Public Pathology
AUSTRALIA

MBS Review Submission

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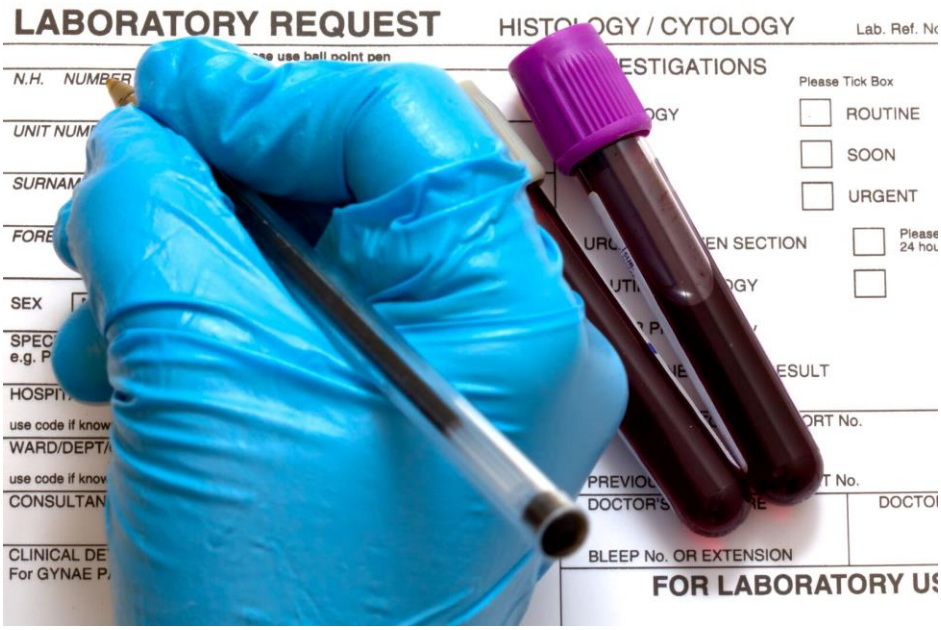

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Executive Summary

This paper outlines the position of Public Pathology Australia's (PPA) in relation to the MBS Review recommendations of the Pathology Clinical Committee and Diagnostic Medicine Clinical Committee.

PPA notes that the Department of Health granted targeted stakeholders two months to prepare submissions. A two-month consultation period is adequate for determining the clinical appropriateness of recommendations given the expertise contributed by public pathology representatives of PPA. However, two months is insufficient time to also determine fees and properly model the financial impact of changes. Modelling is required after the agreed recommendations are endorsed as coning will affect the overall financial impact of the changes. Where the financial impact is known to be significant, moderate or minimal in the absence of modelling, this is identified in this submission as it influences the prioritisation of recommendations.

To improve accessibility to pathology tests, it is imperative that all pathology providers are paid the same for the same test. This paper is founded on the premise that ***funding parity will be implemented as first priority of the Commonwealth Government*** and before the agreed MBS Review recommendations are implemented.

A staid characteristic of public pathology services is their support and promotion of clinical appropriateness and rational requesting. This submission on the MBS Review reflects this fundamental approach to pathology taken by the public sector.

A summary of PPA's position at a discipline level is summarised below. Within each discipline, PPA has assigned priorities against individual recommendations int the body of this submission.

Discipline Group	Position	Priority	Comment
Anatomical Pathology	Agree. Need for additional Level 7 complexity items	High	Straightforward to implement and important to improve equity of access for testing
Haematology	Agree, with exception of reduction in coagulation tests and removal of massive transfusion items.	Low	Given the significant funding adjustments required, sufficient time is required to progress the agreed changes
Genetics	Agree, with exception of 100 kb variant threshold. Underfunded tests need fee adjustments	High	Straightforward to implement and items must be updated to match contemporary tests
Immunology	Agree, with minor amendments to coeliac disease testing	Medium	Prioritisation is influenced by the volume of tests and the insufficient fees in this group
Chemical	Agree, with minor clarification	Low	Highly complex changes to this group requires extensive modelling and a long lead time to implement
Microbiology	Agree, with minor amendments	High	Easy to implement, reflective of technological advancement and for public health benefit.
Diagnostic Medicine Clinical Committee	Agree, with minor amendments	Medium	Significant financial impact assuming implementation is feasible and properly implemented. Implementation is dependent on the adoption of clinical decision support and education of requesters.

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Background

PPA represents the government owned and operated pathology services across Australia. The services differ in their mix of Commonwealth Medicare Benefits Schedule (MBS) funded non-inpatient to State Government funded inpatient activity.[1] State Government funded inpatient pathology activity is beyond the scope of the MBS Review. However, it is important to note that many State Government funded Health and Hospital Networks[2] and private hospitals pay for pathology services – whether provided by public or private pathology providers - by reference to the MBS.

In pathology, MBS item fees do not reflect the cost of the tests performed. MBS pathology fees may exceed the cost of providing the test or be less than the cost of the tests. That is, there is a significant degree of cross-subsidisation within the Pathology Services Table (PST) of the MBS. Where MBS fees are less than the cost of the tests, pathology providers may charge a co-payment or not offer the test. This affects the ability of patients to access the pathology services that they need. This submission attempts to address some areas of significant cross-subsidisation in the PST to improve accessibility of all pathology tests to patients across Australia.

A fundamental impediment to equitable access to pathology testing is the lower MBS fees rebated to public pathology providers compared to private pathology providers. The last major revision of the PST was undertaken in the 1990s. This saw the introduction of a two-tiered funding formula with test fees and episode fees (Patient Episode Initiation (PEI) fees). It was several years later that the public sector was granted access to the PEI fees at a nominal fee of $2.40, with the intention to remove the distinction between the nominal public PEI fee and private pathology provider PEI fees (which range from $5.95 to $17.60 depending on the type of specimen collection).[3] The Commonwealth Government must ensure that there is a neutral competitive environment. This requires the Patient Episode Initiation (PEI) and Bulk Billing Incentive (BBI) fees for public pathology providers to be to be the same as those rebated to private pathology providers.

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1 For example, SA Pathology has 35% market share of the community MBS market in South Australia (http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp, accessed November 2018).

2 Names differ across jurisdictions – e.g. Local Health Districts (LHDs) in NSW, Hospital & Health Services (HSSs) in Qld, Local Health Networks (LHNs) in SA.

3 Department of Health (30 April 2004), correspondence to National Coalition of Public Pathology and Pathology Quality and Outlays Memorandum of Understanding (MOU) between the Commonwealth Government and the pathology sector 2004-2009.

