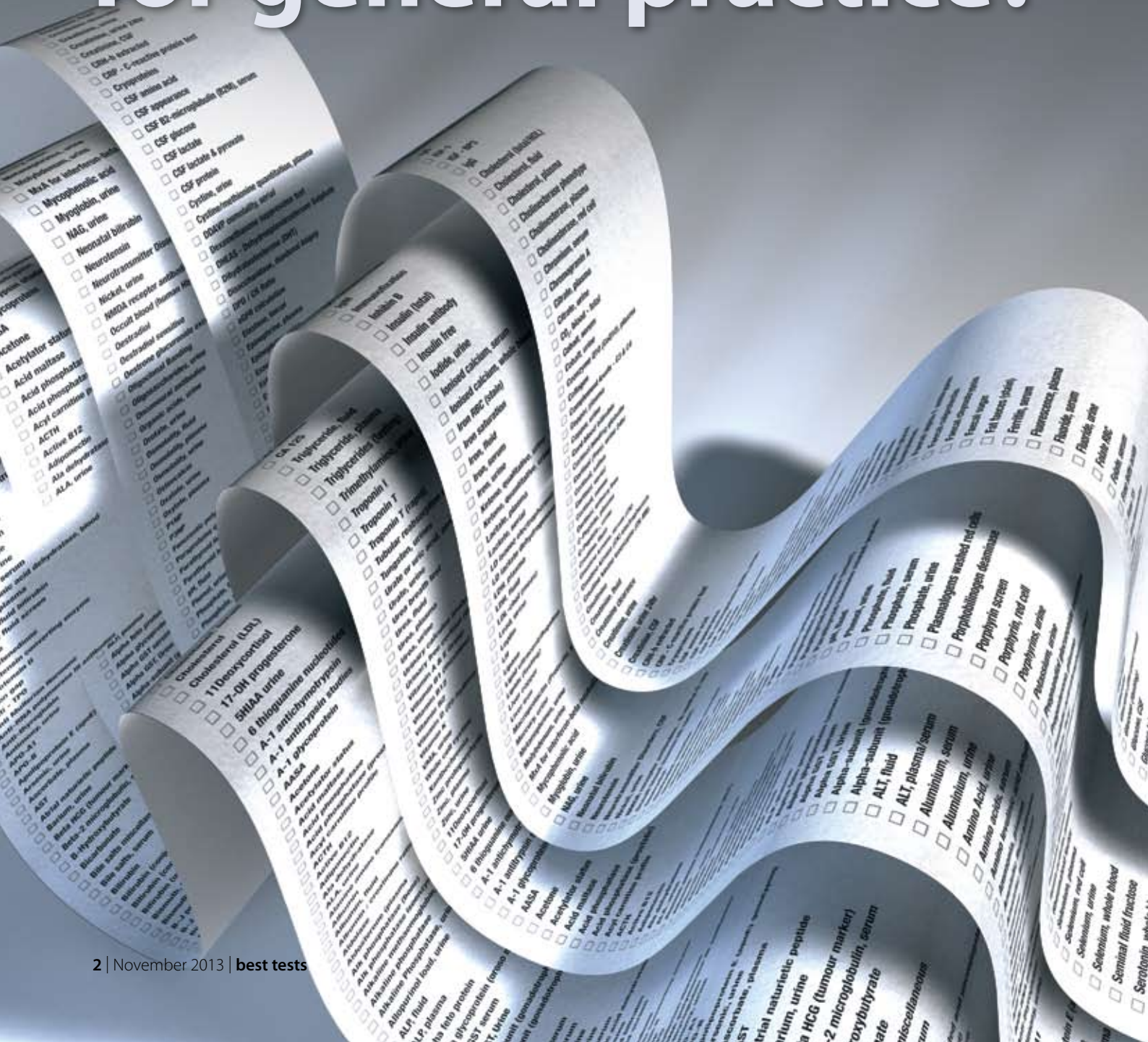
The New Zealand Laboratory Schedule and Test Guidelines: **What does it mean for general practice?**



A new schedule for laboratory testing in New Zealand

In October, 2013, a new laboratory test schedule and accompanying referral guidelines were completed and are now available online. It is anticipated that clinicians will become more aware of these guidelines over time as District Health Boards (DHBs) begin to adopt the recommendations.

