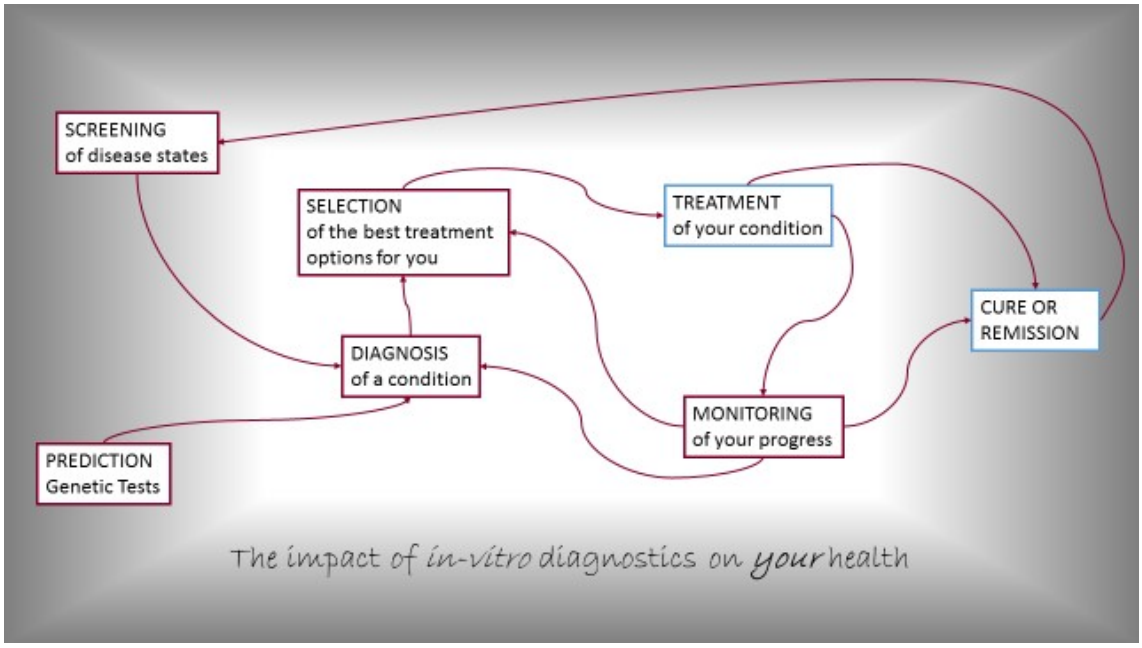
IVD AUSTRALIA

The industry where innovation saves more Australian lives



Advocacy Agenda

for a Healthier Future

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ADVOCACY AGENDA

Improving our Children's Health through Innovation

Policy Focus: The Genomic Revolution

Technological advances and automation have made tests easier to use and more accurate, and have led to more precise and more timely reports. A key advance, made possible by discoveries about the human genome, has opened the door to personalised medicine approaches that can tailor medical treatment to individual patient needs, transforming modern medicine. The impact of the rapidly growing range of pharmacogenomic (PGx) tests, often referred to as personalised medicine are the result of advances in next generation sequencing.

The main difference between genomics and genetics is that genetics scrutinizes the functioning and composition of the single gene whereas genomics addresses all genes and their inter relationships in order to identify their combined influence on the growth and development of the organism.

An example: It has been estimated that between 10 and 60% of patients do not respond to statins. Improvements in prescribing based on assessment of response could possibly result in significant savings to the community. the use of a PGx test to stratify patients on cholesterol reduction medication could save up to $400 million in unnecessary prescriptions alone.

In-vitro diagnostic technology is developing rapidly and, if an application for funding through MSAC takes 3 or 4 years, there is every likelihood that the test may have been superseded by an improved or superior test. This could certainly be the case in the genomic and personalised medicine area where new tests are being released almost every day. Whilst use of these tests may add to the overall cost of pathology, the benefits that they offer, not only in economic terms through savings on unnecessary pharmaceuticals, but also in reduced side effects and better patient compliance, greatly exceed the cost involved in performing them.

The ACHR Study (2008) identified a number of areas where the use of genomics is expected to have a substantial impact on diagnosis and treatment, including: Colorectal cancer; Inflammatory bowel disease; Thromboembolism and stroke; HIV and AIDS; Depression; Cardiovascular Disease; Breast and other Cancers.