This submission is formulated on the premise that the Commonwealth Government will ***rectify funding disparity as its first priority*** before implementing any of the MBS Review recommendations. Without this being addressed, the financial impact of all recommendations will be greater on public pathology providers and against the principles of competitive neutrality adopted by the Commonwealth Government and agencies such as the Australian Competition and Consumer Commission.[4]

A staid characteristic of public pathology services is their support and promotion of clinical appropriateness and rational requesting. This position paper on the MBS Review reflects this fundamental approach to pathology taken by the public sector. PPA's response is framed around each Pathology Clinical Committee (PCC) report and the Diagnostic Medicine and Clinical Committee (DMCC) report.

PPA supports the MBS Review's aim to align items on the MBS with contemporary clinical evidence and practice and improve health outcomes for patients. PPA believes its response to the MBS Review recommendations will allow the MBS to achieve its goals of:

- Affordable and universal access to healthcare
- Best practice health services
- Value for the individual patient
- Value for the health system.

Under the MBS Review, the PCC reviewed 352 items and the DMCC reviewed six (6) items on the PST. PPA provides feedback on the DMCC report and all seven sub-speciality (pathology discipline) reports of the PCC, being: Anatomical/Cytology (Group P5/P6 PST), Chemical 2nd and 3rd (Group P2 PST), Genetics (Group P7 PST), Haematology (Group P1 PST), Immunology (Group P4 PST) and Microbiology (Group P3 PST). PPA has already made a submission on the first Chemical Pathology report (dated October 2017) and that does not form part of this submission.

The review into the PST is welcomed as funding should not be quarantined into separate silos which cross-subsidise each other. Advances in technology also means that tests within some disciplines overlap and many item rebates are not in line with the cost of tests.

[4] Harper Review, 2015 with recommendations adopted by Commonwealth Government http://competitionpolicyreview.gov.au/final-report/

The financial impact of the MBS Review in pathology depends on the Commonwealth's neutrality modelling as there will be winners and losers in items and fees. Currently anatomical pathology, microbiology and genetics is underfunded, and is cross-subsidised by chemistry and haematology. Anatomical pathology, microbiology and genetics should gain new items, have less coning and increased fees in balance, providing increased revenue for these disciplines as a proportion of all disciplines. There is a significant risk that the changes will reduce overall revenue in that balance, with chemistry and haematology not compensating. The MBS should to disincentivise over ordering whilst encouraging appropriateness of pathology ordering and rebates must cover the actual costs of providing the tests in pathology episodes.

Public pathology pathologists and PPA Executives have been involved in the Working Groups in their capacity as independent, experts in the field and not in their capacity as representatives of public pathology or PPA. This response reflects the combined response from PPA member organisations across Australia.

PPA notes that the following is out of scope for this submission: detailed modelling; how items are listed to the MBS (MSAC application process); MBS processing and claiming rules and issues. These items have an affect of the overall financial impact of the recommendations and therefore should be attended to in due course.

Position

There are many significant changes of the PST proposed in the MBS Review and these are largely well reasoned, sensible and in line with modernised clinical care and testing approaches within pathology laboratories.

Changes to the PST will have to be scheduled to minimise disruption and balance negative changes with positive financial outlays. Modelling the impact of changes and fees based on input from pathology sector costings is important before the changes take effect. A Pathology Advisory Committee should be established to oversee the necessary modelling and impact analysis and develop an implementation strategy. This committee should also be responsible for the ongoing review of the PST so that it remains contemporary and aligned with best clinical practice. A separate committee is also needed to resolve issues with MBS claiming and processing and this should involve representatives from the pathology sector, Department of Human Services and the Department of Health. PPA would welcome representation these committees should they be formed.

There is a need to ensure that the PST reflects both contemporary clinical practice and the cost of tests. This requires some degree of cost shifting from other areas of the MBS. Significant cost savings from laboratory automation, reduction in staffing and centralisation of services have been made over time, but these innovations have mainly come in the areas of high volume haematology and chemical pathology tests where there is little pathologist input and it has not been possible to extend these savings to some of the other areas of pathology particularly anatomical pathology which remains medically and scientifically labour intensive. Maintaining silos of funding for each discipline over the years to reflect relativities established when Medicare began in the 1980s has been in part responsible for the current state of underfunding of certain tests as they grew in complexity and cost over the decades. MBS rebates should cover the costs of providing pathology tests. Funding inequities can lead to perverse incentives to promote particular profitable tests at the expense of the less profitable tests. This can result in reduced access to less profitable tests and can waste health dollars if the profitable tests can be subject to over-ordering. The submission reflects PPA position that pathology ordering profiles should be determined only by clinical need.

Anatomical Pathology

PPA strongly endorses the Anatomical Pathology (AP, Tissue/Cytopathology) MBS Review recommendations.

The recommendations relate to:

- Changes to the histopathology (tissue pathology) complexity levels table
- Item tiering and coning in tissue pathology services
- Item tiering and coning in cytology services
- Alignment and coning of immunohistochemistry (IHC) and immunocytochemistry items
- Electron microscope rebate
- Frozen-section items
- Second-opinion items
- Pathologist-determinable items.

Changes to complexity levels

PPA agrees with the changes to complexity levels and the rationale behind these changes. There should be equity of classification based on comparable work. For this reason, inflammatory skins should be raised from complexity level 4 to level 5. Inflammatory skins are relatively complex, although the load on the laboratory is not high. Mandating structured reporting of cancer cases mitigates clinical risk and should be adopted.

The complexity table needs further revision to bring it into line with current AP practice as there has been many changes in surgical practice since the complexity table was devised in the 1990s. PPA recommends the following changes to the complexity level table:

- Brain or meninges, for epilepsy- temporal lobe (level 6)
  Remove the "temporal lobe" requirement as many cases of epilepsy surgery are now done of non-temporal lobe cases which have an equivalent level of complexity (including large numbers of blocks and stains).

- Liver biopsy
  Add liver biopsy, transplant including special stains – level 6 as per the recommendation for kidney transplant biopsies. Liver transplant biopsies are of at least equal complexity with a similar requirement for special stains and standardised reporting including Banff Rejection Activity Scores.

- Bone resection, neoplasm (level 6)
  An option of "bone neoplasm, post-chemotherapy with grid assessment of tumour viability" (with structured report) should be added and this item classified as a level 7. This requires significant handling / often sectioning with band-saw, large numbers of blocks and assessment of percentage of post-chemotherapy tumour viability.

PPA recommends additional level 7 items for types of surgery which were not performed significantly when the original list was compiled but reflect current oncological practice. Case numbers may be low and the failure to change would threaten the continuation of these services which are concentrated in a small number of centres. There are already some very uncommon cases for which there is a separate item number such as 71828 (level 4 18+).

