Minutes- Final

National Pathology and Laboratory Round Table

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<tr>
<th>Date:</th>
<th>5 March 2019</th>
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<tr>
<td>Time:</td>
<td>10.30 am – 3.00 pm</td>
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<tr>
<td>Location:</td>
<td>Bunker room, Miramar golf course, 1 Stewart Duff Drive, Miramar, Wellington</td>
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<td>Chair:</td>
<td>Andy Simpson</td>
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<td>Minutes:</td>
<td>Anna Kula</td>
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**Attendees:** Anja Werno, Cynric Temple-Camp, Deborah Powell, Peter Gootjes, Richard Massey, Ross Hewett, Russell Cooke, Ruth Rhodes, Don Mikkelsen, Gloria Crossley, Ross Boswell, Virginia Hope, Jo Anson (guest speaker), Ben Campbell-Macdonald (guest speaker), Geraldine MacGibbon (guest speaker), John Manderson (guest speaker), Shaun Costello (guest speaker), Guoying Yuan (guest speaker), Christine Fowler (guest speaker)

**Apologies:** Libby Harrison, Chris Davey, Campbell Kyle, Adri Isbister, Kirsten Beynon, Sarah Prentice, Nicole Kramer, Trevor English

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<thead>
<tr>
<th>Item</th>
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<tr>
<td>Welcome Minutes and Open Actions</td>
<td>Amendment to previous meeting minutes under “other business”- $12.50 up until 18 years old, and $18.50 for others. Opt on for primary care.</td>
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<td></td>
<td>#76- Ministry of Health’s legal team response on use of residual specimens was provided to the group. Anna to follow up letters sent to colleges and consider sending to the College chairs directly.</td>
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<td>There was some discussion about the use of assays which are not IANZ accredited. Laboratories use tissue donated to tissue banks to develop new genomic tests which are not standardised and not yet IANZ accredited. The tissue bank has patient consent to use tissue samples for future testing and analysis. This makes up a very small proportion of laboratory work and is treated as research which requires an ethics application. The health legal response suggests that this would not be permitted.</td>
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<td>If laboratories wish to use patient tissue samples to develop novel tests they can apply to the Health and Disability Ethics Committee (HDEC) for a ‘scope review’ which does not require ethics approval. This was not covered by health legal response.</td>
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<td>#108- Confirm the criteria for an HDEC ‘scope review’ for developing new tests to disseminate to the group.</td>
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The teleconference held on 26 February was chaired by Kate Neas. A number of actions and key issues were discussed by the laboratory subgroup, whose members represent 3 labs based in Auckland, Wellington and Christchurch. Key discussion points and actions included:

- a stock take was made of laboratory tests offered
- change review processes and staff levels were discussed
- concern raised for testing in the absence of patient consent
- consensus reached on the consistent practice and national approach to prenatal arrays across the 3 laboratories.

#109- Ross to disseminate the 50 exome pilot to NPLRT which supports exome sequencing in NZ.

GHANZ discussed data storage with the potential to look into centralised storage facilities for bioinformatics in New Zealand. The group also explored options for creating post graduate qualifications in bioinformatics in the future.

Genomics Aotearoa have updated their website to include information on clinical genomics, bioinformatics, genetic translation and SING Aotearoa an internship programme to encourage more Māori to enter the field of genomic research.

A memorandum of understanding has been signed between the Human Genetics Society of Australasia and GHANZ, outlining each parties’ requirements and responsibilities.

It was noted that Australia has a national framework and committed resources to develop the genetic space for clinical genetics, a possible future direction for NZ. Supervision of genomics testing is currently a NPAC requirement in Australia. In NZ qualified scientists or geneticists are qualified to interpret genomic tests. RCPA recently reviewed the scope of practice for pathologists to apply for an extension to their scope of practice to provide supervision in Australia. This is not yet a requirement in the NZ genetics/laboratory space but should be kept in mind in the future.

#98- Follow up with T&DS on the status of the NZPOCS work. In the agenda.

#105- Deferred to next meeting. Diane Sarfarti’s discussion paper on genetics to be disseminated to the group.

#107- MOJ will consider impact on mortuary staff workforce in their quarterly reporting. Action closed.

| PHARMAC-health technology assessments | PHARMAC presented on their process for economic assessments of new drugs, including the cost of laboratory testing. A copy of the presentation will be disseminated to the group. All proposals and recommendations are readily available to the public, however PHARMAC cannot disclose which proposals will be approved as this underestimates the negotiation process. PHARMAC receives clinical advise on test costs and have access to over 100 clinicians, however there are few pathologists in this group. This advice is also publically available. |
Members of the NZPLRT felt that laboratories were poorly consulted in the economic assessments for emerging drugs and the associated implication for laboratories and testing. One example was the decision to approve EGFR testing without; recommendations for testing, consideration for the financial impact of testing costs, effect on laboratory work flow, patient safety and the need to integrate a new clinical pathway for the ways in which tests are requested. As a result EGFR testing was implemented and carried out ad hoc in laboratories around New Zealand.

