

If you have any questions or concerns about this booklet, please call the IMAP Study Team:

1300 363 803

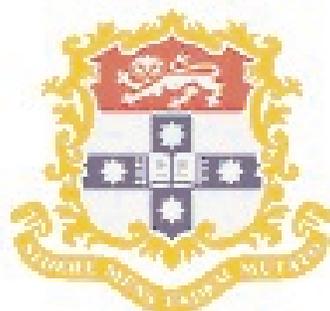
Making Choices™

A Decision Aid for Women with a mildly abnormal Pap smear



Screening & Test
Evaluation Program
School of Public Health
Edward Ford Building (A27)
University of Sydney NSW 2006

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Evaluation Program
School of Public Health
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SHFPACT

SEXUAL HEALTH AND FAMILY PLANNING ACT





This Decision Aid was developed by:

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Acknowledgement

This decision aid was developed using the decision support format of the Ottawa Health Decision Centre at the University of Ottawa and Ottawa Health Research Institute, Ontario, Canada.
www.ohri.ca

What do I do next?

- Fill in the attached preference sheet to tell us which test you would prefer.
- Place the sheet in the FREEPOST envelope and return it to the IMAP team.
- If you have chosen an HPV test, **telephone your FPA clinic now to make an appointment.**
- If you have chosen usual care (a repeat Pap test), please make a note to telephone and book your appointment **in 6 months time**
- **When you telephone tell the receptionist you are part of the IMAP study.** She will make an appointment for you for whichever test you prefer.
- If you have any difficulties, please call the IMAP team.
- We will send you a letter confirming your selection.

More information

If you would like to find out more about the information and statistics presented in the Decision Aid you can find it in the technical appendix: <http://www.health.usyd.edu.au/research/step.html>

Or telephone the IMAP enquiry line and we will send you a copy.

For more information about cervical screening:

NSW Cervical Screening Program www.csp.nsw.gov.au Tel: 13 15 56 (Toll free)

Cancer Council Australia Cancer Helpline Tel: 13 11 20 (Toll free)

NSW Cancer Council www.cancerCouncil.com.au

Queensland Cancer Fund www.qldcancer.com.au

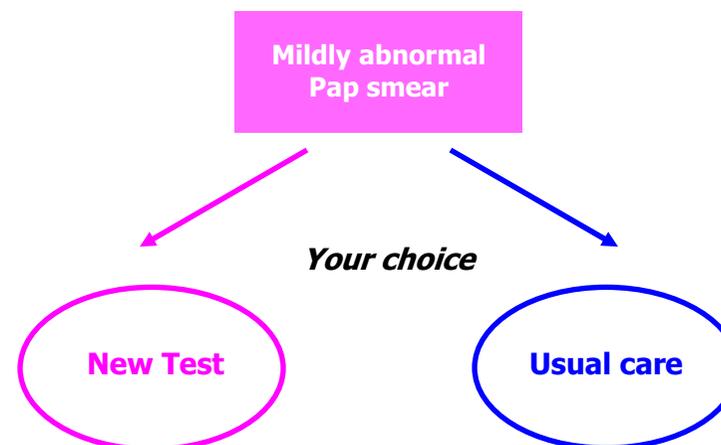
American Cancer Society www.cancer.org

Cancer Research UK www.cancerresearchuk.org, www.cancerhelp.org.uk

Making choices for management of your mildly abnormal Pap smear

A **new test** is available for women with a mildly abnormal Pap smear. It is called the **HPV test**.

You can choose whether you would like the new test or the standard **usual care** for women with a mildly abnormal result, **a repeat Pap smear** in 6 months.



Both managements are highly effective, however, each has its own advantages and disadvantages.

This workbook is designed to help you make an **informed choice** about which management you would prefer.

If you have any questions or concerns, or you would like to discuss any of the information presented in the book please call the IMAP study team:

Tel: 1300 363 803.

Adriana is 37 and is married with 2 children. She works part-time in the City.

STEP 1 How important are the advantages of HPV testing and usual care for Adriana?

Adriana fills in her worksheet to show how important she feels the advantages are for each test (see over the page).

