



# PathWay

THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA



JUNE 2014 | Published by RCPA

Issue #037

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- Know Pathology Know Healthcare campaign kicked off at Canberra's Parliament House with blood tests for our polities
- HPV test may renew Australia's National Cervical Screening Program
- Quality assurance processes are finally catching up with the genetic revolution
- Changing our sunlight exposure habits may help prevent melanoma and other diseases

## Interesting Facts

6830

The number of people (so far) who have signed up to the [Know Pathology Know Healthcare](#) website to show they value pathology.

70%

The proportion of medical decisions that rely on laboratory tests.

## Introduction



### *Cathy Freeman OAM*

Often the arena of blood curdling battles, Parliament House in Canberra saw blood spilled for a different reason last week. Our politicians were offered an HbA1C blood test to check for diabetes as part of the official launch of the **Know Pathology Know Healthcare** campaign. Olympic champion and diabetic Cathy Freeman was also present to show her support for pathology. Our article this month highlights this new campaign.

The other articles are testimony to the breadth of pathology and its dynamic nature at the heart of medicine. There are snapshots of research into the cause of melanoma, and the reasons behind the proposed new regime for cervical screening. We've also looked at how the pathology profession is responding to the challenge of quality assurance for genetic tests.

# Over 50 million

The number of pathology tests performed in Australia last year.

Source: *Know Pathology Know Healthcare website*

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Don't forget to check our [Facebook](#) page regularly and keep up-to-date with what's happening in pathology by following our CEO Dr Debra Graves (@DebraJGraves) or the College (@PathologyRCPA) on Twitter.

While you're online, check out the *Know Pathology Know Healthcare* [Facebook](#) page as well.

## Know Pathology Know Healthcare campaign kicked off at Canberra's Parliament House with blood tests for our polities



*Dr Graham Jones*

Pathology Awareness Australia kicked off their *Know Pathology Know Healthcare* campaign on June 16 by offering HbA1c blood tests to parliamentarians at Canberra's Parliament House. Just a single HbA1c test can confirm the diagnosis of diabetes and is one example of the value pathology brings to the health care table for thousands of people every day. Former Australian of the Year and Olympic Champion Cathy Freeman OAM attended the launch to discuss the personal value of pathology in managing her diabetes.

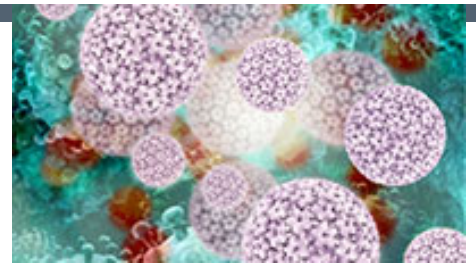
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## HPV test may renew Australia's National Cervical Screening Program

A cervical screening test that detects human papillomavirus (HPV)<sup>[1]</sup> infection may replace the



current Pap smear<sup>[2]</sup> test as part of Australia's National Cervical Screening Program (NCSP). The HPV test, along with other proposed changes, is part of a Renewal strategy based on the best available evidence about the early detection of cervical cancer.



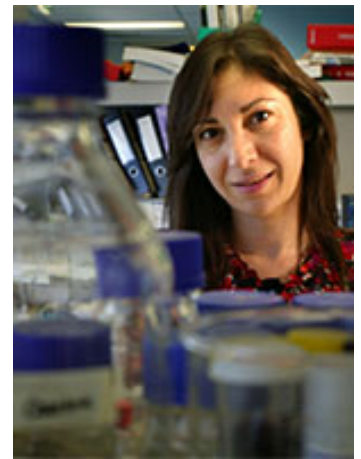
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## Quality assurance processes are finally catching up with the genetic revolution

The genetic revolution didn't walk into town. It galloped. Keeping pace with the changes it brought to medicine presented new challenges, including meaningful quality assurance (QA)<sup>[1]</sup> processes.

