Unleashing the Hidden Potential: Reframing Pathology Technology's Role in Australian Healthcare

PATHOLOGY TECHNOLOGY AUSTRALIA

HTANALYSTS

ACKNOWLEDGMENTS

We would like to thank all the people who have generously contributed their time to the development of this report, especially the people living with diseases or disorders whose personal stories are included in this report, and who have helped guide our work on realising the value of innovative pathology technology.

CONTENTS

FOREWORD (PTA)

Pathology Technology Australia is a member-based organisation representing the manufacturers and suppliers of > 95% of diagnostic tests and technology utilised in pathology labs, hospitals and primary care facilities.

At the heart of Australia's healthcare system lies a significant opportunity to elevate innovative pathology technology and fully realise the often overlooked value it brings. Underpinning the vast majority of diagnostic and treatment decisions in healthcare is a test or a technology [1-3] that most people are completely unaware of – this is pathology technology. Almost all of us have benefitted from pathology technology by way of a specimen being sent to the lab. The results provided determine the path of a patient's journey and, for some, these results can be life-changing.

Innovation in pathology technology enables our healthcare system to become more predictive, preventative, personalised, and patient-centred – helping tackle many of Australia's pressing health challenges, particularly across infectious and chronic disease. When properly supported, innovation enables the use of tests earlier in a patient's journey, driving better patient outcomes with lower total healthcare costs [4]. Yet, a lot of this potential remains untapped. Generation of the evidence required for the funding application process is costly, complex, and time-consuming – averaging 2 - 3 years for local evidence base. This delay has resulted in many tests cleared through the Therapeutic Goods Administration (TGA) being underutilised by patients, and new tests slow to market, or never reaching Australian shores. This comes at a cost – expenses escalating, and health outcomes compromised – that could have been averted.

Unless we shift our perspective from one focused on initial cost outlay towards that of investment across the patient care spectrum, we will continue to limit the adoption of technology innovation and its life-changing impact. This report illuminates this straightforward reality: we are not capitalising on the vital and pivotal role that pathology technology plays in the value chain of health.

The World Health Organization (WHO) through its Seventy-sixth World Health Assembly (WHA) [5] highlighted the vital role diagnostics play in the "prevention, diagnosis, case management, monitoring and treatment of communicable, noncommunicable, neglected tropical and rare diseases, injuries and disabilities".

These critical tools in our healthcare landscape impact quality of care and equity of access to care across every patient touchpoint, again recognised by the WHA noting "equitable access to safe, effective and quality assured diagnostics required a comprehensive health-systems approach that addresses all stages of the value chain". The WHA urges Member States to establish "national diagnostics strategies, as part of their national health plans," as well as "prioritising and rapidly reviewing clinical evidence for new diagnostic interventions, services or products for consideration in guidelines and across diseases." Calls we strongly echo.

The value pathology technology brings, and the ramifications of delays in access when this technology is not readily funded, most deeply affect patients, families, and communities. You will hear their voice throughout this report, speaking to the impact pathology technology had on their lives. These patients and the wider community are often unaware of the transformative power that pathology technology offers, or the costly delays and complex funding pathways navigated. We are missing an opportunity.

We can embrace the innovations in pathology technology that offer a pathway from our current 'diagnose and treat' (sickness) model of healthcare to a 'detect and prevent' (wellness) model. This is not a new concept.

Progressive economies around the world are adopting technologies such as genomics, point of care testing, and digital health systems to improve health outcomes and reduce the burden of disease on their economies. Value is not always provided through just-launched invention. Some of the case studies in this report highlight simple tests that have been available for years yet are either partially funded or not funded at all, often due to the complex, costly and time consuming processes in place.

Amid the challenges of increasing chronic disease and an ageing population and rising costs across healthcare, a call to action emerges. Our mission is clear: to evolve a position that effectively values pathology technology and seamlessly integrates technology-driven solutions into our healthcare fabric. This necessitates a clear policy framework that acknowledges the importance of pathology technology and charts a path for equity of access while accelerating funding and adoption processes.

The Australian healthcare system has been among the best in the world, but we are slipping. It is said that we are up to ten years behind comparable economies in the funded deployment of genomic technologies and probably further behind in adequate support of point of care technologies. Our once capable and world-class systems for funding health services is no longer fit for purpose. Medicare Benefits Scheme (MBS) funding for in vitro diagnostics (IVDs) in Australia can be delayed up to 8 years from regulatory clearance due to the complexity and costs associated with data generation and HTA modelling requirements [6].

This Health Economic Report shines a light on the true value of pathology technology to health consumers, healthcare providers and to our economy. Providing an evidence base to catalyse the significant change we need to evolve how healthcare is delivered in Australia. The pathology technology revolution affords an opportunity to move from a sickness to a wellness focused healthcare system. We can identify health conditions earlier, initiate treatment sooner and keep people healthy and productive.

While this report highlights just a handful of cases, the underlying technologies address a broad range of conditions, from cancers to mental health, contagions, and antibiotic resistance, as well as in the optimisation of therapeutics for targeted care. There is substantial opportunity to change the way healthcare is delivered, and now is the time to embrace this change.

