Pathology Reports and the Personally Controlled Electronic Health Record (PCEHR) Agreed High Level Solution Design

Wednesday 26 November 2014

A third Pathology Consultation Workshop was held on 26 November for the integration of pathology reports into the PCEHR. A range of key stakeholders participated, including representatives from professional bodies, clinician groups, pathology providers, consumer groups, software vendors and jurisdictions. It was noted by the chair that throughout the consultation process key design principles have been considered to guide the development and implementation of a solution design that is useful, usable and safe. Participants are listed at Attachment A.

This paper summarises the outcomes agreed at the workshop. It builds on the high level solution design circulated following the 8 August workshop. It reflects input from the co-design working groups, written feedback and other consultation workshops.

Agreed High level design principles

The following section summarises the key agreed design principles.

Policy

1) The design should aim to improve timely access to pathology reports for healthcare providers (via the PCEHR) so that:
   a) The amount of time spent on collection of information is reduced,
   b) Duplicate testing is reduced; and
   c) The clinicians outside the circle of care of the patient will be able to obtain the pathology report more readily.
   NOTE: *The inclusion of pathology reports in the PCEHR does not replace existing point to point communication of pathology reports.*
2) The design should support better engagement of individuals with their own healthcare, by:
   a) Allowing individuals to view pathology reports in their PCEHR using the National Consumer Portal; and
   b) Allowing individuals to have control over who has access to their pathology reports, provide the ability for the individual to withdraw consent for a specific report to be uploaded to their PCEHR or to remove a report from the PCEHR – consistent with access controls for other clinical documents;
3) The design should be evidence based and result in no increased clinical risk to patients. New or existing risks will be monitored and managed with a focus on "First do no harm, then do some good".
4) The quality and integrity of the pathology report information must be maintained:
   a) The authoring pathology provider will upload pathology reports to the PCEHR.
   b) The pathology provider will take reasonable steps to ensure that reports are accurate, up to date and not misleading (e.g. a report that is uploaded to the wrong patient).
   c) The design will include a process for making inaccurate reports (such as if a report is attached to the wrong record) inaccessible to users of the PCEHR system and also to enable an updated version of a report to be uploaded.
5) The PCEHR should maintain a history of pathology reports. The PCEHR currently has capability to manage and maintain updates to clinical documents and this will be used to maintain current and historical versions of pathology reports. There is clinical benefit in preliminary, final and corrected reports being available to the PCEHR.
6) The design should leverage existing clinical workflows wherever possible and not increase medico legal responsibilities.
7) Barriers to participation and use by healthcare providers and individuals should be minimised;
8) The design should support the appropriate communication of results to the patient by a healthcare provider responsible for follow-up care, wherever possible. At time of referral the majority of results can be authorised to be uploaded automatically to the PCEHR. Once posted by the pathology provider, the reports will be available for clinicians (but not patients) to view for seven days. This is to enable clinicians to process reports received from pathology providers by routine point to point messaging. Once the seven days elapse, the report will also be made available on the PCEHR for the patient to view.
9) Upload of a pathology report may be delayed in an exception situation following discussion between the pathology provider and requesting provider. In this case, the requesting provider decides on the appropriate response ie whether the report should be posted in line with the original yes message or not.

10) An exception situation may arise where the result is unexpected or raises additional questions about whether more tests should be performed or an error has occurred. Guidance on exception situations should be developed.
11) In an exception situation, the requesting provider should contact the patient to discuss the results and agree whether the results should be uploaded or not.
12) Results that have been delayed should be uploaded if the requesting provider is unable to contact the patient – a 30 day target is considered appropriate for this action. (It's preferable that a patient is informed on exception results via the PCEHR than not at all).
13) Pathology providers will maintain statistics on the number of exceptions and the periods that it had taken to resolve/decide upon them, and these will be assessed at 6 and 12 months from initial implementation.
14) The report metadata will be available immediately to the patient, (but not the PDF report) and they may choose to remove or restrict access to the report at any time (including during the 7 day period.)
15) There are classes or categories of tests that for legal or policy reasons should not be automatically uploaded to the PCEHR.
16) Wherever possible the model for incorporating pathology and DI reports into the PCEHR should be consistent.
17) The design of the system to allow the uploading and viewing of Pathology reports in the PCEHR will be reviewed in 12 months to assess whether the system is working effectively, and to determine whether adjustments need to be made to improve the workflows, or the efficacy of the data. During this period, the performance and statistics of "exception cases" will be reported at 6 and 12 monthly intervals, to assist in determining whether or not this needs to be adjusted. The terms of reference of this review will be developed in collaboration with key stakeholders in early 2015.

