Visual inspection with acetic acid (VIA): Evidence to date

Original source:

Alliance for Cervical Cancer Prevention (ACCP) www.alliance-cxca.org

Overview:

- Description of VIA and how it works
- Infrastructure requirements
- What test results mean
- Test performance
- Strengths and limitations
- Program implications in low-resource settings

Types of visual inspection tests:

- Visual inspection with acetic acid (VIA) can be done with the naked eye (also called cervicoscopy or direct visual inspection [DVI]), or with low magnification (also called gynoscopy, aided VI, or VIAM).
- Visual inspection with Lugol's iodine (VILI), also known as Schiller's test, uses Lugol's iodine instead of acetic acid.

What does VIA involve?

- Performing a vaginal speculum exam during which a health care provider applies dilute (3-5%) acetic acid (vinegar) to the cervix.
 - Abnormal tissue temporarily appears white when exposed to vinegar.
- Viewing the cervix with the naked eye to identify color changes on the cervix.
- Determining whether the test result is positive or negative for possible precancerous lesions or cancer.

What infrastructure does VIA require?

- Private exam area
- **Examination table**
- Trained health professionals
- Adequate light source
- Sterile vaginal speculum
- New examination gloves, or HLD surgical gloves
- Large cotton swabs
- Dilute (3-5%) acetic acid (vinegar) and a small bowl
- Containers with 0.5% chlorine solution
- A plastic bucket with a plastic bag
- Quality assurance system to maximize accuracy

Categories for VIA test results:

VIA Category	Clinical Findings
Test-negative	No acetowhite lesions or faint acetowhite lesions; polyp, cervicitis, inflammation, Nabothian cysts.
Test-positive	Sharp, distinct, well-defined, dense (opaque/dull or oyster white) acetowhite areas—with or without raised margins touching the squamocolumnar junction (SCJ); leukoplakia and warts.
Suspicious for cancer	Clinically visible ulcerative, cauliflower-like growth or ulcer; oozing and/or bleeding on touch.

Categories for VIA tests results:

- Acetowhite area far from squamocolumnar junction (SCJ) and not touching it is insignificant.
- Acetowhite area adjacent to SCJ is significant.



Negative



Positive

Photo source: JHPIEGO

Categories for VIA tests results:

Suspicious for cancer

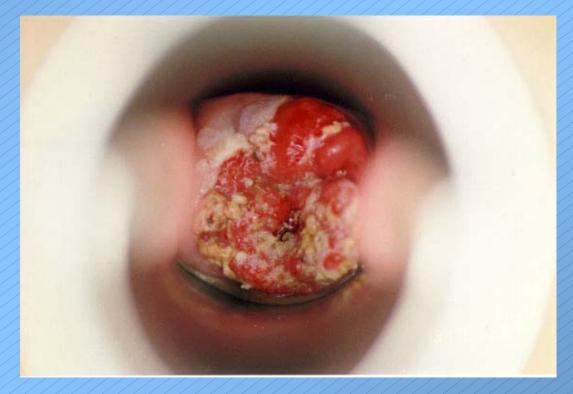


Photo source: PAHO, Jose Jeronimo

Management options: What to do if the VIA test is positive?

Offer to treat immediately.

Refer for confirmatory diagnosis or adjunctive test.

Test performance: Sensitivity and specificity

- Sensitivity: The proportion of all those with disease that the test correctly identifies as positive.
- Specificity: The proportion of all those without disease (normal) that the test correctly identifies as negative.

VIA test performance (n=7):

	Sensitivity	Specificity
Minimum	65%	64%
Maximum	96%	98%
Median*	84%	82%
Mean*	81%	83%

^{*} Weighted median and mean based on study sample size

Source: Adapted from Gaffikin, 2003

Strengths of VIA:

- Simple, easy-to-learn approach that is minimally reliant upon infrastructure.
- Low start-up and sustaining costs.
- Many types of health care providers can perform the procedure.
- Test results are available immediately.
- Requires only one visit.
- May be possible to integrate VIA screening into primary health care services.

