**Title: The race up for PrEP implementation in Spain**

**Título: La carrera por la implementación de la PrEP en España**

**Abstract**

The process towards PrEP implementation in Spain has been long and found a number of barriers. Coordinated work of relevant actors was necessary to achieve this goal and overcome those barriers, but there is still much to do in order to make PrEP a fully accessible strategy that leads to a control of the HIV epidemic in Spain.

**Keywords:** PrEP. HIV prevention. Public Health

Pre Exposure Prophylaxis (PrEP) for HIV is a prevention strategy for HIV consisting on daily or occasional uptake of antiretrovirals prior to HIV exposure. PrEP has proved to be effective and safe, and it adds a new tool to the set of preventive strategies available for HIV, such us condom use, treatment as prevention or post-exposure prophylaxis. It is addressed to people at high risk of HIV infection, such as gay, bisexual and other men who have sex with men or sex workers who do not use condom consistently.

The Food and Drug Administration approved PrEP use back in 2012, and both the European and Spanish Medicine Agencies (EMEA and AEMPS, respectively) did so in 2016. Despite the scientific evidence regarding the efficacy, safety and the cost-effectiveness of PrEP was robust, the process towards to PrEP implementation in the National Health System took more than two years. In the meantime, other European countries where either setting big scale implementation studies, this was the case of the Impact Trial in UK, or announcing a national-wide PrEP implementation as France did in March 2017.

The Spanish HIV National Programme (PNS) announced in 2017 the setting of a PrEP feasibility study to evaluate PrEP efficacy, although the efficacy of PrEP had been extensively confirmed in several clinical trials and already approved by the regulatory agencies. This national study was aimed to include 400 people, which were not enough to provide urgent access to those individuals at higher risk of HIV acquisition. Moreover, some administrative processes regarding the regulation of PrEP drugs prices were confusing and it was unclear who were responsible of pushing the process forward whether the public administration, the pharma industry or both.

In this context, the scientific community and HIV NGOs in Spain recognized the need to work together for a better identification of those barriers for PrEP implementation to achieve and avoid more delay in the process.

During the SEISIDA (Spanish Interdisciplinary Society) meeting in 2018, a group of clinicians, researchers, Public Health specialists, NGO leaders and community members, met for the first time to discuss together about the situation for PrEP implementation in Spain. This workgroup was named *PrEP Think Tank*, and agreed on work together to push for PrEP implementation as an “ethical lobby”. The group published an article (García-Sousa et al., Enferm Infecc Microbiol Clin 2018) summarizing the analysis regarding the politic and administrative challenges for PrEP implementation in Spain. Additionally, the *PrEP Think Tank* group elaborated a draft of a non-legislative proposal in favor of PrEP implementation that was supported by all the political parties, and created a position statement document that was presented publicly.

At the same time, members of the *PrEP Think Tank* conducted a research study analyzing PrEP awareness, knowledge and need (Iniesta et al., PLOS One 2019; Ayerdi et al., Enferm Infecc Microbiol Clin 2019). Additionally, some potential implementation models were also proposed (Mir et al., Enferm Infecc Microbiol Clin 2020). The results of these studies were discussed in different scientific conferences prior to publication.

Additionally, the Spanish Network on HIV Research (RIS), organized several events during the Gay Pride Celebrations, in Madrid where community members, clinicians and researchers were invited to informally talk about PrEP and raise awareness on the need of implementing PrEP in order to avoid new HIV infections. This event, called “Prepared Party”, was of great success and was held in 2017, 2018 and 2019).

In 2018, the new National HIV Program team, highly committed with the urgent need for PrEP implementation, made huge efforts to achieve this goal. Even so, it still took one more year until PrEP was finally approved in November 2019. This was possible thanks to a comprehensive effort, providing evidence even before it was required, moving public opinion in favor of PrEP, raising awareness among policy makers, etc.

Finally, the feasibility study promoted by the PNS in 2017 also contributed somehow to PrEP approval, showing the different delivery models that would be viable within the National Health System (<https://www.mscbs.gob.es/ciudadanos/enfLesiones/enfTransmisibles/sida/docs/INFORMEFINAL.pdf>).

One year after PrEP approval, its implementation is still unequal across Spain, and worryingly those cities with a higher incidence of HIV have months of waiting lists to get PrEP. A cohort of PrEP users (SIPrEP) was set on July 2020 by the PNS, in collaboration with the National Center of Epidemiology and the RIS. This monitoring tool, aimed to recruit most of the centers that provide PrEP in Spain, could give us a clearer picture of how PrEP implementation is going. However, the coronavirus pandemic is impacting negatively and adding more delay for the full PrEP implementation and its monitoring.

We have largely failed to achieve the UNAIDS 2020 goal of reducing by 75% the number of new HIV infections since 2010. PrEP is an extraordinary tool that can allow us to get beyond this goal. To make this strategy widely accessible, the commitment and collaboration that led to PrEP approval in Spain are still necessary.

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