

# Appendix 1

## FIGO staging of cervical carcinomas

### Stage I

Stage I is carcinoma strictly confined to the cervix; extension to the uterine corpus should be disregarded. The diagnosis of both Stages IA1 and IA2 should be based on microscopic examination of removed tissue, preferably a cone, which must include the entire lesion.

**Stage IA:** Invasive cancer identified only microscopically. Invasion is limited to measured stromal invasion with a maximum depth of 5 mm and no wider than 7 mm.

**Stage IA1:** Measured invasion of the stroma no greater than 3 mm in depth and no wider than 7 mm diameter.

**Stage IA2:** Measured invasion of stroma greater than 3 mm but no greater than 5 mm in depth and no wider than 7 mm in diameter.

**Stage IB:** Clinical lesions confined to the cervix or preclinical lesions greater than Stage IA. All gross lesions even with superficial invasion are Stage IB cancers.

**Stage IB1:** Clinical lesions no greater than 4 cm in size.

**Stage IB2:** Clinical lesions greater than 4 cm in size.

### Stage II

Stage II is carcinoma that extends beyond the cervix, but does not extend into the pelvic wall. The carcinoma involves the vagina, but not as far as the lower third.

**Stage IIA:** No obvious parametrial involvement. Involvement of up to the upper two-thirds of the vagina.

**Stage IIB:** Obvious parametrial involvement, but not into the pelvic sidewall.

### Stage III

Stage III is carcinoma that has extended into the pelvic sidewall. On rectal examination, there is no cancer-free space between the tumour and the pelvic sidewall. The tumour involves the lower third of the vagina. All cases with hydronephrosis or a non-functioning kidney are Stage III cancers.

**Stage IIIA:** No extension into the pelvic sidewall but involvement of the lower third of the vagina.

**Stage IIIB:** Extension into the pelvic sidewall or hydronephrosis or non-functioning kidney.

### **Stage IV**

Stage IV is carcinoma that has extended beyond the true pelvis or has clinically involved the mucosa of the bladder and/or rectum.

**Stage IVA:** Spread of the tumour into adjacent pelvic organs.

**Stage IVB:** Spread to distant organs.

Source: TNM Classification of malignant tumours. L. Sobin and Ch Wittekind (eds.), UICC International Union against Cancer, Geneva, Switzerland, pp155-157; 6th ed. 2002.

# Appendix 2

## INFORMED CONSENT

The doctor/health worker explained to me in detail about the vinegar (VIA)/iodine (VILI) test(s)\* for the early detection and prevention of cancer in the neck of my womb (uterine cervix). I understand that the surface of my cervix will be visually inspected after application of 5% acetic acid/dilute iodine solution to detect or to exclude precancer/cancer. I understand that these procedures are generally harmless, but may occasionally cause some irritation or mild bleeding, which can be easily controlled.

I understand that, if the test is positive, other tests such as magnified inspection of the cervix with an instrument called a colposcope and examination of a sample of the tissue in my cervix (biopsy) may be recommended before treatment is provided. I have been informed that treatment by medicines or cryotherapy (destroying the diseased portion of the cervix by an ice-cold metal probe) or removing the diseased portion by minor surgery or major surgery and/or treatment with x-rays, may be required, in the event of any abnormality (infection or precancer or cancer or complications) being detected.

I hereby express my willingness to undergo the above tests and treatment, if advised.\*  
/ I am not willing to undergo the above procedures. \*

Signature:

Date:

Name:

Address:

\* Delete as appropriate

# Appendix 3

## Format for reporting results of VIA and VILI

### Screening with VIA and VILI

1. Clinic/Serial/Unique number \_\_\_\_\_
2. Date of testing [ ][ ]-[ ][ ]-[ ][ ]  
(day (2 digits)-month (2 digits)-year (2 digits)):
3. Name: \_\_\_\_\_
4. Address: \_\_\_\_\_  
\_\_\_\_\_
5. Age (in years) [ ][ ]
6. Education (1: Nil; 2: Primary; 3: Middle;  
4: High school; 5: College; 9: Not known) [ ]
7. When did you have your last menstruation?  
(1: Less than 12 months ago; 2: More than 12 months ago) [ ]
8. Marital status: (1: Married; 2: Widowed; 3: Separated;  
8: Other; 9: Not known) [ ]
9. Age at marriage or first sexual intercourse: (99, if not known) [ ][ ]
10. Total number of pregnancies/miscarriages: [ ][ ]
11. Do you suffer from the following?  
(use ✓ to indicate if the response is yes; otherwise, leave blank):
  - Excessive vaginal discharge
  - Itching in the external anogenitalia
  - Ulcers in the external anogenitalia
  - Lower abdominal pain
  - Pain during sexual intercourse