Limitations of VIA:

- Moderate specificity results in resources being spent on unnecessary treatment of women who are free of precancerous lesions in a single-visit approach.
- No conclusive evidence regarding the health or cost implications of over-treatment, particularly in areas with high HIV prevalence.
- There is a need for developing standard training methods and quality assurance measures.
- Likely to be less accurate among post-menopausal women.
- Rater dependent.

Conclusions:

- VIA is a promising new approach.
- Ongoing VIA-based projects by ACCP partners in a number of countries are investigating long-term effectiveness of the VIA test-and-treat approach.
- Several questions remain, including:
 - Which factors maximize VIA's performance?
 - How can quality of VIA services outside of a controlled setting be ensured?
 - How can VIA best be incorporated into prevention programs?
 - What is the long-term impact on cancer mortality from programs incorporating VIA?

References:

- ACCP. <u>Visual screening approaches: Promising alternative screening strategies</u>. Cervical Cancer Prevention Fact Sheet. (October 2002).
- ACCP & World Health Organization. <u>Cervical cancer prevention in developing countries: A review of screening and programmatic strategies</u>. (Forthcoming, November 2003).
- Gaffikin L, Lauterbach M, Blumenthal PD. "Performance of visual inspection with acetic acid for cervical cancer screening: A qualitative summary of evidence to date," *Obstetrical and Gynaecological Review* 58(8):543-550. (August 2003).
- McIntosh N, Blumenthal PD, Blouse A, eds. Cervical cancer prevention guidelines for low-resource settings. Baltimore, MD:JHPEIGO. (2001).
- Riegelman RK and Hirsch RP. <u>Studying a study and testing a test: How to read the medical Literature</u> (2nd Edition). Boston, MA:Little, Brown and Company. (1989).

For more information on cervical cancer prevention:

- The Alliance for Cervical Cancer Prevention (ACCP) www.alliance-cxca.org
- **ACCP** partner organizations:
 - EngenderHealth www.engenderhealth.org
 - International Agency for Research on Cancer (IARC) www.iarc.fr
 - JHPIEGO www.jhpiego.org
 - Pan American Health Organization (PAHO) www.paho.org
 - Program for Appropriate Technology in Health (PATH) www.path.org

Visual inspection with acetic acid (VIA): Evidence to date

Original source:

Alliance for Cervical Cancer Prevention (ACCP)
www.alliance-cxca.org

Introduction: This presentation provides a summary of the latest evidence, as of 2003, on visual inspection with acetic acid as a test for the detection of cervical cancer.

Overview:

- Description of VIA and how it works
- Infrastructure requirements
- What test results mean
- Test performance
- Strengths and limitations
- Program implications in low-resource settings

Slide overview: In this presentation we will discuss the following topics.

Types of visual inspection tests:

- Visual inspection with acetic acid (VIA) can be done with the naked eye (also called cervicoscopy or direct visual inspection [DVI]), or with low magnification (also called gynoscopy, aided VI, or VIAM).
- Visual inspection with Lugol's iodine (VILI), also known as Schiller's test, uses Lugol's iodine instead of acetic acid.

Slide overview: This is a partial list of the types of vision-based tests available for testing for cervical cancer or precancer. The key differences in these tests are whether or not magnification is used, and whether acetic acid or some other technique of highlighting abnormalities is used.

•Note for after last bullet: This talk focuses on VIA, which has also been referred to as cervicoscopy, or direct visual inspection (DVI).

What does VIA involve?

- Performing a vaginal speculum exam during which a health care provider applies dilute (3-5%) acetic acid (vinegar) to the cervix.
 - Abnormal tissue temporarily appears white when exposed to vinegar.
- Viewing the cervix with the naked eye to identify color changes on the cervix.
- Determining whether the test result is positive or negative for possible precancerous lesions or cancer.

Slide overview: VIA is a relatively simple procedure.