Advantages of HPV testing

- Adriana thinks that the chance of having a negative HPV result and no follow-up examination for a year is a big advantage to the HPV test. *She fills in all 7 circles on her worksheet.*
- Adriana worries when waiting for testing & test results. She feels that having the test straightaway means she will spend less time worrying. *She fills in all 7 circles.*
- Other: Adriana would rather have the test now because it is more convenient for her to get her mild abnormality sorted out straightaway. *She fills in 5 circles.*

Advantages of usual care

- Adriana isn't too worried about having a higher chance of colposcopy and biopsy. *She fills in 1 circle on her worksheet.*
- Although she would quite like to give her abnormal cells a chance to get better on their own, it is more important to her to have any problem sorted out straight away. *She fills in 2 out of 7 circles.*

STEP 2 Which way is Adriana leaning in her decision?

Adriana thinks that she is leaning towards HPV testing. She shades in the box on the left hand side on the scale (see over the page).

STEP 3 Adriana thinks about the disadvantages of HPV testing & usual care

Adriana reads through the disadvantages of both options and thinks about her decision. She doesn't mind having a higher chance of colposcopy and biopsy, and doesn't think that she will feel too upset if she has an HPV positive test result. Most important to her is the waiting time. She would rather this is as short as possible so she doesn't worry over an extended period of time.

Pap screening and mildly abnormal Pap smears

- Background information about Pap screening
- What is a mildly abnormal Pap smear result?

Usual care for a mildly abnormal Pap smear

- Repeat Pap testing
- What is a Colposcopy?
- What is a Biopsy?

A new approach to managing a mildly abnormal Pap smear

- Background information about HPV?
- A new approach: HPV testing

Comparing HPV testing against usual care

- Your chance of needing a colposcopy
- The timing of testing
- How likely is it that your abnormal cells will get better on their own?

Choosing the right management for you

- Steps to consider when making your decision
- Your personal worksheet
- Examples from other women
- What do I do next?
- More information

Each section is colour coded to allow you to find the relevant section quickly and easily.

We have included some examples of how other women made their decision about HPV testing and usual care. ***If you are happy filling out your worksheet and don't feel you need them, skip to page 33 to find out what to do next.***

Tara is 25 and is a student. She works part-time at a bookshop.

STEP 1 How important are the advantages of HPV testing and usual care for Tara?

Tara fills in her worksheet to show how important she feels the advantages are for each test (see over the page).

Advantages of HPV testing

- Tara thinks that the chance of having an HPV negative result and no follow-up examination for a year is an advantage to the HPV test. *She fills in 5 circles.*
- Tara doesn't feel that it is important to have a test straight away and does not mind waiting. *Tara fills in 1 of the circles on her worksheet.*

Advantages of usual care

- Tara feels worried about having a colposcopy and biopsy so having a lower chance of these if she chooses usual care is important to her. *She fills in all 7 circles.*
- Tara would rather wait to see if her abnormal cells clear up by themselves before having any further examinations. *She fills in 6 out of 7 circles.*
- Other: Tara has important exams coming up and does not want to have to worry about follow-up tests while her exams are going on. She would rather wait and have a repeat Pap test in 6 months. *She fills in all 7 circles on her worksheet.*

STEP 2 Which way is Tara leaning in her decision?

Tara thinks that she is leaning towards usual care. She shades in the box on the right hand side on the scale (see over page).

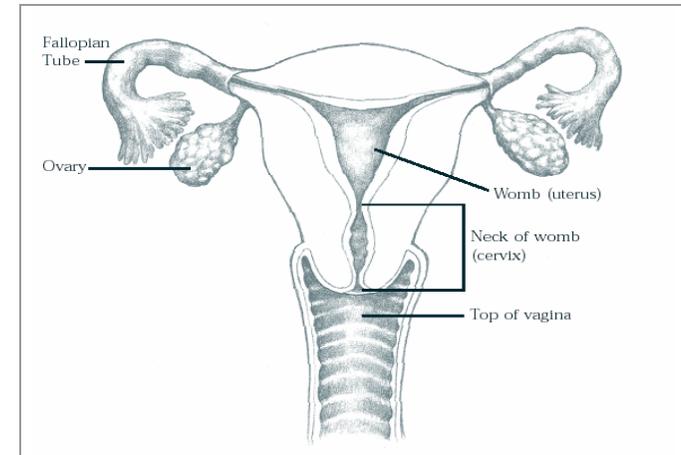
STEP 3 Tara thinks about the disadvantages of HPV testing & usual care

Tara reads through the disadvantages of both options and thinks about her decision. Although she may have to wait 2 years for her cells to get better, she feels she would rather give them a greater chance to clear up by themselves before she has any further examinations. She doesn't feel worried about the waiting time for testing and feels happy to choose usual care (a repeat Pap Test).