Legal exceptions

Exceptions to the automatic upload of reports to the PCEHR exist:

- Where patient consent has been withdrawn:
    - Standing consent applies to patients with an eHealth record – a registered healthcare provider organisation can upload a document to the PCEHR that includes health information about the patient.
    - A patient may advise the healthcare provider organisation that a particular record (or a specified class of records) must not be uploaded.

- Where it is not legal to disclose:
    - State/Territory laws may require that additional consent be provided in order to upload documents to PCEHR (i.e. positive confirmation of consent, rather than relying on standing consent).
    - Examples of these include (in NSW - based on preserved laws in that state):
        - a registered medical practitioner cannot disclose the name or address of a consumer who is to be or has been tested for, or has, HIV or AIDS unless the patient gives express consent to the disclosure; and
        - a person cannot disclose the identifying information of a woman who has had a cervical cancer test, in conjunction with the test result without the woman's written consent.

- Where withholding access to the patient is supported under the Australian Privacy Principles (where providing the information may cause a serious threat to the life, health or safety of an individual).

Technical

18) The design should leverage existing technical infrastructure wherever possible and avoid redefining existing HL7 2.x messages.
19) Healthcare Identifiers (for individuals and healthcare providers) to be used across the integrated solution.
20) The patient's IHI and demographic details should be sent to the pathology provider from the requesting provider (at a minimum, the demographic details used to obtain the IHI must be passed).
21) In the initial PCEHR implementation pathology reports to be uploaded to PCEHR in PDF format. The development and implementation of standardised terminology, is required before pathology reports that include atomic data can be made available through the PCEHR.
22) The report for the purposes of the PCEHR is the PDF generated by the pathology provider which should be based on the report that the pathology provider produces for the requester of the pathology service. Overtime it would be desirable for the layout of pathology reports sent to the PCEHR to be standardised in line with recommendations of the professional body.
23) One request for pathology services may result in multiple PDF pathology reports being produced or a PDF pathology report may be produced which contains details of more than one test i.e. all tests requested. A PDF pathology report may also include cumulative results. There should be an education process regarding cumulative reports that contain results that may have previously had consent withdrawn regarding posting.

24) There may be multiple versions of a pathology report issued by the pathology provider. Each version of a report produced by a pathology provider will have a status for that report.
25) The PCEHR should be capable of indicating the status of a report. The PCEHR will use AS 4700.2 terms for the status of a report, final result, preliminary result (interim), corrected result – or a result with an addendum.
26) To support the searching, viewing, provenance, updating and auditing of pathology reports in the PCEHR, the PDF report will be provided with key information (metadata). As part of the detailed design process further work is required to map HL7 2.x (AS 4700) data elements to the PCEHR Pathology Report CDA Specification.
27) The PCEHR will only use standard terms for filtering, grouping or searching of pathology reports in the National Provider and Consumer Portals. Guidance and conformance requirements will be provided to software vendors on how pathology report views should be displayed and managed in their systems.

1. Agreed Model for making Pathology Reports available to the PCEHR

The following has been agreed:

- Healthcare providers will have a default set to enable all reports from all pathology requests to be uploaded to the PCEHR.
- In the requesting process, healthcare providers will be able to indicate that the patient has withdrawn their consent, and these will not be uploaded to the PCEHR.
- There will be categories of results from requested tests that will not be uploaded the PCEHR because of legal requirements or where a patient has withdrawn their consent.
- A pathology report is uploaded to the PCEHR by the pathology provider and is not made visible to the patient for seven days.
- Upload of results may be delayed in an exception situation following the pathology provider's discussion of the situation with the requesting provider. The upload will be stopped and a record made of the decision. The requesting provider should advise the patient of the results and agree with the patient whether the report will be posted to the PCEHR or not.
- Once the requesting provider has discussed the results with the patient, or has attempted to contact the patient without success, the requesting provider may advise the pathology provider to upload the results to the patient's eHealth record. This should occur unless a discussion with the patient has resulted in consent to upload being withdrawn. Uploads should be within 30 days.
- A record should be made of the final outcome regarding delayed reports i.e. was it uploaded or not? Healthcare providers will have access to reports during the 7 day delay period with reports not accessible by the patient until after 7 days.
- Current systems and processes where patients have access directly and immediately to pathology results from the healthcare provider or the pathology labs will continue to be in place.
- The pathology report metadata will be available immediately to the patient within the PCEHR, (but not the report) and they may choose to remove or restrict access to the report at any time (including during the 7 day period).