- •Note for bullet 1: Acetic acid is used to enhance and "mark" the acetowhite change of a precancerous lesion or actual cancer. Differences in precancerous cell proteins make the abnormal cells temporarily appear white when exposed to vinegar.
- *Note for bullet 3:* Results of the test are available immediately and do not require laboratory support.

What infrastructure does VIA require?

- Private exam area
- **Examination table**
- Trained health professionals
- Adequate light source
- Sterile vaginal speculum
- New examination gloves, or HLD surgical gloves
- Large cotton swabs
- Dilute (3-5%) acetic acid (vinegar) and a small bowl
- Containers with 0.5% chlorine solution
- A plastic bucket with a plastic bag
- Quality assurance system to maximize accuracy

Slide overview: The supplies and equipment required to provide VIA testing are listed here. Most of these supplies are available at even the most basic levels of the health care system in low-resource countries.

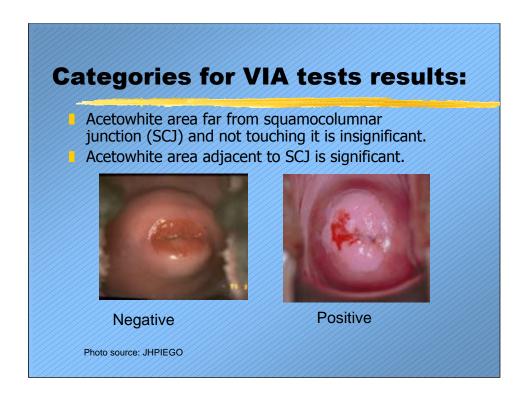
- •Note for bullet 4: Preferably, a bright halogen lamp that can be easily directed at the cervix. The light source needs to be something other than daylight. It can be a flashlight or torch, or a gooseneck lamp. The stronger and more consistent the light source, the easier it will be for health care providers to identify abnormalities.
- *Note for bullet 7:* Cotton swabs can be handmade using cotton batting and broomsticks or ring forceps.
- •Note for bullet 10 (second to last): A bucket is used to dispose of contaminated swabs and other waste items.
- •Note for last bullet: Elements of a quality assurance system include (but are not limited to) supervision, periodic refresher training, evaluation of on-going program activities and long-term impact, a mechanism for constructive feedback from women and health care providers, and an effective information system.
- •Note at the end: Other necessary supplies that should be available at any clinic setting include cotton balls, gauze, and rubber or plastic sheets for the table.

Categories for VIA test results:

VIA Category	Clinical Findings
Test-negative	No acetowhite lesions or faint acetowhite lesions; polyp, cervicitis, inflammation, Nabothian cysts.
Test-positive	Sharp, distinct, well-defined, dense (opaque/dull or oyster white) acetowhite areas—with or without raised margins touching the squamocolumnar junction (SCJ); leukoplakia and warts.
Suspicious for cancer	Clinically visible ulcerative, cauliflower-like growth or ulcer; oozing and/or bleeding on touch.

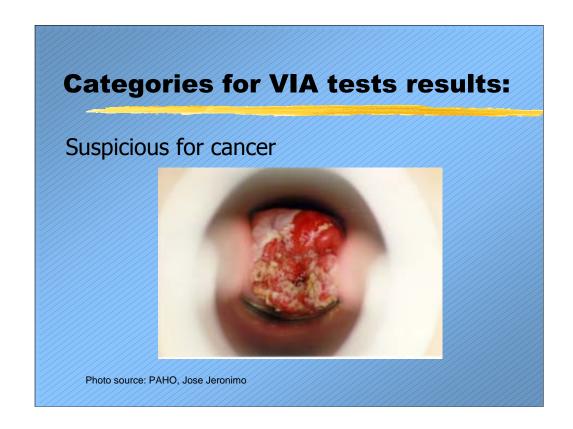
Slide overview: Here is an overview of VIA test result categories and a very general description of the clinical findings for each.

• After discussion of the table: Training manuals including classification tables with more detailed descriptions are available to help providers differentiate between the three generally used test result categories.



