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Cervical screening

Changes to HbA_{1c} reporting

Hepatitis quiz feedback

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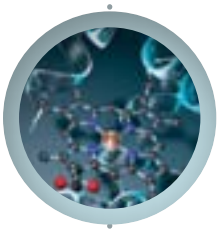

Cervical screening in New Zealand

Key reviewer:
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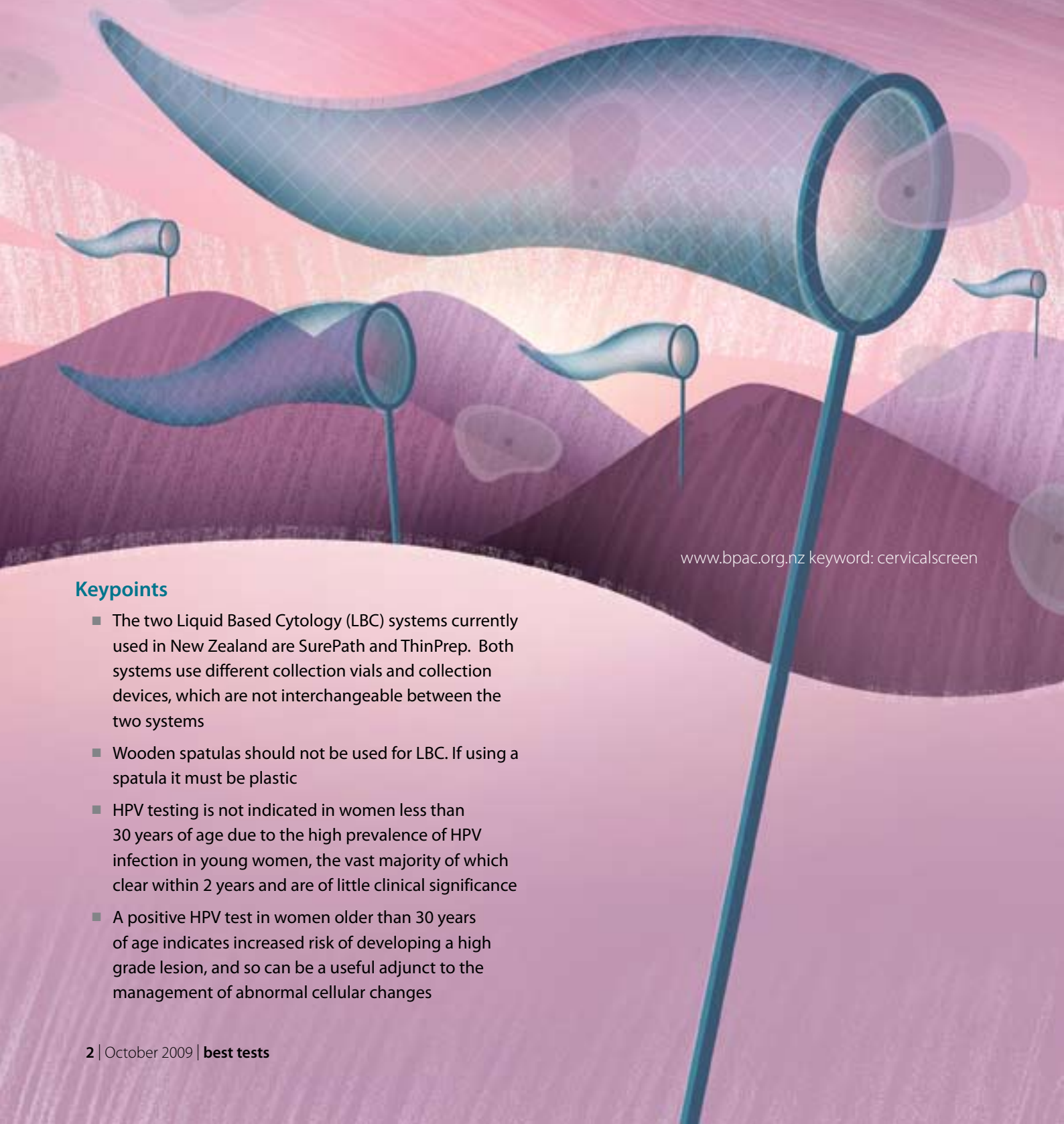

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Keypoints

- The two Liquid Based Cytology (LBC) systems currently used in New Zealand are SurePath and ThinPrep. Both systems use different collection vials and collection devices, which are not interchangeable between the two systems
- Wooden spatulas should not be used for LBC. If using a spatula it must be plastic
- HPV testing is not indicated in women less than 30 years of age due to the high prevalence of HPV infection in young women, the vast majority of which clear within 2 years and are of little clinical significance
- A positive HPV test in women older than 30 years of age indicates increased risk of developing a high grade lesion, and so can be a useful adjunct to the management of abnormal cellular changes

Liquid-based cytology (LBC) and Human Papillomavirus (HPV) testing have recently been adopted to aid with the collection, diagnosis and management of cervical cytology.

The main advantages of LBC are a reduction in the rates of unsatisfactory smears, shorter time required for interpretation, and the ability to use the same sample for HPV testing.

