a switch option.[5,6] Nevertheless, adequate implementation of such a treatment strategy in clinical practice is far from being reached.[7–9] Studies have documented several barriers and facilitators to be considered for LAI_CAB/RPV implementation, but up to now the literature has focused primarily on patients' perceptions and preferences, with limited attention to

centre-related barriers. Several indicators have been identified as effectors of implementation process, such as acceptability, appropriateness, feasibility, cost, penetration and sustainability; specific measures of these outcomes have been validated for monitoring and evaluating the success of the implementation process of a specific intervention. In particular, three implementation measures, of acceptability (Acceptability of Intervention Measures, AIM), appropriateness (Intervention Appropriateness Measure, IAM) and feasibility (Feasibility of Intervention Measure, FIM) have been developed through a psychometric assessment as valid and reliable measures of implementation outcomes.[10]

The objective of the study is to evaluate the implementation stage of LAI cART in Italy, identifying readiness and barriers to LAI_CAB-RPV administration at the national level.

Materials and methods

The ICONA Foundation Study is an Italian cohort of PWH.[11] All the 61 infectious diseases (ID) centres belonging to the ICONA Foundation constitute the ICONA network, which is often involved for dissemination of surveys and other scientific projects among PWH and healthcare workers in each centre.

An anonymous online cross-sectional survey was conducted within the ID centres of the ICONA network and administered to both ID doctors and nurses involved in HIV care during December 2023 to February 2024. The survey included questionnaires based on a preliminary evaluation of the readiness of the centre, three implementation measures described next and a questionnaire exploring barriers to implementation. The questionnaires on readiness and barriers were developed on the basis of experiences of the members of the writing group as well as on previous published surveys.[8]

The primary measures of interest were: (i) the Acceptability of Intervention Measure (AIM), defining acceptability as the perception that the intervention is agreeable, palatable and satisfactory; (ii) the Intervention Appropriateness Measure (IAM), defining appropriateness as the perceived fit, relevance or compatibility of the innovation and (iii) the Feasibility of Intervention Measure (FIM), where feasibility is the extent to which the intervention can be successfully carried out within the given setting. The details and psychometric properties of these measures are described elsewhere.[12]

Questions in the implementation measures were scored with a Likert scale from 1 (strongly disagree) to 5 (strongly agree). Higher average scores indicate greater readiness. Questions regarding barriers to implementation were based on five-point Likert scales; respondents were asked to rate each potential barrier with responses ranging from 1 (not a barrier at all) to 5 (extreme barrier).

The survey has been designed and conducted by using REDCap electronic data capture tools hosted in the ICONA Foundation servers. The structure and questions of the survey are reported as Supplementary material (available as Supplementary data at *JAC* Online).

Participant consent statement

This study did not include any PWH, only healthcare workers involved in the long-acting treatment administration. The data collection was anonymous, no personal data were collected and specific techniques were adopted to ensure anonymization (e.g. age strata not year of birth, region of residence). Participants were asked for their willingness and authorization to participate and to process the data provided for the purpose of scientific research, with the option of stopping or withdrawing any time and for any reason.

Statistical analysis

All the survey items were summarized with means and standard deviations (SD) for continuous and frequencies and percentages for categorical measures. For primary outcomes, AIM, IAM and FIM were calculated by summing the scores for the individual questions. Each scale consists of four items scored 1 to 5; each measure score ranges from 4 to 20. Means and SD were calculated for each measure. Associations of AIM, IAM and FIM with other measures, such as clinic characteristics of patients followed at the centre of respondent physician/nurse, were assessed using unadjusted and adjusted linear regression model. Factors with $P < 0.100$ in the crude models were retained in the adjusted model. For barrier measures, mean values were calculated for each potential barrier, with higher scores indicating a major barrier. A comparison of all the items of the survey have been also reported according to the strata of numbers of PWH in care in the centres. Only centres with at least a completed survey from an ID specialist and a nurse have been included to avoid an imbalance between centres where the answers between the two professional figures could be substantially different in quantity.

Results

Characteristics of the centres and respondents

Out of 61 centres, 51 in the ICONA network participated in the survey (83.6%). As only centres with at least one survey completed by both an ID specialist and a nurse were included, 13 other centres were excluded from the analysis. Therefore, 38 HIV clinics belonging to ICONA entered in the analysis representing 62% of ICONA centres. Characteristics of the centres are reported in Table S1 (Supplementary Materials).