- Pelvic exenteration for cancer
  This specimen includes most or all the pelvic organs and sometimes portion of the sacrum or other pelvic bones. They are variable in their structure and require pathologist input at the dissection/description stage as well as a large number of blocks to identify tumour post chemoradiotherapy and for margin assessment. The surgery is performed in a small number of centres but is not separately identified in the current specimen complexity list.

- Complex large head and neck resection for cancer

  These may involve complex resections of craniofacial bones and other structures such the orbit or ear canal. All of these structures have complex anatomy and the surgical specimens vary with each patient. There have also been significant advances in reconstruction techniques and intensity modulated radiotherapy. Thus, most of these surgeries are performed in multidisciplinary units and the specimen orientation requires close consultation with the surgeon. Multiple mucosal, soft tissue, bony and neurovascular margins need to be annotated and sampled for histologic examination. There is very little room for error as any close or positive margins will result in the graft being taken off or radiotherapy to critical structures including the brain and the eyes. Thus, the macroscopic examination requires a high degree of supervision for each specimen. Given the anatomic complexity, even senior registrars also require consultant input and supervision. All specimens need to be x-rayed, differentially inked in multiple planes and it needs to follow the CT/MRI planes.

- Peritonectomy
  This usually involves a large number of separate specimens requiring a large number of blocks. Unless a segment of involved bowel is removed, they are currently level 4.

- Odontogenic lesions (level 6)
  This was an omission from the specimen types in the original schedule. These are of similar complexity to a bone neoplasm, currently level 6.

- MRI targeted biopsy of prostate gland (level 5)
  Targeted biopsies of prostate are increasingly becoming the standard of care following advances in MRI. In contrast to traditional systematic or non-targeted biopsies, most specimens require complex grading, measurement and reporting of multiple pathological parameters to guide clinical decision making between active surveillance on one hand and radical prostatectomy or radiotherapy on the other.

Other changes

PPA supports an increase in the fee for electron microscope (EM) to reflect costs. A detailed costing analysis should be undertaken and this may indicate that the rebate should be in the order of $450 to reflect the time spent by scientists and pathologists in diagnosis.

PPA agrees with the immunohistochemistry and review/second opinion changes.

The removal of coning in AP is justified due to the inability to capture any economies of scale in tissue pathology practice due to the high level of manual technical work in dissection and slide preparation and the need for pathologists to review virtually all of the slides. There are no cost or time savings as there are with anaesthetics when several surgical procedures are done within the one anaesthetic episode.

Episodes involving the production of large numbers of slides and complex reports should not be coned out when there is a ladder system to cover lower complexity items. As coning does not apply to specialist referrals elsewhere in the PST, it is unfair to apply it in these tests when virtually all of the items of complexity level 5-7 items are referred by specialists. AP is highly labour intensive in both its laboratory processes, which are very difficult to mechanise and in the reporting of cases where virtually all cases are examined and reported by a pathologist. The productivity gains made elsewhere in pathology have not been applicable in AP, in fact the increased level of detail required particularly in cancer reports has made both the laboratory and reporting activities more labour intensive and more expensive over time. Cross-subsidisation has allowed large comprehensive practices to use savings elsewhere in the schedule to maintain AP services, but in the long term, failure to fully fund AP, particularly complex AP, will adversely affect patient access to these services.

PPA supports the removal of coning in AP as it would provide a much more transparent view of work performed for data and activity analysis. It would have the benefit of more appropriately funding the highly technically and medically intensive work which have been loss making. This could improve access to these tests and remove some perverse incentives which previously unduly favour lower complexity histopathology tests.

Impact

High complexity histopathology has had to be cross-subsidised heavily and this impacts on access to testing and also cost recovery from Health and Hospital Networks. The starting premise for the MBS Review should be that all tests should be funded to cover costs with some profit margin and to eliminate the existing inequities and cross-subsidisation.

Limits may not need to be set in the AP complexity items as its unlikely extra biopsies will be taken for financial gain.

The changes to complexity levels recognise the current level of pathologist and technical input required in the current era for these tests. This will require additional funding which is likely to need to be found in savings in other parts of the schedule. The addition of mandatory structured reporting to access the higher level fee would bring benefits of improvement in completeness and accuracy of cancer reporting with cost benefits in terms of need for additional reviews and decreased costs within cancer registries.

Removal of coning for levels 5-7 is of high priority and removal of all coning needs to be explored for the benefits for service modelling. The cost of removal of coning for levels 5-7 would require a small amount of additional funding for the benefits received. Removal of coning for levels 3-4 could be arranged to be cost neutral within those levels but would provide additional side benefits in terms of service planning.

PPA's proposed additional level 7 items would require a minimal amount of additional funding given the volume of testing for these items.

Overall, the changes should improve access to testing. As the high complexity tests are a small minority of histology testing, the overall budget impact is not likely to be major.

Prioritisation
PPA recommends the following items be prioritised:

1. The changes to complexity levels to recognise the current level of pathologist and technical input for these tests.
2. Removal of coning, particularly for Levels 5-7 is of high priority and removal of all coning needs to be explored for the benefits for service modelling.
3. Additional level 7 items.
4. The other agreed recommendations should then be progressed.

Chemical Pathology

Chemical Pathology (2nd Report)

PPA agrees with the Chemistry (2nd report) MBS Review recommendations with some clarification required.

Significant recommendations relate to frequent and common clinical chemistry tests being grouped into three panels, antenatal testing for chromosomal abnormalities in pregnancy, quantitation of HDL-cholesterol and tumour markers. Items recommended for MSAC consideration are ApoB and Lipoprotein (a), brain natriuretic peptide (BNP), chromogranin A, and human epididymis protein 4 testing.

Frequent and common clinical chemistry tests

Grouping commonly requested tests into three panels is a significant change to the Group P2 Chemical tests in the PST. This recommendation introduces three new items that would group some of the tests covered under 66500 into three requested panels: electrolytes, urea and creatinine (EUC), liver function tests (LFTs) and calcium, phosphate with albumin. PPA is in favour of this change to item 66500 and the associated ladder items (66503, 66506, 66509, 66512).

While the existing items have generally served laboratories well, they do not reflect clinical ordering practice. Grouping the tests under three panels would improve standardisation of ordering and data collection for public health purposes.

The separation of glucose testing from the EUC panel is logical, and there is HbA1c to screen for diabetes mellitus. The only usefulness of glucose in the EUC group is in the context of measuring osmolar gap.

Laboratories should have a choice whether to include chloride as part of EUC. Chloride is a less reliable method but may be a contributor to the detection of acid base abnormalities when blood gases are not available. Its interpretation is tied to that of the other electrolytes and analytically it is usually measured with Na and K. Most public laboratories have blood gas analysers and chloride is part of the ABGs or VBGs.