An evaluation of the upload of pathology reports will be performed considering a number of aspects of the model raised during discussion:

- The 7 day delay period
- The occurrence of exception situations:
    - numbers involved,
    - type of exceptions,
    - outcome (was the patient contacted, was the report upload agreed to, how long it took)
- The access of pathology results by other than the requesting provider during the 7 day delay period

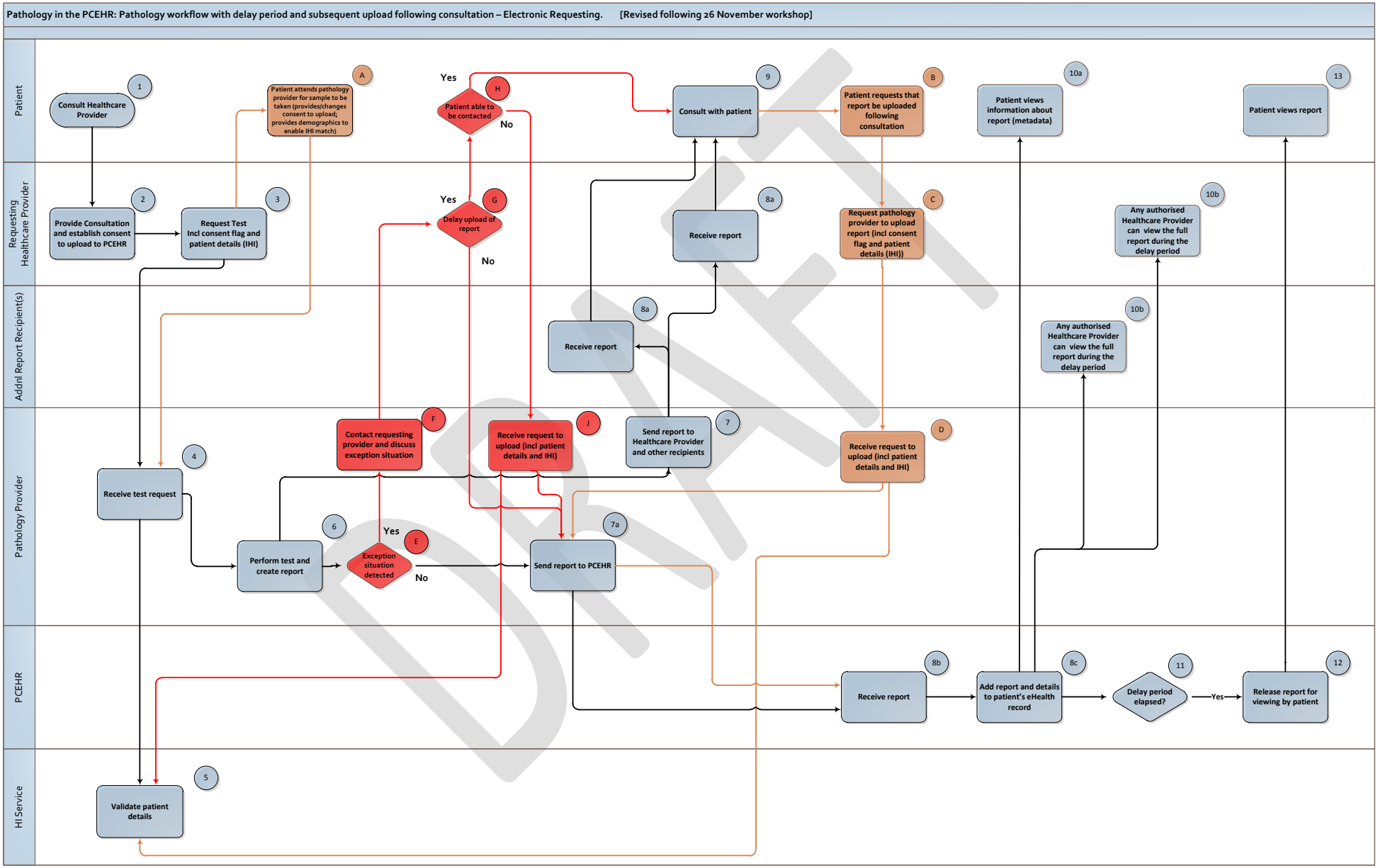
2. Detailed implementation considerations

The following table reflects implementation areas requiring further consideration following the 26 November workshop. The areas identified will be progressed by the organisation or through the forums identified below.