If you already know about Pap screening and abnormal Pap smears – skip to page 10

- The Pap smear (also called the Pap test) checks for changes in the cells at the neck of the womb (the cervix) at the top of the vagina.
- It detects early changes in the cells which if left untreated **may** become cancer.
- Most cancers of the cervix take up to 10 years to develop.

Diagram of the Female Reproductive System



- All women over 18 years who have ever had sex are advised to have a Pap smear every 2 years.
- When a Pap smear is carried out, a small sample of cells is taken from the cervix and is examined under a microscope.
- Although Pap screening is very effective, like all screening tests, the Pap smear has its limitations and occasionally abnormal cells are missed.
- Regular Pap smears every 2 years can prevent the most common type of cervical cancer in up to 90% of cases.

What is a mildly abnormal Pap smear?

- An 'abnormal' Pap smear result means that some of the cells of the cervix have been found to differ in some way from the normal cells.
- The abnormal cell changes **ARE NOT** cancer.
- There are different categories of abnormal cells from mild to moderate to severe. These are described in the table below.
- It is important to remember that medical care for abnormal cells of the cervix (including all types described below) is **very effective**.

Abnormal cell type	Description	Other terms
Atypia (mildly abnormal)	Very slight changes in the cells of the cervix	Low grade abnormality
'Human Papillomavirus (HPV) effect'	Very slight changes in the cells of the cervix which also show the presence of human papillomavirus (HPV)	
CIN 1 (mild dysplasia)	Mild or slight changes in the cells of the cervix	High grade abnormality
CIN 2 (moderate dysplasia)	Moderate changes in the cells of the cervix	
CIN 3 (severe dysplasia)	Severe changes in the cells of the cervix. <i>These changes are not cancer</i>	

C I N stands for cervical intraepithelial neoplasia. It is the medical term for cervical cell changes.

The highlighted areas show the categories that are relevant to you now.

Your personal worksheet

STEP 1 How important are the advantages of HPV testing & usual care to you?

ADVANTAGES OF HPV TESTING

I may test negative for HPV and not need another Pap smear for 1 year

Not at all Extremely Important

I can get the test done straight away and any problem treated quickly so the waiting time is shorter

Not at all Extremely Important

Other _____

Not at all Extremely Important

ADVANTAGES OF USUAL CARE

I have a lower chance of having a colposcopy & biopsy

Not at all Extremely Important

I give my abnormal cells more time to clear up by themselves so I am less likely to need further examinations & treatment

Not at all Extremely Important

Other _____

Not at all Extremely Important

STEP 2 Which way are you leaning in your decision?

Fill in one of the squares below to indicate which way you are leaning in your decision.

HPV testing					Not sure	Usual Care				

STEP 3 Now think about the disadvantages of HPV testing and usual care

DISADVANTAGES OF HPV TESTING

- I have a higher chance of having a colposcopy & biopsy. A colposcopy may make me anxious & a biopsy can cause mild pain and some inconvenience.
- Testing HPV positive may make me feel upset and distressed.

Write down any other disadvantages to HPV testing that are important to you

DISADVANTAGES OF USUAL CARE

- I may have to wait up to 2 years before my cells get better themselves. During this time I will need to have several repeat Pap tests.
- Waiting for testing & test results for an extended period may make me anxious.

Write down any other disadvantages to usual care that are important to you

STEP 4 Would you like any further information before you decide?

If yes, please call the IMAP team on 1300 363 803

STEP 5 Now it is time to decide which test you would prefer

HPV test **Usual care**



STEP 1

- Think about the advantages of HPV testing and usual care.
- Mark on your worksheet (across the page) how important each one is for you by filling in the circles using your pink IMAP pen.
- Fill in more circles to show that you feel something is more important to you.