PPA agrees with:

- Lactate dehydrogenase as a stand-alone test.
- The removal of acid phosphatase, as this has been superseded and is now done only for rare clinical conditions.
- The removal of LDH isoenzymes although in some rare cases it may have some differential diagnostic value.
- Measuring AST as a reflex test only if ALT is abnormal.

PPA notes that urinary iodine has no clinical utility for individuals due to extremely high intra-individual variability.

Testing in pregnancy

PPA agrees with the removal of foetal lung maturity test (item 66749) as in practice, this test has not been routinely available for several years.

Clarifying first or second trimester testing for items 66750 and 66571 is sensible.

The antenatal markers refer to chromosomal abnormalities, but NTD and others are relevant. Furthermore, these and other tests are likely to be applied in cases of eclampsia in the near future.

Cardiac risk/health failure markers

PPA agrees with the inclusion of only troponin in items 66518 and 66519. It should be noted that in suspected reinfarction, a total creatine kinase (CK) is adequate i.e. CK enzymes are not required.

PPA strongly agrees with the establishing a lipid panel and taking lipids out of 66500 and integrating them into the HDL item 66536. This is consistent with the current Australian recommendations for cardiovascular risk assessment which require HDL and total cholesterol.

The panel (change to item 66536) should cover all four analytes, total cholesterol, triglyceride, HDL and calculated LDL. LDL should not be separated out from lipid studies. However, if direct measurement of LDL is performed (instead of calculated LDL) when triglycerides > 4.5 or higher >6.0 mmol/L, there should be a separate fee for analysing this for the extra labour and reagent.

The lipid studies panel fee would benefit from further modelling. An anticipated frequency of about 4 / year was applied to HDL at one stage in the past. There's always an exception to the rule, and patients with TG > 10 mmol/l at any stage should be able to test TG more frequently. The MBS could aim to harmonise with AACB's harmonised lipid reporting principles.

Having a separate lipid group also makes sense with the possibility of including newer items for future consideration. The future consideration of Apo B and Lipoprotein (a) is appropriate. Apo B has been considered by MSAC and the application is being clarified. There is no intention to reflex test Apo B because NHDL cholesterol usually suffices. In terms of the different lipid categories with restriction of Apo B and Lp(a) testing, clarification is required of hypertriglyceridaemia i.e. trig cut-off and reflex testing.

Brain Natriuretic Peptide (BNP)

The inclusion of BNP / ProBNP is appropriate, assuming it can be ordered by specialists as well as General Practitioners. It is imperative that item 66830 still applies to patients in hospitals. The proposed modification to the item requires knowledge that there was no previous myocardial infarction. Laboratories will not have this knowledge so it will be difficult to implement. It should also be noted that BNP could be confounded by neprilysin treatment.

Urine and faeces testing

Faecal fat should be removed from the PST. Faecal elastase is a better and more user-friendly test for fat malabsorption. The addition of faecal elastase in item 66674 reflects best clinical practice as recommended by gastroenterology groups.

Therapeutic drug monitoring

PPA supports the merging of items 66800 – 66806 and removal of certain drug tests as recommended. Therapeutic drug monitoring is not required for salicylate monitoring. However there needs to be a separate item for salicylate testing in hospital settings to test for suspected overdose.

Testing for phaeochromocytome - metabolite such as 3-methoxytyramine (dopamine metabolite) should be included as part of plasma or urine metanephrine screening. An isolated increase in dopamine should still be reported to clinicians as there can be rare dopamine secreting adrenal tumours.

Proteins and electrophoresis

PPA supports the new restrictor for Alpha-1 antitrypsin deficiency testing in items 66638 and 66639. Clarification of an abnormally low level (cut-off) is required.

Caution will be needed if adding CK enzymes to item 66641 as this is likely to increase substantially as laboratories will bill CKMB under this item. Suggest detection of macro enzymes also be specified as well as electrophoretic methods.

Thyroid antibodies

PPA agrees that anti-thyroglobulin antibodies should be coupled with thyroglobulin. However, the proposed descriptors would be difficult for laboratories to enforce as they require checking of notes for duration of Graves disease or duration of hyperthyroidism.

Metals for toxicity or deficiency

PPA supports the explanatory notes for copper and zinc testing (items 66819, 66822). Clarification is required as to whether this will also be reflected in clinical restrictions.

Comments on the items reviewed by the Diagnostic Medicine Clinical Committee (DMCC) contained within Chemical Pathology 2nd Report are located in the DMCC section of this paper.

Chemical Pathology 3rd Report

PPA agrees with retaining the ability of the laboratory to determine whether two (2) or three (3) faecal occult blood tests are appropriate in item 66764.

Impact

One of the most important changes involves the compartmentalisation of item 66500. Whilst this may work well for blood samples, modelling should be conducted to ensure that it is also appropriate for the assessment of all other body fluids.

Splitting the general chemistry items to three panels will affect coning as there are now potentially three (3) tests instead of one (1). This change needs detailed financial modelling. The recommendations mean that chemistry is likely to bear the brunt of the financial impact compared to other disciplines.

The impact of the fees incorrectly set will further cross-subsidisation of items per discipline. The making of a suite of 66500 tests separately billed also runs the risk of over ordering, ordering a EUC and an extra Chloride on each patient for the extra 66500. The fee should be set appropriately on the proposed single 66500 tests and preferably new items created so they are visible in billing. Removing glucose from the EUC group should not have a major impact.
Using volume of testing as an indicator, then merging of items 66800-66806 will have an impact.

The MBS rebate for HDL is currently $11.05 and it is reasonable to include total cholesterol, triglycerides and LDL with HDL for a marginally higher fee to reflect costs.

Prioritisation
PPA recommends that the separation of glucose and the merging of items 66800-66806 be prioritised.

The recommendation to introduce three new commonly requested chemistry panels under item 66500 is a significant change. Modelling such a change requires stability of other items in the PST. Given the volume of testing under item 66500, significant modelling of this change is required. To allow time for modelling and to examine the impact on the overall funding of pathology via the MBS, this recommendation should be assigned a low priority.

Haematology

PPA generally agrees with the Haematology MBS Review recommendations **except** for the reduction in coagulation tests and the removal of the item for massive transfusion.

The recommendations relate to:

- Blood grouping and blood group antibodies
- Compatibility testing
- Coagulation studies
- D-dimer tests
- Platelet assessment
- Haemolysis or metabolic enzyme assessment
- Full blood examination
- Thrombophilia tests
- Erythrocyte sedimentation rate
- Release of immunoglobulin
- Alpha thalassaemia genetic tests
- Warfarin care programs.

PPA agrees with the recommendations relating to: blood grouping, compatibility testing, D-dimer testing, separation of platelet function testing.