The Industry where Innovation saves more Australian Lives…

Detection of Disease Before Symptoms Appear

Prediction of Beneficial and Adverse Treatment Effects

Enables Personalised Treatment Regimens

Facilitation of Rapid Results, Near-Patient and Point-of-Care Testing

Government Action Needed

- The Government must also take the opportunity to obtain the benefits offered by the increasing number of pharmacogenomic tests that are now available – through the MBS Review currently underway.

Looking to the Future

Policy Focus: Health Economics and Evidence

Healthcare systems throughout the world including Australia are facing several similar and fundamental challenges which impact on all aspects of care including pathology. The overriding concern is an unsustainable growth in health expenditure due to various factors but including:

- People living longer and reaching ages where the demand on healthcare is higher
- Increased chronic health conditions such as diabetes, cancer, mental illness or heart disease accounting for 70% of total healthcare expenditure.
- Inadequate technology assessment leading to costs of technology outweighing benefits.

Accompanying these factors is the demand from patients and their carers for more personalised healthcare. Collectively all of this is forcing the need for change in how healthcare is delivered.

New tests go through a review process for reimbursement that requires both clinical and economic evidence of effectiveness. The profession and the industry need to collaborate to ensure assessment moves beyond the traditional, analytical quality and diagnostic accuracy, to studies of outcomes with evidence. The extent of this existing economic evidence database is relatively small and there is a need to expand it through more well designed studies, another challenge to be taken up by both the industry and the profession.

When investigating the impact of new technology in healthcare there are three primary considerations (i) the impact on patient outcomes, (ii) the impact on the process of care, and (iii) the impact on resource utilisation.

The first is concerned with the raison d'être of the technology, and the innovation, whilst the other two are concerned with the adoption of the technology. All innovation involves change by definition, and when the primary outcomes relate to the patient outcomes, and their impact (including economic) on the individual patient and society; the impact on process and resource utilisation is more policy focussed on healthcare provision.

In addition to generating more economic evidence, new initiatives are required in determining alternative value models for pathology including how value-adding services can potentially influence test utilization and improve the cost-effectiveness of pathology services. Identification of such value-adding services can then lead to reimbursement models which reflect to a greater deal the value rather than the cost of a test (A. St John, 2015).

Government Action Needed

- Provide pathways, and participate in, the development of standardised protocols that provide details on requirements for legitimate studies, timelines, costs, and expected outcomes.

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The IVD Industry is the R & D of Pathology

Policy Focus: Reimbursement

The IVD Industry rapidly and consistently produces diagnostic tests with greater sensitivity, accuracy and reliability. With the aligned potential savings, the benefits of these technological advances should be recognised and embraced. Out of the accompanying research, we have seen the rapid growth and sophistication of many 'new' life-saving, cost reducing diagnostic tools. Next Generation Sequencing and Companion Diagnostics are but two of many exciting developments.

MBS reimbursement does not recognise the value new tests provide. The current approach to approving reimbursement for new tests does not support the return on investment that would support the generation of the evidence needed to fully evaluate clinical performance prior to marketing, and, by Policy Focusing on matching new tests to existing tests (and their payment rates), it provides little reward for creating additional value. Inconsistencies in test reimbursement force IVD companies to cross-subsidise tests for which reimbursement is too low, and they distort laboratory incentives for efficiency, threatening patient access.

The difficulties faced in reimbursement are compounded for companion diagnostic applications. Although, the development of companion diagnostics is surging across the developed world, regulation and reimbursement, in Australia, of both the pharmaceutical and diagnostic raise issues:

Examples of savings not realised:

- The use of a PGx test to stratify patients on cholesterol reduction medication could save up to $400 million in unnecessary prescriptions;
- Helicobacter pylori stool antigen testing which enables detection of ulcer causing bacteria (an Australian discovery) at a cost of $12-15 as opposed to a gastric biopsy at $400-500;
- Lab based tests for mesothelioma at a cost of $20 which replace a PET scan at a cost of $1000;
- Home-based blood glucose testing which offers the opportunity to reduce the secondary morbidity of diabetes for up to 1 million Australian NIDDM patients.

Government Action Needed

- Utilisation of statistics that reflect the true impact of pathology testing in Australia;
- A straightforward methodology to price new tests and correction of longstanding, historical anomalies in reimbursement-setting;
- Improved processes that reflect the innovative and dynamic nature of the industry; and
- IVD specialist representation on MSAC.

REIMBURSEMENT

In broad terms reimbursement strategies are based on the complexity of the test, which can be summarised as the cost of the reagents and the investment in resources to perform the test.