Dean Whiting

Chief Executive Officer

EXECUTIVE SUMMARY

This Health Economic Report shines a light on the true value of pathology technology to health consumers, healthcare providers and to our economy. Providing an evidence base to catalyse the significant change we need to evolve how healthcare is delivered in Australia. The pathology technology revolution affords an opportunity to move from a sickness to a wellness focused healthcare system. We can identify health conditions earlier, initiate treatment sooner and keep people healthy and productive.

While this report highlights just a handful of cases, the underlying technologies address a broad range of conditions, from cancers to mental health, contagions, and antibiotic resistance, as well as in the optimisation of therapeutics for targeted care. There is substantial opportunity to change the way healthcare is delivered, and now is the time to embrace this change.

Pathology testing and technology underpins every aspect of our medical system. It plays a vital role across all facets of healthcare throughout our lives by providing crucial diagnostic information, enabling the selection of proper treatments, aiding in choosing preventive actions, and offering vital data to enhance care management.

Pathology technology is a rapidly evolving area, continuously offering faster, more informative results for patients who have access to these innovations. Faster integration of these innovative technological advances enables the creation of a better, more robust healthcare system that optimises patient-centred care in every instance, regardless of geography, age, and socioeconomic status. Failure to appropriately invest in and fund this innovative technology in a timely fashion impacts the present-day quality of our healthcare system. Our future capability is enhanced by integrating new advancements to upgrade the care we provide to Australians.

As Australia's population ages and the risk of chronic diseases, cancer, and new infections or pandemics rise, the Australian healthcare system and those around the world are navigating challenges to address the unmet healthcare needs of patients. At the same time, Governments have a responsibility to ensure that healthcare spending remains sustainable while providing equal access to high-quality care.

Our failure to recognise the broader value of pathology technology is resulting in stagnant funding processes and slow adoption of innovative technologies that includes genomics, point of care and digital health. Intangible value, such as the value of knowing and the value of community, are overlooked. There is also inadequate consideration of the cost and realised value that shifts between federal jurisdictions and that of States and Territories. The complexity of these factors results in a lost opportunity to measure the true impact of life-changing technology.

We have an opportunity to invest and provide Australians with timely access to such technology so that Australia does not miss out on direct savings to the healthcare system and the broader social and economic benefits that pathology technology has to offer.

PTA VALUE FOUNTAIN

Responsiveness

Personalisation

Prevention

Life

Community

Hope

Equity

Cure

Knowledge dissemination

Knowing

Efficiency

Resource optimisation

AFFECTS PATIENTS

AFFECTS CARERS/FAMILY

AFFECTS GOVERNMENT

$7.0 BILLION
in value FORGONE
over 2-20 years

CHILDREN WITH SUSPECTED GENETIC CONDITIONS

The high cost of delaying access to innovative genomic tests: Whole exome/genome sequencing

Next generation sequencing techniques such as whole exome sequencing, whole genome sequencing and rapid whole genome sequencing have revolutionised the diagnosis of rare genetic conditions and continue to rapidly advance in their speed and accuracy. Barriers preventing faster access to these diagnostic technologies has resulted in a loss of over **$529.6 million** in value over the past 5 years.

Realise the value with a diagnostics expert advisory body

$15.2 M

in benefits forgone by **patients** with suspected genetic conditions through better access to support and special education services.

$152.4 M

in benefits forgone by **parents** of children with suspected genetic conditions through reduced productivity loss, the value of knowing, improved mental wellbeing, increased opportunity for cascade testing and reduced out of pocket costs.

$361.9 M

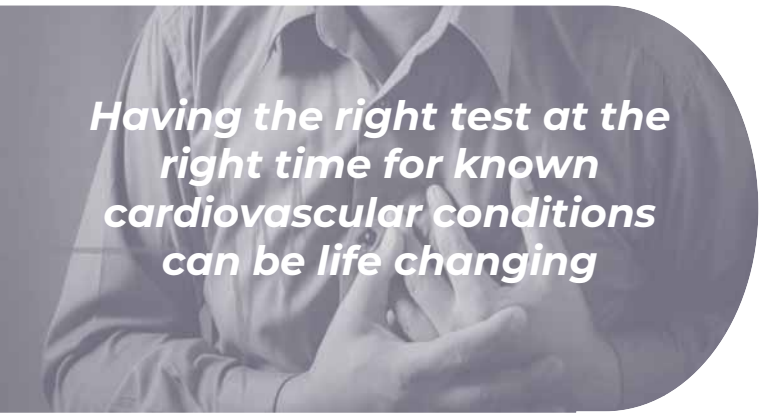
in benefits forgone by the **Government** through reduced spending on appointments, tests, treatments, reduced hospital length of stay and mental healthcare services, as well as reduced lives lost.