PPA strongly supports the recommendation to split the current FBC item 65070 into two items; one for the automated FBC parameters including automated WBC differential and a second item covering the additional expense of performing a manual WBC differential. This would allow for both a more accurate reflection of the work involved in this testing and provide more accurate data on the number of manual differentials performed.

PPA also supports the recommendations relating to testing for alpha thalassaemia by genetic analysis and warfarin care programs.

PPA disagrees with the recommendation to delete item 65129. Reducing coagulation tests from four (4) to three (3) could miss serious acquired and inherited bleeding disorders being diagnosed. Providers would still use PT, APTT TCT and fibrinogen to exclude DIC or rarer inherited coagulopathies.

PPA disagrees with the recommendation to remove item for massive transfusion (>6 units). This item should be maintained regardless of antibody status of patient as there is more work involved with additional units as blood groups need to be checked on all donor units. In the case of antibodies, each donor unit will also have to be phenotyped and serologically cross-matched (IAT). The item fee should be increased to $300 to align with changes to items for antibody positive compatibility testing.

PPA supports addition of explanatory note for item 65175 thrombophilia testing.

PPA agrees with the suggestion that the addition of the release of intravenous immunoglobulin to existing item 65109 (as an “or”) for the dispensing of other blood products.

Impact
There is a need for greater fees for the more complex positive antibody items over the negative antibody items. This requires a significant adjustment of funding between items in the haematology group of the PST.

Detailed and accurate modelling is required to define a cost based price for blood grouping, compatibility testing, massive transfusion and release of intravenous immunoglobulin items.

Prioritisation
The high volume and significant funding adjustments in this part of the schedule warrant low prioritisation to allow sufficient time to progress the changes agreed to by PPA.

Genetics

PPA agrees with the MBS Review recommendations in genetics as these tests have become mainstream testing in patient management, with the **exception** of the 100kb variant threshold as this could result in missed diagnoses. The PST does not cover an appropriate range of genetic tests and the existing items are underfunded.

The recommendations relate to:

- Chromosome analysis by cytogenetic techniques (items 73287, 73289, 73290)
- Chromosome analysis for specific constitutional abnormalities (item 73291)
- Chromosome analysis by genome-wide microarray (item 73292)
- Detection of FMR1 gene mutation (items 73300 and 73305)
- In-situ hybridization (ISH) test for HER2 for access to PBS listed trastuzumab for breast cancer (item 73332) and gastric cancer (item 73342)
- Analysis of gene mutations in the investigation of venous thromboembolism (items 73308, 73309, 73311 and 73312).

<u>Chromosome specific constitutional abnormalities, Chromosome by genome-wide array</u>

The proposed new descriptors for items 73291 and 73292 introduce a threshold cut-off for a genetic abnormality of at least 100 kb in size. Funding for variants less than this size will not be available under the proposed changes to the PST. This is restrictive as a number of pathogenic variants that are smaller than 100 kb in size have been identified. There is therefore a risk of missing a diagnosis in these patients. The approach is also inconsistent with the new item descriptor for analysis of chromosomes by genome-wide microarray in diagnostic studies of a pregnancy (item 73292) which does not have a 100 kb cut-off.

The recommendation report stated that 'restricting the resolution to at least 100 kb in size will discourage whole genome sequencing'. However, this can be achieved by stating in the descriptor "Analysis of chromosomes by genome-wide microarray..." or including a statement as in item number 73287 "This excludes genomic sequencing technologies, such as whole exome and whole genome sequencing".

PPA supports the microarray on multiple myeloma and CLL.

<u>FMR1 gene mutation</u>

PPA supports the removal of the older Southern blot item and review of the cost of contemporary test methods to diagnose fragile X syndrome (FMR1 gene mutations) for items 73300 and 73305. Southern blot is now very rarely performed due to the ability of newer PCR based technologies to detect large FMR1 expansions although it may still occasionally be used for the detection of low level mosaicism of FMRI expansions. PPA notes that some laboratories will need to continue to use the Southern Blot method to accurately size the expansion size for fragile X and this should be covered by item 73000.

ISH for HER2 for PBS breast cancer program
PPA supports amended descriptors for the Her-2 item 73332.

Factor V Leiden
PPA supports the recommendation to limit 73308-73312 tests to include only the gene mutations and populations where there is sufficient evidence to support testing by only analysing for Factor V Leiden (FVL) and Prothrombin 201210>A (PT) gene mutations, by only analysing for these gene mutations in those persons who have an Activated Protein C Resistance (APCR), and by no longer testing first degree relatives of persons proven to have abnormal genotypes. Family screening in this disorder is of minimal clinical utility, especially when first degree relatives are asymptomatic. However, a number of laboratories no longer provide APCR testing. Additionally, there are spurious cases of APCR like elevated Factor VIII that have no relevance to genetic testing. If a clinician suspects genetic thrombophilia on the basis of unprovoked thrombosis or thrombosis at unusual sites with a family history, then the best testing algorithm is to proceed directly to Factor V Leiden / prothrombin gene testing.

Funding Gaps
There are several items on the PST that are underfunded and do not reflect the cost of performing the tests. This should be addressed as a priority. Examples include:

- Detection of germline mutations of the Von Hippel-Lindau (VHL) gene (item73333), current fee $600.00. This gene is now tested as part of a cancer panel by Next Generation Sequencing and should be $1,200.00 in line with item 73295.
- Analysis of the PMP22 gene (73294), current fee $230.95. This item should be $400 in line with item 73297.
- Detection of the C282Y genetic mutation of the HFE gene (73317), current fee $36.45. This item should be $51.95 in line with item 73327.

There is a need for more Medicare funding for genetic tests for tumours (by FISH but also by sequencing via Sanger or Next Generation Sequencing (NGS)). There is a need for an MBS item for FISH for non-acute leukaemias and lymphomas. Without listing on the MBS, many of these tests are inaccessible for members of the public. The PST needs to be brought up to date to reflect changes to genetic testing technology and costs. The cost of interpretation in addition to the cost of testing must be factored into the MBS item fee. It may be more appropriate to have MBS AP items based on the WHO classification of haematological tumours and its Anatomical Pathology counterpart where tumours are classified and treated on their genetic abnormalities (sequence variants, fusion genes, loss of tumour suppressor genes). A gene panel approach to MSAC applications such as that recently for BRCA1 and BRCA2 should be considered for other items.

There is an urgent need for greater funding of specific applications of MPS (Massively Parallel Sequencing) with evidence for clinical utility, otherwise there will be pressure to maintain older methodologies which fosters gaps in testing.

Cancer

Somatic - MPS of tumours is playing an increasing role in predicting targeted therapy response and gene panels are being increasingly used in place of sequential single gene approaches. This applies to both solid tumours and haematological tumours. As MPS fusion gene and copy number detection is increasingly used this panel approach will potentially reduce the need for expanded FISH testing items and therefore providing flexibility in methodology used for some item numbers should be considered.