Area	Actions
Material to be developed to explain the exception situations that might result in a delayed upload. This is to be used to inform both providers and individuals.	1. **Department** to work with stakeholders to develop a description of what might be considered as exception situations that would today result in a phone call being made to the requesting provider.
The situation for 14-18 year olds who have not taken control of their eHealth record and	1. **Department** to provide the policy setting regarding the treatment of 14-18 year olds and vulnerable persons.

vulnerable individuals needs to be considered in light of the upload of pathology results.	
Uncertainty regarding the outcomes and impacts of the use of access controls by individuals.	1. **Department** to provide an explanation of the access controls available to individuals and how this will impact access and use of information by healthcare providers.
Confirmation sought from jurisdictions regarding whether there are any broader legal issues involved in the upload of pathology documents.	1. **Department** to confirm with jurisdictions whether there is any area not previously considered that may impact on the ability for providers to upload pathology results to the PCEHR.
Confirmation sought regarding whether there are any issues involved in the upload of pathology documents where the individual may not be the initiator of the test performed (correctional services, drug testing, blood alcohol testing, DNA testing)	1. **Department** to confirm whether there are any restrictions on the upload of these types of tests. 2. Individual can withdraw consent for these types of tests and can remove/restrict access to documents should they be uploaded on the basis of standing consent.
Discussion regarding supporting the development of point to point specifications to commence in the coming 3 to 6 weeks.	1. **NEHTA** to initiate workshops to commence discussion and development of the point to point messaging necessary to support the carriage of connect and demographic details.
Design and workflow for requesting providers to be closely aligned for both diagnostic imaging and pathology.	1. **Department** to revisit diagnostic imaging design and workflow in light of the finalisation of the pathology design and amend as necessary.
Options for system implementation approaches excluding of certain test results or categories of tests need to be defined	1. **NEHTA** to include the consideration of whether GP CIS's be configured to stop default authorisation of upload of certain results in certain jurisdictions as part of **CCA/CUP** activities.
The information (metadata) to be provided with a pathology report needs to be mapped to the existing standard HL7 v2 (AS 4700) to support implementation by software vendors/system implementers.	1. Metadata and HL7 data mapping document agreed with co-design working group and circulated for reference. 2. **NEHTA** to work with implementers on the specifics of their mappings.
How to include a verified IHI in the pathology report to be sent to the PCEHR	1. eRequest or separate message to include verified IHI and the demographics used to obtain it 2. Printed request to include IHI (and associated demographics) 3. Pathology provider uses middleware to interact with HI Service to validate details provided 4. Pathology provider interacts directly with HI Service to validate details provided 5. To progress further through implementation support provided by **NEHTA.**
How to provide information to the pathology provider that information that a report should be posted to the PCEHR.	1. eRequest or separate message to include information that the report is to be posted. 2. Printed request to include information that the report is to be posted. 3. To progress further through implementation support provided by **NEHTA.**

Model – Report sent to PCEHR by Pathology Provider – report available in PCEHR immediately for clinicians and after 7 days for patients:

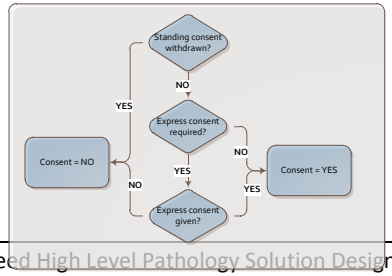


1 - Patient consults with healthcare provider
2 - During consultation, the healthcare provider identifies a need for a pathology test to occur. The healthcare provider can see that the patient has an eHealth record and may discuss whether the patient wants the test results (report) uploaded to their eHealth record (standing consent will allow for the report to be uploaded but there are cases where express consent might be required). Where consent exists, the report is pre-authorised for upload to the PCEHR.
3 - The healthcare provider requests the pathology test and provides the consent information with the request along with the IHI and patient details matching the IHI. This could be via an eRequest or via printed paper request.
4 - The pathology provider receives the test request, demographics and consent information.
5 - The pathology provider validates the patient details with the HI Service (to confirm that IHI and demographics match)
6 - The pathology provider performs the test on the specimens collected and creates a report detailing the test outcomes.
7 - When complete, the pathology provider sends the report to the requesting healthcare provider and any other healthcare providers that are to be copied on the report
7a - When complete the pathology provider sends the report to the PCEHR (where consent was provided and patient details were validated). In most circumstances it is expected that this will occur simultaneously to step 7.
8a - The healthcare provider and any 'copy to' providers receive the pathology report via the current point to point messaging flows.
8b - The PCEHR receives the pathology report and validates it.
8c - The PCEHR system places the report on the patient's eHealth record. The details of the report are made visible to the patient but the release of the report is set to a future date, after the expiry of the delay period (proposed 7 days). Authorised Healthcare Providers are able view the full report during the delay period.
9 - The healthcare provider consults with the patient if the results warrant discussion.
10a - The patient is able to view the details of the test performed but not the outcome. This enables the patient to remove it from their eHealth record should they wish to do so, or to apply access controls regarding who may view the report.
10b - Healthcare providers are able to view the pathology report at any time once uploaded to a patient's record.
11 - The PCEHR system monitors the delay period.
12 - Once the delay period has expired, the PCEHR system makes the report available for viewing by the patient through their eHealth record.
13 - The patient is able to view the report containing their test outcomes through their eHealth record.