- Bleeding after intercourse
- Intermenstrual bleeding
- Low back ache

## 12. Visual examination findings

(use ✓ to indicate if the response is 'Yes', otherwise, leave blank):

- Squamocolumnar junction fully seen
- Cervical polyp
- Nabothian follicles
- Cervicitis
- Leukoplakia
- Condyloma
- Growth

## 13. Findings one minute after application of 5% acetic acid (VIA)

(1: Negative; 2: Positive; 3: Positive, invasive cancer) [ ]

## 14. If VIA positive, does the acetowhite lesion extend into the endocervical canal?

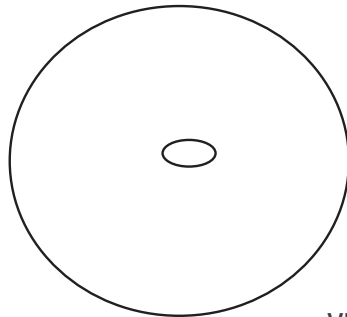
(1: Yes; 2: No) [ ]

## 15. If VIA positive, how many quadrants are involved in the acetowhite lesion(s)?

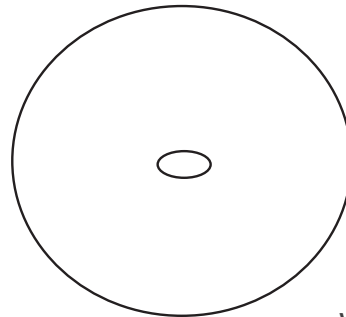
(1: Two or less; 2: Three; 3: Four quadrants) [ ]

## 16. Diagram

(Draw the location of the squamocolumnar junction with a dotted line and the acetowhite/iodine non-uptake area(s) as a continuous line)



VIA



VILI

## 17. Findings after application of Lugol's iodine (VILI)

(1: Negative; 2: Positive; 3: Positive, invasive cancer) [ ]

## 18. If invasive cancer, stage (1: IA; 2: IB; 3: IIA; 4: IIB;

5: IIIA; 6: IIIB; 7: IVA; 8: IVB; 9: Not known) [ ]

19. Biopsy taken? (1: Yes; 2: No)  
(If yes, indicate the biopsy site(s) in the diagram with 'x' mark) [ ]
20. Action taken: (1: Advised follow-up after five years;  
2: Advised medication for cervicitis and follow-up after six months;  
3: Referred for colposcopy; 4: Referred for immediate treatment;  
5: Referred for staging and treatment of invasive cancer;  
6: Other, specify \_\_\_\_\_) [ ]

## Appendix 4

### Cleaning and sterilization of instruments and materials used for early detection and treatment of cervical neoplasia:

Instrument/material	Processing	Suggested procedure
Vaginal speculum, vaginal retractors, biopsy forceps, toothed forceps, ring forceps, Cheatle's forceps.	Decontamination and cleaning followed by sterilization or HLD.	Decontamination by immersing in 0.5% chlorine for 10 minutes followed by cleaning with water and detergents; cleaned instruments may be immersed in boiling water for 20 minutes (high-level disinfection) or may be sterilized using autoclave before re-use.
Gloves.	Decontamination and cleaning followed by sterilization.	Decontamination by immersing in 0.5% chlorine for 10 minutes followed by cleaning with water and detergents; sterilized using an autoclave in wrapped packs.
Examination table, halogen lamp, torch lights, instrument trolley, trays.	Intermediate or low-level disinfection.	Wipe with 60-90% ethyl or isopropyl alcohol or with 0.5% chlorine solution.