Introduction of liquid based cytology for cervical smears

Cervical screening started in New Zealand the 1950s, then in 1991 the National Cervical Screening Programme (NCSP) was launched. Since then the vast majority of cervical smears collected over the last 50 years have been performed by the traditional Pap smear method of cells being spread onto a glass slide and a fixative used to prevent air drying.

Liquid based cytology has been available in New Zealand for approximately 10 years. This has had variable uptake most likely due to the additional surcharge that was previously passed on to the patient. Now that LBC has become the method of choice for cervical cell cytology, it is being rolled out throughout New Zealand at no cost to practice or patient.

LBC represents the first major change in preparation method for cervical screening samples for over 50 years. Instead of cells being smeared onto a glass slide, they are washed into a vial of fixative. Then at the laboratory a random sample of cells is presented in a thin layer on a glass slide. These slides can then either be screened in the usual manner or subjected to partially automated imaging. The process is being widely used in the United States, the UK and in many European countries, where they no longer routinely collect conventional Pap smears.

The National Cervical Screening Programme has agreements in place for gynaecological cytology with a number of providers around New Zealand. All providers will be using liquid based cytology for cervical smears by the end of 2009.

Why the change?

There are number of reasons that have led to the adoption of liquid based cytology in New Zealand.

1. The strong influence of international research and laboratory trends

Most research has concluded LBC is at least as sensitive as conventional Pap smear with the advantage of a reduction of unsatisfactory slides. LBC for cervical smears has become the method of choice in a number of countries.

2. The introduction of the "Guidelines for Cervical Screening in New Zealand" (2008)[1]

The guidelines state cervical smears may be collected by either conventional Pap smear or by LBC, but they acknowledge there may be situations where liquid-based cytology offers some advantage over conventional smears. For instance, women with:

- excessive cervical mucus, discharge or blood
- recurrent inflammatory smears
- recurrent unsatisfactory smears

In addition, the guidelines make provision for the availability of HPV testing in some specific situations. Liquid based cytology has the practical advantage in that it offers a platform for combined cytology and HPV on one cervical cytology specimen.

If required the HPV test can be added to the original sample, with no need for the women to return for additional testing. In most situations HPV testing will be triggered automatically by the laboratory based on the cervical cytology result (ie "reflex" testing).

3. Liquid based cytology can be automated

While most areas of the medical laboratory have become increasingly automated, until recently cytology has remained a labour intensive process. The LBC methodology allows for the integration of automation. This will mean a faster turnaround of results, and the ability for the laboratory to process increased numbers of specimens.

4. Better quality slides

Most artifacts can be removed, resulting in a reduction in the number of unsatisfactory slides, meaning less recalls for repeat smears and less uncertainty for women.

Practical implications for smear takers of LBC

The key differences for smear takers between the LBC method and the conventional Pap smear are:

- Wooden spatulas should not be used for LBC, if using a spatula it must be plastic
- Cervical cells are transferred into a vial of fixative and not smeared onto a glass slide
- Collection devices are specific for the system e.g the SurePath cervibroom must be used with the SurePath system and not with the ThinPrep system

Cell Collection

The ideal sample consists almost entirely of squamous cells which line the ectocervix and a small number of endocervical glandular cells to indicate that the squamocolumnar junction has been sampled.

Squamous cell carcinoma of the cervix accounts for 60–80% of invasive cancers of the cervix. It begins as cervical intraepithelial neoplasia (CIN) at the squamocolumnar junction which is why it is so important to sample this site to detect early changes.

Thorough inspection of the cervix is important. This can be achieved by wiping away excess cervical mucus and using a good light source.

Relevant points to remember when collecting the sample

If possible avoid:

- Vaginal Medication e.g vaginal anti-fungals, spermicidals, oestrogen cream
- Douches
- Menses
- Lubricant:
  - If lubricant must be used, it is advisable to use a water based product sparingly, trying to avoid the tip of the speculum.
  - Warm water may be used to lubricate and warm the speculum.

If the cervix looks abnormal or there are abnormal symptoms the woman should be referred for colposcopic examination irrespective of the cytology report.

The most common collection devices (Figure 1) for cervical or vault smears are a cervibroom, or a spatula and cytobrush (preferably used in combination). Both have similar efficacy and so the choice usually depends on practitioner preference. Many practitioners prefer the cervibroom, since only one specimen needs to be collected.

Cervibroom

This device is usually used alone. The central bristles of the broom should be inserted into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently and rotate the broom clockwise 3 to 5 times.

Spatula and Cytobrush

It is ideal to collect the spatula specimen first because of the tendency of the cytobrush to cause bleeding. The spatula should be inserted into the cervical canal and rotated 360°.

While an adequate sample can be achieved with just a spatula, using a cytobrush increases the likelihood of obtaining endocervical cells. Indications for using a cytobrush are:[2]

- repeat smears on patients with abnormalities e.g. CIN (cervical intraepithelial neoplasia), HPV
- where the anatomy of the canal has been altered by age as in post-menopausal women or by treatment such as cone biopsy
- repeating a smear where previously no endocervical cells were obtained
- abnormal bleeding

The cytobrush should be inserted into the cervical canal until the bottom bristles are only just visible. To avoid bleeding, only rotate a ¼ to ½ turn.