PHARMAC representatives noted that implementation can be delayed if services are not ready to roll out new drugs and testing requirements.

PHARMAC will open to widening their consultation network to include laboratory managers and will consider NPLRT proposal to increase pathologist membership in the cancer treatment sub group. PHARMAC will advise NPLRT if microbiology, genetics or pathology expertise is required.

PHARMAC is releasing a consultation which considers a framework to assess new medical devices which are will impact laboratory space and are often more expensive than testing. This will be disseminated to the NPLRT group, with feedback due by June.

It was noted that costs savings on medical devices are not collected by PHARMAC. It is the DHBs decision as to where these cost savings are reallocated to, whereas pharmaceutical savings are put back into the pharmaceutical budget.

PHARMAC is eager to collaborate and consult NPLRT testing costs and whether tests are available in New Zealand in the future, and will be in contact as required.

NHC has in the past produced a foundation paper of how genetics and genomics testing is progressed in the future. This may be useful for future consideration.

# 110- Genetics and Genomics discussion paper to be disseminated to the group (Anna).

NPLRT members outlined a number of key issues and considerations for future economic assessments including:

- the cost of new testing and the development of new assays
- whether a new drug requires off-the-shelf testing or tests with a clinical diagnosis, noting that off-the-shelf products require validation by individual labs which have an increased lead up time

There appears to be some inconsistency with individual DHBs not fund testing for some PHARMAC funded drugs. DHBs find that they have had to fund tests outside of budget for drugs approved by PHARMAC and it is difficult to capture savings in hospital laboratories. It was further acknowledged that 80% of pathology laboratory testing not done by DHBs but by private providers.

Training or education session for new tests was discussed as training is not often provided by pharmaceutical company, however this is outside of scope for PHARMAC. However, it was noted that the absence of consistent training gives way to plurality in the ways of testing, which can be beneficial in some circumstances.

| Ministry Cancer Team Update | Guoying Yuan presented on the New Zealand Cancer Registry (NZCR). The presentation will be disseminated to the group following this meeting, key points are summarised in the meeting minutes. |
The registry helps maintain a cancer incidence reporting system and is a resource for cancer research. Laboratory data accounts for 89% of all registrations.

NZCR coders rely on hospital coding quality for clinical diagnosed cancer patients with hospital admissions. Sometimes cancer diagnoses are missed for patients who do not have a hospital admission or are treated privately.

Examples of ‘under-reporting’ by laboratories include:
- operation histological reports have not been sent (ie wide local excision, colectomy) required to complete the data set after initial registration
- negative cancer related histological and biopsy reports not sent
- positive further excision histological reports not sent
- cases of cancer in situ histological reports have not been reported

Examples of ‘over-reporting by laboratories to NZCR include:
- duplicated reports
- supplement reports sent separately alongside combined reports
- non-valued reports

Clarification on reports which could improve NZCR efficiency and quality:
- overseas diagnosed cancer to be routinely stated on pathological reports
- basal cell cancer and squamous cell cancer arising in the skin including metastatic cancer from skin other than genital area to be stated on the report
- clear interpretation of IHC, molecular and genetic tests
- clarification of the edition of AJCC used
- clarification of pT0 (whether staging based on biopsy or resection)
- possible M staging by pathologists

Dr Shaun Costello and John Manderson presented on the cancer staging project. The presentation will be disseminated to the group following this meeting, key points are summarised in the meeting minutes.

The cancer staging project aims to improve cancer quality data by capturing stage and clinically diagnosed cancer patient data at a national level. The project team is working with sector experts to define stage requirements and working with providers to understand their readiness to collect and submit stage data, while identifying ways to improve quality of existing cancer data.

Group consensus for the use of AJCC 8th edition for cancer staging and reporting.

There was discussion around when staging information should be gathered to provide the most accurate data and diagnosis, including issues around re-staging and staging in cases of pre-operative treatment.

Issue raised regarding cancer staging information held by private cancer centres.

Pathologists are likely to have information of T and N staging, a Radiologist would have M staging data so therefore the treating clinician would have the complete diagnoses. There is the option of collecting cTNM staging via a surgical pathology request form provided electronically, to be provided to the
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<th>Standards Update</th>
<th>Written update will be provided to the group. #98 close action until further updates.</th>
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| Therapeutic products bill and control of medical devices | Therapeutic Products Bill (TPB) will replace the Medicines Act which was used to control medicines coming into the market and post market. Currently the Act does not control medical devices coming into the market and controls only post market use only. The TPB will look at regulating medical devices as they come into the market, as well as manufacture, pharmacy and prescribing controls in both technical and operational detail.  