Not at all Important Extremely Important
 e.g. **very important**

Not at all Important Extremely Important
 e.g. **Not at all important**

- Add any extra advantages that are important to you.

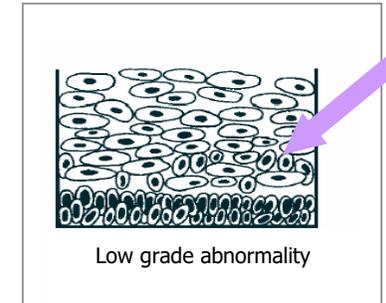
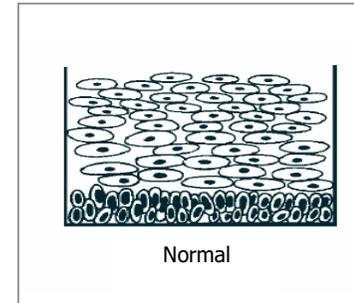
STEPS 2 to 5

Follow the rest of the steps on the next page and fill in as instructed.

If you would like more help filling in your worksheet, look at the examples given on pages 31-34.

- A **mildly abnormal Pap result** means that **very slight** changes in the cells have been found. These are shown in the diagram below.

Diagram of normal and mildly abnormal cells



- Your Pap smear showed you have very slight changes in your cervical cells.
- The cause of the cell changes is often not clear. They are commonly caused by the presence of **Human Papillomavirus** (*pap-illoma-virus*) also called **HPV** for short.
- In many women, the slight cell changes will return to normal by themselves without need for treatment. On average this takes 6-18 months.^{1,2,3,4}
- Research also shows that between 5 and 15 out of 100 women (5-15%) who have a mildly abnormal Pap smear, already have more serious abnormal cell changes, such as CIN 2 or CIN 3.^{5,6}

Usual care for a mildly abnormal Pap smear:

Repeat Pap Testing

Steps to consider when making your decision

Remember, there is no right or wrong decision; it is simply a matter of which management you would prefer.

STEP 1 Think about the advantages of HPV testing and usual care (they are listed below to help you). How important are they for you?

Advantages of HPV testing

- You may test negative for HPV and not need another Pap smear for a year.
- You can have the HPV test straight away and any problem sorted out quickly. This means the waiting time is shorter.
- Think about any other advantages to HPV testing that are important to you.

Advantages of usual care

- You have a lower chance of having a colposcopy and biopsy.
- You give your abnormal cells more time to clear up by themselves so you are less likely to need further examinations and treatment.
- Think about any other advantages to usual care that are important to you.

STEP 2 Which way are you leaning in your decision?

STEP 3 Now think about the disadvantages of HPV testing & usual care

Disadvantages of HPV testing

- You have a higher chance of having a colposcopy and biopsy. A colposcopy can cause some women to feel anxious. A biopsy can cause mild pain and some inconvenience afterwards.
- Testing HPV positive may make you feel upset and distressed.
- Think about any other disadvantages to HPV testing that may be important to you.

Disadvantages of usual care

- You may have to wait up to 2 years before your cells get better themselves. During this time you will need to have several repeat Pap tests.
- Waiting for testing and test results for an extended period of time may make you feel anxious.
- Think about any other disadvantages to HPV testing that may be important to you.

STEP 4 Do you want any extra information before you decide?

If yes, please call the IMAP team on 1300 363 803

STEP 5 Making your decision

Which management is right for you: HPV testing or usual care?

- It is now up to you to decide which management you would prefer for your mildly abnormal Pap smear, HPV testing or usual care.
- The following pages set out some steps to help you make your decision.
- After the steps are described, you will be asked to fill in your own personal worksheet to help you work out what factors are important to you in your decision.
- To help you, examples of the decision made by other women are given on pages 31-34.
- If you have any questions, please call the IMAP study team:
Tel: 1300 363 803.
- **Please note:** The costs of any extra tests included in the study will be covered by the research team, if undertaken at Family Planning clinics. If you wish to be treated privately or as a private patient in a public hospital, we regret that it is not possible for us to reimburse treatment costs.