Figure 1: Cervical cytology collections devices (left to right) cytobrush, spatula, cervibroom.

SurePath and ThinPrep LBC

The two liquid based cytology systems currently used in New Zealand are SurePath (Figure 2) and ThinPrep (Figure 3). There is no evidence of benefit of one method over the other. Both systems use different fixatives in their collection vials and the collection devices are not interchangeable between the two systems.

Placing Specimen in fixative

For SurePath: The tips of the spatula and cytobrush are snapped off and placed in the fixative. The head of the cervibroom slides off and is placed in the fixative.

For ThinPrep: The collection device is swirled in the fixative (rotating 10 times for spatula and brush, and by pressing the brush or broom against the side of the vial), the collection device is then removed and discarded.

When using a combination of collection devices e.g. spatula with cytobrush, they should both be placed together into the same vial of fixative (for SurePath) or rinsed in the same vial of fixative (for ThinPrep).

Advantages of LBC over conventional cytology

The advantages of this system are:

- Nearly all the cells collected are transferred into the vial of fixative from which a representative homogeneous smear can be made.
- Most obscuring blood and inflammatory debris can be removed.
- There are no preparation artifacts such as air drying.
- Multiple slides can be prepared from one sample and part of the sample might be used for other purposes e.g. HPV testing.
- If the initial preparation is unsatisfactory, the LBC vial containing the sample can be re-examined and a second slide may be prepared.
- It gives better quality slides leading to a decrease in the number of smears called "unsatisfactory".
- With computer assisted screening it is expected that the average cytologist will be able to increase their throughput.

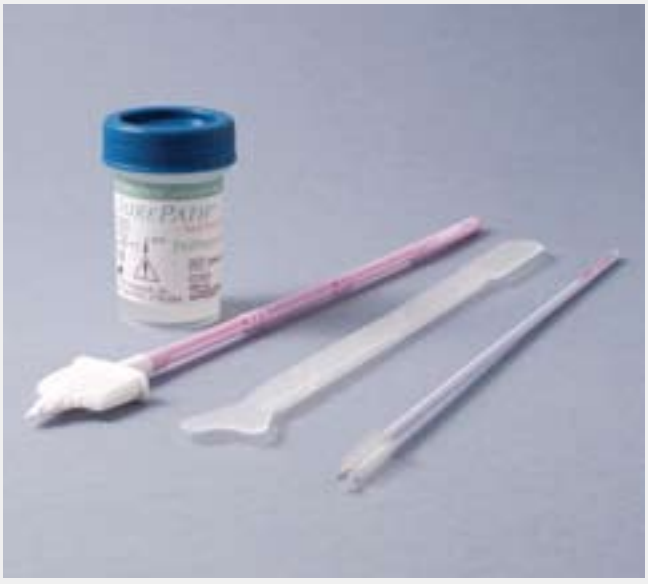


Figure 2: SurePath cytology collection system

Figure 3: ThinPrep cytology collection system

HPV testing

The National Screening Unit has confirmed that from 1st October 2009 there will be an integration of HPV testing into the cervical screening programme guidelines. This coincides with the national adoption of LBC as the primary means of cervical cytology, although HPV testing may not be available in all areas until funding is approved by the Ministry of Health.

HPV is one of the most common sexually transmitted infections in the world. 15–20% of young sexually active women acquire genital HPV infection per year. Adolescents who are sexually active have the highest rates of prevalent and incident HPV infection rates with over 50–80% having infections within 2–3 years of initiating intercourse.[3] Although HPV infection is common, studies suggest approximately 90% of infections clear within 2 years[4] with only a small proportion progressing to cervical pre-cancer and cancer.

HPV types 16, 18, 31, 33 and 39 have a higher risk of progressing to cancer. A cervical smear showing dysplasia, intraepithelial neoplasia or cervical cancer is almost always a result of persistent HPV infection, whereas in the absence of persistent infection with high-risk HPV types, cervical cancer is not expected to develop.

There is good evidence that appropriately applied testing for high risk HPV types can play a useful and cost-effective role in the management of women with abnormal cervical smears. HPV testing currently tests for 13 high risk HPV types and has a very high negative predictive value (approx 99%).[5]

HPV testing can be performed at the laboratory from the same specimen as the smear (LBC), or can be performed on a separate swab.