The project, which involved a review of all publicly funded laboratory tests available in New Zealand, was managed by DHB Shared Services. The schedule and guidance documents were developed by the Laboratory Schedule Review group and several specialist subgroups (see opposite).

The aim of the laboratory schedule review project was to develop a consistent list of tests that are available and funded across DHBs. These tests have been categorised into two groups, termed Tier One and Tier Two (Page 4). Guidelines for the appropriate ordering of selected tests were also developed. Laboratory tests that were regarded as obsolete or clinically inappropriate have been removed, or in some cases superseded with newer tests.

The Laboratory Schedule Test List and Laboratory Test Guidelines are available from:
www.dhbsharedservices.health.nz/Site/Laboratory/Laboratory-Schedule-Review-Project.aspx

Why was the review required?

In the longer term it is expected that the Laboratory Schedule will form the basis of a national test schedule. A key future goal is the integration of the test schedule and referral guidelines into Practice Management Systems in preparation for fully supported electronic test ordering (e-requests). Until that time, the schedule and guidelines are intended to form a framework and to provide recommendations for the appropriate ordering of tests. How the recommendations are implemented at this stage will be determined by individual DHBs. The guideline document aims to provide DHBs with information on which to base local clinical care pathways and funding decisions. While the test guidelines are not intended to take precedence over established local care pathways or other guideline documents, over time they should enable clinical pathways to become more nationally consistent.

Laboratory Schedule Review Group

The Laboratory Schedule Review Group included representatives from primary and secondary care, medical laboratory scientists and clinicians, and specialists and managers from DHBs, with project sponsorship and management from DHB Shared Services.

Laboratory Subgroup Members included specialists in the following fields: microbiology, clinical biochemistry, haematology, immunology, histology, cytology, anatomic pathology and genetics.

Guidance for the ordering of laboratory tests by Midwives was also developed. A separate list of tests that can be ordered by a Midwife is included in the Laboratory Schedule Test List document.

Groups of health care professionals that were not able to be considered during the development of the documents included Nurse Practitioners and community Dietitians, and clinicians who order tests in a hospital setting as part of a specialist team, e.g. House Surgeons, Dietitians and Resident Medical Officers. Management of test ordering by these health care professionals should continue as per current guidelines within each DHB or within the clinician's specialist scope of practice.

The Laboratory Schedule Test List

The Laboratory Schedule Test List categorises tests into general areas, e.g. chemical pathology, haematology, and then further categorises the tests into Tier One and Tier Two tests.

A Tier One test can be ordered by any medical practitioner* with a current practising certificate in New Zealand. Tier One tests include the "core" tests requested frequently in primary care, e.g. full blood count, INR, creatinine and electrolytes, along with many other tests that are only ordered intermittently by General Practitioners.

* A separate list has been developed for midwives (see: "Laboratory Schedule Review Group, previous page).

A Tier Two test is regarded as a specialist test that can only be ordered by a clinician with "appropriate vocational registration or credentialing". It is intended that the ordering of some Tier Two tests is restricted to the specialists named in the schedule, e.g. a request for sex hormone binding globulin (SHBG) should be from an Endocrinologist, O&G specialist or Chemical Pathologist. In practice, however, the "rules" are not intended to be unnecessarily restrictive and any practitioner can order a Tier Two test if they have endorsement or pre-authorisation by a relevant specialist, or if the test falls within their area of expertise. The clinician requesting the test can also consult with a laboratory pathologist for advice and approval for the use of the test.