*Melody Caramins*

"When next generation sequencing (NGS)<sup>[2]</sup> arrived about six years ago, platforms and technologies changed so rapidly we couldn't validate the processes at the same pace," explains Dr Melody Caramins, Chair of the Royal College of Pathologists of Australasia (RCPA) Genetics Advisory Committee. "The situation is starting to stabilise now because the changes are not as rapid."



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## Changing our sunlight exposure habits may help prevent melanoma and other diseases

Humans have a love-hate relationship with the sun. We've worshipped it, written about it and celebrated it. Without it there would be no life on earth, yet it's one of the most constant and significant environmental carcinogens we are exposed to. And we still don't know how much sunlight is enough to harness its benefits and avoid its risks; but we're getting closer to solving this puzzle.



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## Previous Editions



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ISSUE #036

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- Whooping cough vaccine still protective against severe disease
- Saving lives through early detection is the message for Bowel Cancer Awareness Month
- New Centre for Personalised Immunology aims to close the gap

### Introduction

Whooping cough (pertussis) is back in the headlines due to concerns the vaccine is losing its effectiveness. We've asked Professor Lyn Gilbert, microbiologist and former Director of Laboratory Services at the Centre for Infectious Diseases and Microbiology in Sydney, to clarify what is happening and why.

It's also Bowel Cancer Awareness Month in June. We've lent our support to this important initiative from Bowel Cancer Australia and looked at the reasons why bowel cancer screening is important.

Last month heralded another step towards personalised medicine with the launch of the Centre for Personalised Immunology at the John

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## Know Pathology Know Healthcare campaign kicked off at Canberra's Parliament House with blood tests for our polities



(l-r) Scott Jansson, Neville Moller, John Crothers, James Bateman

Pathology Awareness Australia kicked off their *Know Pathology Know Healthcare* campaign on June 16 by offering HbA1c blood tests to parliamentarians at Canberra's Parliament House. Just a single HbA1c test can confirm the diagnosis of diabetes and is one example of the value pathology brings to the health care table for thousands of people every day. Former Australian of the Year and Olympic Champion Cathy Freeman OAM attended the launch to discuss the personal value of pathology in managing her diabetes.

"I, like most Australians, rely heavily on Australian pathology," explains Ms Freeman. "I feel so happy to know that when I do go and get my blood checked to better manage my Type 2 diabetes that my blood is in safe hands and that essentially my future health is in safe hands."

Dr Debra Graves, CEO of the Royal College of Pathologists of Australasia (RCPA), says the *Know Pathology Know Healthcare* campaign is an exciting initiative that has been 18 months in the planning.

"It's also a world first in terms of the range of health care providers from both the public and private sectors who have come on board to support pathology," explains Dr Graves.

Chair of Pathology Awareness Australia, Mr John Crothers, says pathology is the engine room of medicine.

"Like most engine rooms pathology is hidden from view yet nothing moves forward without it," explains Mr Crothers. "The general public see the tube of blood or the urine specimen, but don't really know what happens to it between the test and the report."

The pathology profession employs over 25,000 people including pathology specimen collectors, scientists and specialist

pathologists who have a minimum of 13 years of medical training. This profession diagnoses 280 Australians with diabetes every day, and is then an integral part of monitoring their diabetes to avoid complications such as blindness, kidney disease and circulatory problems that can lead to gangrene or amputation. And that's the value their expertise gives to patients with one disease.

Seventy percent of medical treatment decisions and 100% of cancer diagnoses rely on pathology services, which are delivered to all Australians for less than three percent of the health care budget. To borrow the current 'budget terminology', the pathology profession is made up of 'lifters' who punch above their weight.

"Now that we've launched the *Know Pathology Know Healthcare* campaign we will keep it going through the website, Facebook page and collection centres," says Dr Graves.

More than 10,000 people have already signed up to show they value pathology on the Know Pathology Know Healthcare website and Facebook page, although Mr Crothers is aiming for 1,000,000 supporters.