Using cervical cytology and HPV together

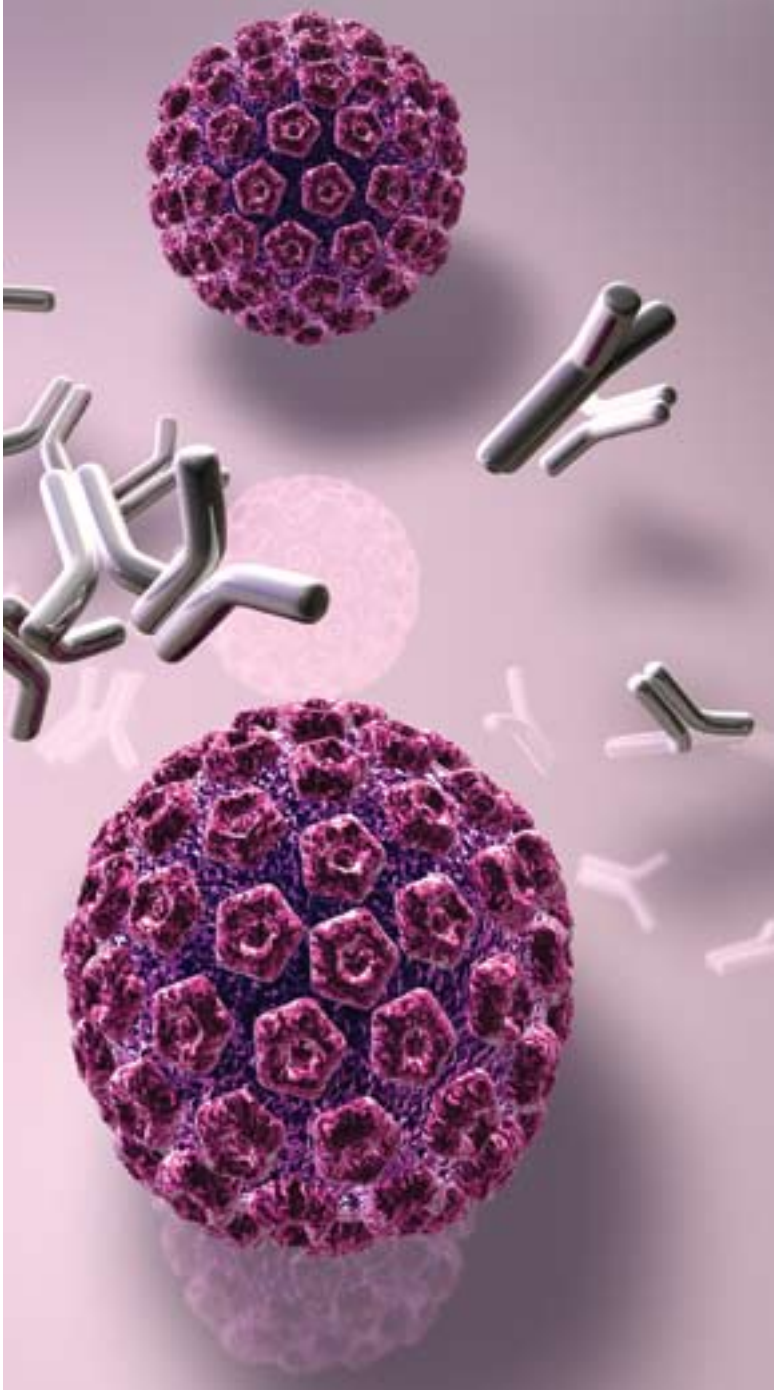
The Cervical screening guideline identifies particular areas of management of asymptomatic women with abnormal cervical smears who may benefit from HPV testing.

This includes:

1. The triage of women 30 years and over with ASCUS or low grade changes (without an abnormal smear in the last five years).

HPV vaccination

Gardasil was introduced to New Zealand's vaccination programme in 2008, and offers protection against HPV types 16 and 18 (as well as 6 and 11 genital wart types).[6] It is anticipated that the HPV vaccination programme will bring about a reduction in cervical cancer rates in the future, in the meantime cervical screening is the most effective way to reduce morbidity and mortality from cervical cancer.[7]



2. The follow-up of women who have been treated for a high-grade lesion.
3. Post colposcopy management of women with discordant results

HPV is used to determine the likelihood of a low grade lesion progressing to high grade lesion for women over 30 years

There is clear agreement that women with high grade abnormalities should be referred to colposcopy but what is less clear is how to care for women with less severe abnormalities. The complexity of managing low-grade abnormalities relates to their mostly self-limiting nature, as well as the evidence that they harbour high grade lesions in up to 20% of cases.[8] A small number of cases of cervical cancer are diagnosed quite soon after low-grade cytology.

HPV testing in women over 30 years old will help in the management of these situations. A positive HPV test indicates increased risk of developing a high grade lesion, and so can be a useful adjunct to the management of abnormal cell changes seen in smears.

HPV testing is not indicated in women less than 30 years of age due to the high prevalence of HPV infection in young women, the vast majority of which clear within 2 years and are of little clinical significance.

Women over 30 years of age with atypical squamous cells of undetermined significance (ASCUS) or a low grade abnormality who tests positive for HPV should be referred to colposcopy. Women who are found to be HPV negative can be followed up with repeat cytology testing. Following a negative cytology result at 12 months, a woman can return to normal three yearly screening.

Follow-up of women who have been treated for a high grade lesion

Women who have been previously treated for CIN2/3 are at increased risk of further high grade disease and cervical cancer. HPV testing changes the management of these women and may negate the need for annual smears for life for many.

Following two consecutive negative smears and HPV tests, 12 months apart, the woman will be able to return to normal three yearly screening intervals.