SUSPECTED HEART FAILURE IN THE GP SETTING

Optimising the utilisation of scarce healthcare resources: NT-proBNP

The delay in providing access via MSAC to NT-proBNP in the GP setting has resulted in an estimated loss of **$5.9 billion** in value over the past 20 years that could have positively impacted patients, their carers and the Government.

Realise the value with an accelerated funding model



$50.6 M

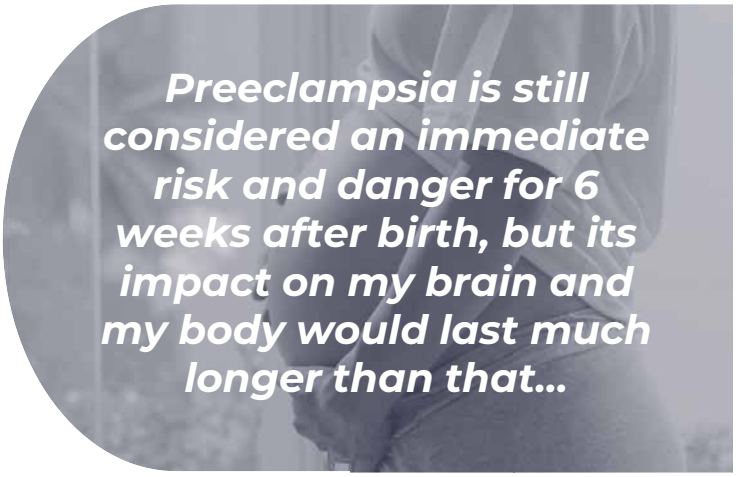
in benefits forgone by **patients** with suspected heart failure through reduced productivity loss and reduced out of pocket costs.

$26.2 M

in benefits forgone by **friends/family** of patients with suspected heart failure through reduced productivity loss.

$5.8 B

in benefits forgone by the **Government** through a reduction in ED visits and subsequent hospitalisations, reduced echocardiograms and increased government taxation revenue.



PRE-ECLAMPSIA

Unlocking better pregnancy outcomes while reducing healthcare expenditure: the pre-eclampsia (PE) ratio test

The delay in providing access to the PE ratio test in Australia means the broader value of the test is not being realised, especially when considering that the test was TGA approved in 2011. An estimated loss of **$235.3 million** in value has been forgone to the Government over the past 12 years as a result of this delayed access.

$235.3 M

in benefits forgone by the **Government** through a reduced hospital admissions.

OVARIAN CANCER

Improving efficiencies within the healthcare system: HRD test

The delay in providing access via MSAC to HRD testing for women with newly diagnosed ovarian cancer who are BRCAwt HRD positive has resulted in an estimated loss of **$319.1 million** in value over the past 2 years that could have positively impacted patients, their carers and the Government.

Realise the value with an accelerated funding model

$3.7 M

in benefits forgone by **patients** with BRCAwt HRD+ ovarian cancer in reduced palliative care costs, reduced productivity loss and improved mental health.

$4.4 M

in benefits forgone by **friends/family** of patients with BRCAwt HRD+ ovarian cancer through reduced informal care and improved mental health.

$310.8 M

in benefits forgone by the **Government** through avoided deaths and increased tax revenue.

$160.9 K

in benefits forgone by the **employers** of carers to patients with BRCAwt HRD+ ovarian cancer through reduced presenteeism.

$1.8 BILLION
in value GAINED
over 1 year

COVID-19

Towards health equity: COVID-19 point of care (POC) test

The more infectious a disease and the more remote a community, the more valuable POC testing becomes. The provision of POC testing during a global pandemic when the effects of a viral infection were largely unknown enabled the protection of communities who may have otherwise been hard to reach. The implementation of the POC testing program in a swift manner ensured that the true value of the POC test was realised, saving the Government **$112 billion** over two years.

HEPATITIS C INFECTION (HCV)

Single visit, lasting cure: HCV POC test

There is a cure available for those diagnosed with HCV. However, it relies on detection of the infection. The value of a cure can be realised with access to the HCV POC test. Access holds the potential to save lives and enhance health outcomes, saving the Government **$1.9-6.2 million** per year in lives saved. This can also bring us closer to achieving the WHO's goal of HCV elimination by 2030.

$337 M- $1.8 B

in benefits gained by the **Government** through a reduction in COVID-19 infections which prevented the cost of hospitalisations, ICU admissions and medical evacuations.

Capitalise on, and expand the value with a National Diagnostics Strategy and Roadmap

$1.9- $6.2 M

in net benefits gained by the **Government** through the avoidance of between 9 and 29 HCV deaths as a result of the implementation of the HCV program for one year.

$1.8 BILLION
in POTENTIAL value
over 10 years

MENINGITIS AND ENCEPHALITIS

Timely diagnostics, tangible savings: the multiplex polymerase chain reaction (PCR) test

The impact of the multiplex PCR test is far-reaching. Multiplex PCR testing in children with CNS infections enables access to the right treatment at the right time, helping to ensure antibiotics are used appropriately and reducing the risk of death, illness and time spent in hospital. Providing access to multiplex PCR testing could result in the creation of **$35.2 million** in value over 10 years.