For some tests in each tier a clinical guideline has been developed to direct appropriate use (see opposite). This is indicated in the comments section of the Laboratory Schedule Test List with the word "Guideline". If there are specific requirements that apply when ordering a test, these are identified within each individual guideline with the words "Referral criteria available". The laboratory may query the test if the reason for requesting it is not within these parameters. Examples of Tier One tests for which a guideline has been developed include growth hormone, amino acids, faecal calprotectin, T3 and T4 and carcinoembryonic antigen (CEA).

Some tests are categorised as both Tier One and Tier Two and also have supporting information to guide appropriate use. In some situations a Tier One test can only be ordered if the referral form contains appropriate clinical information, otherwise the test is regarded as a Tier Two test, and it should be ordered by a specialist as indicated in the schedule. For example, serum cobalt and serum chromium can be ordered by any medical practitioner if the clinical information provided states that this test is being used in a patient with a metal-on-metal joint replacement. If this indication is not specified, then the test is regarded as a Tier Two test and the laboratory may not proceed with the request.

How is the Laboratory Schedule Test List organised?

In the Laboratory Schedule Test List, tests are listed alphabetically, e.g. in the chemical pathology and microbiology test sections, or are listed in relevant subcategories within a specialty, e.g. coagulation tests within the haematology section and allergy tests within the immunology section. Approximately 80% of the tests are in the chemical pathology section.

For each individual test:

- The Tier is indicated
- Specialists who can order the test may be listed for some of the Tier Two tests
- A note in the comments box may indicate if there is a guideline available that restricts or recommends the use of the test, if there are specific referral criteria for the use of the test or if the test is unfunded and there may be a charge to the patient

In addition, the microbiology section has an extra column indicating whether the infection being tested for is Notifiable under the Health Act or the Tuberculosis Act. A number of notes also follow giving more specific advice about notification, e.g. patients with acute hepatitis B and C (including those with neonatal hepatitis B and documented hepatitis C seroconversion within 12 months) should have their condition notified to the Medical Officer of Health. Some microbiology tests include a comment that consultation with a Public Health specialist is indicated. This consultation can fulfil the requirement for specialist advice prior to ordering of tests.

The genetics section of the schedule varies from the other sections because, due to the rapid increase in the number of tests now available, it was recognised that these could not all be itemised. The list of genetic tests therefore includes the most commonly requested tests. The majority of the genetic tests listed are classified as Tier Two tests and in most situations it is anticipated that General Practitioners will not be ordering these tests. It is recommended that advice be sought before any genetic tests are requested. Genetic tests usually require prior written consent from patients. In addition, these tests are often very costly for the laboratory to undertake.

Laboratory Test Referral Guidelines

Referral guidelines have been developed for approximately 50 individual tests on the schedule. These guidelines provide recommendations for the ordering of tests, and for certain tests, referral criteria.

Depending on the individual test, each guideline may include:

- An overview of the place of the test in a clinical setting
- Supporting information explaining why the test is subject to a guideline
- Indications for the test and any referral criteria (this should be included in the clinical information on the request form)
- Specific instructions for collection of the specimen
- Information on the frequency of testing
- Links to further information
- References for the information in the guideline

What impact will the schedule and guidelines have on primary care?

At the present time, clinicians are unlikely to notice a change to their current practice as the majority of tests ordered by primary care clinicians are either Tier One tests, or within the clinician's vocational scope of practice as a Tier Two Test. Almost all of the "day-to-day" tests used in the community, such as a full blood count, CRP and liver function tests are Tier One tests and do not have a guideline or specific referral requirements.

Tests that are Tier Two and do not fall under the scope of practice for the clinician can still be ordered, but this requires prior discussion and approval from a relevant specialist or laboratory Pathologist.

Some unfunded tests are also listed. Generally these are tests where there is a limited body of evidence to support the use of the test or the test has been replaced with either a more accurate or more cost-effective alternative. For example, salivary testosterone is no longer funded due to lack of accuracy and Chlamydia IgG is also not funded because a more appropriate test is available (Chlamydia trachomatis nucleic acid amplification test – NAAT).