Inherited - MBS listing for BRCA1/2 and other related genes has been well accepted however there are a number of other cancer predisposition syndromes that would benefit from MBS listing for similar reasons. For example, bowel cancer predisposition syndromes such as Lynch syndrome and others.

Rare diseases

Exome sequencing is increasingly favoured as the first test for a number of genetic situations (including intellectual disability and developmental delay) and with reducing costs provides a much more cost effective testing strategy than multiple tests to find the underlying cause. Some flexibility in item descriptors in terms of methodology will assist in the transitioning phase. This comment also applies to testing in the reproductive medicine space including prenatal testing.

Pathogen detection

WGS (Whole Genome Sequencing) is increasingly being used in the control of outbreaks from both the hospital and public health perspective and consideration should be given to include these approaches where relevant.

Impact

The MBS fees in genetics do not cover the cost of tests. Items need to be costed and fees set appropriately.

Prioritisation

Genetics is a rapidly evolving area and the PST has fallen behind contemporary practice. Therefore, all of the agreed recommendations should be assigned a high priority.

Immunology

PPA agrees with Immunology MBS Review recommendations, with some minor amendments to coeliac disease testing.

The major recommendations relate to antinuclear antibodies and quantitation of complement components. It is noted that the MBS Review Committee recommended to retain the Erythrocyte Sedimentation Rate (ESR) as it is used in some prognosis scoring systems and Pharmaceutical Benefits Scheme authority criteria.

Minor amendments are required to the following recommendations:

- Coeliac disease panel (71163, 71164)

  In line with the MBS Review's aim of modernising descriptors to reflect best practice, the term gliadin antibody is outdated and should be changed to specify deamidated gliadin. Gliadin testing has similarly been removed from the Royal College of Pathologists of Australasia Quality Assurance Programme and replaced with deamidated gliadin testing to discourage use of outdated gliadin antibody testing.

- Genotyping for coeliac disease risk for DQ2 and DQ8 (71151)

  Coeliac risk alleles mostly comprise DQ2 and DQ8 but association with DQ7 has been well described. Therefore, the descriptor should include DQ7, especially as testing is mostly on the basis of its negative predictive value.

Additionally it is recommended that Rule 23 should be revised to permit bidirectional testing, in keeping with the "Revised 2017 international consensus on testing" (*Bossuyt X et. al. Nature Reviews Rheumatology 13, p683–692 (2017)*). Currently testing for antibodies to MPO and PR3 are deemed as included in the request for ANCA when immunofluorescence is abnormal or has been abnormal. The international consensus recommends that testing for antibodies to MPO and PR3 should precede immunofluorescence, with the latter only if the testing for these antibodies is abnormal.

It is a move forward to aim to change the requesting frequency of antinuclear antibodies (ANA), extractable nuclear antigens (ENA) and immunoglobulin E (IgE). Haematologists will need to be made aware that the use of serum free light chain testing (sFLC) in the assessment of lymphoma will not be Medicare rebated under item 71200. The change of wording for testing of molecular components in the context of peanut and venom allergy reflects current practice.

Impact
These recommendations will have limited financial impact as the majority of the recommendations are likely to be cost neutral or cost saving. The three recommendations that will increase costs are cryoprecipitate testing (although likely to remain small numbers), additional testing for IgA anti-phospholipid antibodies and development of additional item number for 5 or more antibodies to tissue antigens (which reflects current testing for certain conditions e.g. scleroderma or myositis). Patients will not be impacted by the changes recommended.

Prioritisation

1. Improving education on use of ANA testing should be a high priority given the high volume and often inappropriate use, predominantly by GPs.
2. Changes to cryoprecipitate testing, IgA for antiphospholipid antibodies and recombinant specific IgE testing should be medium priority to reflect current laboratory costs and appropriate clinical practice
3. Additional changes are of low priority although should be simple to implement

Microbiology

PPA supports the Microbiology MBS Review recommendations with some minor changes.

The microbiology recommendations cover:

- System framework for microbiology testing using Nucleic Acid Amplification Techniques (NAAT)
- Hepatitis serology
- Serology items/EBV
- Site-specific culture and microscopy tests
- HIV/STI Rule 3 exemption
- Complicated hospital specimens
- Microscopy wet film
- Antenatal bundle.

System based NAAT testing

PPA agrees with the adoption of an anatomical and physiological system framework for microbiology testing using Nucleic Acid Amplification Techniques (NAAT). This involves splitting generic molecular items (69494, 69495 and 69496) into system-specific MBS items for NAAT testing. Molecular testing should be separated from antigen testing. This recommendation is in line with increasing moves to NAAT testing and syndromic testing (multiple targets) rather than disease specific testing. It does not complicate the PST. The recommendation better reflects the type of testing being undertaken in contemporary microbiology practice and will result in more meaningful data being collected.

PPA supports the new NAAT items and makes the following comments in relation to certain NAAT tests.

The report recommends including parasites in the new faecal NAAT item (4.2) and retaining the parasite microscopy item 69339. The latter should be used as a supplementary item on the same specimen as NAAT testing when parasite MC&S is needed for items not included in NAAT and history indicates that the patient is at high risk (e.g. overseas travel, indigenous, immigrant).

The urogenital NAAT item (4.3) is supported as testing for additional organisms and multiple site testing is common.

There are some amendments required in the respiratory NAAT recommendation (4.4). Nasopharyngeal swabs need to be included in the descriptor (p19, s4.4.1, table 9). The GeneXpress influenza product insert identifies only nasopharyngeal swabs as being suitable for use with their cartridges. A correction is also required in 4.4.2 Rationale 4: the third point should include *Mycoplasma pneumoniae* not *Mycobacterium pneumoniae*.

The new skin NAAT item (4.6) is supported by should include dermatophyte detection by NAAT. Alternatively, dermatophyte detection by NAAT could be created as a separate item.

Hepatitis serology

The hepatitis testing model is supported as it is scientifically sensible, but it may be difficult to implement. The hepatitis serology item must cover the ASHM testing guidelines. The lack of clinical detail on request forms could be addressed by removing the words "in writing" from the explanatory note PN0.19 so that it reads 'the requesting practitioner suspects the patient is suffering from …hepatitis, rather than "requesting practitioner indicates in writing that the patient is suspected of suffering from hepatitis".

Serology items

PPA supports the reinstatement of the old serology item number 69399 for six or more tests. Fees should be determined with input from the pathology sector.

Site specific culture and microscopy

There needs to be consistency in the table and item descriptors for 69303, 69306, 69312 and 69318 regarding removal of microscopy and culture on specimens from other sites.

