AUSTRALASIAN ASSOCIATION OF CLINICAL BIOCHEMISTS INC

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Community Affairs Legislation Committee
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

Re: Request for consultation and response in relation to Health Insurance Amendment (Pathology Requests) Bill 2010 Inquiry

From July 1, 2010 it is proposed that patients will be able to attend the pathology laboratory of their choice for testing, regardless of the laboratory specified on the pathology request form. The Australasian Association of Clinical Biochemists (AACB) is recognised by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) as Australia and New Zealand's peak Professional body in relation to matters of Clinical Biochemistry and Laboratory Medicine, particularly in relation to matters of analytical methods, quality control and assurance, reference intervals, reporting units, laboratory systems analysis and Point of Care Testing. Our membership is closely involved with pathology testing and wishes to bring to the Government's attention a number of operational issues with the potential to affect patient safety which may arise during any implementation of this proposal.

The key issue underlying our concerns relates to patients who are being monitored by analytical tests using different methods that may not have been "harmonised" or which may have different units of reporting. Medical referrers, and General Practitioners in particular, may not be aware of these methodological or unit reporting differences especially if the result transfer from the laboratory to the General Practice does not show the units of reporting or different assay methods are in use. This can be a problem in some current electronic practice management systems, which utilise only selected parts of the electronic result transmission.

There are implications for the amalgamation of results from different pathology providers and the use of electronic results messages being used to create a central electronic health medical record database of results for a patient. IT and e-Health providers should be made aware that in the real analytical world of pathology testing there can be complex methodological problems that are not always obvious or simple to define.

The following examples highlight the above issues.

Reporting Units:

1. Some therapeutic agents are particularly dangerous where the difference between S.I. and mass units is relatively small (e.g. Digoxin 1.0 nmol/L = 0.8 ng/mL). A difference caused by two laboratories reporting results in different measurement units may be too small to cause clinical awareness, but may have significant adverse therapeutic implications. It is essential that the different reporting units between such laboratories be highlighted in the receiving doctor's medical records.

2. The cardiac marker troponin is widely used to diagnose myocardial infarction and for risk prognostication of acute coronary syndrome. Troponin T high sensitive assays use units of ng/L whereas results from previous generations of this same analytical system have usually been reported in µg/L. The reporting of this more clinically sensitive assay produces results that are a thousand-fold different to results by other less sensitive assays, and thus has the potential for confusion.

3. For the reporting of the hormone prolactin some laboratories use mass units (µg/L with a reference interval of <20 µg/L) whereas others use S.I. units (mIU/L with a reference interval <400 mIU/L). The 20-fold difference has the potential for result misinterpretation.

Method Differences:

1. Some tumour markers, e.g. beta-hCG isoforms or PSA, may have results that vary between laboratories due to different methods being used.

2. hCG for pregnancy purposes is another situation where it is important that sequential analyses should be performed at the same laboratory. The following actual patient report example illustrates this point:

Date	Quantitative hCG (IU/L)
1/12/09	844
1012/09	3526
22/12/09	742

REPORTING COMMENT: Quantitative hCG has declined since 1/12/09; this should not occur in the first trimester of pregnancy when the hCG approximately doubles every 48 hours. N.B. The result from 10/12/09 was measured by a different assay system and these results cannot be compared. Recommend this result be removed from the patient record.

3. Heterophile antibody interference for tumour marker and hormone assays is well documented as a confounding artefact for immunoassay methods and can occur in any particular manufacturer's assay. It is not uncommon to observe examples of different results between laboratories using different methods particularly where the tumour marker level appears to be increasing thus causing clinical confusion, inappropriate investigations and possibly even surgery. The $US16 million lawsuit for hCG in the early 2000's is one major example in the public domain.

These examples serve to highlight the risk for potential patient safety issues arising when monitoring disease progress using testing by multiple different pathology providers. It is recommended that for any individual patient, serial measurements for monitoring their disease use the same pathology provider or pathology network provider. Where it is necessary to change testing laboratories, the referring doctor should be made aware of the possibility of resultant unit and method differences when interpreting results from different pathology providers.

The AACB has a number of expert working groups with specialised knowledge in the reporting and technical areas of pathology testing. We have already identified as key issues the need to define and encourage adoption of common measurement units, common reference intervals, standardisation, and harmonisation of methodology, all designed to enable e-Health interoperability, empower the consumer and to focus pathology and laboratory medicine on the patient journey, rather than on the technical details. We believe that these confounding issues need to be identified, addressed and solutions found as part of the process of introduction of request form portability and a single EHR for Australian citizens.

We would be pleased to indicate our availability to offer advice to the Department on such matters to assist in ensuring that Policy implementation addresses these important operational issues.

Sincerely,

Jill Tate
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Chair, Scientific & Regulatory Affairs Committee

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