HLD: High-level disinfection

### **Preparation of 0.5% chlorine solution:**

The general formula for making a dilute chlorine solution from a commercial preparation of any given concentration is as follows: Total parts of water = [% concentrate/% dilute] - 1. For example, to make a 0.5% dilute solution of chlorine from 5% concentrated liquid household bleach = [5.0%/0.5%] - 1 = 10 - 1 = 9 parts of water; hence add one part of concentrated bleach to nine parts of water.

If one is using commercially available dry powder chlorine, use the following formula to calculate the amount (in grams) of dry powder required to make 0.5% chlorine solution:

Grams/litre = [% dilute/% concentrate] x 1000. For example, to make a 0.5% dilute

chlorine solution from a dry powder of 35% calcium hypochlorite = [0.5%/35%] x 1000 = 14.2 g. Hence add 14.2 grams of dry powder to 1 litre of water or 142 grams to 10 litres of water. The instruments should not be left in dilute bleach for more than 10 minutes and should be cleaned in boiled water immediately after decontamination to prevent discolouration and corrosion of metal.

### **Decontamination of the floor of the screening clinic:**

The floor of the screening clinic should be decontaminated on a daily basis with chemical disinfectants including iodophores (e.g., 10% povidone iodine).



# Appendix 5

## Preparation of 5% acetic acid, Lugol's iodine solution, and Monsel's paste

### 5% dilute acetic acid

Ingredients	Quantity
1. Glacial acetic acid	5 ml
2. Distilled water	95 ml

#### Preparation

Carefully add 5 ml of glacial acetic acid into 95 ml of distilled water and mix thoroughly.

**Storage:** Unused acetic acid should be discarded at the end of the day.

**Label:** 5% dilute acetic acid

**Note:** It is important to remember to dilute the glacial acetic acid, since the undiluted strength causes a severe chemical burn if applied to the epithelium.

### Lugol's iodine solution

Ingredients	Quantity
1. Potassium iodide	10 g
2. Distilled water	100 ml
3. Iodine crystals	5 g

#### Preparation

- Dissolve 10 g potassium iodide in 100 ml of distilled water.
- Slowly add 5 g iodine crystals, while shaking.
- Filter and store in a tightly stoppered brown bottle.

**Storage:** 1 month

**Label:** Lugol's iodine solution; Use by (date)

## Monsel's paste

Ingredients	Quantity
1. Ferric sulfate base	15 g
2. Ferrous sulfate powder	a few grains
3. Sterile water for mixing	10 ml
4. Glycerol starch (see preparation below)	12 g

### Preparation

Take care: The reaction is exothermic (emits heat).

- A. Add a few grains of ferrous sulfate powder to 10 ml of sterile water in a glass beaker. Shake.
- B. Dissolve the ferric sulfate base in the solution by stirring with a glass stick. The solution should become crystal clear.
- C. Weigh the glycerol starch in a glass mortar. Mix well.
- D. Slowly add ferric sulfate solution to glycerol starch, constantly mixing to get a homogeneous mixture.
- E. Place in a 25 ml brown glass bottle.
- F. For clinical use, most clinics prefer to allow enough evaporation to give the solution a sticky paste-like consistency that looks like mustard. This may take 2 to 3 weeks, depending on the environment. The top of the container can then be secured for storage. If necessary, sterile water can be added to the paste to thin it.

Note: This preparation contains 15% elementary iron.

Storage: 6 months

Label: Monsel's solution; Shake well; External use only; Use by (date)

## Glycerol starch (an ingredient in Monsel's paste)

Ingredients	Quantity
1. Starch	30 g
2. Sterile water for mixing	30 ml
3. Glycerine	390 g

### Preparation

- A. In a china crucible, dissolve the starch in the sterile water.
- B. Add the glycerine. Shake well.
- C. Heat the crucible and its contents over a bunsen burner. Mix constantly with a spatula until the mass takes on a thick, swelling consistency. Take care not to overheat so as not to let it turn yellow.

