REVIEW OF SCREENING RECOMMENDATIONS FROM AROUND THE WORLD

LATIN AMERICA

CARLOS H PÉREZ M

SOCIEDAD DE CIRUGÍA DE BOGOTÁ - COLOMBIA – HOSPITAL DE SAN JOSÉ

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Disclosures

I have been a speaker through the Colombian Colposcopy Association for MSD, Roche, GSK and Abbott.
Content

1. Introduction
2. Estampa Study
3. Implementation of HPV test in Central America
4. New HPV-FASTER protocol in Mexico
5. New DNA Methylation test
6. Folate Receptor-Mediated Staining Solution test (FRD)
7. Conclusions
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INTRODUCTION

- Magnitude of social and economical burden of unhealthy life-styles predisposing cancer and other Non-communicable chronic diseases (NCDs)
- This is the greatest threat for global public health and national prosperity.
- By 2025, cancer, heart disease, and Alzheimer will affect 1.2 million individuals older than 60 years old.
- Positive strides are being adopted by some countries and Latin America in tobacco, salt diet control, and HPV vaccination.
Estimates of number of new cases of cervical cancer (2012): 527,624 cases

- **NORTH AMERICA**: 14,377
- **EUROPE**: 58,373
- **AFRICA**: 99,038
- **CENTRAL & SOUTH AMERICA**: 63,800
- **ASIA**: 284,283

*Age-standardised rates: Incidence 2012*

(Source: GLOBOCAN 2012, IARC)
Within-country variations in mortality rates from cervical cancer

Parkin et al., Vaccine 2008
Cervical cancer incidence in South America

<table>
<thead>
<tr>
<th>Country</th>
<th>No. new cases per year</th>
<th>CC ranking respect to other cancers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>18,503</td>
<td>1°</td>
</tr>
<tr>
<td>Venezuela</td>
<td>4,973</td>
<td>2°</td>
</tr>
<tr>
<td>Argentina</td>
<td>4,956</td>
<td>3°</td>
</tr>
<tr>
<td>Colombia</td>
<td>4,661</td>
<td>2°</td>
</tr>
<tr>
<td>Peru</td>
<td>4,636</td>
<td>3°</td>
</tr>
<tr>
<td>Ecuador</td>
<td>2,094</td>
<td>1°</td>
</tr>
<tr>
<td>Bolivia</td>
<td>2,029</td>
<td>4°</td>
</tr>
<tr>
<td>Chile</td>
<td>1,441</td>
<td>2°</td>
</tr>
<tr>
<td>Paraguay</td>
<td>1,022</td>
<td>2°</td>
</tr>
<tr>
<td>Uruguay</td>
<td>402</td>
<td>3°</td>
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<tr>
<td>Guyana</td>
<td>161</td>
<td>2°</td>
</tr>
<tr>
<td>Suriname</td>
<td>107</td>
<td>2°</td>
</tr>
<tr>
<td>French Guyana</td>
<td>35</td>
<td>2°</td>
</tr>
</tbody>
</table>

SOURCE: GLOBOCAN 2012, IARC
Cervical cancer incidence in South America

Ranks as the most common in Bolivia and Peru. Second in Brazil, Colombia, Ecuador, Mexico and Paraguay. Third in Guayana Surinam and Venezuela.

The annual current burden of HPV-related diseases has been estimated in 610,000 cancer cases and 320 million cases of anogenital warts worldwide in both genders.

Of these, 75,000 cancer cases are diagnosed in Central and South America and 25,000 in North America.
Cervical cancer studies in Latin America

IFCPC 2017 World Congress
Almonte et al., Vaccine 2008
HPV vaccine in the Americas, 2015
Cervical Cancer Prevention in Latin America

- HPV vaccination
- Women born before 2000 will not benefit from vaccination
- It will take several decades to see the impact of vaccination on cervical cancer rates

=> SCREENING SHOULD CONTINUE
Cervical cancer incidence in South America

HPV testing should be introduced in primary screening

Unanswered questions:

- What is the best way to triage HPV positive women?
- What is the best way to screen women in very difficult settings?
- What are the minimal requirements to establish a sustainable organised screening program?
Cervical cancer incidence in South America

Latin America main changes for cancer control:

The implementation of both a population-based cancer registry and a national cancer plan.