MAJOR BLEEDING

Save lives with less blood: POC coagulation test

The POC coagulation test as part of patient blood management has the potential to enhance healthcare delivery and optimise resources throughout Australia, moving beyond the specific states or hospitals that currently use it. With faster and more precise treatment decisions, the POC test improves patient health outcomes and reduces medical expenditures, resulting in the creation of between **$1.4 and $1.8 billion** in value over 10 years if adopted nationally.

$35.2 M

In potential benefit to the **Government** through the reduction in hospital length of stay.

Overcome budgetary silos, and realise the value with a National Diagnostics Strategy and Roadmap

$1.4-$1.8 B

In potential value to the **Government** through the reduction in blood product utilisation, hospital length of stay and transfusion administration.

CALL TO ACTION

As stated in the recent Intergenerational Report, "Australia's ability to meet challenges while seizing future opportunities depends on choices made **today**". This report highlights the **forgone value** and cost to the health economy of delaying access to high-medical value tests and technology. Unlocking the true value of pathology technology for the patients of today will reduce the pressures on the future of healthcare. If a forward-thinking mindset is adopted, Australia can achieve better patient care at a lower total cost with a more robust healthcare system.

At the heart of moving Australia to a wellness-based health economy is the realisation of the full value offered by pathology technology. There is forgone value in the tests and technology that are available today - but not funded and therefore rarely used - and the innovative new technology rapidly piling up at our doorstep. The patient, societal and economic benefits from these technologies, currently unrealised, can be unlocked in several very clear ways:

- Establish a Diagnostic Advisory Group with stakeholders including healthcare professionals and laboratory service providers, patient advocacy groups, industry bodies, and Government representatives.
- Draw on the Advisory Group for the formation of a National Diagnostics Strategy and Roadmap.
- Use the Strategy to guide a range of critical activities such as sovereign supply, stockpile and manufacturing; purposeful R&D and horizon scanning for high-medical value technology; adjudication on accelerated access pathways to fund high-medical value technologies; identification of technology needs for Australia's key healthcare programs, working with manufacturers to ensure objectives of the programs are met.
- Use the Advisory Group in an ongoing capacity to provide input on future direction of the Strategy.
- In the short term, the Group could identify currently available, but underutilised, high-medical value tests and technology for accelerated pathways through funding and adoption processes.

INTRODUCTION

This report outlines several specific case studies assessing the broader social and economic benefits of early investment into innovative pathology technologies or the impact of delayed investment.

Australia's healthcare system, and healthcare systems worldwide, are facing challenges in meeting the needs of patients due to the ageing population and the increasing risks of chronic diseases, cancer, and emerging infections or pandemics. At the same time, governments have a responsibility to ensure that healthcare spending remains sustainable while providing equitable access to high-quality care. [8]

Longer, healthier lives can be achieved by preventing or slowing disease progression and facilitating recovery through prompt diagnosis and appropriate clinical management. Pathology technology assists by providing crucial diagnostic and prognostic information, enabling the selection of appropriate treatments, aiding in choosing preventative actions, and offering vital data to improve patient care. [9]

In Australia, over the past three decades, advancements in pathology technology have played a crucial role in driving ongoing enhancements in diagnostic service efficiency and overall healthcare outcomes [10]. During this period, diagnostic services have benefitted from these innovations – transforming laboratories from testing a few hundred patient samples a day to many thousands, reducing the time it takes to run a test, and taking the testing platforms out of the lab to bring them closer to the patient.

Pathology technology continues to experience remarkable advancements, with innovations emerging at an unparalleled rate. These advancements promise enhanced healthcare system efficiencies and positive patient outcomes. Yet these benefits will only be realised if the Australian healthcare system keeps pace with this innovation, acknowledges the value of such technology, and finds a way to deliver these advancements to all Australians equitably.

This report... seeks to uncover the unrealised value of pathology technology

This report will... showcase 8 pathology technologies and the broader social and economic impacts

The challenge for Australia, and all countries, lies in evaluating the affordability of pathology technology and determining how to gauge the value of these technological advancements. Health Technology Assessment (HTA) is the preferred tool for the Australian Government to assess the value of new technologies. In Australia, entities like the Medical Services Advisory Committee (MSAC) heavily depend on HTA, and MSAC plays a pivotal role in recommending which new medical technologies and services should receive funding for the Australian population. Nonetheless, both MSAC and other state funding organisations tend to have a limited focus, primarily emphasising traditional clinical and health economic aspects. The full range of potential benefits of diagnostic technology beyond these traditional measures – such as providing patients and their families with knowledge or hope – is often overlooked [8]. As a result, we overlook the broader economic value in terms of cost-containment as well as fostering improved health outcomes, ultimately leading to more efficient use of resources.

Australia has been slow to fund the adoption of innovative pathology technology, including genomic, point of care and digital health technologies. Barriers in the funding process delay the investment required for funded access, thus Australia misses out on direct savings to the healthcare system as well as the better patient outcomes, and broader social and economic benefits that pathology technology has to offer.