One hundred and eighty-one participants responded the survey and have been included in the analysis (104 ID physicians and 77 nurses). Characteristics of respondents are shown in Table S1 (Supplementary Materials). Compared to ID specialists, nurses were more frequently females ($P < 0.001$) and older ($P < 0.001$), with a longer experience in caring PWH ($P < 0.001$).

The mean proportion of PWH on LAI_CAB/RPV over the overall number of PWH in care in each centre was 4.5% (SD ± 3.0), and 14 centres (38.9%) reported that at least 5% of PWH started the LAI_CAB/RPV regimen.

The implementation readiness of the centre according with the number of PWH followed up is shown in Table S2 (Supplementary Materials). A significant higher proportion in terms of application of standardized procedures for LA implementation was reported for centres with higher number of PWH followed up (>1000 PWH) versus the other ranks ($P = 0.009$).

Acceptability, appropriateness and feasibility of implementing LAI_CAB/RPV in the centres

The means ($\pm SD$) for the specific measures of outcome implementation were: AIM 16.0 (± 3.3), IAM 16.0 (± 3.0) and FIM 16.0 (± 2.9), respectively. Figure 1 shows the proportion of responses that were 'agree' or 'completely agree' for each item of the implementation measures. Of note, 60.8% of participants reported that LAI_CAB/RPV is implementable (FIM), 65% reported that the strategy seems fitting (IAM) and 67.4% that it is appealing (AIM). No significant differences were detected in the specific answers to each questionnaire or in the mean scores according to the dimension of the centre.
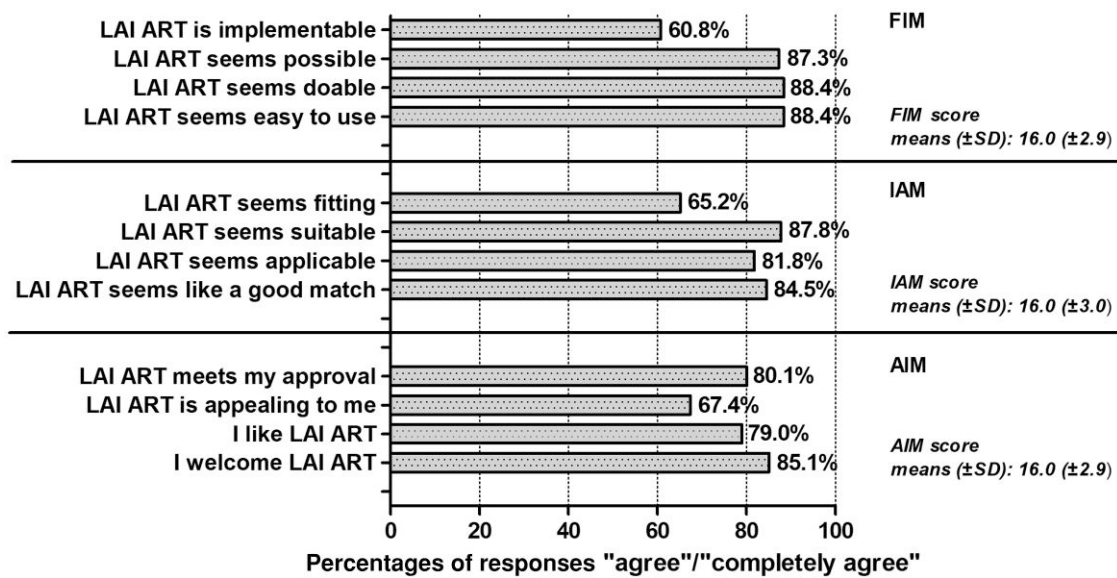
Figure 1. Percentage of participants who responded 'agree'/'completely agree' on the 1–5 Likert scale for each item of the FIM, IAM and AIM. The two answers are summed together to express the proportion of participants with a positive response to each question. Mean scores with ±SD are also reported for the three implementation measures (scale 4–20).

Association between implementation measures and characteristics of centre

As shown in Table 1A, after fitting an adjusted linear regression model, a higher appropriateness of implementation measure (AIM) score was found with participants who followed a slightly higher number of PWH on LAI_CAB/RPV (for 25–50 PWH on LAI_CAB/RPV versus reference <25 PWH, beta 2.75; 95%CI 0.91,4.60; P=0.004), lower for healthcare workers who were part of academic/university centres (beta −1.59; 95%CI −2.74,4.43; P=0.007) and the absence of a systematic assessment of the staff requirement (beta −1.98; 95%CI −3.31,0.65; P=0.004). No other significant associations were observed with implementation measures IAM and FIM in the adjusted models (Table 1b and c).