Cancer surveillance in LA is largely inexistent

Incidence data are derived from national mortality estimates using modelled survival rates.

These registries provide information of good quality to be included in GOBOCAN
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Estudio de Tamizaje y Triaje con pruebas de Papillomavirus
The ESTAMPA study

Multicentric study of cervical cancer screening and triage with Human papillomavirus testing
Background

Infection with high-risk HPV is a major cause of cervical cancer
HPV infection is age dependent
  ❖ High prevalence among young women
Most HPV infections clear spontaneously
  ❖ Especially those in young women
Most women with HPV infection will not have a cervical disease and will not require treatment
Recent knowledge allows the use of HPV molecular tests for screening

- Highly sensitive to detect precancer
- Highly reproducible

HPV detection will soon become standard for primary screening over 30 years in many places including Latin America:

- Approved for primary screening in Mexico, Argentina and Colombia
New methods are required to select HPV positive women who are at risk of having or developing precancer and therefore require evaluation and treatment.

These methods are also required to define the management of HPV positive - cytology negative women in places where co-testing is the standard.

Multiple methods under development, but more data are required on their performance.
Study design

Multicentric screening study
50,000 women 30-64 years old
Primary screening with HPV test
Referral to colposcopy of all HPV positive women
Second round for HPV positives 18 months later
Main endpoint: HSIL+ on biopsy defined as in LAST (p16+, CIN2, CIN3, AIS or worse)
Aims

To investigate the performance of emerging cervical cancer screening and triage techniques in women 30y+

To evaluate the feasibility of different approaches for the implementation of organized HPV-based screening programs
Primary Objective

To estimate the performance characteristics (sensitivity, specificity, positive and negative predictive value) of multiple techniques alone or in combination for detection of HSIL on biopsy among HPV positive women 30-64 years old
Secondary Objectives

- Evaluate performance of triage techniques in women with negative cytology
- Estimate proportion of HPV+ women referred to colposcopy by triage techniques
- Establish specimen biobank & database to evaluate future screening and triage techniques
- Evaluate feasibility of implementing organized HPV screening within local health systems
- Estimate rates of over-diagnoses, overtreatment, and other short-term clinical complications associated with the screening process
Ancillary Objectives

Evaluation of the psycho-social impact of the HPV test results
Cost-benefit evaluation of different screening strategies for the different countries
Assessment of knowledge and attitudes about HPV in individuals and health personnel in the communities where the study is being conducted
Main Protocol

50,000 Women 30-64y

HPV

50,000 Women 30-64y

Routine recall

Neg

Pos

Repeat HPV test 18-30m

Colposcopy & Treatment

Pos

Colposcopy & Treatment

Neg

Colposcopy & Treatment

Pap

Dry Dacron

PreservCyt

Blood

PreservCyt

Pap

Dry Dacron

PreservCyt

IARC 2013
Possible Triage Tests
(In all colposcopy patients)

VIA
Cytology (liquid vs. conventional)
COBAS/ABBOTT (DNA HPV 16, 18)
PreTec Proofer (RNA, HPV 16, 18, 31, 33, 45)
p16/ki67
E6 strip (oncoprotein HPV 16, 18, 45)
HC type specific
Methylation
First meeting ESTAMPA pathologists
First meeting ESTAMPA colposcopists
Preliminary Results
Prevalence HR HPV Infection in ESTAMPA

<table>
<thead>
<tr>
<th>Age</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-34</td>
<td>19.1%</td>
</tr>
<tr>
<td>35-39</td>
<td>16.6%</td>
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<tr>
<td>40-44</td>
<td>13.6%</td>
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<tr>
<td>45-49</td>
<td>12.4%</td>
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<td>50-54</td>
<td>11.7%</td>
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<tr>
<td>55-59</td>
<td>13.6%</td>
</tr>
<tr>
<td>60-64</td>
<td>12.7%</td>
</tr>
</tbody>
</table>
CURRENT STATUS OF ESTAMPA CENTERS