It could be argued that this approach has spawned the prevalent business model in laboratory medicine - namely one that rewards on the basis of cost per test - and thence a drive to perform more tests to sustain the business. This has led to an explosion in automation of testing to increase the productivity of the testing service.

However this development has been at the expense of the immediacy in the relationship between clinician and patient. The value of tests are then seen in the context of their cost rather than their impact on health outcomes.

Improving Consumer Health Now

Policy Focus - Point of Care Testing is underutilised in Australia

The development of centralised laboratories utilising modern IVDs has however brought greatly improved medical and scientific training, economies of scale and reliable quality assurance. However, with the development of enabling technologies by the IVD Industry, it is now feasible for many tests that could formerly only be carried out in sophisticated laboratory settings, to be performed in situations such as a hospital ward or clinic near to the patient or whilst the patient waits in a GP practice, in a health clinic or in a pharmacy.

People want greater control over their own healthcare including where and when they are tested, what they are tested for and who does the test. Clinicians require more and faster results. The government aims for more choice, devolution of control to primary care and a greater emphasis on the prediction and prevention of chronic disease. The implication of these drivers for the pathology sector, both providers and suppliers, is that PoCT is likely to grow in the number of tests performed, the range of analytes and available locations for testing in the coming years.

Point of Care Testing (PoCT) is performed widely throughout Australia. However, in many aspects we are behind the rest of the world. Connectivity and data capture is uncommon and few states have PoC managers available to coordinate training and support.

Because of the lack of reimbursement for the testing done, clinicians and healthcare professionals can be more Policy Focused on price being paid for the test rather than the accuracy and quality of the result. Quality Control and correct training on the PoCT method can also be difficult to manage.

RESULTS OF THE ABS AUSTRALIAN ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH SURVEY: BIOMEDICAL RESULTS, 2012–13

11.1% of Indigenous adults had diabetes, making them more than three times as likely as non-Indigenous people to have it.

Of the Indigenous people with diabetes in the survey, more than 1 in 10 did not know they had diabetes and were diagnosed as part of the biomedical testing, indicating that there are a large number of Indigenous people with undiagnosed diabetes.

An additional 4.7% had blood test results that indicated they were at high risk of diabetes. Over half of those with diabetes (53.1%) also had signs of chronic kidney disease. In total, 17.9% of Indigenous adults had signs of chronic kidney disease.

Those in remote areas were more than twice as likely as those in urban areas to have signs of chronic kidney disease.

Government Action Needed

- Appropriate reimbursement schedules for PoCT; and
- A simplified accreditation standard that reflects PoCT requirements and users outside the traditional laboratory setting.

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Sustainable Business Environment to Encourage Investment

Policy Focus: Sustainable Regulation

IVD Australia promotes the value of innovative, safe, and effective diagnostic tests and advocates for risk-based regulation of all diagnostics. However, minimisation of the regulatory burden for IVD sponsors and manufacturers is urgently needed to ensure timely entry to market of leading edge diagnostic testing while ensuring appropriate levels of safety and efficacy of IVD products supplied to the Australian market. These barriers are potentially being addressed through the *Expert Review of Medicines and Medical Devices*.

Importation of products is subject to delays and inconsistencies through customs and unnecessary damage to shipments is costly to suppliers. Additional Red Tape for manufacturing and importing goods already regulated by the TGA has designated as safe and approved for sale in Australia. There should be a pathway for low-risk and no further assessment should be required. This results in increased costs without additional benefit too either industry or Australian consumers.

IVD Australia strongly believes that the reliance by some Australian State Governments on a single third party catalogue is anti-competitive and damaging to the industry and should be reviewed. Vendor Credentialling for sponsors with products registered on the ARTG is an unnecessary impost on a highly regulated industry.

IVD Australia, along with all other industry Associations, was pleased that the Parliamentary Secretary under the previous government supported the development of the sector Codes of Conduct through allocation of $1.4 million over 4 years in the 2012 Budget. However, any benefit of this allocation has yet to be realised. **IVD Australia** was a member of both the *Working Group on Promotion of Therapeutic Products* and the *Code of Conduct Implementation Advisory Group*. The Working Group unanimously recommended that all sponsors (regardless of association membership) be required to subscribe to a nominated industry code of practice as a condition of registration or listing.

Unfortunately, the Government in response to the Working Group's Report did not support this recommendation. We now have what can only be described as an inequitable situation in which members of the industry associations are held accountable to their Code of Practice and non-members are free to promote their products to healthcare professionals without oversight or sanction. Adoption of such a recommendation would allow control through the self-regulatory codes of practice backed by the force of the Therapeutic Goods Act and the Therapeutic Goods Regulations.