Repeat Pap testing

- Usual care for a mildly abnormal Pap smear is to have a repeat Pap smear at 6-12 months.
- If you choose usual care the first repeat Pap smear will take place in 6 months.
- It is exactly the same as your normal routine Pap smear.
- The result of the first repeat Pap smear decides the rest of your follow-up management. This is explained below and will be discussed with your doctor or nurse.

Results of the repeat Pap smear and follow-up management

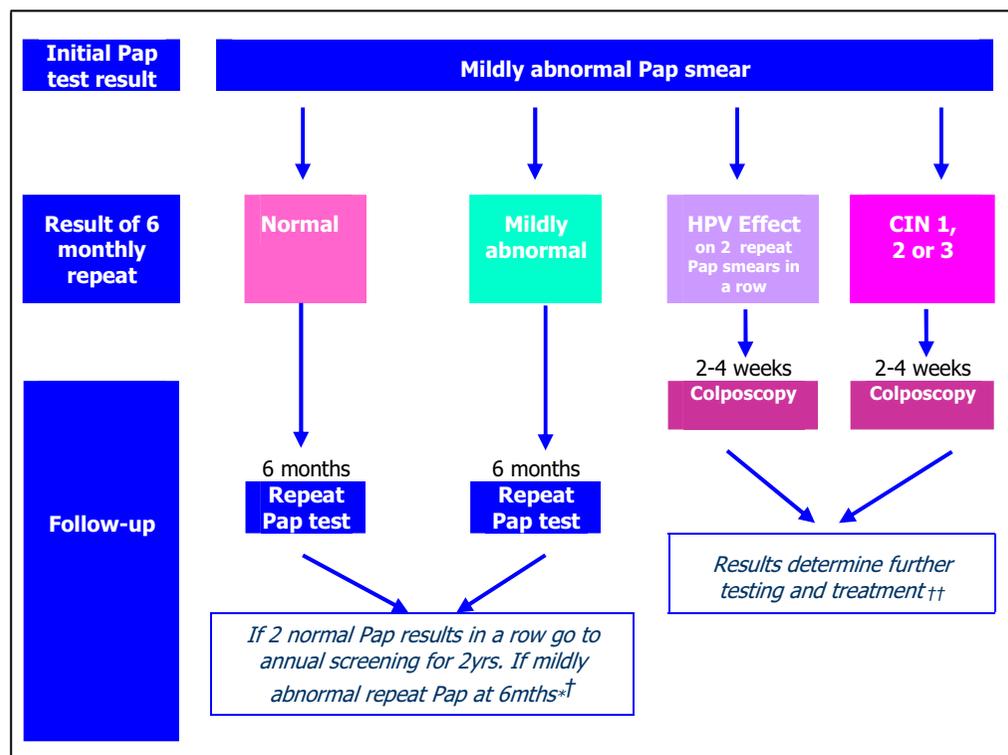
See diagram over the page

- **A normal repeat Pap result** means that your abnormal cells appear to have cleared and you will be asked back for another Pap smear in 6 months. The second repeat Pap smear will check that your cells remain normal.
- **A mildly abnormal result with no signs of 'HPV effect'** means that your abnormal cells have not cleared. The doctor will invite you back for another repeat Pap smear in 6 months.
- **A mildly abnormal result with some 'HPV effect'** means that your abnormal cells have not cleared and there are some signs of HPV infection. If your first and second Pap smear showed HPV effect you may be invited for a colposcopy. A colposcopy is a closer examination of your cervix and is explained in more detail on page 13.



Repeat Pap testing

- **A CIN 1, CIN 2 or CIN 3 result** shows that your cell changes have become more serious and you will be invited for a colposcopy (see page 13).



* If your repeat Pap test result shows you have CIN 1, 2 or 3 at any stage you will be invited for colposcopy.