"About 12,000,000 Australians have a pathology collection every year, and more than 50,000,000 tests, so that number of supporters is definitely achievable," he says.

You can sign up to support the *Know Pathology Know Healthcare* campaign through the campaign's [Facebook](#) page, [website](#) or at a pathology collection centre.

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## HPV test may renew Australia's National Cervical Screening Program



A cervical screening test that detects human papillomavirus (HPV)<sup>[1]</sup> infection may replace the current Pap smear<sup>[2]</sup> test as part of Australia's National Cervical Screening Program (NCSP). The HPV test, along with other proposed changes, is part of a Renewal strategy based on the best available evidence about the early detection of cervical cancer.

The NCSP Renewal commenced in November 2011 in response to new evidence about the optimal screening age range and interval for cervical cancer, new technologies available and the introduction of the HPV vaccine. HPV infection is the main risk factor in developing cervical cancer.

"The recommended changes to the National Cervical Screening Program have been approved by the Medical Services Advisory Committee (MSAC) and by the pathology profession," says Dr David Papadimos, Chair of the Royal College of Pathologists of Australasia (RCPA) Cytopathology Advisory Committee. "If they are approved by the Federal Health Minister there will be significant changes to the current screening program."

The potential changes include:

- a HPV test every 5 years instead of the current second yearly Pap smear test
- cervical screening to start at 25 years of age instead of between the ages of 18 and 20 years, or one or two years after first having sexual intercourse, for the first Pap smear test
- an exit HPV test between 70 and 74 years of age instead of the last Pap smear at the age of 70 years for women who have had two normal Pap smears within the last five years.

"The HPV test will still be collected from the patient in the same way as the current Pap smear, but it will be analysed at the

pathology laboratory using a different test,” explains Dr Papadimos. “If the HPV test is positive then a reflex cytology test, where a cytologist examines the cervical cells under a microscope in the same way as a Pap smear test, will follow.”

Dr Papadimos says there is also provision in the proposed program for groups who are currently under screened for a variety of reasons, such as cultural sensitivities or poor access to health care facilities, to self-collect their sample.

“Women will have the option of taking a swab of their vagina if they have objections or barriers to the normal collection method,” he says. “This is not the ideal collection method, but it can mean women who currently fall through the cracks can still be screened because the HPV test is sensitive enough to pick up evidence of an HPV infection from this type of sample.”

The proposed program will not only affect patients. There are significant implications for pathology laboratories across Australia as well.

“Pathology laboratories will need to manage changes such as accommodating the different testing method and developing quality assurance standards for this test,” explains Dr Papadimos. “There are also changes to reporting results and staffing in laboratories to consider.”

Dr Papadimos says about 2 million Pap smears are collected annually in Australia. This will be reduced to around 400,000 HPV tests under the proposed program which has implications for the number of cytologists currently working in laboratories across Australia.

The proposed NCSP changes are still recommendations to the Australian Government, and until they are approved, and details of how to implement the proposed new program are worked out, it’s business as usual under the existing program.

“There is no set date for implementing the proposed program even though it is aiming for a 2016 start,” explains Dr Papadimos. “Women should therefore continue with their second yearly Pap smears until they are notified that the change has happened.”

[1] HPV and cervical cancer is covered in [April 2011](#) edition of ePathWay

[2] Pap smears is covered in [October 2011](#) edition of ePathWay

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## Quality assurance processes are finally catching up with the genetic revolution



The genetic revolution didn't walk into town. It galloped. Keeping pace with the changes it brought to medicine presented new challenges, including meaningful quality assurance (QA)<sup>[1]</sup> processes.

"When next generation sequencing (NGS)<sup>[2]</sup> arrived about six years ago, platforms and technologies changed so rapidly we couldn't validate the processes at the same pace," explains Dr Melody Caramins, Chair of the Royal College of Pathologists of Australasia (RCPA) Genetics Advisory Committee. "The situation is starting to stabilise now because the changes are not as rapid."