When cytology and colposcopy results are inconsistent, HPV testing can help to clarify appropriate management

A single colposcopic examination can miss significant lesions. Discordant results are when a smear result differs from the physical appearances seen at colposcopy e.g. high grade cytology with negative or satisfactory colposcopy.

In these situations HPV testing will assist in management. Following two consecutive negative smears and HPV tests, 12 months apart, the woman will be able to return to normal three yearly screening intervals.

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Changes to laboratory reporting of HbA_{1c}

Since the beginning of August 2009, general practitioners and nurses will have noticed the change to dual reporting of HbA_{1c} results. Previously, results had only been reported in percentages (%), but now are being reported with molar units (mmol/mol) alongside (Table 1).

This practice of dual reporting will continue for two years after which time laboratories will likely only report molar units.

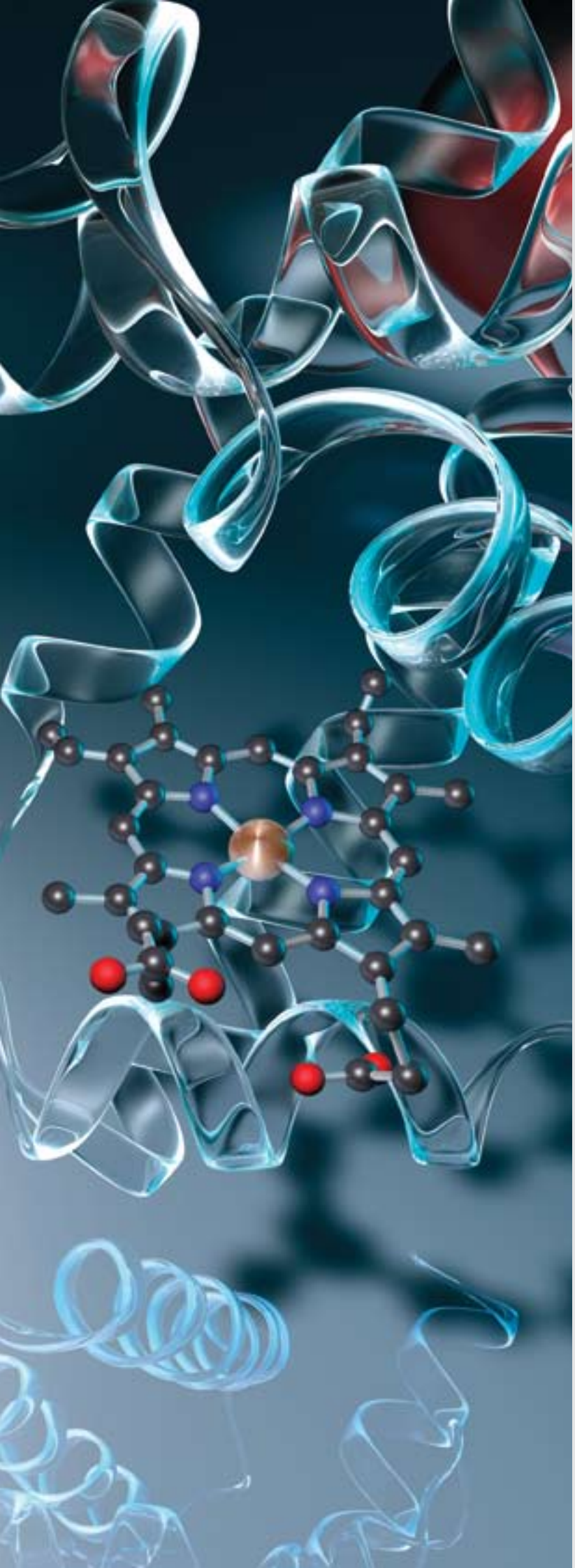
The reason for this change to molar units backdates to August 2007 when there was international agreement that a change in HbA_{1c} units was needed.[1]

The equivalent for the current HbA_{1c} target of 7% is a new HbA_{1c} target of 53 mmol/mol.

There is some concern that patients or their carers may become confused with the change in reporting of their HbA_{1c} results and that their diabetic control may deteriorate due to lack of understanding of the new molar units. It is hoped that the dual reporting system will allow time for both practitioners and their patients to become familiar with the new units, interpretation and utilisation.

Table 1: Comparision of HbA_{1c} units

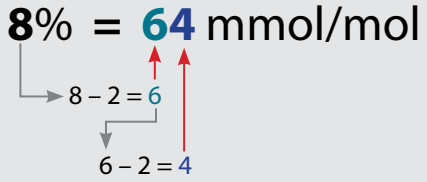
Percentage units (%)	Molar units (mmol/mol)
6.0	42
6.5	48
7.0	**53**
7.5	59
8.0	64
8.5	69
9.0	75
9.5	80
10.0	86
10.5	91
11	97



Kilpatrick's Kludge* and other conversion formulae

An easily remembered way to approximate the conversion from % to molar units is by using "Kilpatrick's Kludge": [2] – minus 2, minus 2.

For example: for the HbA_{1c} result of 8%, the mmol/mol result is eight minus two (6), minus two (4) equaling 64 mmol/mol.