A paradigm shift is required for MSAC and other state funding bodies to realise the broader value of pathology technology and view it as an investment rather than a cost. We also need an accelerated pathway for funding and adoption of high-value medical tests and technologies and those that address under-served needs.

BACKGROUND

WHAT IS PATHOLOGY TECHNOLOGY?

Pathology technology drives the provision of high-quality, accessible, and affordable healthcare services. It stands as a cornerstone in modern medicine, offering critical insights that influence patient care decisions every day. Over 70% of medical diagnoses and management decisions rely on pathology test results, including 100% of cancer diagnoses. Early disease detection using this technology aids healthcare provision by informing care decisions, leading to decreased healthcare costs [8].

Pathology technology is at the heart of Australia's health care system.

It underpins every aspect of medicine, from diagnostic testing and monitoring of chronic diseases to cutting-edge genetic research and blood transfusion technologies.

Every advancement in this field improves our ability to detect diseases earlier, understand them better, and treat them more effectively. For instance, the rise of molecular diagnostics has revolutionised our approach to various cancers, allowing for targeted therapies tailored to individual genetic profiles. Moreover, in an era where infectious diseases can swiftly become global pandemics, rapid and accurate diagnostic tools in pathology become our first line of defence, guiding timely interventions. The true value of pathology technology, therefore, lies not just in its diagnostic precision but in its profound impact on enhancing patient outcomes, reducing resource use, and improving health inequalities.

The future of patient care relies on a healthcare system that is resilient for future populations - technology and patient, family and society outcomes are not separate entities, they are intricately connected components.

"Diagnostic services are vital for the prevention, diagnosis, case management, monitoring and treatment of communicable, noncommunicable, neglected tropical and rare diseases, injuries and disabilities" – WHO [5]

70%

Of all medical diagnoses

100%

of all cancer diagnoses

RELY ON **PATHOLOGY** FOR DIAGNOSIS AND CARE MANAGEMENT

PATHOLOGY APPLICATIONS

PREDICT

Predict susceptibility to disease

PREVENT

Prevent disease by identifying risk factors in patients that can be modified

DIAGNOSE

Diagnose many diseases. For cancer, every case is diagnosed by pathology

DETERMINE

Determine patient prognosis

IDENTIFY

Identify the presence or absence of infection

MONITOR

Monitor disease, identifying whether treatments work or should be adjusted or avoided

PERSONALISE

Personalise treatment to get the best result

INNOVATION IN PATHOLOGY

Innovation, derived from scientific development, is a core component of quality improvement in healthcare. While innovation in pathology technology is anticipated and appreciated in the field of medicine, it frequently goes unnoticed or remains unrecognised because of a fragmented funding process and a failure to acknowledge the potential value it could offer.

Pathology technology is a rapidly evolving area, continuously offering faster, more informative results for patients who are provided access to these innovations. The progress made offers significant opportunity for new and upgraded approaches to individual and public health challenges in Australia. Faster integration of these innovative technological advances creates a better, more robust healthcare system that optimises patient-centred care in every instance, regardless of geography, age and socioeconomic status.

Earlier in 2023, the World Health Organization (WHO) conducted a horizon scan to identify trends and emerging technologies in health which could be harnessed to improve the health of populations [11]. The report highlighted the importance of adopting a "future-thinking mindset" to ensure equitable and timely access to these new innovations and ranked these technologies into the overall top five most promising areas of innovation. Unsurprisingly, pathology technology featured – directly or indirectly – in all five areas. Timely investment in such technology is crucial for the Australian healthcare system, ensuring it remains adaptive, responsive, and equipped to provide world-class care.

> Making sure all Australians have access to the latest medicines and medical tests is an Albanese Government priority.
>
> The Hon Mark Butler [1]

TOP 5 AREAS OF PROMISING INNOVATION

01

GENOMICS

Application of genomics for early diagnosis and pre-diagnosis of diseases to guide management and treatment

Example: Whole genome sequencing to diagnose individuals with rare disease (see pg. 44)) [12-13]

02

VACCINES

Better coordinated, more effective systems of vaccine production and global distribution

Example: Genetic sequencing of the coronavirus to better understand its makeup and develop an mRNA vaccine [190]

03

LOW-COST VIRAL DIAGNOSTICS

Rapidly design and construct cost–effective point-of-care diagnostics for viruses

Example: POC test to diagnose Hepatitis C and provide a cure (see pg. 55) [14]

04

ANTIMICROBIAL DRUGS

Broad-spectrum antimicrobial drugs that do not cause resistance or tolerance; e.g. adapt their conformation to structural changes or mutations in the target

Example: Genetic sequencing of infectious organisms that cause pneumonia to better understand their makeup and develop drugs which evade their processes of resistance [15]

05

RAPID REMOTE DIAGNOSTICS

Connect people through cell phones, watches and other devices that can provide information on key markers and link health information in real-time to clinicians, people and other (public) health entities, supporting individual health promotion, disease prevention and disease (self) management

Example: Wearables which conduct ECGs that assist in the diagnosis of cardiovascular disease [16]

