



# Enfermedades Infecciosas y Microbiología Clínica

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Original article

## Economic impact of optimising antiretroviral treatment in human immunodeficiency virus-infected adults with suppressed viral load in Spain, by implementing the grade A-1 evidence recommendations of the 2015 GESIDA/National AIDS Plan<sup>☆</sup>



Esteban Ribera <sup>a,\*</sup>, José Manuel Martínez-Sesmero <sup>b</sup>, Javier Sánchez-Rubio <sup>c</sup>, Rafael Rubio <sup>d</sup>, Juan Pasquau <sup>e</sup>, José Luis Poveda <sup>f</sup>, Alejandro Pérez-Mitru <sup>g</sup>, Celia Roldán <sup>h</sup>, Beatriz Hernández-Novoa <sup>h</sup>

<sup>a</sup> Servicio de Enfermedades Infecciosas, Hospital Universitari Vall d'Hebron, Barcelona, Spain

<sup>b</sup> Servicio de Farmacia, Complejo Hospitalario de Toledo, Toledo, Spain

<sup>c</sup> Servicio de Farmacia, Hospital Universitario de Getafe, Getafe, Madrid, Spain

<sup>d</sup> Unidad de Infección VIH, Hospital Universitario 12 de Octubre, Madrid, Spain

<sup>e</sup> Sección de Enfermedades Infecciosas, Hospital Universitario Virgen de las Nieves, Granada, Spain

<sup>f</sup> Servicio de Farmacia, Hospital Universitari i Politècnic La Fe de Valencia, Valencia, Spain

<sup>g</sup> Oblikue Consulting S.L., Barcelona, Spain

<sup>h</sup> Departamento Médico, Bristol-Myers Squibb, Madrid, Spain

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### ABSTRACT

**Introduction:** The objective of this study is to estimate the economic impact associated with the optimisation of triple antiretroviral treatment (ART) in patients with undetectable viral load according to the recommendations from the GeSIDA/PNS (2015) Consensus and their applicability in the Spanish clinical practice.

**Methods:** A pharmacoeconomic model was developed based on data from a National Hospital Prescription Survey on ART (2014) and the A-I evidence recommendations for the optimisation of ART from the GeSIDA/PNS (2015) consensus. The optimisation model took into account the willingness to optimise a particular regimen and other assumptions, and the results were validated by an expert panel in HIV infection (Infectious Disease Specialists and Hospital Pharmacists). The analysis was conducted from the NHS perspective, considering the annual wholesale price and accounting for deductions stated in the RD-Law 8/2010 and the VAT.

**Results:** The expert panel selected six optimisation strategies, and estimated that 10,863 (13.4%) of the 80,859 patients in Spain currently on triple ART, would be candidates to optimise their ART, leading to savings of € 15.9 M/year (2.4% of total triple ART drug cost). The most feasible strategies (>40% of patients candidates for optimisation, n=4,556) would be optimisations to ATV/r+3TC therapy. These would produce savings between € 653 and € 4,797 per patient per year depending on baseline triple ART.

**Conclusion:** Implementation of the main optimisation strategies recommended in the GeSIDA/PNS (2015) Consensus into Spanish clinical practice would lead to considerable savings, especially those based in dual therapy with ATV/r+3TC, thus contributing to the control of pharmaceutical expenditure and NHS sustainability.

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\* Corresponding author.

E-mail address: [eriberap@gmail.com](mailto:eriberap@gmail.com) (E. Ribera).

## **Impacto económico asociado a la implementación de las recomendaciones con grado de evidencia A-I del documento de consenso de GeSIDA/PNS (2015) relativas a la optimización del tratamiento antirretroviral en adultos infectados por virus de la inmunodeficiencia humana con carga viral suprimida en España**

### RESUMEN

**Palabras clave:**  
 Virus de la inmunodeficiencia humana  
 Tratamiento antirretroviral  
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 Coste  
 Gasto sanitario  
 Impacto presupuestario

**Introducción:** El objetivo de este estudio es estimar el impacto económico en España de la optimización del tratamiento antirretroviral (TAR) triple en pacientes con carga viral suprimida según las recomendaciones GeSIDA/PNS (2015) y su aplicabilidad en la práctica clínica.

**Métodos:** A partir de los datos de prescripción del TAR de la encuesta hospitalaria 2014, siguiendo las recomendaciones de GeSIDA/PNS de optimización de TAR con grado de evidencia A-I, se desarrolló un modelo farmacoeconómico. Las pautas de optimización, la voluntad de optimización y demás asunciones y resultados del modelo fueron validados por un panel de expertos en la infección por VIH (infectólogos y farmacéuticos hospitalarios). El análisis se realizó desde la perspectiva del SNS, considerando el coste farmacológico anual, precio de venta del laboratorio notificado, deducción RD-Ley-8/2010 e IVA.