Diabetes UK provide the following conversion equation[3] between conventional HbA_{1c} % results and HbA_{1c} molar units:

$$HbA_{1c}(\text{mmol/mol}) = (HbA_{1c}(\%) - 2.15) \times 10.929$$

*A kludge is a workaround, a quick-and-dirty solution, a clumsy or inelegant, yet effective, solution to a problem

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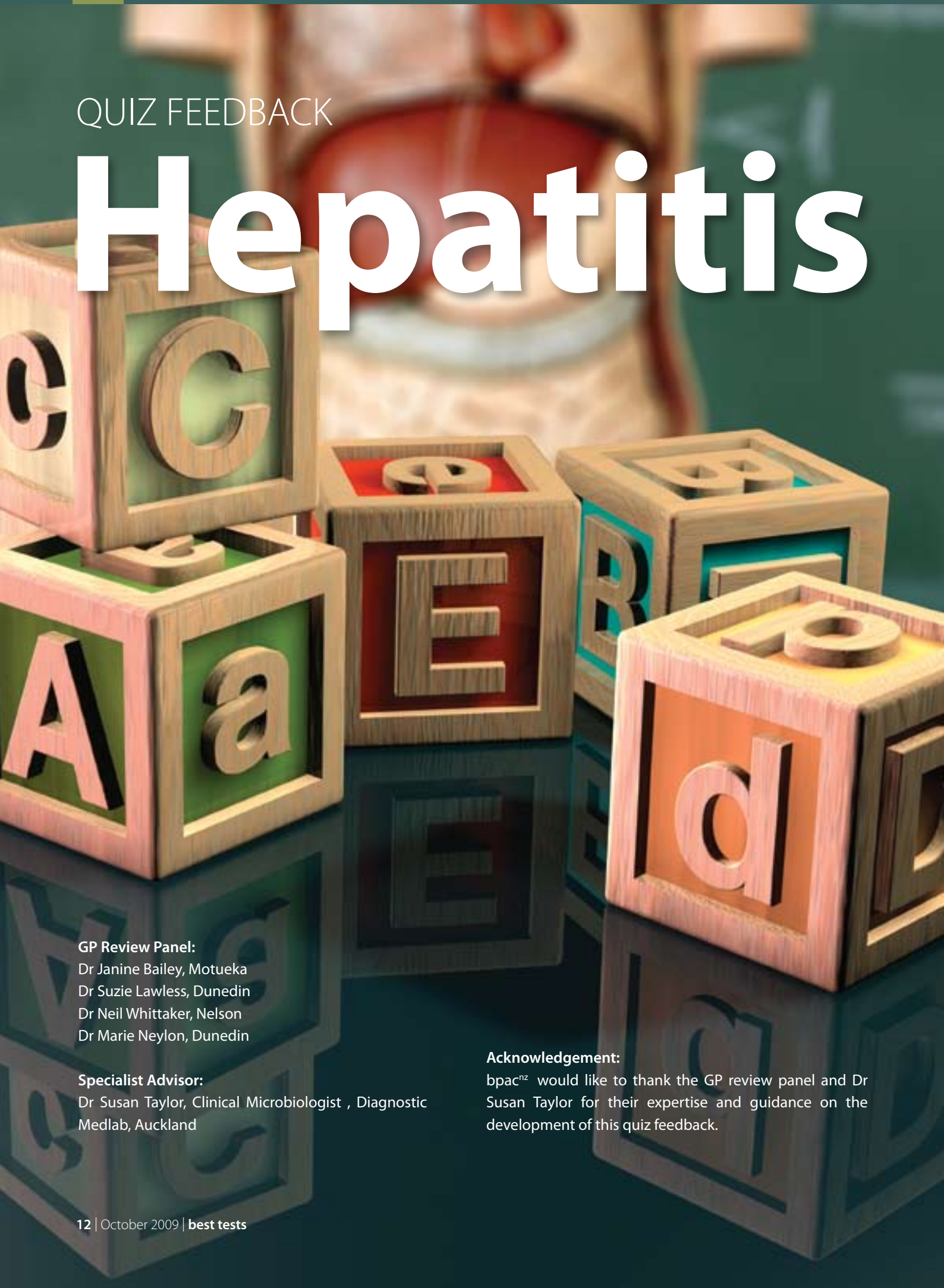
QUIZ FEEDBACK

Hepatitis



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Acknowledgement:
bpac^{nz} would like to thank the GP review panel and Dr Susan Taylor for their expertise and guidance on the development of this quiz feedback.

Introduction

This quiz provides an opportunity to revisit the recent bpac "best tests" that had a key focus on hepatitis testing.

The resource provided an overview of testing for hepatitis infections, including an overview of risk factors. A number of scenarios were discussed, particularly including pre- and post-immunisation situations, that a GP may be faced with in their day-to-day practice.

A key message that came through strongly from the quiz feedback is the importance of considering a number of factors when ordering hepatitis tests. It is important to think about patient's history, age, risk factors, vaccination status and any previous hepatitis test results.

The quiz feedback includes the aggregated responses from GPs that completed the quiz, comments from the GP review group and specialist commentary from Dr Susan Taylor.