HIV/STI

PPA supports the rule 3 exemption for HIV/sexually transmitted infection (STI) testing as this reduces a barrier to testing.

Complicated hospital specimens

Respiratory specimens from CF patients should be added to complicated hospital specimens. Laboratories are expected to do normal MC&S; exclude B cepacia: increasingly exclude non-tuberculous mycobacteria; perform simple fungal cultures; and often identify and perform susceptibility testing on multi-resistant organisms. These cultures take four days or more.

Wet film microscopy, antenatal bundle and low volume/obsolete items

These recommendations are supported.

Recommendations to MSAC

PPA supports an item for testing orthopaedic tissues (5.1) as these are complex specimens needing two weeks culture and every organism needs ID&S in sterile-site specimens.

PPA supports an item for multi-resistant organism (MRO) screening (5.2.1) as this is increasingly important for patient management and infection control. Public pathology laboratories should be eligible to claim for this item on public health grounds. This recommendation does not address the use of NAAT as the primary screen for resistance (e.g. MRSA PCR) and then reflex culture if required. The MRO culture item must include the option for using NAAT to screen MROs.

Reflex culture/packaging of PCR-positive enteric and STD specimens (5.2.2) is very important for public health and individual patient care. For example, expert antibiotic susceptibility testing can impact patient treatment and provision of chemoprophylaxis for contacts (e.g. meningococcal disease); molecular detection of resistance genes impacts both care and infection control (e.g. carbapenemases); and serotyping (e.g. for H. influenza) impacts on immunisation and treatment of contacts.

Some private laboratories have ceased forwarding these important public health isolates because of the unfunded expense. It must be supported through the referral process. The reflex culture and referral item has been a high priority for the Public Health Laboratory Network (PHLN). Where reflex culture and isolates have been sent to a reference laboratory, it is imperative that there is an accompanying MBS item for the actual tests performed (e.g. Salmonella typing). Public pathology providers should be eligible to claim tests referred from the private sector on the grounds of public health (e.g. MRO typing, TB typing, respiratory virus typing, vaccine preventable disease typing).

Impact
The recommendations are supported and can be split into two groups. The first group are proposals that don't cost any money and should be done for clarity and modernisation of the schedule, viz:

- System based NAAT testing.
- Fixing up the M pneumoniae mistake.
- Removal of the need for microscopy from 69303, 69306, 69312, 69318 for payment. Laboratories can still do microscopy, but they don't have to and, in many instances, microscopy for these items is not helpful clinically.
- Standardisation of terminology for hepatitis antigens and antibodies.
- Inclusion of nasopharyngeal swabs.

The second group of proposals will cost more money but are important developments in patient care. Public hospitals care for many patients with prosthetic bone and joint infections, patients with cystic fibrosis and patients who require screening for MROs. Pathology providers usually do this testing at a loss and this must be addressed.

PPA supports the NAAT recommendations as they encourage pathology laboratories to select the most appropriate test (either MC&S or NAAT) but not do both (unless it is an organism of public health importance). On this basis, generally, the NAAT recommendations should not have any major financial implications unless they are inappropriately funded. Costing and modelling are essential here.

There are some exceptions, however. If parasites were to be included in the faceces NAAT item (gastrointestinal, 4.2), this would have a negative financial impact. The urogenital NAAT item may have some negative financial impact as both CT and NG usually occurs although these are not always both billed.

Multiplex NAATs with more than one target must be treated as more than one test to reflect the cost of tests.

The fee for item 69399 requires costing of multiple serology tests. This should reflect the cost of the more esoteroic antibody tests performed as well as routine serology items.

Prioritisation
System based NAAT testing should be prioritised. The other recommendations are also important particularly for public health benefit and should be implemented as a priority.

Diagnostic Medicine Clinical Committee

PPA is generally in favour of the recommendations proposed by the Diagnostic Medicine Clinical Committee (DMCC) relating to: vitamin B12, iron studies, folate, urine testing, vitamin D testing and prostate specific antigen (PSA) testing. Some refinements are proposed in order to improve clarity of ordering and to ensure that access to testing is not compromised where a clinical need for that testing exists.

PPA strongly supports the need for the following primary supports across all the recommendations and this should be funded by the Department of Health as a matter of priority:

- Clinical decision support (CDS)
- Requester and consumer education
- Nationally harmonised reference limits for a consistent definition to what constitutes a low or equivocal test result.

CDS facilitates better requesting of pathology via up to date clinical advice at the point of care. A fully functional CDS system should also feature consumer-based education which could be delivered simultaneously in the consultation or handed to the patient for consideration at a later stage. Work has been undertaken to scope CDS systems in pathology and this should be leveraged. A CDS system would need to be funded and integrated with clinical software – both general practice software and systems used in the hospital/outpatient/community health setting.

<u>Vitamin B12</u>
PPA supports the following DMCC recommendations to:

- Apply a 12-month frequency restriction on item 66839.
- Change the explanatory notes that lethargy/tiredness alone is not an adequate or appropriate indication for testing under 66838 and 66839.
- Harmonise serum vitamin B12 decision limits.

PPA notes that the MBS claiming data for items 66838 and 66839 presented in the DMCC report may be affected by coning (whereby the three most expensive pathology tests ordered by a GP are claimable by the pathology provider).

Contrary to the recommendations, having just the one test for B12 being the active B12 (marker) test would reduce ambiguity in test ordering. Therefore item 66839 should remain and item 66838 should be removed. The removal of serum vitamin B12 for testing for vitamin B12 deficiency is supported as the relevance of total B12 is reducing and it is often inappropriately combined with red cell folate or serum folate.

If holotranscobalamin (HoloTC) was the first line test for assessment of B12 deficiency, clinicians still need to be able to request methylmalonic acid and homocysteine in cases that are not clear cut. HoloTC would need to be costed.

Harmonised vitamin B12 decision limits should be pursued in order to achieve clarity for requesters and pathology providers.

Iron Studies

PPA is generally supportive of the DMCC recommendations to:

- Restructure and relabel iron studies and ferritin testing into three items, being 'iron overload studies', 'iron deficiency studies' and 'exception item for full testing where there is evidence that ferritin alone is an unreliable indicator of iron status.
- Have iron studies as the default iron test unless clinical suspicion is iron overload.
- Make iron overload pathologist determinable under certain conditions.
- Apply a three-month restrictor to iron deficiency item 66593.

While ferritin has relevance for haemachromatosis and anaemia, PPA agrees that iron deficiency is best determined by a sole ferritin test in uncomplicated presentations. There is a need for including the soluble transferrin receptor test to diagnose iron deficiency in patients with inflammatory conditions, as ferritin is too non-specific in this circumstance. A clear consensus on the ferritin cut-off in the setting of inflammation and infection is important to ensure the appropriate requesting of these items.