Examples from the Schedule and Guideline

C-Reactive Protein (CRP)
This is a Tier One test with no restrictions, referral criteria or guideline attached.

Erythrocyte Sedimentation Rate (ESR)
This is a Tier One test with a guideline that provides recommendations for appropriate use. Many individual laboratories have already produced guidance regarding the appropriate use of ESR, but the new Schedule and Guideline aims to standardise this information.

The ESR guideline provides a brief overview of the limitations of the test in terms of the accuracy of measurement, the influence of physiological variables (other than inflammation) and the role of other factors such as the patient's haemoglobin and plasma protein levels. CRP is recommended as the preferred investigation of disorders due to inflammation or infection.

The conditions included in the guideline, where it is recommended that ESR may have a role, are:

- Systemic lupus erythematosus
- Rheumatoid arthritis
- Kawasaki disease
- Rheumatic fever
- Hodgkin lymphoma
- Temporal arteritis (giant cell arteritis)
- Inflammatory bowel disease in children (initial assessment)

If the patient is suspected to have a plasma cell dyscrasia, ESR, although not restricted, is not recommended as a "screen" - the appropriate initial test is protein electrophoresis (which may be followed by serum free light chains).

Vitamin D
Vitamin D is an example of a test that is regularly used in primary care but is not strongly supported by evidence. Under the new Laboratory Schedule, vitamin D is categorised as both a Tier One and a Tier Two test, and also has an accompanying guideline.

General Practitioners can request the test, but only when following the vitamin D guideline. The guideline outlines

the limited indications for which the test can be requested by a General Practitioner. The specific indication must be clearly specified on the request form. The requirements are that the person must be at high-risk of vitamin D or calcium abnormalities, for example:

- Patients with rickets or osteomalacia, known osteoporosis, abnormalities of calcium/phosphate metabolism or a raised ALP with a likely bone origin
- Patients with cystic fibrosis, those who require a special diet (e.g. PKU), patients with a renal transplant or those taking anticonvulsant medicines
- Children aged under 16 years, refugees, and patients prior to treatment with bisphosphonates for osteoporosis, or interferon for hepatitis C

As a Tier Two test, vitamin D may be ordered by an Endocrinologist, Hepatologist, Rheumatologist, Nephrologist, Gastroenterologist or Gastrointestinal Surgeon. However, General Practitioners or any other relevant specialist, may also order the test with pre-authorisation from any of the specialists listed or a Chemical Pathologist.

Insulin (total)

Total insulin is categorised as both a Tier One and Tier Two test and a guideline has been developed for the test. As a Tier One test, total insulin can only be requested by General Practitioners for a patient following bariatric surgery in order to investigate hypoglycaemia. This indication and the patient's relevant clinical information should be included on the request form.

As a Tier Two test, total insulin may be ordered by a Paediatrician, Endocrinologist, Hepatologist or Gastrointestinal Surgeon. General Practitioners can still request the test provided they have prior authorisation from these specialists or a Chemical Pathologist.

Insulin can be an important test when used in the investigation of hypoglycaemia, particularly if an insulinoma or islet cell hyperplasia is suspected, however, investigation of a patient in this clinical situation would normally be carried out in conjunction with an Endocrinologist. A plasma glucose test should also be simultaneously collected to allow correct interpretation of the results. In addition, the guideline states that fasting insulin is not recommended for assessing insulin resistance, although experts continue to debate the clinical usefulness of doing so.

Catecholamines (urine)

Testing for catecholamines in the urine is categorised as a Tier Two test. While phaeochromocytoma is a rare but important cause of secondary hypertension to consider in some patients, the most sensitive and specific first-line test is urine or plasma metanephrines, both Tier One tests. The decision on which of these tests to use will depend in part on local availability. Catecholamines should only be requested in specific and limited circumstances, such as in a patient where there is suspicion of neuroblastoma or malignant phaeochromocytoma. Investigation of these conditions would normally be done in consultation with a relevant specialist in a hospital setting.

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