Barriers to implementation of LAI_CAB/RPV

In Table S3 (Supplementary Materials), the barriers to implementation of LAI_CAB/RPV are shown. Overall, the most prevalent identified barriers were the need for cold storage of the drug (48%), people's issues when accessing bimonthly HIV clinics (48%), the PWH adherence at every other month's access (46%), the lack of dedicated and trained staff (42%) and the lack of dedicated rooms for injections (40%).

Discussion

After >1 year from availability in clinical practice of a long-acting regimen for HIV treatment, this study evaluated the acceptability, appropriateness and feasibility of implementing LAI_CAB/RPV among the most representative HIV clinics in Italy. The results demonstrated a mean level of implementation measures slightly lower compared to other studies performed in different geographical settings and in different periods, mostly before the implementation of LAI_CAB/RPV in clinical practice.[8] These results may be due to structural and organizational differences between healthcare systems (i.e. American and Italian) and are therefore difficult to comment on.

Nevertheless, the identification of health care system-related barriers could represent a model to address these barriers and favour access to treatment to those people who would benefit the most from this strategy. Overall, the most prevalent barriers identified in literature and also in our study were the concerns regarding PWH transports and adherence to a bimonthly visit; need for dedicated staff, nurses and location and need of a refrigerator for drug storage.[12,13] Specifically, in a recent study performed in Florida, the need for extra staffing, the increased burden on existing staff and the problems with the transport of PWH were identified as barriers to implementation similar to our study.[13] Moreover, there is a marked difference in terms of the preparedness of the centre and its adaptation to the structural changes linked to the introduction of a new administration regimen between larger centres, which were more ready for change and implementation, and smaller centres. Despite an overall 60% level of preparedness, larger centres implemented standardized procedures more frequently than smaller ones, even though smaller centres performed a systematic pre-evaluation of the candidate patients more frequently.

CUSTOMIZE hybrid III reported a level of acceptability, appropriateness and feasibility of implementation of LAI_CAB/RPV that increased over time from baseline to month 12, from providers', nurses' and PWH points of view.[7,14] In this study, the barriers to implementation identified at baseline were mitigated and adjusted during the study period.

Our study has indeed several limitations. The cross-sectional evaluation of the level of implementation did not allow for detection of the reduction of the barriers and the measurement of its

Table 1. Association between AIM score (A), IAM score (B) and FIM score (C) and respondent/centre characteristics by means of unadjusted and adjusted linear regression models

(A) AIM score	Unadjusted model			Adjusted[a] model		
	beta	95%CI	P	beta	95%CI	P
N. PLHW in FU						
<500	1					
500–1000	0.199	(−1.337; 1.734)	0.799			
>1000	−0.567	(−1.911; 0.778)	0.407			
Calendar period start, per quadrimester increase	0.130	(−0.429; 0.688)	0.648			
N. PLWH on LAI CAB/RPV						
<25	1			1		
25–50	1.975	(0.189; 3.762)	0.030	2.757	(0.91; 4.604)	0.004
250–100	0.097	(−1.075; 1.269)	0.871	1.112	(−0.213; 2.437)	0.099
>100	0.812	(−0.511; 2.136)	0.228	1.083	(−0.205; 2.372)	0.099
Type of centre, university (versus hospital)	−0.983	(−1.968; 0.002)	0.050	−1.595	(−2.746; −0.443)	0.007
No systematic assessments of patient needs	0.012	(−1.500; 1.525)	0.987			
No systematic assessments requiring staff	−1.971	(−3.329; −0.614)	0.005	−1.982	(−3.31; −0.655)	0.004
No activation of standardized procedures in the centre	−1.239	(−2.904; 0.426)	0.144			
Nurse (versus physician)	−0.697	(−1.684; 0.289)	0.165			
Age, years						
<35	1					
35–50	0.183	(−1.249; 1.615)	0.802			
>50	0.380	(−0.951; 1.710)	0.574			
Years FU HIV						
≤5	1					
5–10	0.986	(−0.586; 2.559)	0.218			
10–20	0.535	(−0.93; 2.001)	0.472			
>20	0.371	(−0.89; 1.633)	0.562			
Sex, female	−0.438	(−1.513; 0.638)	0.423			