The current Kidney Health Australia-CARI guidelines for use of iron in chronic kidney disease include both ferritin and transferrin saturation (i.e. full panel), measured 1 to 3-monthly in haemodialysis and 3-monthly in peritoneal dialysis. This should be considered.

Folate

PPA is generally supportive of the DMCC recommendations to:

- Change the descriptor by limiting the testing of folate to patients with malabsorption conditions or macrocytosis and including groups of patients who should be given folate supplements without folate testing.
- Apply a 12-month frequency restrictor to item 66840 (except for repeat testing following low results).
- Add an explanatory note as to when testing is warranted and when patients should be taking supplementation without testing.
- Nationally harmonise serum folate reference limits.

The incidence of folate deficiency is virtually non-existent with folate fortification of wheat flour.

Folate testing should only be for patients 'with' '*or suspected of*' having malabsorption conditions or macrocytic anaemia.

There is no need to perform red cell folate. Most laboratories will not perform red cell folate as this is labour intensive. There is good evidence that serum folate correlates well with red cell folate. It is always difficult to interpret the restrictors for ordering folate, "suspected" or clinical malabsorption or macrocytosis. The private labs often interpret "suspected" as if doctors request the test, the patient is "suspected" to have malabsorption.

Vitamin B12 and folate are moderately inter-dependent but separation in testing seems appropriate, especially in the context of antenatal health.

Urine

PPA is generally supportive of the DMCC recommendations to:

- Change item 69333 descriptor so that urine testing is only required when symptoms of a urinary tract infection are present with specified exceptions.
- Add an explanatory note that urine microscopy and culture should not be performed in asymptomatic patients (with specified exceptions) or as repeat testing in the absence of symptoms.

PPA agrees with the change to urine testing because urine investigations are grossly over-utilised and lead to poor antibiotic stewardship. A common reason for urine tests, particularly in hospitals, is the work-up of a febrile and/or confused patient and this should be included.

Usually the laboratory has to assume that all requests are from symptomatic patients and that the requester has made the request in consideration of the patient's presenting symptoms. Changing item 69333 without education and support systems will not see a change in practice.

Vitamin D

PPA is generally supportive of the DMCC recommendations to:

- Change the 66833 descriptor for testing to be undertaken when the patient has or is at risk of both bone disease and vitamin deficiency.
- Include an explanatory note as to when testing is warranted.
- Apply a 12-month restrictor.
- Create a new item for additional vitamin D testing in patients with confirmed vitamin D deficiency and bone disease with a three-month restrictor.
- National standard for defining serum levels of vitamin D deficiency.
- Commission a Medical Services Advisory Committee (MSAC) review.

PPA agrees with change to Vitamin D testing but this needs some refinement based on current clinical restrictors (e.g. consideration of transplant risk factors to all transplants). PPA agrees with quarterly Vitamin D testing to monitor patients with actual bone disease. The restrictor "lack of sun exposure" is probably being used inappropriately and should be removed.

PSA

PPA is generally supportive of the DMCC recommendations to:

- Apply a frequency restrictor of 23 months to 66655.
- Change the descriptors for items 66659 and 66660.
- Add an explanatory note linking the Prostate Cancer Foundation and Cancer Council of Australia PSA testing recommendations.

PPA agrees with the PSA recommendations but notes that often the laboratory has no way of confirming whether a man is at increased risk. The laboratory must assume that the requesting clinician has determined this. The definition of previously diagnosed prostate disease needs clinical notes to verify, unlike the current threshold where laboratories can use historical results to determine eligibility.

Impact

Vitamin D needs a comprehensive public health plan that resolves competing advice about sun exposure. It may be a marker of chronic disease susceptibility, but treatment is only effective for frank deficiency.

If the recommendations result in a reduction of iron studies and Vitamin D, this will have a significant negative financial impact on pathology funding under the MBS. This must be reinvested in the PST to ensure the ongoing viability of pathology services. It is imperative that all recommendations are workable for laboratories, particularly given the level of information generally received on request forms from clinicians.

Prioritisation

PPA ranks the DMCC items in the following order:

1. PSA is the most urgent test requiring clarification in the DMCC report as this would provide greater clarity for clinicians and patients.
2. Vitamin D is a high priority due to poor awareness of appropriate testing guidelines.
3. Iron studies is a medium priority and may have significant financial impact.
4. Vitamin B12 is a medium priority as the preferred approach is to have a single marker test.
5. Urine is a medium priority as although investigations may be overutilised, this recommendation is highly dependent on education and support systems which are not in place.
6. Folate is a low priority as the volume of folate testing is declining

General Impact

If the public pathology providers continue to receive less PEI and BBI fees compared to private pathology providers, the financial impact of all the MBS review recommendations will be greater on public pathology providers and the modelling based on test costs will not reflect the true cost of pathology episodes. A failure to instigate funding parity under the MBS and reduce unfair competitive advantages in a Commonwealth Government funded market is against the competitive neutrality principles adopted by the Commonwealth Government and other agencies.[5]

When changes to PST items are announced, there must be sufficient lead time to enable services to perform the IT work to program systems and educate requesters. In the cases of major changes to the PST, the lead time would be at least 12 months in the public sector as laboratory information systems and billing modules are third party software and IT support and billing teams may be based within public pathology providers or external to pathology but within Hospital and Health Networks.

The restructure of the general chemistry tests will require adjustment within laboratories for coding and billing. Many of the proposed chemistry item descriptors require verification by laboratories or an assumption that documentation exists with the requestor.

Where the reports quote an “expected” rate of more complex testing, there needs to be an understanding that referral base differs for each laboratory.

MBS rebates must reflect the reality of testing costs. The following groups of tests are significantly underfunded: AP, genetics, haematology, microbiology NAAT. This requires detailed costing from all types of providers in the pathology sector and PPA is willing to work with the Department of Health on this.

[5] Harper Review, 2015 with recommendations adopted by Commonwealth Government http://competitionpolicyreview.gov.au/final-report/

Conclusion

Overall, the PCC and DMCC recommendations are sensible recommendations. Some minor adjustments are required. When these adjustments have been made, PPA believes that the recommendations will achieve the goals of the MBS Review providing tests and episodic costs are appropriately rebated.

There is a need to address cross-subsidisation and to ensure MBS rebates reflect the cost of tests. This must be considered in an episodic sense and therefore public sector PEI and BBI fees must be increased to achieve parity with other providers before the MBS recommendations are implemented.

Financial neutrality must be achieved when making changes to the PST to ensure the sustainability of the pathology sector so that patients have access to the testing they need. This requires modelling after recommendations have been agreed to.

A committee which is responsible for the ongoing review of the PST is necessary to ensure that it remains in line with best clinical practice and PPA would welcome involvement should this be formed.

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