QA regulatory standards and processes that lead to accreditation through the National Pathology Accreditation Advisory Council (NPAAC) and National Association of Testing Authorities (NATA)/RCPA take about two years. When technology changes rapidly this time frame doesn't work.

"We had to develop a more dynamic and flexible approach to QA so we are using the process of benchmarking and peer review," says Dr Caramins. "This means the pathology laboratories who offer genetic testing are setting standards by national and international peer review, using guidelines developed by the RCPA, while they wait for the regulatory bodies to catch up. There are about six genetic laboratories in Australia and New Zealand that are now NATA/RCPA accredited for the new massively parallel sequencing methodologies."

Dr Cliff Meldrum, Deputy Director of Molecular Medicine at Pathology North - Hunter, has been through these processes. His laboratory offers NGS, but its many different applications have proved challenging when it comes to QA.

"There were no QA programs to follow for NGS when we started validating our tests. We started with the BRCA1 and BRCA2 genes because we had a high throughput of these tests in our laboratory, therefore access to numerous appropriate controls,"

he explains.

Dr Meldrum's validation process involved comparing NGS with the older genetic technology used for BRCA1 and BRCA2. He says the results were comparable but NGS was quicker, more efficient and provided greater capacity.

"We found we could process 42 patients at one time instead of just one, and our turn around times for these tests were considerably shorter at less than four weeks compared to three months using the older technology. We completed our validation process using around 400 samples last year, and RCPA/NATA accreditation followed. We are now validating about five more genetic testing panels using a similar approach."

Dr Meldrum says the issues associated with QA for genetics are multifactorial in terms of the number of platforms used, the way the data is handled and interpreted, how it is put into databases and then reported on.

"The interpretation and management of the large data sets generated by genetic testing is also an issue because it involves many different skill sets and reliance on local, national and international data repositories," he says.

The genetic revolution has now slowed from a gallop to a trot, but it's still moving rapidly enough to keep presenting challenges. A framework for accreditation for NGS through NATA/RCPA has been developed and is being used as a starting platform.

"We've used a grass roots approach instead of a top down approach because the rules were being written as we went along," says Dr Caramins. "Proceeding slowly is important for QA because we have to talk to peers here and overseas, and gather input from a wide range of stakeholders both within pathology and from other medical specialists. But, the RCPA is committed to ensuring meaningful QA processes are developed for genetic testing."

[1] Quality assurance is also covered in the [June 2012](#) and [August 2012](#) editions of ePathWay.

[2] Next generation sequencing is an umbrella term used to describe a number of different modern sequencing technologies.

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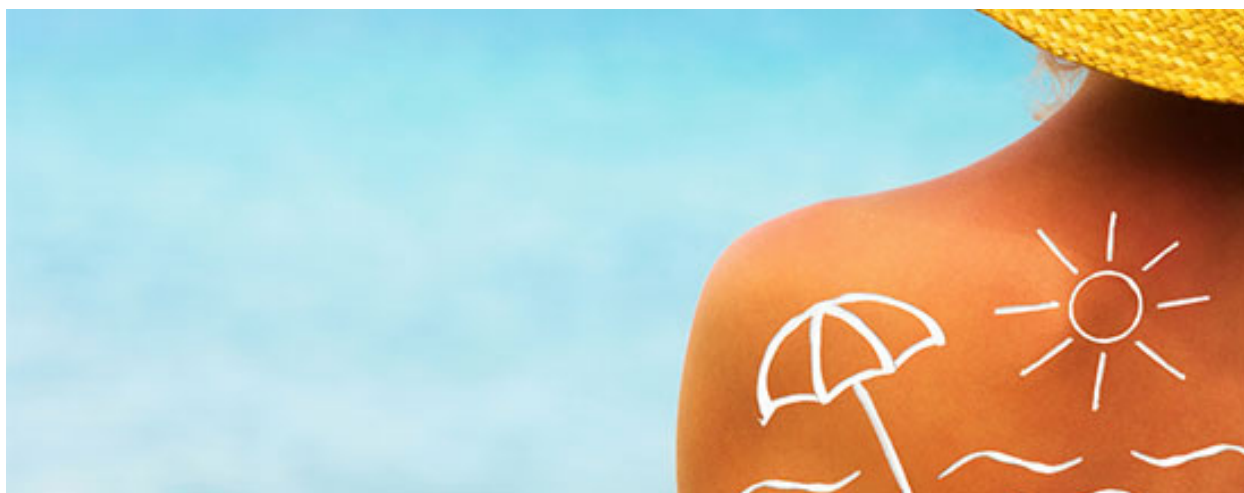
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## Changing our sunlight exposure habits may help prevent melanoma and other diseases



