Background: in developed countries where modern antiretroviral treatments (ART) are available and generalized, more than 90% of people living with HIV/AIDS (PLHWA) have obtained an immunovirological success but this is not the case in the developing world. The need for strict adherence to ART, the potential ART side effects and the emergence of drug–resistant viruses are important challenges to life-long ART. So, there is a need for an HIV cure. There is currently intense research into the development of therapeutic vaccines against HIV and, in the future, PLHWA are expected to benefit directly from such vaccines. A preventive HIV vaccine would also be a great tool to prevent, control and maybe eradicate the pandemic [Pul RL et al. 2006]. The Thai RV144 phase III trial vaccine showed a modest efficacy. Anticipate the acceptability of vaccines by the public has become an increasingly important factor in considering which vaccines should be given [Rkp-Ngarm et al. 2009]. In the recent years, prophylactic vaccinations appear to be less and less accepted by a wider part of the general French population. It is therefore important to study the acceptability of a HIV therapeutic vaccine in PLHWA in France.

Objectives: Measure the acceptability of a future HIV therapeutic vaccine and the willingness to participate to a HIV vaccine trial in HIV-infected patients aged 18-75 followed in 3 French hospitals.

Methods
Study design: prospective, non-randomized, multicenter, intervention, qualitative and quantitative study. Between December 2013 and may 2014, all consecutive outpatient followed in 3 hospital-based infectious diseases departments were included. During their semestral follow up visit for HIV, the 3 participating centers were chosen to be representative of French PLHWA described in the nationally representative VESPA survey.

Ethics: each patient received an information notice about the study. Prior written consent was sought before entering the study. Questionnaires and interviews were anonymous. The study was approved by an Ethics Committee patients.

This study was registered on Clinical trials.gov ID: NCT02077701.

Uninclusion criteria:
- age between 18 and 75 years old,
- being infected with HIV-2,
- having a French medical insurance.

Exclusion criteria: patients who understood French poorly or were illiterate.

Qualitative analysis: A review of the literature identified HIV vaccine acceptability determinants: trust in doctors, knowledge, perceptions of illness, stigma, quality of life (Qol). Individual interviews were performed by a trained psychologist. The selection of patients was done to reflect the socio-demographic characteristics of the PLHWA-population in France. The interviews of 45 to 60 minutes duration were recorded and the verbatim transcribed. The analysis was performed manually by two experienced researchers. Open coding was performed within a framework predetermined by the themes in the interview guide. A first list of codes was carried out independently and then pooled together to check for discrepancies. A common list was then used and enriched for further analysis.

Quantitative analysis:
- The RAVVIH questionnaire contained items identified in several preventive vaccine acceptability studies. Items were assessed by a scientific committee and tested by a group of PLHWA before the beginning of the study. RAVVIH questionnaire contains 72 items: 14 socio-demographics. A addition-related and 50 vaccination-related item.
- The Brief Illness Perception Questionnaire (BIPQ) is a 9-item questionnaire designed to rapidly assess cognitive and emotional representations of illness. The Brief IPQ uses a single-scale approach to assess perception on a 0–10 scale. The Brief IPQ comporges 5 items on cognitive representation of illness perception: consequences, timeline, personal control, treatment control, and identity.

The Patient-reported outcomes quality of life HIV instrument (PROQOL-HIV) contains 43 items, reflective of the themes that dominate the experience of HIV patients living in the HAART era. General health perception, social relationships, emotions, energy/activation, sleep, cognitive functioning, physical and daily activity, coping, future, symptoms, and treatment. It has been developed simultaneously across 9 countries, following rigorous international guidelines.

The distribution of acceptability score was summarized using the usual indicators (mean and median) and dispersion (standard deviation, interquartile and range).

Table 1 Clinical characteristics of patients (N=215)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N=215</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>French born</td>
<td>80</td>
<td>37</td>
</tr>
<tr>
<td>Secondary school completed</td>
<td>58</td>
<td>27</td>
</tr>
<tr>
<td>Single</td>
<td>47</td>
<td>22</td>
</tr>
<tr>
<td>Married</td>
<td>59</td>
<td>27</td>
</tr>
<tr>
<td>Being in couple</td>
<td>45</td>
<td>21</td>
</tr>
<tr>
<td>No children</td>
<td>57</td>
<td>26</td>
</tr>
<tr>
<td>Secure employment</td>
<td>88</td>
<td>41</td>
</tr>
<tr>
<td>Additional private insurance</td>
<td>86</td>
<td>40</td>
</tr>
<tr>
<td>Give up some medical care for financial reasons</td>
<td>11</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Socio-demographic characteristics

Table 3. Interviewees: vaccine expected benefits

Expected benefits:
- Life impact

Suppression of treatment daily constraint
Reduce daily burden

At least efficacy required as important as ongoing ART

Table 4. Interviewees: minimal HIV therapeutic vaccine requirements

Minimal acceptable delay between 2 immunizations
6 months

At least efficacy required as important as ongoing ART

Some patients (4/20): No change expected from the vaccine: “the vaccine is still there”, “I am sick, I am sick, nothing will change”

Multivariate analysis: therapeutic vaccine acceptability was not correlated with gender (Pearson r=2, p=0.487), age (Welch test, p=0.521), education (Secondary school completed or not, p=0.688) or disease duration (p=0.921).

Discussion: To our knowledge, for the first time in France our study provides data about acceptability of a future HIV therapeutic vaccine by the PLHWA in clinical practice. In spite of growing scepticism in the French general population concerning prophylactic vaccination our quantitative and qualitative analysis showed that PLHWA have a high acceptability of HIV therapeutic vaccine. Our study has limitations, we did not included patients who understood French poorly and HIV-2 patients; study acceptability was high but we cannot exclude a recruitment bias. The 3 infectious disease departments who participated in the study are actively involved in regular preventive vaccine coverage which is not the case in all hospitals. The study acceptability was very high (around 90%). This study shows that the individual benefit of the future HIV therapeutic vaccine is so important that its acceptance is not correlated with mode of contamination, age, gender, illness perception, socio demographic characteristics or duration of disease. On the other hand, vaccine acceptability is strongly associated with the attitude in treating physician and vaccine characteristics (efficiency, expected benefits). Our results show a high rate of willingness to participate to a vaccine clinical trial as previously reported by others (Dong et al 2014).

Conclusion: This study explored the perception of therapeutic vaccine by a representative sample of PLHWA in France. Patients are receptive to the idea of receiving a HIV therapeutic vaccine and the confidence in their treating clinician is a key factor of acceptability.