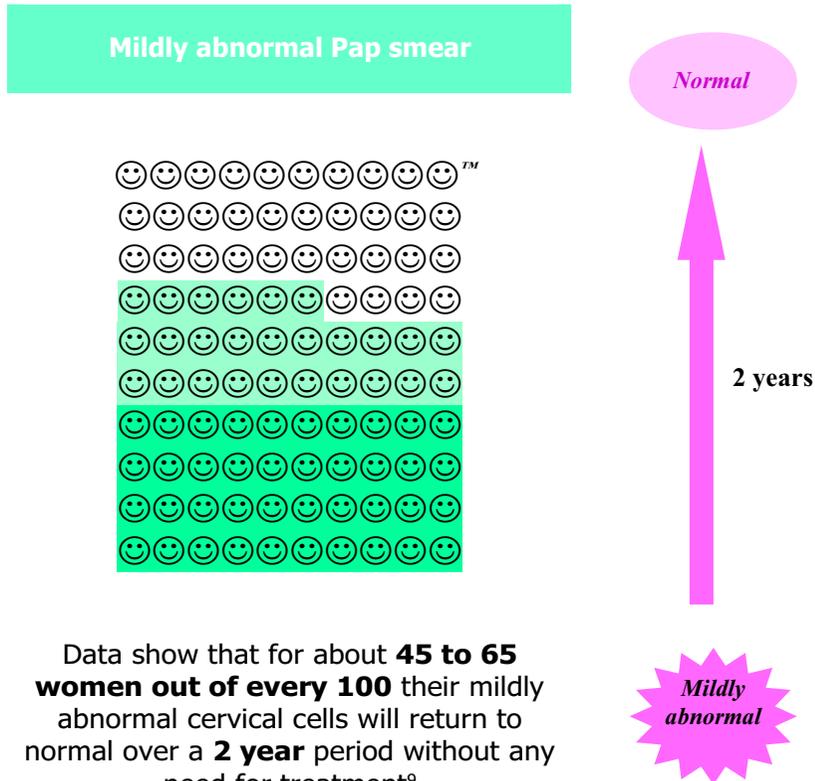
† If your repeat Pap test is normal and you have had 2 normal Pap smears in a row, you will be advised to have annual screening. If this Pap smear is normal, you can then return to routine 2 yearly screening.

++ If you have CIN 1 you have a choice of treatment or more regular Pap tests. Treatment is always recommended for CIN 2 or 3.

Choosing the Right Management for You

How likely is it that your abnormal cells will get better on their own?

The diagram below shows how likely it is that your mild abnormality will clear up on its own, without treatment, within a period of 2 years.



Data show that for about **45 to 65 women out of every 100** their mildly abnormal cervical cells will return to normal over a **2 year** period without any need for treatment⁹

What is a colposcopy?

- A colposcopy (*col-pos-copy*) is a more detailed examination of your cervix using an instrument called a colposcope, which is like a pair of binoculars on a stand.
- The colposcope stands at the foot of the bed and the doctor looks through it to closely examine the cervix
- This allows the doctor to have a magnified view.

How is a colposcopy done?

- A colposcopy can be performed at an FPA clinic or at your local hospital by a specialist as recommended by your doctor or nurse.
- You lie on an examination couch with your legs resting on special supports.
- The doctor then inserts a speculum into the vagina to hold it open, as was done for the Pap smear.
- The cervix is painted with a liquid which makes any abnormal areas change colour.
- The doctor looks through the colposcope to examine the cervix, to see the location and pattern of the abnormal areas.
- A colposcopy usually takes only 10 to 15 minutes and most women do not experience any pain. Some discomfort may result from having the speculum inside the vagina.

What is a biopsy?

- During the colposcopy, a small sample of tissue, called a biopsy, may be taken from any abnormal looking areas of the cervix.
- A biopsy is taken to confirm a diagnosis of abnormal cells.
- When a biopsy is taken, mild pain or discomfort may be experienced for a short time (such as a stinging feeling or a mild cramp).
- After the biopsy you are likely to have some light bleeding for a few days. Some women continue to have spotting for up to 2 weeks.
- The sample is sent to a pathology laboratory for testing and the results will take about a week to come back to the doctor.
- Arrangements will be made for you to return to discuss the results with the doctor and whether any further treatment is needed.
- After a biopsy you may be advised that you should avoid:
 - heavy exercise the following day
 - sexual intercourse, swimming, having a bath or spa for a few days after the procedure (showering is fine)

If you need to have a colposcopy and biopsy you will have the chance to talk to a doctor or nurse in more detail.