**Storage:** 1 year

**Label:** Glycerol starch; Store in a cool place; For external use only; Use by (date)

**Note:** Do not overheat, otherwise the mixture will turn yellow.

## Suggestions for further reading

- Ottaviano, M. & La Torre, P. (1982) Examination of the cervix with the naked eye using acetic acid test. *Am. J. Obstet. Gynecol.*, **143**, 139-142.
- Cecchini, S., Bonardi, R., Mazzotta, A., Grazzini, G., Iossa A. & Ciatto, S. (1993) Testing cervicography and VIA as screening tests for cervical cancer. *Tumori*, **79**, 22-25.
- Östor, A.G. (1993) Natural history of cervical intraepithelial neoplasia: a critical review. *Int. J. Gynecol. Pathol.*, **12**, 186-192.
- Sankaranarayanan, R., Wesley, R., Somanathan, T., Dhakad, N., Shyamalakumary, B., Sreedevi Amma, N., Parkin, D.M. & Krishnan Nair, M. (1998) Performance of visual inspection after acetic acid application (VIA) in the detection of cervical cancer precursors. *Cancer*, **83**, 2150-2156.
- Walboomers, J.M.M., Jacobs, M.V., Manos, M.M., Bosch, F.X., Kummer, J.A., Shah, K.V., Snijders, P.J., Peto, J., Meijer, C.J. & Munoz, N. (1999) Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. *J. Pathol.*, **189**, 12-19.
- Sankaranarayanan, R., Shyamalakumary, B., Wesley, R., Sreedevi Amma, N., Parkin, D.M. & Krishnan Nair, M. (1999) Visual inspection with acetic acid in the early detection of cervical cancer and precursors. *Int. J. Cancer*, **80**, 161-163.
- University of Zimbabwe/JHPIEGO Cervical Cancer Project (1999) Visual inspection with acetic acid for cervical-cancer screening: test qualities in a primary-care setting. *Lancet*, **353**, 869-873.
- Denny, L., Kuhn, L., Pollack, A., Wainwright, H. & Wright, T.C., Jr (2000) Evaluation of alternative methods of cervical cancer screening for resource-poor settings. *Cancer*, **89**, 826-833.
- Belinson, J.L., Pretorius, R.G., Zhang, W.H., Wu, L.Y., Qiao, Y.L. & Elson, P. (2001) Cervical cancer screening by simple visual inspection after acetic acid. *Obstet. Gynecol.*, **98**, 441-444
- Sankaranarayanan, R., Budukh, A.M. & Rajkumar, R. (2001) Effective screening programmes for cervical cancer in low- and middle-income developing countries. *Bull. World Health Org.*, **79**, 954-962.
- Goldie, S.J., Kuhn, L., Denny, L., Pollack, A. & Wright, T.C. (2001) Policy analysis of cervical cancer screening strategies in low-resource settings: clinical benefits and cost-effectiveness. *JAMA*, **285**, 3107-3115.
- Denny, L., Kuhn, L., Pollack, A. & Wright, T.C., Jr (2002) Direct visual inspection for cervical cancer screening: an

- analysis of factors influencing test performance. *Cancer*, **94**, 1699-1707.
- Mandelblatt, J.S., Lawrence, W.F., Gaffikin, L., Limpahayom, K.K., Lumbiganon, P., Warakamin, S., King, J., Yi, B., Ringers, P. & Blumenthal, P.D. (2002) Costs and benefits of different strategies to screen for cervical cancer in less-developed countries. *J. Natl. Cancer Inst.*, **94**, 1469-1483.
- Ferenczy, A. & Franco, E. (2002) Persistent human papillomavirus infection and cervical neoplasia. *Lancet Oncol.*, **3**, 11-16.
- Royal Thai College of Obstetricians and Gynaecologists (RTCOCG) and the JHPIEGO Corporation Cervical Cancer Prevention Group (2003). Safety, acceptability, and feasibility of a single-visit approach to cervical-cancer prevention in rural Thailand: a demonstration project. *Lancet*, **361**, 814-820.
- Sankaranarayanan, R., Wesley, R., Thara, S., Dhakad, N., Chandralekha, B., Sebastian, P., Chithrathara, K., Parkin, D.M. & Krishnan Nair, M. (2003). Test characteristics of visual inspection with 4% acetic acid (VIA) and Lugol's iodine (VILI) in cervical cancer screening in Kerala, India. *Int. J. Cancer*, **106**, 404-408.