(B) IAM score	Unadjusted model			Adjusted[a] model		
	beta	95%CI	P	beta	95%CI	P
N. PLHW in FU						
<500	1			1		
500–1000	−0.574	(−1.960; 0.812)	0.415	−0.332	(−1.742; 1.078)	0.643
>1000	−1.098	(−2.312; 0.116)	0.076	−1.102	(−2.373; 0.169)	0.089
Calendar period start, per quadrimester increase	0.216	(−0.290; 0.723)	0.400			
N. PLWH on LAI CAB/RPV						
<25	1					
25–50	1.011	(−0.627; 2.650)	0.225			
250–100	−0.016	(−1.091; 1.059)	0.976			
>100	0.154	(−1.060; 1.368)	0.803			
Type of centre, university (versus hospital)	−0.852	(−1.745; 0.041)	0.061	−0.778	(−1.707; 0.151)	0.100
No systematic assessment of patient needs	−0.193	(−1.566; 1.180)	0.782			
No systematic assessment requiring staff	−1.361	(−2.604; −0.118)	0.032	−0.732	(−2.092; 0.627)	0.289
No activation of standardized procedures in the centre	−1.344	(−2.85; 0.162)	0.080	−1.465	(−3.144; 0.214)	0.087
Nurse (versus physician)	−0.352	(−1.249; 0.545)	0.44			
Age, years						
<35	1					
35–50	0.248	(−1.048; 1.544)	0.707			
>50	0.542	(−0.662; 1.746)	0.376			
Years FU HIV						
≤5	1					

Continued

Table 1. *Continued*

(B) IAM score	Unadjusted model			Adjusted[a] model		
	beta	95%CI	P	beta	95%CI	P
5–10	0.417	(−1.013; 1.847)	0.566			
10–20	0.380	(−0.953; 1.712)	0.575			
>20	0.244	(−0.903; 1.392)	0.675			
Sex, female	−0.301	(−1.277; 0.674)	0.543			

(C) FIM score	Unadjusted model			Adjusted[a] model		
	beta	95%CI	P	beta	95%CI	P
N. PLHW in FU						
<500	1			1		
500–1000	−0.290	(−1.605; 1.026)	0.665	−0.042	(−1.433; 1.349)	0.952
>1000	−0.969	(−2.121; 0.183)	0.099	−0.979	(−2.223; 0.264)	0.122
Calendar period start, per quadrimester increase	0.313	(−0.165; 0.791)	0.198			
N. PLWH on LAI CAB/RPV						
<25	1					
25–50	0.160	(−1.401; 1.722)	0.84			
250–100	0.113	(−0.911; 1.137)	0.828			
>100	−0.266	(−1.423; 0.890)	0.65			
Type of centre, university (versus hospital)	−0.983	(−1.827; −0.139)	0.023	−0.845	(−1.755; 0.064)	0.068
No systematic assessment of patient needs	−0.321	(−1.623; 0.982)	0.628			
No systematic assessment requires staff	−1.177	(−2.361; 0.007)	0.051	−0.478	(−1.806; 0.849)	0.478
No activation of standardized procedures in the centre	−1.214	(−2.651; 0.223)	0.097	−1.268	(−2.914; 0.378)	0.13
Nurse (versus physician)	0.139	(−0.714; 0.992)	0.748			
Age, years						
<35	1			1		
35–50	0.801	(−0.412; 2.013)	0.194	0.258	(−1.201; 1.718)	0.727
>50	1.408	(0.281; 2.534)	0.015	0.652	(−0.937; 2.241)	0.419
Years FU HIV						
≤5	1			1		
5–10	0.334	(−1.009; 1.677)	0.624	0.363	(−1.118; 1.843)	0.629
10–20	0.915	(−0.337; 2.166)	0.151	0.808	(−0.635; 2.251)	0.27
>20	1.073	(−0.004; 2.150)	0.051	0.449	(−1.060; 1.958)	0.558
Sex, female	−0.224	(−1.151; 0.702)	0.633			

[a]Adjusted for the factors shown in table.

effectiveness. Even though a preliminary survey on PWH preferences regarding LA cART was previously performed within the same network,[15] we did not carry out a systematic evaluation of measures of implementation from PWH perspectives after the availability of the regimen in the clinical practice. This could have allowed a correlation between the barriers identified by healthcare workers and the PWH to optimize the implementation process. An estimate of PWH potentially eligible for clinical/virological reasons and willing to undertake the long-acting regimen would have made it possible to define a more precise denominator that could be used to estimate the best target to be achieved and the possible barriers that each centre must overcome.

In conclusion, our study documented, for the first time in Italy, the level of penetration into clinical practice of the first long-acting regimen for HIV infection. The implementation of this intervention was found to be dependent on the preparedness and size of HIV clinics. The systematic evaluation of the barriers limiting adequate implementation is essential. Continued synergy between clinical staff and PWH is essential to guarantee that each person with HIV who could benefit from this regimen could easily get access to it.

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Supplementary data

Tables S1 to S3 are available as Supplementary data at JAC Online.

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