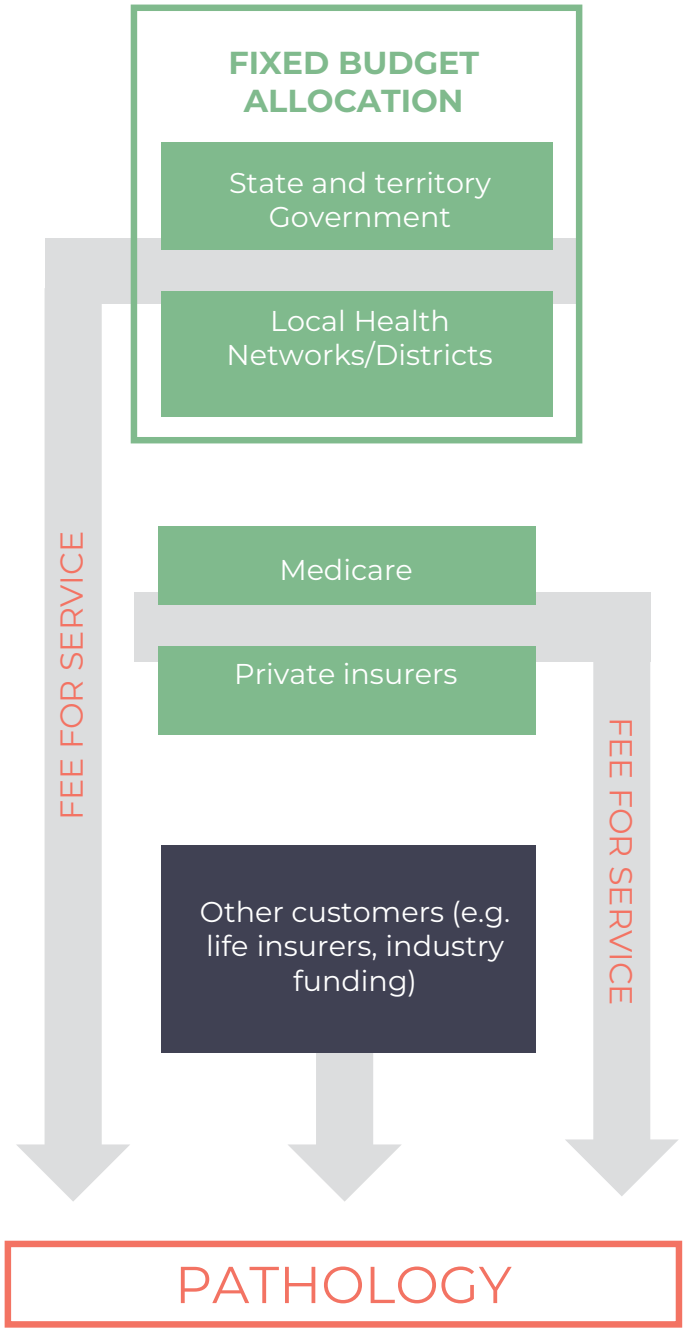
Source: 1. Lunke [12], Tan [13]; 2. Saravanan [190]; 3. Shih [14]; 4. Quinton [15]; 5. Bayoumy [16]

FUNDING INNOVATIVE PATHOLOGY TECHNOLOGY

Australia needs equitable and timely access for the full value of pathology technology to be realised. However, the key to access relies upon changes to our current policies, frameworks, and funding of innovative pathology technology.

Pathology relies on a mix of federal funding from the Medicare Benefits Scheme (MBS), state funding from public hospitals, and clinical trials. State Governments assign funds to Local Health Networks, which in turn distribute them to their respective hospitals. Typically, hospitals have a set budget designated for pathology. [17]

Laboratories typically charge hospitals for pathology tests on a fee-for-service basis. Federal Medicare funding is also fee-for-service according to the MBS item schedule fee. Despite the lower relative cost of testing compared to treatments, pathology has typically been underfunded compared to pharmaceuticals [17]. In addition, coupled with the underfunding of pathology, MBS funding is not directed to the technology supplier but to the laboratory that completes the test. The suppliers thus rely on a trickle down of reimbursement [18]. Technology that falls outside the use pattern of private or public laboratories (such as point of care (POC) testing, or at-home testing) also does not meet the current funding model criteria of 'fee-for-service'.



FRAGMENTED FUNDING

Disconnect between state and federal funding of pathology technologies

Australia has a complex and fragmented healthcare system that splits and shares the funding and provision of services between the federal and state governments. The division or roles and responsibilities between levels of Government results in "cost and blame shifting" leading to gaps in services [19] and also budget silos that undermine efficiency [20].

The current financing structure reflects a complex and fragmented health care system that struggles to provide effective patient-centred care. Patients experience a lack of access to care, inequities of access depending on where they live, and delays in access, all of which could result in poorer health outcomes [20].