Recommendation 5 from the Working Group Report stated:

... recommends that TGA include on its application forms (whether electronic or paper) a requirement for an applicant to nominate the relevant code of practice to which it will subscribe as a condition of registration/listing on the ARTG.

Government Action Needed

- Focus government's resources on tests that pose the highest risk to patients, removing unnecessary barriers;
- Require all sponsors (regardless of association membership) to subscribe to a nominated industry code of practice as a condition of registration or listing; and
- Take action against anti-competitive activities by some governments.

ADVOCACY AGENDA

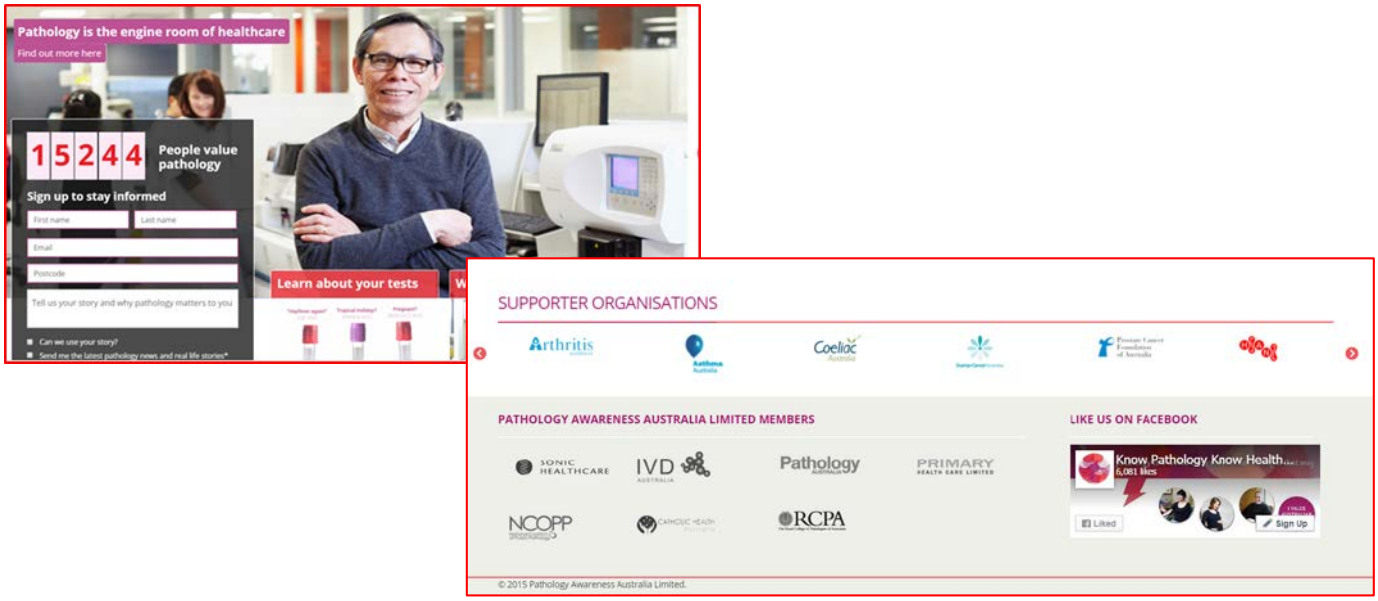
IVD Industry Policy Priorities

Priority 1: Improving our Future Health through Innovation
Priority 2: Health Economics and Evidence
Priority 3: The IVD Industry is the R & D of Pathology
Priority 4: Improving Consumer Health Now
Priority 5: Sustainable Business Environment to Encourage Investment

About IVD Australia

IVD Australia is the peak body representing sponsors and manufacturers of in vitro diagnostics based in Australia.

IVD Australia was formed in July 2009 and currently represents Australian manufacturers, multi-national and local distributors of IVDs, as well as regulatory consultants working in the IVD sector. Our members currently supply products valued at over $AU1.2 billion per annum and they employ over 2500 staff in multinationals, local distributors, local manufacturers and exporters and regulatory consultant companies; the majority of which are SMEs.



IVD Australia

is a founding member of Pathology Awareness Australia, a group that represents interests across the entire field of pathology in Australia. This body is conducting the Know Pathology, Know Healthcare Campaign on behalf of public pathology laboratories, private pathology companies, pathology professionals and manufacturers and suppliers to industry.