<table>
<thead>
<tr>
<th>ESTAMPA Centers</th>
<th>No. recruited/Date of start</th>
<th>No. to be recruited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soacha, Colombia</td>
<td>4661 Jan 2016</td>
<td>10000</td>
</tr>
<tr>
<td>Apartado, Colombia</td>
<td>803 Jan 2016</td>
<td>2000</td>
</tr>
<tr>
<td>Asunción (1), Paraguay</td>
<td>1820 Febrero 2016</td>
<td>5000</td>
</tr>
<tr>
<td>F. Morazán, Honduras</td>
<td>1525 Febrero 2016</td>
<td>5000</td>
</tr>
<tr>
<td>Montevideo, Uruguay</td>
<td>461 Abril 2016</td>
<td>2000</td>
</tr>
<tr>
<td>Puntarenas, Costa Rica</td>
<td>254 Abril 2016</td>
<td>5000</td>
</tr>
<tr>
<td>Buenos Aires (1), Argentina</td>
<td>79 Febrero 2016</td>
<td>5000</td>
</tr>
<tr>
<td>La Perla, Callao, Perú</td>
<td>52 Abril 2016</td>
<td>5000</td>
</tr>
<tr>
<td>Asunción (2), Paraguay</td>
<td>Febrero 2016</td>
<td>1000</td>
</tr>
<tr>
<td>Santiago, Chile</td>
<td>Abril 2016</td>
<td>1000</td>
</tr>
<tr>
<td>Morelos, México</td>
<td>Abril 2016</td>
<td>5000</td>
</tr>
<tr>
<td>Buenos Aires (2), Argentina</td>
<td>En planeación</td>
<td>1000</td>
</tr>
<tr>
<td>Porto Alegre, Brasil</td>
<td>En planeación</td>
<td>3000</td>
</tr>
<tr>
<td>Sucre, Bolivia</td>
<td>En planeación</td>
<td>5000</td>
</tr>
</tbody>
</table>
Members of the Central Coordinating Group & DSMB

**Grupo de Coordinación Central**
- Maribel Almonte (PI)
- Silvina Arrossi
- Nathalie Broutet
- Teresa Darragh
- Catterina Ferreccio
- Paula González
- Rolando Herrero (PI)
- Jose Jerónimo
- Eduardo Lazcano
- Silvana Luciani
- Raul Murillo
- Gloria Sanchez

**DSMB**
- Peter Sasieni
- Walter Prendiville
- Nico Wentzensen
- Silvia Lara
- Raquel Amaya
- Helene Sancho-Garnier
- Maria Leon-Roux
ESTAMPA Investigators

- IARC: M Almonte, ML Hernandez, R Herrero, R Murillo
- Colombia:
  - Bogota: C Wiesner, M Gonzalez
  - Medellin: G Sanchez
- Paraguay:
  - Asuncion (1): E Kasamatsu, L Mendoza, MI Rodriguez, M Paez
  - Asuncion (2): V Villagra, N Maldonado, ML Bobadilla, G Chamorro
- Honduras: A Ferrera, J Figueroa
- Uruguay: G Rodriguez
- Costa Rica:
  - Guanacaste: P Gonzalez
  - Puntarenas: A Calderon, LB Saenz
- Argentina:
  - Buenos Aires (1): S Tatti, L Fleider
  - Buenos Aires (2): A Picconi, J Mural
- Peru: G Venegas, Y Bellido, A Romero, J Arias-Stella, M Miraval
- Mexico: E Lazcano, A Cruz, P Hernandez, J Salmeron
- Brasil: P Naud
- Chile: L Baez, C Molina
- Bolivia: C Teran
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Implementation of HPV testing in national programs in Central America

Integrating HPV testing into public health care systems in:
- Guatemala
- Honduras
- Nicaragua

Limited resources:
- Staff.
- 100,000 tests per country.
- More realistic algorithms.
Self-Sampling a Key Strategy
Five key areas

1. **Updating national guidelines incorporating HPV tests.**
2. Procurement, supply, storage, and distribution systems.
3. Health information systems.
5. Personnel capacity for screening, treatment, and laboratory procedures.
Strategies for changing practices of providers

Sharing experiences from other countries in the region.

Engagement of international organizations

Meeting of regional and international experts.

