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## Rationale of the study

- Since antiretroviral therapy (ART) changed the management of HIV over time, improving the efficacy profile both in terms of optimization of the patient's clinical pathway and the tolerability and safety of the therapy itself, decision makers and clinicians could select a growing number of HIV medications
- Therefore, clear data and evidence are needed to select the best therapeutic strategy, focusing on both effectiveness – widely proven by pivotal studies – and managerial benefits for the healthcare system, which have a potential impact on the organizations treating people with HIV (PWH)

## Objectives



This study aims to generate economic and organizational evidence that may support a rational use of resources for the treatment of both naïve and experienced HIV individuals, within the Italian National Healthcare Service (NHS), operating informed and conscious choices

## Methods

- A budget impact analysis (BIA), representing the Italian NHS healthcare expenditure evolution over three years, was developed, considering the overall Italian HIV treated population (N=101,819: 24,916 treatment-naïve and 76,903 treatment-experienced individuals)
- Scenario A, representative of the current situation of consumption and penetration rate of the different therapeutic alternatives (derived from the most update guidelines), was compared with a Scenario B, assuming a greater adoption of BIC/FTC/TAF
- Besides the BIA, an organizational impact assessment was conducted to determine the impact on the use of healthcare resources, assessing the release of organizational hospital assets, focusing on the management of drug-related adverse events
- Patient's treatment history, treatment regimen, development of adverse events, achievement of an undetectable viral load and direct healthcare total costs were the model input variables
- Data were collected from scientific evidence, Italian national and regional legislations, and healthcare professionals' reports

## Results

### A focus on the Scenarios under assessment

| Scenario A         |                                      |                                     |                                  | Scenario B         |                                      |                                     |                                  |
|--------------------|--------------------------------------|-------------------------------------|----------------------------------|--------------------|--------------------------------------|-------------------------------------|----------------------------------|
| Treatment regimens | Prevalent treatment-naïve population | Incident treatment-naïve population | Treatment-experienced population | Treatment regimens | Prevalent treatment-naïve population | Incident treatment-naïve population | Treatment-experienced population |
| BIC/FTC/TAF        | 24%                                  | 50%                                 | 25%                              | BIC/FTC/TAF        | 35.00%                               | 60%                                 | 40%                              |
| 3TC/ABC/DTG        | 44%                                  | 22%                                 | 4%                               | 3TC/ABC/DTG        | 37.63%                               | 17.60%                              | 3.52%                            |
| FTC/TAF+DTG        | 12%                                  | 8%                                  | 3%                               | FTC/TAF+DTG        | 10.26%                               | 6.40%                               | 2.08%                            |
| DTG/3TC            | 15%                                  | 15%                                 | 40%                              | DTG/3TC            | 12.83%                               | 12.00%                              | 32.00%                           |
| FTC/TAF/RPV        | 1%                                   | 1%                                  | 10%                              | FTC/TAF/RPV        | 0.86%                                | 0.80%                               | 8.18%                            |
| FTC/TAF/DRV/COB    | 1%                                   | 1%                                  | 1%                               | FTC/TAF/DRV/COB    | 0.86%                                | 0.80%                               | 0.62%                            |
| FTC/TAF/EVG/COB    | 1%                                   | 1%                                  | 1%                               | FTC/TAF/EVG/COB    | 0.86%                                | 0.80%                               | 0.80%                            |
| FTC/TAF+RAL        | 1%                                   | 1%                                  | 1%                               | FTC/TAF + RAL      | 0.86%                                | 0.80%                               | 0.80%                            |
| FTC/TDF/RPV        | 1%                                   | 1%                                  | 0%                               | FTC/TDF/RPV        | 0.86%                                | 0.80%                               | 0.00%                            |
| DTG/RPV            | 0%                                   | 0%                                  | 15%                              | DTG/RPV            | 0.00%                                | 0.00%                               | 12.00%                           |