Slide overview: The location of the acetowhite area needs to be considered in the final judgment call as whitish areas representing metaplasia, or other things may make assessment of acetowhite changes more challenging.

- •Note for bullet 1: The squamocolumnar junction (SCJ) is the point at which columnar cells meet ectocervical squamous cells on the cervix. This junction marks the furthest extent of the transformation zone towards or, in the case of postmenopausal women, into the cervical canal. Whitish areas far from the SCJ are more likely to be metaplasia or warty lesions; the woman should not be considered test-positive.
- •Note for bullet 2: Acetowhite areas that are present on, abutting, or immediately adjacent to the SCJ are more likely to be precancerous; the woman should be considered test-positive.



Slide overview: This imageshows a VIA test result that is suspicious for cancer.

Management options: What to do if the VIA test is positive?

- Offer to treat immediately.
- Refer for confirmatory diagnosis or adjunctive test.

Slide overview: Because the results of VIA testing are available immediately to the provider and the woman, there are several clinical management options at that time, including the offer of immediate treatment. This is an advantage of VIA testing in settings where transportation and time spent away from home and family activities can be particularly problematic.

- •Note for bullet 1: Programs offering immediate treatment cryotherapy should only treat lesions that:
 - (a) Occupy less than 75% of the cervical area; and
 - (b) Do not extend onto the vaginal wall; and
 - (c) Do not extend beyond the limits of the cryotherapy probe (including into the endocervical canal or os).
- Additional note for bullet 1: Test-positive lesions not meeting the above criteria must be referred to facilities offering other treatment options besides cryotherapy.

Test performance: Sensitivity and specificity

- Sensitivity: The proportion of all those with disease that the test correctly identifies as positive.
- Specificity: The proportion of all those without disease (normal) that the test correctly identifies as negative.

Slide overview: The test performance of each screening method is rated by its sensitivity and specificity. Before discussing VILI's test performance, it is important to understand what sensitivity and specificity mean.

VIA test performance (n=7):

	Sensitivity	Specificity
Minimum	65%	64%
Maximum	96%	98%
Median*	84%	82%
Mean*	81%	83%

^{*} Weighted median and mean based on study sample size

Source: Adapted from Gaffikin, 2003

Slide overview: A number of cross-sectional studies have assessed VIA's performance as a primary screening test and their findings are presented here.

- •*Note:* The range of estimated sensitivity of VIA from seven cross-sectional studies specifically addressing the accuracy of VIA was 65% to 96%; the range of specificity was 64% to 98%.
- •*Note:* The positive predictive value (which is greatly affected by prevalence of a condition) ranged from 10% to 20% and the negative predictive value ranged from 92% to 97%.
- •*Note:* The weighted mean sensitivity and specificity of VIA of these studies were 81% and 83%, respectively (weights based on study sample size).

Strengths of VIA:

- Simple, easy-to-learn approach that is minimally reliant upon infrastructure.
- Low start-up and sustaining costs.
- Many types of health care providers can perform the procedure.
- Test results are available immediately.
- Requires only one visit.
- May be possible to integrate VIA screening into primary health care services.

Slide overview: VIA is an alternative test for precancer or cancer in low-resource settings because it meets a number of criteria for a good screening test.

- *Note for bullet 1:* Assuming sufficiently trained providers are available, VIA is a simple approach. Health care providers can be trained in a short period of time (1 to 2 weeks).
- *Note for bullet 2*: In most settings, costs associated with launching and sustaining VIA-based programs are lower than other methods. VIA can be performed in extremely low-resource settings.
- Note for bullet 3: In situations in which health care providers can receive adequate and ongoing training, VIA has the potential for adequate population coverage. Results from a cluster randomized controlled trial carried out by ACCP in south India have shown that two-thirds of women invited for screening accepted the offer and were screened, indicating that a moderate level of participation with screening can be reached through appropriate service delivery systems (Sankaranarayanan R, Rajkumar R, Arrossi S, Theresa R, Esmy P O, Mahe C, Muwonge R, Parkin DM and Cherian J. "Determinants of participation of women in a cervical cancer visual screening trial in rural south India." Cancer Detection and Prevention, 2003. In press.)
- *Note for bullet 4:* Because results are available immediately, further investigations (such as colposcopy and biopsy), and treatment (such as cryotherapy or LEEP) can occur during the same visit, if appropriate.
- *Note for bullet 5:* This means that additional visits for investigations and treatments are reduced.