Doctors listen to experts from their own specialty.
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HPV vaccination impact on a cervical cancer screening program: methods of the FASTER-Ttalpan Study in Mexico

Abstract

Objective. To outline the design of a clinical trial to evaluate the impact of HPV vaccination as part of a hrHPV-based primary screening program to extend screening intervals. Materials and methods. A total of 18,000 women aged 15-45 years, attending the regular cervical cancer-screening program in primary health care services in Ttalpan, Mexico City, will be invited to the study. Eligible participants will be assigned to one of three comparison groups: 1) HPV16/18 vaccine and hrHPV-based screening; 2) HPV6/11/16/18 vaccine and hrHPV-based screening. Controls, who will receive only hrHPV-based screening, strict surveillance of hrHPV persistent infection and occurrence of precancerous lesions will be conducted to estimate safety profiles at different screening intervals. Participants will undergo diagnosis confirmation and treatment as necessary. Conclusion. The FASTER-Ttalpan Study will provide insights into new approaches of cervical cancer prevention programs. It will offer valuable information on potential benefits of combining HPV vaccination and hrHPV-based screening.
The HPV-FASTER protocol: an interesting alternative for Latin America

Fills the gap by combining both strategies (screening and vaccination), the end-purpose is to accelerate reduction of cervical cancer incidence and mortality.

Based on the results from two phase III trials comparing HPV vaccination against placebo among adult women (age 45 for quadrivalent and 55 for the Bivalent).

All groups report HPV and cytology status at the time of vaccination.

The HPV-Faster protocol offer HPV vaccination to woman in a broad age ranged 9-45/50, irrespective of HPV infection status.
The figure shows exemplary cervical cancer prevention strategies based on cytology, HPV testing, and HPV vaccination with the effective total number of screens among screen-negative women per lifetime. Modified from Schiffman M, Wentzensen N. Human papillomavirus infection and the multistage carcinogenesis of cervical cancer. Cancer Epidemiol Biomarkers Prev. 2013; 22(4):553-60.9

**Figure 1. Evolution of cervical cancer prevention**
The HPV-FASTER protocol: an interesting alternative for Latin America

Women at any age above 30 would be, in addition, screened with a HPV test as part of their first vaccination visit.

HPV positive women would be offered triage and diagnostic/treatment follow up in accordance with recommended guidelines.

HPV negative women at baseline, once vaccinated, would have a very low risk of cervical cancer and little requirements of further HPV screening.
The HPV-FASTER protocol: an interesting alternative for Latin America

Latin America fulfills several criteria to consider HPV-Faster as an alternative:

- The burden of disease is high
- Conventional cytology based screening programs have had limited impact in reducing mortality.
- Now exists an adequate progress, to sustain on time, campaigns of HPV screening and triage.
- Infant vaccination programs are achieving high coverage.
The HPV-FASTER protocol: an interesting alternative for Latin America

In Latin America we have an HPV-Faster protocol (denoted as FRIDA-2) in two semi-rural areas of Mexico, Tlaxcala and Morelos.

The aim is to demonstrate the viability of this strategy and to refine the protocol (i.e. to determine the age at first HPV screen, the upper age limit for HPV vaccination, and the number of HPV screening events required in vaccinated women and others).

Women 25-45 years from a borough in Mexico City

Recruitment and Informed consent

Randomization (3 arms)

- HPV 16/18 vaccine N=6,000
- HPV 6/11/16/18 vaccine n=6,000
- Control arm N=6,000

Dose 1

Urine collection for hrHPV testing (Validation of urine HPV test)
Cervical sampling for hrHPV-based screening

Dose 1

Negative → Triage in hrHPV+

Colposcopy Dx & Tx

Dose 2

Negative → Triage in hrHPV+

Colposcopy Dx & Tx

Dose 2

Negative → Triage in hrHPV+

Colposcopy Dx & Tx

ENDPOINTS

2.5 yrs. assessment:
6m-hrHPV persistence

Urine collection for hrHPV genotyping

Urine collection for hrHPV genotyping

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Methylation Analysis of the FAM19A4 Gene in Cervical Scrapes Is Highly Efficient in Detecting Cervical Carcinomas and Advanced CIN2/3 Lesions

Lisa M.A. De Strooper¹, Chris J.L.M. Maljaar¹, Johannes Berkhof², Albertus T. Hesselink¹, Peter J.F. Snijders¹, Ranise D.M. Steenbergen¹, and Daniëlle A.M. Heideman¹