## Economic results

From an economic perspective, any modification in the current case-mix of HIV therapy (thus hypothesizing a greater use of BIC/FTC/TAF) is related to an **economic saving equal to -€26.040.271**, in total health spending, for the Italian NHS

|              |              | Adverse Events       | Achievement of virological control | Treatment costs        | Total                  |
|--------------|--------------|----------------------|------------------------------------|------------------------|------------------------|
| Scenario A   | Year 1       | 14,373,262 €         | 165,181,955 €                      | 712,966,190 €          | 892,521,408 €          |
|              | Year 2       | 14,238,219 €         | 163,972,388 €                      | 712,839,013 €          | 891,049,621 €          |
|              | Year 3       | 14,207,605 €         | 162,763,747 €                      | 712,555,775 €          | 889,527,128 €          |
|              | <b>Total</b> | <b>42,819,087 €</b>  | <b>491,918,092 €</b>               | <b>2,138,360,979 €</b> | <b>2,673,098,159 €</b> |
| Scenario B   | Year 1       | 14,059,147 €         | 152,314,202 €                      | 717,505,672 €          | 883,879,022 €          |
|              | Year 2       | 13,947,065 €         | 151,205,592 €                      | 717,214,038 €          | 882,366,695 €          |
|              | Year 3       | 13,918,959 €         | 150,100,825 €                      | 716,792,384 €          | 880,812,169 €          |
|              | <b>Total</b> | <b>41,925,173 €</b>  | <b>453,620,619 €</b>               | <b>2,151,512,094 €</b> | <b>2,647,057,887 €</b> |
| Delta (Euro) | Year 1       | -314,114 €           | -12,867,753 €                      | 4,539,481 €            | -8,642,386 €           |
|              | Year 2       | -291,153 €           | -12,766,796 €                      | 4,375,024 €            | -8,682,925 €           |
|              | Year 3       | -288,645 €           | -12,662,922 €                      | 4,236,609 €            | -8,714,959 €           |
|              | <b>Total</b> | <b>-893,914.09 €</b> | <b>-38,297,472 €</b>               | <b>13,151,115 €</b>    | <b>-26,040,271 €</b>   |
| Delta (%)    | Year 1       | -2.19%               | -7.79%                             | 0.64%                  | -0.97%                 |
|              | Year 2       | -2.04%               | -7.79%                             | 0.61%                  | -0.97%                 |
|              | Year 3       | -2.03%               | -7.78%                             | 0.59%                  | -0.98%                 |
|              | <b>Total</b> | <b>-2.09%</b>        | <b>-7.79%</b>                      | <b>0.62%</b>           | <b>-0.97%</b>          |

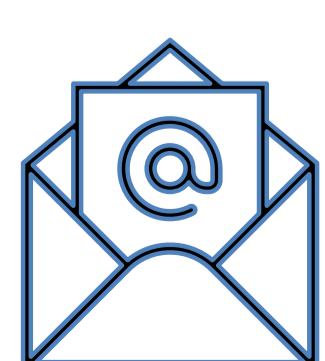
## Organizational results

From an organizational perspective, this modification would reduce the overall hospital accesses devoted to the management of adverse events and/or complications, generating an **overall saving of 245,938 hours**, considering the time spent by the healthcare professionals involved in the care and treatment of individuals with HIV

| Definition of the organizational impact (outpatients)      |  |  |  |                |
|--|--|--|--|----------------|
| Year   | Scenario A (outpatient hours)                                      | Scenario B (outpatient hours)                                      | Difference (outpatient hours)                                      | Difference (%) |
| Year 1   | 70,413   | 72,995   | 2,581  | 3.67%          |
| Year 2   | 71,715   | 74,055   | 2,340  | 3.26%          |
| Year 3   | 71,921   | 74,237   | 2,316  | 3.22%          |
| <b>Total</b>   | <b>214,050</b>   | <b>221,287</b>   | <b>7,237</b>   | <b>3.38%</b>   |
| Definition of the organizational impact (hospitalizations) |  |  |  |                |
| Year   | Scenario A (days of hospitalization, expressed in inpatient hours) | Scenario B (days of hospitalization, expressed in inpatient hours) | Difference (days of hospitalization, expressed in inpatient hours) | Difference (%) |
| Year 1   | 459,297  | 368,999  | -90,298  | -19.66%        |
| Year 2   | 417,403  | 335,443  | -81,961  | -19.64%        |
| Year 3   | 412,365  | 331,449  | -80,917  | -19.62%        |
| <b>Total</b>   | <b>1,289,065</b>   | <b>1,035,890</b>   | <b>-253,175</b>  | <b>-19.64%</b> |
| <b>Total (outpatients hours + hospitalizations hours)</b>  | <b>1.503.115</b>   | <b>1.257.177</b>   | <b>-245.938</b>  | <b>-16.36%</b> |

## Conclusions

- BIC/FTC/TAF represents an interesting possibility for the rapid initiation of ART, as well as for switches, being able to optimize the clinical pathway of a patient with HIV, from an economic and organizational perspective
- Results provide a holistic view of the related benefits, reflecting the importance of considering non-clinical outcomes, such as economic sustainability and resource utilization, in the evaluation of ART regimens



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