Limitations of VIA:

- Moderate specificity results in resources being spent on unnecessary treatment of women who are free of precancerous lesions in a single-visit approach.
- No conclusive evidence regarding the health or cost implications of over-treatment, particularly in areas with high HIV prevalence.
- There is a need for developing standard training methods and quality assurance measures.
- Likely to be less accurate among post-menopausal women.
- Rater dependent.

Slide overview: VIA also has limitations as a primary test in low-resource settings.

- •Note for bullet 1: The single-visit, "test-and-treat" approach results in over-referral and over-treatment of women who do not actually have precancerous lesions. Over-referral has important cost implications in settings with scarce resources.
- •Note for bullet 2: The test-positive rate and resulting referral or treatment rate vary from 10% to 35% in most reported and ongoing studies involving asymptomatic, low-prevalence populations with limited or no previous screening (see references at the end). The health and cost implications of over-treatment or over-referral are currently under investigation.
- •Note for bullet 3: The Alliance for Cervical Cancer Prevention (ACCP) is currently investigating these elements.
- •Note for bullet 4: VIA identifies disease in the ectocervix only when the transformation zone remains at least partially on the visually exposed part of the cervix. Since the transformation zone recedes to the endocervical canal in postmenopausal women, VIA is likely to be less accurate among these older women.
- •Note for bullet 5: "Rater dependent" means the test's performance depends on the abilities of the person doing the test (versus a machine, as for HPV testing). This means that even when service providers have training, test performance may vary depending on service delivery conditions and other factors. Along these lines, the definition of test-positive requires careful description.

Conclusions:

- VIA is a promising new approach.
- Ongoing VIA-based projects by ACCP partners in a number of countries are investigating long-term effectiveness of the VIA test-and-treat approach.
- Several questions remain, including:
 - Which factors maximize VIA's performance?
 - How can quality of VIA services outside of a controlled setting be ensured?
 - How can VIA best be incorporated into prevention programs?
 - What is the long-term impact on cancer mortality from programs incorporating VIA?

Slide overview: VIA is a promising, new approach that has been under investigation since 1982 and continues to be explored.

- •Note for bullet 2: Ongoing ACCP studies are examining the usefulness of VIA in different ways and in different settings.
- •Note for bullets 2 and 3: Because VIA has been used to date mostly in research or controlled demonstration projects, there are various programmatic questions remaining to be answered.

References:

- ACCP. <u>Visual screening approaches: Promising alternative screening strategies</u>. Cervical Cancer Prevention Fact Sheet. (October 2002).
- ACCP & World Health Organization. <u>Cervical cancer prevention in developing countries:</u> A review of screening and programmatic strategies. (Forthcoming, November 2003).
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- Riegelman RK and Hirsch RP. <u>Studying a study and testing a test: How to read the medical Literature</u> (2nd Edition). Boston, MA:Little, Brown and Company. (1989).

Slide overview: Information and study results in this presentation are drawn from the following references as well as other ACCP work.

For more information on cervical cancer prevention:

- The Alliance for Cervical Cancer Prevention (ACCP) www.alliance-cxca.org
- **ACCP** partner organizations:
 - EngenderHealth <u>www.engenderhealth.org</u>
 - International Agency for Research on Cancer (IARC) www.iarc.fr
 - JHPIEGO www.jhpiego.org
 - Pan American Health Organization (PAHO)
 www.paho.org
 - Program for Appropriate Technology in Health (PATH) www.path.org