A legislation draft was released for consultation at the end of last year with consultation will be open until 18 April for feedback. The draft legislation and consultation paper can be sent to the group.  

There was some concern raised by the group that there was not enough time to make decision with so few details. While the draft legislation is not explicit in its scope as details, however this will be covered in the regulations as they are developed. Regulations are made by the governor general and exercised by the regulator, which is the next level of detail in the Bill.  

The draft bill provides a high level framework and is completed initially. It may take up to 3 years to write all the necessary regulations and laboratories will have further opportunities to comment on this. Any concerns can be forwarded from the group to secretariat to forward to the Ministry of Health. Examples of concerns about certain devices can be sent through via the consultation which will help with the next tranche.  

Currently medical devices have an international model of regulation created by the US, UK, Canada, Australia overlooked by WHO, which is largely based on European system. The model of regulation explains the essential principals of safety, quality and performance (in relation to reliability and precision). This covers in-virto devices and other devices (ie surgical and diagnostic instruments). All devices are put into risk categories and must be fit for purpose.  

There are 4 risk classes ranging from whether failure of a device poses low risk to individual and low public health risk (lowest risk category) to high individual risk and high public health risk (highest risk category eg donor screening for HIV).  

Manufacturers must shows that it meets the set principal’s conformity assessment, assessed by an external party. The TPB states that the regulator must make an independent decision and may rely on decisions made by trusted overseas bodies. NZ has a mutual recognition agreement with Europe which covers many devices with the EU mark have automatic approval.  

The European system has set of approved regulatory bodies/professional bodies who may act as regulators, as a single national regulator will not have all the necessary expertise. However, regulation has become less vigorous using these professional bodies which has now been tightened.  

The TPB allows for other forms of authorisation ie in case of a pandemic permits can be issued for product authorisation. Some products will be exempt from product approval when manufacturing controls are better applied through the manufacturer, ie a custom made device made to suit the needs of one individual.  

Product applications will need to be put in place by device suppliers in NZ, individuals or a body corporate with access to technical data from the
manufacturer and a contract agreement and is responsible for reporting of adverse events. Significant product enhancement to existing approved product will need approval and some in-house made devices should also be regulated. Registration by competent overseas bodies should be approved by NZ bodies. The product supplier/applicant must provide a risk category, technical information and provide evidence of registration overseas.

Members of the NPLRT noted that laboratories manufacture a range of things and there was concern raised that the TPB could classify computer software or microscopes and other regular devices as a product requiring an application for approval. Members voiced that it would be helpful to see detail of what is in or out as set out by the regulations.

#111 - Interested NPLRT members group to form a subgroup and organise a meeting with TPB group from the Ministry to discuss the consultation results (Anna).

| Shared health records | An shared electronic health record system has been discussed over the last few years with little progress made. Unfortunately there has been a recent fatality as a result of a patient’s allergy not being entered into the national medical warning system by the clinician of the domicile DHB. The host DHB did not have this information and administered the drug, resulting in patient fatality. There was uncertainty about how private providers have access to the medical warning system or other patient records. |
| Draft HIS0 document | #109- Send link for HIS0 draft document for Bowel Screening to group (Anna). |
| Future meetings | Future agenda items  
- Perinatal pathology service roll out  
- Cancer staging project update  
- NSU update on the screening programme and register  
- Regional updates  
- Update on forensic and pathology workforce (Deborah/Ross)  

#112- Regular update on the forensic and pathology workforce (Deborah/Ross).  

#113- Disseminate point of care devices testing 2013 document with group (Nicole/Anna).  

Next meeting will be held July/August, a doodle poll will be sent to confirm date and venue. |

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<td>76</td>
<td>8 Mar 2016</td>
<td>Discuss a National residual specimen policy statement, including risks, benefits and recommendations. Update: Anna to follow up letters sent to colleges and consider sending to the College chairs directly.</td>
<td>Anna</td>
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<tr>
<td>93</td>
<td>14 Mar 2018</td>
<td>GHANZ verbal update will be shared with the group.</td>
<td>Ross H</td>
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| 105 | 4 July 2018 | Draft discussion paper on the process for evaluating new tests or significant changes for clinical, technical and cost utility.  
Diane Sarfarti’s discussion paper on genetics to be disseminated to the group. | Richard, Nicole |
<p>| 108 | 5 March 2019 | Confirm the criteria for an HDEC ‘scope review’ for developing new tests to disseminate to the group. | Anna |</p>
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