Abstract

Primary testing for human papillomavirus (HPV) in cervical screening requires triage to differentiate women with transient infection from those with persistent infection who require more intensive management given their risk for cervical (pre)cancer. In this study, the clinical performance of a novel methylation marker FAM19A4 for the triage of high-risk (hr)HPV-positive women was evaluated. Using a training-validation set approach, we analyzed a FAM19A4 quantitative methylation-specific PCR (qMSP). The training set comprised hrHPV-positive cervical scrapes of 43 women with cervical intraepithelial neoplasia grade 3 or worse (CIN3+) and 135 women with ≤CIN1. The validation set comprised hrHPV-positive cervical scrapes of 52 women with CIN2+, including 33 CIN3+, 19 CIN2, and 166 women with ≤CIN1. The methylation threshold of FAM19A4 qMSP that gave rise to CIN3+ specificity of 70% in the training set was applied in the validation set. This resulted in CIN3+ sensitivity of 75.8% [95% confidence interval (CI), 61.1–90.4] at 67.0% (95% CI, 60.3–73.8) specificity. Next, the validated qMSP was applied to an independent series of hrHPV-positive cervical scrapes of 22 women with cervical cancer, 29 with advanced CIN2/3 [i.e., women with a known preceding hrHPV infection (PHI) lasting ≥5 years as proxy of longer duration of lesion existence], and 19 with early CIN2/3 (i.e., PHI < 5 years). All carcinomas (22/22) and advanced CIN2/3 lesions (29/29) were FAM19A4 methylation-positive, compared with 42.1% (8/19; 95% CI, 19.9–64.3) of early CIN2/3 lesions. In conclusion, FAM19A4 is an attractive triage marker for hrHPV-positive women, with high reassurance for the detection of cervical carcinoma and advanced CIN2/3 lesions. Cancer Prev Res; 7(12): 1251–7. © 2014 AACR.
Safe, Confident, QIAsure
A new cervical cancer screening test
Key benefits:

- **Accuracy**: QIAsure is a quantitative methylation-specific PCR test with high sensitivity and 100% accuracy in detecting biomarkers associated with cervical carcinoma in patients.

- **Objective results**: QIAsure provides objective results on whether a patient has a hrHPV infection that’s actively transforming cervical cells into cancer.

- **Simple sample**: QIAsure can be performed on the same sample (self-sample or physician/gynecologist collected) as the primary screening HPV test.

- **Saves time & money**: QIAsure can help reduce unnecessary colposcopies and cervical treatments.

- **Convenience**: QIAsure can be performed on self-samples collected by the patient without a speculum exam, making it easy and convenient to be tested early and often.

- **Peace of mind**: QIAsure provides test negative patients with peace of mind that they have a low short-term risk of cervical cancer.
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Folate Receptor-Mediated Staining Solution (FRD™)

A special staining method for rapid visualization detecting cervical intraepithelial neoplasia (CIN2+).
A Newly Developed Detection Tool

Folate Receptor-Mediated Staining Solution designed for rapid visualization of the cervical neoplastic epithelia to detect early abnormal of cervical lesions (CIN2+)
Testing Principles

Folate receptors are over-expressed on tumor cell membranes:
- Clinical studies have shown that there is a high expression of folate receptors on tumor cell membranes but a low or no expression on normal cells. Therefore, folic acid derivatives can be used as ligands for folate receptor mediated diagnosis and/or treatment for targeted tumors.

Reactive oxygen species (ROS) accumulate in tumor cells:
- Compared to normal cells, ROS accumulates in tumor cells and oxidative stress occurs.

High demand for iron:
- During cancer development, there is high demand for iron. The labile iron pool which exists in the tumor cells contains iron that can be chelated and participates in redox reaction. It will catalyze the following reaction to enhance the oxidizability greatly.

\[
\text{Fe}^{2+} + \text{H}_2\text{O}_2 \rightarrow \text{Fe}^{3+} + \text{OH}^- + \cdot\text{OH} \quad \text{(Fenton Reaction)}
\]
Mechanism of Action

When the FRD™ staining solution is applied to the cervical epithelial tissue overexpressing folate receptors, folic acid binds to folate receptors, triggering endocytosis of folic acid-methylene blue conjugate.