The Timing of Testing

Usual care (repeat Pap test)

You must wait 6 months for your first repeat Pap test

Calendar			
Month 1	Month 2	Month 3	Month 4
Mildly abnormal Pap test result			
	Repeat Pap test* at 6 months		
			Repeat Pap test* 12 months

* Over 2 years between 20 and 40 women out of 100 will be advised to have a colposcopy

HPV Test

You can have your HPV test straight away

Calendar			
Month 1	Month 2	Month 3	Month 4
Mildly abnormal Pap test result HPV test	HPV+ go to Colposcopy		
			HPV- Pap test at 12 months

Your chance of needing a colposcopy

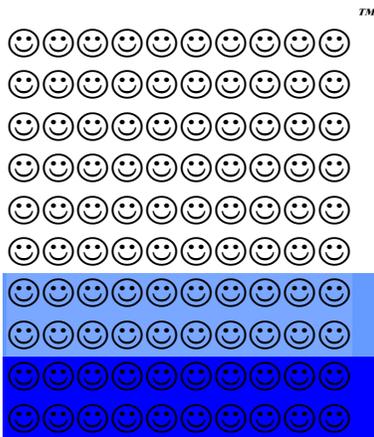
The diagrams below show the key differences between HPV testing and usual care as described on the previous pages.



Your chance of needing a colposcopy examination

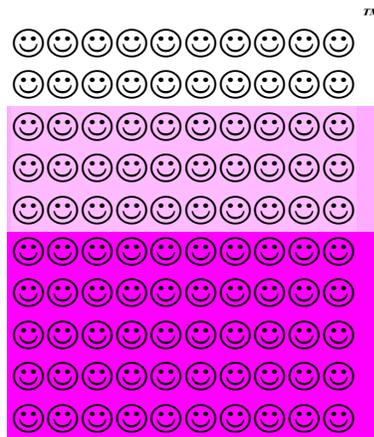
If you have an HPV test you have a higher chance of needing a colposcopy. The pictures below show the number of women out of 100 who will have a colposcopy if they choose HPV testing or if they choose usual care.

Usual care (repeat Pap testing)



Between 20 and 40 women out of every 100 choosing usual care (repeat Pap testing) will be recommended to have a colposcopy examination over a 2 year period⁹

HPV testing



Between 50 and 80 women out of every 100 choosing HPV testing will be recommended to have a colposcopy examination⁸

A New Approach to Managing mildly abnormal Pap smears: HPV Testing

What is Human papillomavirus (HPV)?

- HPV is one of the most common viral infections. It is thought that over 70% of women will have HPV at some stage during their lifetime.
- Recent studies have shown that most cases of cervical cancer are caused by HPV.⁷
- There are many different types of HPV (also called the wart virus). Some HPV types cause warts on hands and feet, and some cause visible genital warts. These types are **not** linked with cervical cancer (*although it is possible to have both types at the same time*).
- HPV types linked to abnormal cervical cells and cancer (also called 'high risk' types) do not cause symptoms.
- HPV is believed to be transmitted during sex as both men and women carry the virus.
- Importantly, HPV can lie inactive for many years (up to 20 years), so it is usually very difficult to tell who it came from and when.

What does it mean to have HPV?

- 'High risk' HPV types cause **very few** problems in **most** women.
- In the majority of women, the HPV infection is cleared by the body's immune system and the cells return to normal without any treatment.
- This clearing process usually takes 6 - 18 months.^{1,2,3,4}
- However, in some women, the HPV infection persists. It stays in the cervical cells and leads to a worsening of the abnormal cells.



Timing



- HPV testing gives you the chance of having an earlier test result because you can arrange to have the test straight away. This means that:
 - If a more serious problem is detected any treatment can be carried out sooner.
 - You have a shorter period to wait for the test results. For some women this means they experience less anxiety and worry.^{10,11}
- In comparison, usual care can sometimes be a long process. You have to wait 6 months for your first follow up Pap smear and it usually takes over 2 years until you return to routine screening. This period of waiting can cause some women to feel worried for a long time.^{10,11}

The chance your abnormality will clear on its own

- Research shows that most abnormalities will clear-up on their own if they are given time⁹.
- If you have an HPV test you may give your abnormal cells less time to clear up by themselves before you have a colposcopy and treatment.
- If you follow usual care, your mildly abnormal cells may get better by themselves by the time you are due for your repeat Pap smear (in 6 months).

