HPV-ISI

Innovative Screening Initiative

HIV/HPV service integration in the experience of the DREAM program in Africa

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Disclosure statement

To my best knowledge, no aspect of my current personal or professional circumstance places me in the position of having a conflict of interest with this presentation.
The experience of the DREAM program
seizing the opportunity
DREAM program (Disease Relief through Excellent and Advanced Means) is the health intervention of the Community of Sant'Egidio in 10 African countries.

DREAM was the first program to bring excellences in diagnosis and treatment for HIV infected patients across the Africa region.

DREAM was born in the suburbs of Maputo in 2002, is now present in 10 African countries:

1. Mozambique
2. Malawi
3. Kenya
4. Tanzania
5. Cameroon
7. Republic of Guinea
8. Eswatini
9. Nigeria
10. Central African Republic
DREAM program has a strong basis on laboratory activities in order to offer the patients a high quality diagnosis and follow-up (data 2020):

- HIV Viral load testing (950,000 tests performed)
- HIV resistance test (525 test performed)
- Haematology (1,6 million tests performed)
- Biochemistry (1,2 million tests performed)
- Tuberculosis molecular diagnosis (2,500 test performed)
- HPV molecular diagnosis – pilot study in Maputo
HIV / HPV integration in DREAM program: HPV-ISI study

Partnership between Community of Sant’ Egidio (DREAM program) Roche Diagnostics Portugal since July 2021
Maputo Central Hospital
HPV in Mozambique

- Mozambique is one of the countries with the highest burden of cervical cancer in the world.

- More than 4,200 new cases and more than 3,300 deaths are registered every year.

- HPV infection is common among Mozambican women, varying from 63.3%\(^2\) to 75.9%\(^3\) according to studies.


Cervical cancer prevention in Mozambique

• According to common practices and national guidelines, the Mozambican national strategy for cervical cancer screening is based on visual inspection with acetic acid (VIA).
  • VIA represents an effective, easy-to-perform, rapid and inexpensive screening tool that is now present in virtually every health unit in the country.
• VIA is recommended for women aged 30 to 55 years.
• Cryotherapy in VIA+ cases - possibly on-site in the same day of the test – is strongly recommended.
Objectives and methodology

• HPV-ISI is conducted in a health centre in Zimpeto (Maputo, Mozambique), and also involves the Maputo Central Hospital.

• The main objective of the study is to evaluate the use of HPV testing as the initial screening test.

• Consequently also to evaluate how many cryotherapies and colposcopies are being unnecessarily performed in HPV-negative women, and how many HPV-positive women are being missed in the VIA-negative population.
HPV-ISI strategy

Women aged 30 - 55 (HIV+/−)

- VIA
  - Positive <75%
    - Cryotherapy
  - Positive >75% or suspect of cancer
    - Colposcopy
  - Negative
    - Follow-up according to national protocols

- hrHPV

Biopsy
Training of local staff and start of enrollment

July 2021
Results
(12 months)

1,323 patients enrolled:
- HIV:
  - 713 (53.8%) HIV-
  - 610 (46.2%) HIV+
- VIA:
  - 1,183 (89.4%) VIA -
  - 140 (10.6%) VIA +
  - (9.4% in HIV- vs 12.0% in HIV+)
HPV testing results

• HPV test:
  • 960 (72.6%) -
  • 363 (27.4%) +
    • 121 HPV-16 and/or -18
    • 242 others

• HPV infection:
  • 18.9% in HIV-
  • 37.4% in HIV+

• HPV-16, -18 (or both):
  • 5.3% in HIV-
  • 13.6% in HIV+
Concordance VIA / HPV

• Overall Concordance VIA/HPV test was 71.9% (63.4% in HIV+!)

• Among 140 women tested VIA+ 74 (52.8%!!) were HPV uninfected (and underwent a useless cryotherapy)

• Among 1,183 women tested VIA- 297 (25.1%!) were HPV infected
Current screening approach

VIA

- VIA + (<75%)  
  >> Tratamento (crioterapia)  
  \[n=70 (9.7\%)]

- VIA + (≥75% ou SCC)  
  >> Referenciamento  
  \[n=12 (0.9\%)]

- VIA-  
  >> Follow-up  
  \[n=1183 (89.4\%)]

\[n=70 \rightarrow \text{hrHPV-}\]

\[n=297 \rightarrow \text{hrHPV+}\]
Table 2.2. The seven algorithms considered

<table>
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HPV: human papillomavirus, VIA: visual inspection with acetic acid.
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What would happen if...?

Real data simulation
HPV DNA

Positivo (+) n = 363

hrHPV 16 e/ou 18 n=121

VIA

VIA+ (≥75%/SCA) n=4

Referenciar

VIA + (<75%) n=86

Bombas relógio

VIA-

Outros 12 hrHPV n=242

VIA

VIA+ (≥75%/SCA) n=4

Referenciar

VIA + (<75%) n=211

Bombas relógio

VIA-

Negativo (-) n=960

VIA

VIA+ (≥75%/SCA) n=70

Termoablação/ Crioterapia desnecessária

VIA + (<75%) n=886

Descartar e marcar nova consulta para 3 anos

VIA-

Verificar a presença de Clamídia e Neisseria

Não descartar a possibilidade de lesão de alto grau resultante de infecção por HPV de baixo risco

N=1323

n=121

n=242

n=4

n=86

n=4

n=211

n=70

n=886

n=4

n=70

n=70

n=4

n=86

n=242

Bombas relógio

Necessidade de tratamento

Novo teste HPV depois de 1 ano. No caso de “persistência” devem ser encaminhadas para hospital para verificar lesão do endocolo.
Lessons learnt from HPV-ISI study

• HPV molecular testing is feasible and easy to set up in a HIV care setting
• Our data confirm higher rates of HPV infection in HIV+ patients in Mozambique (especially HPV-16 and -18).
• Screening approaches based on VIA are not adequate.
• High rate (52.8%) of useless cryotherapies
• A group of women with high risk HPVs escaped screening (81.8% of all the women with HPV infection).

• The introduction of HPV testing as the first step for screening, especially in HIV+ women, is urgently needed and feasible
Possible future steps

- Evaluate results in a larger cohort (DREAM program in Mozambique and Malawi assists more than 30,000 women)
- Evaluate age and correlation with particular risk profile (consider differentiating screening approaches according to age and HIV status?)
- Evaluate cost-effectiveness of screening approaches with real life data
- Evaluate other levels of integration of HIV/HPV care:
  - community activities
  - awareness campaigns
  - self collection and peer-to-peer educators
  - HPV testing in the national laboratory network
Thank you