MSAC PATHWAY

MSAC pathways to reimbursement are long and complex

The MSAC process is often described as a rate-limiting step to accessing innovative technologies and subsequent treatment. The MSAC process, including the data generation and modelling requirements for HTA, is long and complex, which does not match the evolution of innovation and clinical practice. [21, 22]

Currently, the funding application process has many redundancies, requires local data generation, and can be a costly and time-consuming process, thus access to new and innovative technologies is slow. This is evidenced by the fact that Medicare's coverage is limited compared to the number of tests available on the Australian Register of Therapeutic Goods (ARTG) in Australia. [17]

BROADER VALUE

Reimbursement or procurement decisions do not recognise the broader value of pathology technology

State procurement and HTA processes currently undervalue the broader benefits of pathology technology, particularly the value to other parts of the healthcare system.

In order to harness the innovation pipeline, the evaluation process needs to consider and reliably measure the many ways that pathology technology can create value beyond the traditional clinical and safety outcomes. This includes but is not limited to a broad array of patient-centric values such as increased knowledge and hope for a cure, as well as broader healthcare system values including resource optimisation and hospital savings. [17]

As Australia and the world continue to develop novel pathology technologies, we require flexibility and adaptability to ensure they are valued appropriately. At present, there is unrealised value in innovative pathology technology that Australia is failing to tap into.

THE UNREALISED VALUE OF PATHOLOGY TECHNOLOGY

As the pathology technology landscape is vast, dynamic, and continually evolving, the way we assess the funding of such technology must similarly adapt. Relying solely on traditional parameters of clinical and safety outcomes, limited only to immediate returns or a narrow scope of value, is inadequate. The broader value of such technology often lies beyond these primary outcomes, having deeper and sometimes intangible effects on society, including families, carers, employers, and various other sectors of state and federal Government.

To truly understand and appreciate the multifaceted value of pathology technology, funding assessments must consider both the indirect and direct impacts, taking into account the various stakeholders it can benefit. For instance, pathology technologies might not only diagnose diseases, but allow treatment to be identified, enhance workforce productivity, reduce immediate and long-term healthcare costs, and improve general wellbeing for both the patient, their families, and communities.

To demonstrate the elements of value, this report includes a Value Fountain, drawing on previous work [23], which highlights the numerous elements of value that may be overlooked or underappreciated in technology assessments. If Australia is to futureproof our healthcare system and continue to support the development of innovative pathology technologies, a paradigm shift in our perception of value is required.

Neglecting these broader benefits in a Health Technology Assessment (HTA), risks underestimating or undervaluing the transformative potential of innovative technologies, possibly stalling their future development, while denying access to patients. As such, a more holistic or 'whole of Government' approach to valuing technology is needed. It will ensure that we are not solely focussing on the health budget and limited definition of the value technology can provide, but that we leverage the expansive potential technology can bring to our society.

RESOURCE OPTIMISATION

Fast and accurate diagnoses, minimises the need for unnecessary tests, treatments, and hospital stays, facilitating the strategic use of resources.

RESPONSIVENESS

Rapid response to personal or public health crises and helps to control outbreaks, informs the need for vaccines and strengthens the health system

HOPE

Benefits derived by a patient (or a patient's family or carers) from knowing the results of a test that may provide a treatment or a cure in the future

PREVENTION

Early identification of at-risk patients improves patient outcomes and reduces cost

KNOWING

Harms avoided and benefits derived by a patient (or a patient's family or carers) from knowing the results of a test or obtaining a diagnosis

PERSONALISATION

Using test results to tailor individualised treatment options, enhancing patient outcomes through personalised care