Testing positive for HPV

- Testing positive for HPV infection can cause some women to feel upset and distressed.



Importantly, overall, the evidence shows that if women follow all recommended tests and examinations, both HPV testing and usual care are **highly effective** at preventing serious cervical abnormalities and cervical cancer.^{8,9}

HPV testing and usual care (repeat Pap testing) both have advantages and disadvantages which relate to **follow-up examinations**, the **timing** of testing and **your feelings**.

Follow-up examinations



- If you have an HPV test, studies from the USA⁸ show that among women with a mildly abnormal Pap smear:
 - Between 50 and 80 women in every 100 will test positive for HPV and will be advised to have a colposcopy and biopsy.
 - Between 20 and 50 women in every 100 will test negative for HPV and need no further checks for 12 months.
- If you follow usual care your chance of having a colposcopy is lower. Between 20 and 40 out of every 100 Australian women who have a mildly abnormal Pap smear will be advised to have a colposcopy over a 2 year period. This is because many minor abnormalities clear up by themselves over time⁹.
- Having a colposcopy can cause some women to feel worried and anxious.¹²
- Along with a higher chance of colposcopy, women who have HPV testing also have a greater chance of having a biopsy.
- A biopsy can cause mild discomfort and some inconvenience (see p14).

What is an HPV test?

- The HPV test is a test for the 'high risk' types of HPV linked to cervical cancer.
- The HPV test shows whether you might benefit from having a more detailed examination of your cervix by colposcopy or whether you do not need any further checks for 12 months.
- It can be done as soon as you like after your mildly abnormal Pap smear result.
- It is carried out in a similar way to your routine Pap smear and should feel exactly the same.
- HPV testing has been suggested as an alternative to repeat Pap testing.



A new approach: HPV testing

What happens when you have an HPV test?

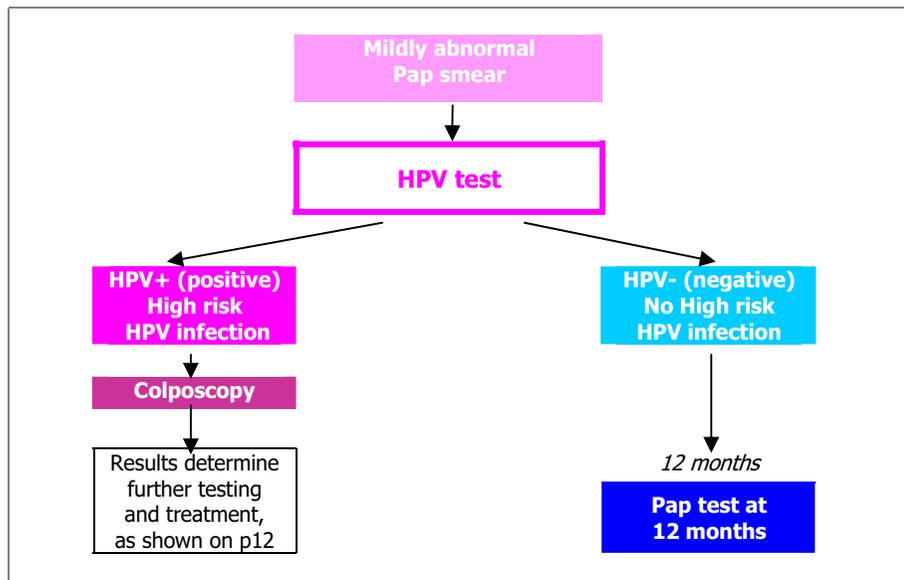
The results of an HPV test can be positive or negative.

A positive HPV test result (HPV+)

- This means you are likely to have an infection with a 'high risk' type of HPV.
- Your doctor will refer you to have a colposcopy and biopsy to examine the cells of your cervix more closely. See page 13-14 for information about the colposcopy and biopsy.

A negative HPV test result (HPV-)

- This means that it is unlikely that you have an infection with the type of HPV that is linked to cervical cancer and you do not need further investigation.
- You will be invited for a repeat Pap smear in 12 months and if this Pap smear is normal you can return to routine 2 yearly screening.



Comparing HPV Testing against Usual Care (Repeat Pap Testing)