All GPs who responded to this quiz receive CME points. After the closing date, the quiz can still be completed online. Currently, there are over 20 interactive cases studies available which provide an ongoing opportunity for accumulating points. These are available from: **www.bpac.org.nz**.

1.	Risk factors for hepatitis A include:		
		Your peers	GP panel
☐	Men that have sex with men	97%	•
☐	IV drug user	90%	•
☐	Infants born to infected mothers	12%	
☐	Previous blood transfusion	2%	

GP panel:

It is clear that most people are aware which of the above are risk factors for hepatitis A. The panel was curious as to why IV drug use is a risk factor, when it is known transmission of hepatitis A is by the faecal-oral route. It was suggested there may be increased risk because the living conditions for many IV drug users may be substandard (with overcrowding and poor personal hygiene) and associated with increased exposure to faecal contamination. Perinatal transmission of hepatitis A is rare. If the mother develops symptoms two weeks before to one week after delivery, the infant may be given IG (0.02 mL/kg), although its efficacy in these circumstances has not been established.

Specialist comment:

The most common reported source of infection is household or other close contact with an infected person. Outbreaks of hepatitis A infection among injecting drug users have been reported in North America and Scandinavia. Several routes of transmission are likely to occur including a combination of person-to-person and percutaneous spread. Poor personal hygiene among drug users may be a source of hepatitis A contamination of drugs or drug paraphernalia, as well as direct person-to-person transmission. Viraemia occurs within 1–2 weeks after hepatitis A exposure and persists through the period of liver enzyme elevation. Virus concentration in serum is 2–3 $\log_{10}$ units lower than in stool. Percutaneous transmission of hepatitis A by needle sharing can occur. Faecal contamination of drugs by rectal transportation has been reported but is probably a rare source of infection.

2.	Risk factors for hepatitis B include:		
		Your peers	GP panel
☐	Men that have sex with men	99%	●
☐	IV drug user	100%	●
☐	Infants born to infected mothers	99%	●
☐	Previous blood transfusion	33%	+/–

GP panel:
Again, these responses demonstrate that GPs are very clear about risk factors for hepatitis B infection.

There were mixed responses to whether a blood transfusion is a risk factor of hepatitis B. It was acknowledged that some people would be chronically infected from receiving infected blood prior to routine blood screening in New Zealand. Following the implementation of blood screening for hepatitis B in New Zealand in 1971, the risk of contracting hepatitis B through a blood transfusion in New Zealand, is now considered extremely low.

Specialist comment:
In the United States, the risk of post-transfusion hepatitis B is estimated to be one to four per million blood component transfused. In endemic countries the risk may be higher, although nucleic acid testing aims to reduce this and has been introduced in some countries.

3.	Risk factors for hepatitis C include:		
		Your peers	GP panel
☐	Men that have sex with men	18%	
☐	IV drug user	100%	●
☐	Infants born to infected mothers	84%	●
☐	Previous blood transfusion	94%	●

GP panel:
The panel discussed the uncertainty that currently exists about how infective Hepatitis C is, particularly in relation to sexual activity. The panel commented they had known of situations when an individual had hepatitis C, but their sexual partner had continued to remain negative for many years.

This led on to a discussion about the likelihood of an increased theoretical risk of transmission from a newly infected person who hadn't yet developed symptoms, ie still in the 'window period'.

Specialist comment:
Successful antiviral therapy may remove the possibility of transmission to partners. Sexual transmission of hepatitis C occurs at a low rate (<1% per year of relationship or about 2% of partners in long-term relationships). These rates increase if the index case is also HIV infected.

Most patients (>60%) do not have symptomatic acute infection. This means many infections are only detected by screening asymptomatic patients at increased risk of infection. HCV RNA is detectable about 2 weeks after infection whereas the appearance of anti-HCV takes 8–9 weeks. For the minority who experience symptoms, these occur around 6–8 weeks after infection.

Vertical (mother to infant) spread also occurs at a low rate (2– 5%). Higher rates are seen if there is HIV co-infection.

4.	What best describes chronic hepatitis A infection?		
		Your peers	GP panel
☐	40–50% of children aged 6-14 will go on to develop chronic hepatitis A	1%	
☐	Only people who develop jaundice go onto to develop chronic hepatitis A	0%	
☐	Chronic hepatitis A only develops in immunocompromised people	1%	
☐	Hepatitis A does not develop into a chronic hepatitis	99%	•

GP panel:
It was clear from the responses that GPs are very aware that Hepatitis A does not develop into a chronic hepatitis. This lead on to a discussion, as to whether there are any long term health issues as a result of hepatitis A.

Specialist comment:
Hepatitis A is rarely complicated by extrahepatic manifestations or fulminant hepatitis. However, the expectation is that patients will recover without sequelae.

5.	Post vaccination immunity check for hepatitis B is indicated for:		
		Your peers	GP panel
☐	High risk occupational or exposure groups	90%	•
☐	5 month of babies born to Hepatitis B surface antigen positive mothers	91%	•
☐	All children in areas with high prevalence of hepatitis B	4%	
☐	People requiring reassurance the vaccine has "worked"	9%	

GP panel:
The panel discussed the scenario of the patient who requests confirmation/reassurance that the vaccine "has worked". They agreed that it would be a situation to discuss the current recommendations that post vaccination immunity check for hepatitis B is not routinely indicated. However ultimately the patient makes an informed choice.