**Resultados:** El panel seleccionó 6 estrategias de optimización y estimó que en España de los 80.859 pacientes actualmente en TAR triple, 10.863 (13,4%) serían candidatos a optimizar su TAR según estas estrategias, generando ahorros de 15,9 M €/año (2,4% del coste farmacológico del TAR triple). Las estrategias más factibles (> 40% del total de pacientes candidatos a optimizar, n = 4.556) y asociadas a mayores reducciones del gasto (ahorro entre 653 y 4.797 €/paciente-año según el TAR triple de partida) serían las optimizaciones a ATV/r + 3TC.

**Conclusión:** La aplicación a la práctica clínica española de las principales estrategias de optimización recomendadas en el documento GeSIDA/PNS (2015) generaría ahorros sustanciales, especialmente aquellas basadas en biterapia con ATV + 3TC, contribuyendo así al control del gasto farmacéutico y a la sostenibilidad del SNS.

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### **Introduction**

It is estimated that around 150,000 people are infected with the human immunodeficiency virus (HIV) in Spain,<sup>1</sup> with numbers increasing by about 4,000 new cases each year.<sup>2</sup> The epidemiological situation, social impact and repercussions for the economy currently make HIV one of Spain's biggest public health problems.<sup>1</sup> Since the availability of highly active antiretroviral therapy (ART), morbidity and mortality have been drastically reduced, and it has even modified the natural course of HIV infection.<sup>3-5</sup> The aim of ART is to achieve sustained viral load (VL) suppression,<sup>6,7</sup> with the combination of two nucleoside analogue reverse transcriptase inhibitors (NRTIs) and a third drug from another family being the standard of treatment.

The improvement in the quality of life and survival of patients with HIV thanks to the efficacy and safety of triple ART,<sup>4,5</sup> combined with the high incidence of HIV in Spain<sup>2</sup> and the current consensus recommendation to initiate ART in all patients independent of CD4 levels,<sup>3,6,7</sup> increases the number of patients to be treated annually.

Although it has been shown to be cost-effective, the fact that triple ART has to be administered for life, and is associated in the medium and long term with a certain level of toxicity,<sup>8</sup> means the economic cost is high.<sup>9,10</sup> Spending on ART in Spain reached €968 M in 2015, representing 12% of hospital pharmacy expenditure.<sup>11</sup>

Since the early 2000s, the search for simpler and less toxic treatments as alternatives to triple ART in patients with undetectable VL has been one of the main challenges in HIV,<sup>12,13</sup> as discussed by the *Grupo de Estudio de Sida/Plan Nacional sobre el Sida* (GeSIDA/PNS) [Expert Study Group on AIDS/Spanish National AIDS Plan]<sup>3</sup> in their recommendations and, to a lesser extent, by the European<sup>7</sup> and North American<sup>6</sup> guidelines.

The aim of optimising ART is to improve the patient's quality of life and their adherence to the therapy, while maintaining its efficacy (virus control and immune response).<sup>3,6,7,13</sup> Optimisation may be desirable to reduce the complexity of the treatment

(reducing the number of antiretroviral drugs [ARD], doses/day, food restrictions, etc.), to adapt the treatment to the requirements and particularities of the patient, or to prevent, reduce and/or reverse the toxicity of the ART.<sup>3,6,7,13</sup>

As a consequence, the cost of ART and the possibility of finding therapeutic options that guarantee efficacy and safety with lower associated costs become increasingly important.<sup>14</sup>

Since 2011, cost-effectiveness analyses of the ART initiation regimens recommended in the current GeSIDA/PNS consensus document<sup>15</sup> have been carried out annually. However, no evaluation has yet been carried out of the economic impact of the implementation of the ART optimisation recommendations on the Spanish National Health Service (SNHS). Therefore, the aim of this analysis is to estimate the economic impact of triple ART optimisation according to the recommendations with the highest level of evidence (AI) in the GeSIDA/PNS consensus document (2015),<sup>16</sup> currently considered most applicable in clinical practice in Spain.

### **Methods**

#### *Study design*

A model was designed for an analysis over one year of the budgetary impact of the application in clinical practice of the A-I evidence recommendations in the GeSIDA/PNS consensus document (2015)<sup>16</sup> regarding the optimisation of triple ART in adults with HIV with undetectable VL.

To design and carry out the study, a panel of six experts with extensive experience in the management of HIV in Spain (three specialists in infectious diseases and three hospital pharmacists) was set up. In parallel, in order to identify the main parameters to be included in the analysis, we carried out a review of the national scientific literature. The initial approach, such as the main inputs and assumptions, were collected through a structured electronic questionnaire designed ad hoc for individual completion by each expert. Subsequently, two face-to-face meetings were held where

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