A – Patient attending collection centre can provide consent/withdraw consent and confirm their demographic details at the time a sample is taken
B – Patient requests that the report be uploaded at some point following the initial consultation (either before the report is authored or after)
C – Healthcare provider requests that the pathology provider uploads the report to the patient's record. Request to upload to include patient details (IHI and demographics) and consent flag.
D – Pathology provider receives request to upload report separate to the initial test request

E – Pathology provider checks results and determines if an exception situation has arisen
F – Pathology provider contacts the requesting provider in an exception situation and discusses their concerns regarding the results of the tests
G – Requesting provider decides whether the report with the exception results should be uploaded to the patient's eHealth record
H – Requesting provider attempts to contact the patient to discuss the exception results.
J – Requesting provider requests the pathology provider to upload the report to the patient's record if they are unable to contact them in an exception situation.

Establish consent to upload (decision making process applied at step 2 above)



- Pathology reports are to be uploaded to the PCEHR by default for individuals with an eHealth record (on the basis of standing consent).
- Where an individual withdraws consent then reports are not to be uploaded (unless consent is subsequently provided).
- Some tests (reports) may require express consent to be provided, in which case standing consent may not be relied upon. Specific consent will be required for reports in this category to be uploaded.

Attachment A

Attending	Organisation
Dr Alex Hope	Aboriginal Medical Services Alliance Northern Territory (AMSANT)
Ms Fiona Kolokas	Australian Association of Practice Managers (AAPM)
Dr Chris Pearce	Australian College of Health Informatics (ACHI)
Dr Jeff Ayton	Australian College of Rural & Remote Medicine (ACRRM)
Dr Meredith Makeham	Australian Commission on Safety and Quality in Health Care (ACQSHC)
Dr Robert Herkes	Australian Commission on Safety and Quality in Health Care (ACQSHC)
Mr Neville Board	Australian Commission on Safety and Quality in Health Care (ACQSHC)
Dr Bev Rowbotham	Australian Medical Association (AMA)
Dr Richard Kidd	Australian Medical Association (AMA)
Mr Adam Stankevicius	Consumers Health Forum (CHF)
Mr Paul Madden	Department of Health
Ms Linda Powell	Department of Health
Ms Nerida Lawrentin	Department of Health
Ms Fifine Cahill	Department of Health
Mr John Clarkson	Department of Health
Dr Troy Browning	Medical Defence: Medical Indemnity Protection Society
Dr Walid Jammal	Medical Defence: Avant
Ms Jenny Sikorski	National Coalition of Public Pathology (NCOPP)
Mr Alan McLeod	National Coalition of Public Pathology (NCOPP)
Ms Cindy Worrall	National Coalition of Public Pathology (NCOPP)
Dr John Alozois	National E-Health Transition Authority (NeHTA)
Dr Ralph Hanson	National E-Health Transition Authority (NeHTA)
Mr Les Schumer	National E-Health Transition Authority (NeHTA)
Mr Peter Fleming	National E-Health Transition Authority (NeHTA)
Mr Bob Whitehead	NT Health
Ms Liesel Wett (CEO)	Pathology Australia
Mr Peter Joseph	Pathology Australia
Ms Josephine Raw	Royal Australian College of General Practitioners
Dr Nathan Pinskier	Royal Australian College of General Practitioners
Dr Debra Graves	Royal College of Pathologists of Australasia (RCPA)
Prof Michael Legg	Royal College of Pathologists of Australasia (RCPA), Medical Software Industry Association (MSIA)
Dr Bronwyn Ross	Royal College of Pathologists of Australasia (RCPA)
Mr Mike Wallace	Australian Commission on Safety and Quality in Health Care (ACQSHC)
Dr Lawrie Bott (via teleconference)	Royal College of Pathologists of Australasia (RCPA)
Ms Julianne Badenoch (via teleconference)	Australian Primary Health Care Nurses Association (APNA)
Ms Jane Connolly (via teleconference)	Australian College of Rural & Remote Medicine