Humans have a love-hate relationship with the sun. We've worshipped it, written about it and celebrated it. Without it there would be no life on earth, yet it's one of the most constant and significant environmental carcinogens we are exposed to. And we still don't know how much sunlight is enough to harness its benefits and avoid its risks; but we're getting closer to solving this puzzle.

Dr Scott Byrne, Senior Lecturer in Immunology at The University of Sydney, and his research team discovered a particular cell in 2005 that might be a missing piece of the puzzle. The cell is called an Ultraviolet (UV) Activated Regulatory B cell (or UV-B<sub>Regs</sub>) and is activated in the lymph nodes that drain our skin in response to UV radiation from the sun. This discovery could have major implications for understanding how melanomas and other UV-related diseases develop.

"Ultraviolet radiation suppresses our cancer-fighting immune system and allows cells to grow and metastasise, which often happens in melanoma. The dose of UV radiation needed to cause DNA damage and immune suppression is actually lower than the dose required to cause sunburn," he explains.

"Activating immuno-regulatory pathways may explain how UV radiation not only causes skin cancer and melanoma, but also how sunlight bestows its many health benefits on us as well."

Dr Byrne says UV-B<sub>Regs</sub> are activated by sub-inflammatory UVB doses. If we activate too many UV-B<sub>Regs</sub> by getting too much sun, then developing skin cancers might be able to escape the anti-tumour immune response. However, if we don't get enough sunlight and fail to activate enough UV-B<sub>Regs</sub> then the immune system may target our own cells and tissues for destruction.

“This may explain the strong link between insufficient exposure to UV and the high risk of developing conditions such as multiple sclerosis,” he explains. “Targeting UV-induced immune suppression by turning UV-B<sub>Regs</sub> on or off may therefore bestow a therapeutic benefit.”

These cells have been successfully turned on and off in animal models, and Dr Byrne is ready to see if this can be translated to humans. To test this hypothesis, Dr Byrne and his team at The University of Sydney will study the UV-B<sub>Reg</sub> cells of four groups of people:

1. Those who have never had skin cancer.
2. Those who have sunspots but no skin cancers.
3. Those who had non-melanoma skin cancers and had them removed.
4. Those who have a lot of non-melanoma skin cancers and have them removed on a regular basis.

“We are recruiting patients for this study right now,” he says. “There will be about 25 people in each of the four groups, and we’ll take just one blood sample from each person to look at the characteristics of their UV-B<sub>Regs</sub>. We are recruiting non-melanoma skin cancer patients, but the research findings will also translate to melanomas.”

Dr Byrne says despite living on a sun-drenched planet, we still don’t entirely know how the sun activates our responses to it. Whole populations have limited their exposure to UV rays yet the incidence of both melanoma and non-melanoma skin cancer continues to rise. Similarly, if boosting vitamin D is such a key part of preventing multiple sclerosis, then Dr Byrne wonders why vitamin D supplements alone aren’t more effective at preventing this disease.

There are still a lot of questions to answer. But as we enter the age of personalised medicine, it may be time to investigate whether an individual approach to sunlight exposure based on age, culture, gender, occupation, skin type and genetics is appropriate. Our individual immune responses to sunlight may be a key piece in solving the puzzle of how much sunlight is enough to bestow its health promoting benefits on us while not provoking melanoma.

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