The panel found it helpful to be reminded of the practice in NZ whereby pregnant women are offered a blood test to see if they are chronic carriers of hepatitis B. Babies born to infectious mothers are immunised soon after birth with Hepatitis B vaccine and immunoglobulin, then receive the national immunisation schedule vaccines at the usual times. At 5 months a blood test is taken to check for seroconversion/antibody levels. If the anti-HBs measurement is less than 10 mIU/mL the baby should be given further doses of vaccine at 6 & 7 months with a repeat blood test at 8 months of age.

Specialist comment
Infants born to hepatitis B infected mothers should be tested at around 5 months for both HBsAg and anti-HBs. In addition to measuring antibody response to vaccine, this is to identify the approx 5% of infants that are hepatitis B infected (and therefore will likely have chronic infection) despite immunoprophylaxis. With appropriate immunoprophylaxis, breast-feeding of infants poses no additional risk for the transmission of hepatitis B.

6.	What tests would be indicated for a person with a clinical presentation of acute hepatitis, with a history of recent overseas travel?	Your peers	GP panel
☐	Hepatitis A IgG antibody	7%	
☐	Hepatitis A IgM antibody	97%	•
☐	Hepatitis B surface antibody	7%	
☐	Hepatitis B Surface antigen	76%	•
☐	Hepatitis B core IgM antibody	64%	•
☐	Hepatitis C antibody	21%	+/–

GP panel:
The panel were in agreement about the tests to be done to help diagnose the cause of an acute hepatitis but voiced that it they might tempting to order a Hepatitis C antibody test for completeness sake even if someone was not a drug user. Although it is worth remembering that the majority of patients with newly acquired hepatitis C will be asymptomatic.

While it is preferable to carefully choose the tests based on the clinical scenario, this can be difficult in practice. In addition the combination of tests is often predefined in the PMS system or on the laboratory form. It is useful to provide clinical details on the laboratory requisition form, as this can help the laboratory with appropriate test choices.

Specialist comment:
No further comment

7.	Which is true about pre-immunisation screening for hepatitis B	Your peers	GP panel
☐	Is only indicated for those at higher risk of being a carrier of hepatitis B	88%	•
☐	People at low risk of hepatitis B may be vaccinated without prior screening	75%	•
☐	Only people travelling to high risk areas should have pre-immunisation screening for hepatitis B	4%	
☐	People that may have been exposed to hepatitis B as a child should be screened prior to immunisation	36%	•

GP panel:
The panel were in agreement that pre-immunisation screening is indicated for those at higher risk of being a hepatitis B carrier. They acknowledged this may include those infected as a child, since approximately 90% of infected infants and 25–50% of infected children aged 1-5 years will remain chronically infected.

The panel were unsure what the risks would be if an immune person or hepatitis B carrier was inadvertently vaccinated for hepatitis B. They were also interested about what further vaccinations were required for someone who had started or partially completed a hepatitis B vaccination course but never finished it.

Specialist comment:
The role of pre-vaccination screening is to identify individuals who do not require vaccination and to reduce unnecessary vaccination. The need for pre-vaccination screening should be guided by the likelihood that an individual has been exposed to hepatitis B. For high risk groups, this may be an opportunity to identify a chronically infected patient who may benefit from ongoing surveillance and treatment. The administration of hepatitis B vaccine to individuals who are infected or immune will not result in any adverse outcome.

Longer than recommended intervals between doses do not reduce final antibody concentrations. An interruption in the vaccination schedule does not require restarting the entire series of vaccination or adding extra doses. If the

vaccination series is interrupted after the first dose, the second dose should be administered as soon as possible. The second and third doses should be separated by an interval of at least two months. If only the third dose is delayed, it should be administered when convenient.

8.	A patient has requested vaccination for hepatitis A prior to travel to Indonesia. What laboratory testing is indicated?		
		Your peers	GP panel
☐	Pre-immunisation screening is not usually recommended	91%	•
☐	Both Hepatitis A IgG antibody and Hepatitis A IgM antibody	1%	
☐	Hepatitis A IgG antibody	24%	•
☐	Hepatitis A IgM antibody	1%	

GP panel:
The panel agreed that for the vast majority of people travelling to a country with high risk of hepatitis A vaccination without prior screening was indicated. In this scenario the panel advocated use of a hepatitis A vaccine (sometimes used in combination with other vaccines such as Hepatyrix or Twinrix) and then another booster within 6 months if the patient wants to maximize duration of future cover.

Specialist comment:
Agree, most people do not require pre-travel screening.

Pre-vaccination antibody screening (Hepatitis A IgG antibody) is only justified in older travellers, those who have lived in areas where hepatitis A is endemic (average prevalence of immunity of over 30 percent), or those with a history of jaundice.

Please note: We no longer send out the personalised printed quiz feedback booklets. Instead it is now available from **www.bpac.org.nz**. GPs who completed this quiz should have received an email with access instructions.

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