FONDO NACIONAL DE RECURSOS
Medicina Altamente Especializada

- Introduction to the Uruguayan NRF
- Management model to replace an original high cost drug with a non-original formulation. Evaluation, monitoring and results.
- Tacrolimus
- Research Background
- Current Evaluation
- Findings
- Current Situation

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Management model to replace an original high cost drug with a non-original formulation. Evaluation, monitoring and results

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NATIONAL RESOURCES FUND

URUGUAY

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NATIONAL RESOURCES FUND

*** National Agency for Highly Specialized Medical Procedures**

*** Created by law in 1980**

*** *Guarantees universal* access to highly specialized medicine (HSM).**

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NATIONAL RESOURCES FUND

*** Budget**

* **U$S 150,000,000 /year**
(6% of health expenditure)

* **U$S 24,000,000 / year** on medicines in 2010

* **U$S 30,000,000** expected for 2011

•It is anticipated that if the current trends continue from 2011 onwards, up to 10% of the country's drug spending will go to the NRF

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Tacrolimus

* Tacrolimus is financed for immunosuppressive treatment in solid organ transplantation.

• The original trademark was exclusive until May 2009, when a non – original formulation was introduced.

•This change was resisted by patients and physicians and a process was designed to follow up the change .

•The new trademark was given to new patients and to those already in treatment who accepted the change.

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- The drug's plasmatic measurements for patients who change to the new trademark started to be paided by the NRF

- Patients who decide to use the original drug continued paying a contribution for plasmatic measurements.

- Results are registered online on the NRF database.

- If patients are not within therapeutic levels, an email is automatically sent to the physicians who monitor the process. Then they contact the corresponding physician treating the patient.

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Research Background

- At month four and at month ten after the start of the treatement with non-original Tacrolimus, all the available data on patients who changed was analyzed.

- In 93 patients analyzed there was a significant drop in Tacrolimus plasmatic levels (7.62/6.14 ng/ml, $p<0.001$) explained by a drop in given dose (5.59/4.81 mg, $p<0.001$).

- Normally, the dose is gradually reduced within the months following the transplatation

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Current Evaluation

- An evaluation was made on 408 patients using both trademarks.

- The differences between consecutive plasmatic measurements with the same trademarks (2,172 cases) were compared with correlative differences between doses.

* An ANCOVA test was run.

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FINDINGS

- Plasmatic values decreased with both trademarks (0.094 ng/ml the original and 0.099 ng/ml the generic)

- The decrease was associated with dose reduction (Beta 0.674 , $p<0.001$)

- The trademarks were not associated with the difference in the plasmatic values ($p=0.972$).

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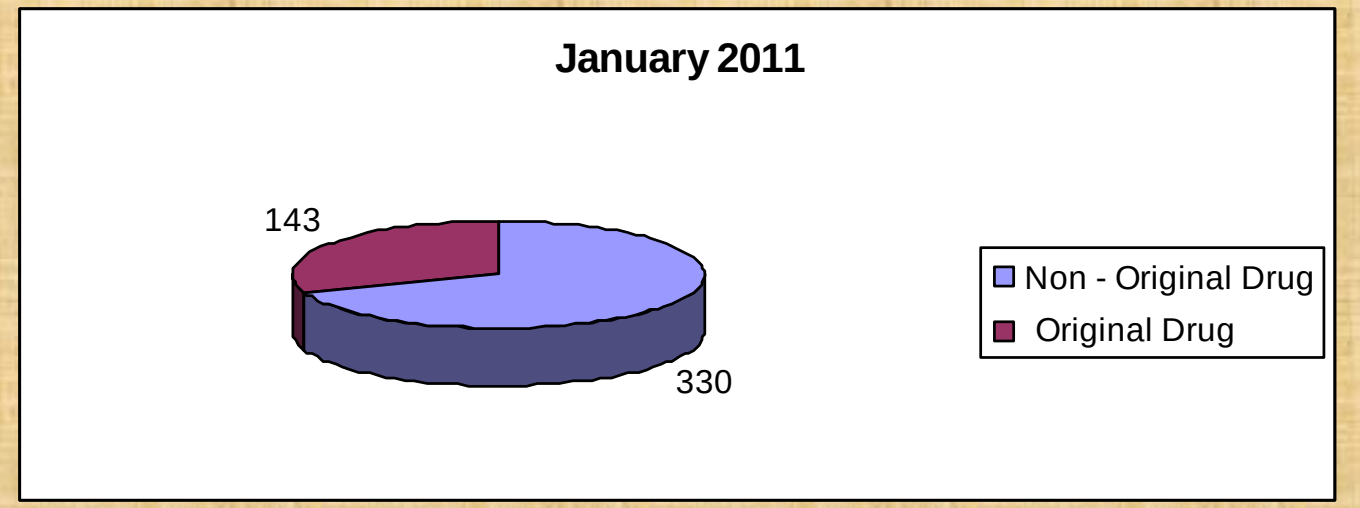
Current Situation

- With the available information, we haven't found differences in terms of plasmatic values between both trademarks.

- More time is needed to evaluate the impact on grafts and patients survival.



Thanks