The acidic microenvironment within the endosome causes dissociation of folic acid and reduced methylene blue from the folate receptors.

Consequently, the dissociated reduced methylene blue (colorless) is oxidized by the intracellular ROS to form oxidized methylene blue (blue).

The oxidized methylene blue leaks out of the epithelial cells which can then be visualized on the tapered applicator, used for the delivery of the FRD™ staining solution to the entire cervical epithelia.

The color change of methylene blue detected on the tapered applicator can be affected by intracellular pH, the amount of ROS, and free radicals.
Mechanism of Action
Results

No change in color (light brown) or a color change to green indicates negative results, suggesting no neoplastic changes of the cervical epithelium.

A color change to blue, bluish black, or black is indicative of abnormal cervical lesions (CIN2+), which warrants follow-up diagnosis/treatment including colposcopy and biopsy as soon as possible.
VIDEO FRD
Demonstration
Precautions

The FRD™ staining solution must be used within 10 minutes after exposure to air. Do not use the FRD™ solution if its color has changed to green or bluish-green.

FRD™ staining solution is not intended for re-use.

After completion of the FRD™ test, clear the remaining solution on the surface of the cervix with distilled water and dry the cervix and vagina with cotton or gauze.

The application of FRD™ staining solution to the cervix has no significant impact on cytology and/or HPV-DNA sampling conducted afterwards.
Precautions

Caution needs to be taken when there is bleeding from the cervix and/or vagina. For subtle bleeding, such as stripping, spotting, or mild contact bleeding, the tester may observe a tiny spot of red color change on the epithelium staining applicator, which should not have an impact on identifying any color changes. However, if significant amount of contact bleeding occurs, a large area of the epithelium staining applicator may be contaminated by the blood, which may lead to a false positive or false negative results due to the interaction between the blood and the color changes.

Not recommended for use in pregnant women or women with total hysterectomy due to lack of clinical data on these population.

For optimal FRD™ testing conditions, please try to avoid the following:

- Douching or packing the cervix and/or vagina with medication within 48 hours;
- Sexual intercourse within 48 hours;
- Cytology or HPV-DNA sampling within 48 hours;
- Colposcopy within 7 days;
- Biopsy or endo-cervical curettage within 14 days;
- Surgery of the cervix within 30 days;
Contraindications

Hysterectomy
Oral and/or injection of anti-cancer drugs
Acute cervical inflammation
Pregnancy
Menstruation
Effects of FRD™ on Other Cervical Examines

No significant impact on other cervical examinations

Clean the residue of FRD™ solution from the cervix afterwards

FRD™ does not affect the results of cytology and HPV-DNA test; there is no need to clean the cervix before taking samples for the above-mentioned tests

It is highly recommended that patients undergo colposcopy as soon as possible, if FRD™ test is positive.
Advantages of FRD™

FRD™ is the first to utilize folate receptor mediated target diagnosis for early detection of CIN2+

Compared with Cytology and HPV test, FRD™ has compatible sensitivity and high specificity to detect high grade cervical lesions.

• Several clinical studies reveals that the sensitivity of the FRD ranges from 72.2%-86.9% and the specificity ranges from 49.2%-78.7% for the detection of CIN2+

Rapid visualization of detection results:

• Test results are determined immediately (within 60 sec) after staining of the entire cervical epithelia
Advantages of FRD™

Complete coverage of entire cervix:

- FRD™ is capable of detecting abnormal lesions of both squamous and columnar epithelium

Localization of abnormal cervical lesions:

- By aligning the labels on the Epithelium Staining applicator to the ecto-cervix, the FRD has the ability to identity the corresponding cervical location of the “abnormal lesions” detected on the applicator
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CONCLUSIONS

Some important tools are now available for improving cervical cancer prevention:

1. Boost secondary prevention
2. Testing for the presence of HPV in cervical specimens and treating HPV induced lesions.
3. Introduce primary prevention by inmunizing against a select group of oncogenic HPV types.

Nowadays strategies that combine HPV vaccination and HPV screening have to be evaluated.
THANKS FOR YOUR ATTENTION
GRACIAS POR SU ATENCION