CURE

Elimination of a disease for individuals and the broader society

KNOWLEDGE DISSEMINATION

Results of a test can be used in research and for future generations of patients

LIFE

The intrinsic and inherent worth of every person

COMMUNITY

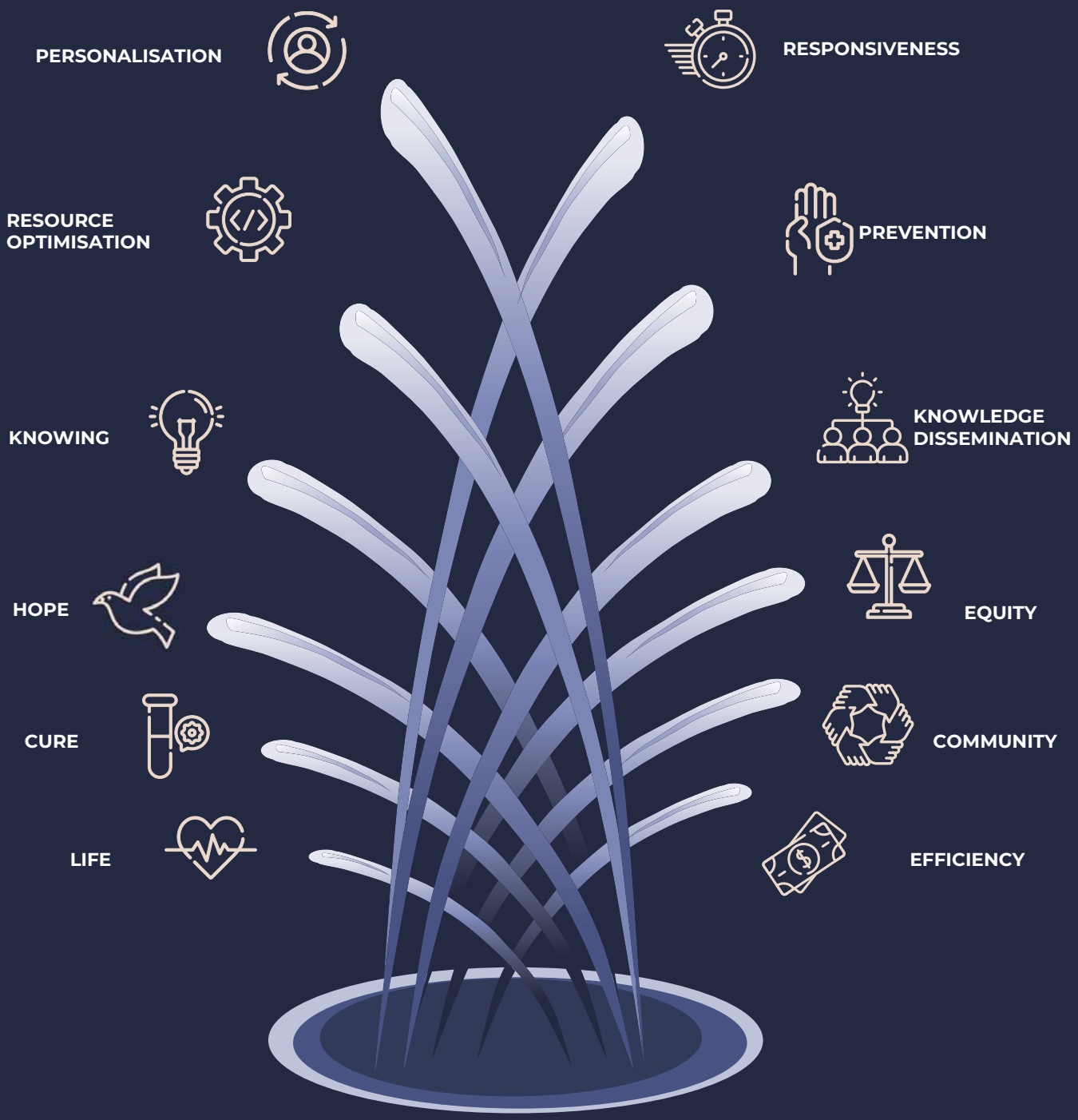
Stopping the spread of disease creates a safe and vibrant society

EQUITY

Redistribution of health from equal access to essential services and resources

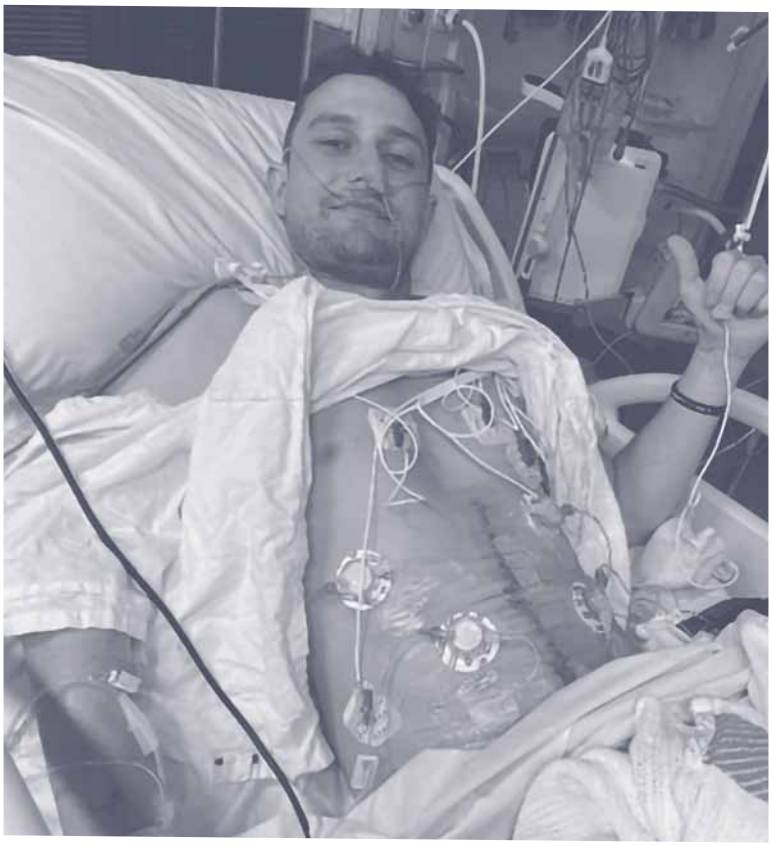
EFFICIENCY

Improved patient outcomes while reducing direct and indirect costs



THE VALUE FOUNTAIN

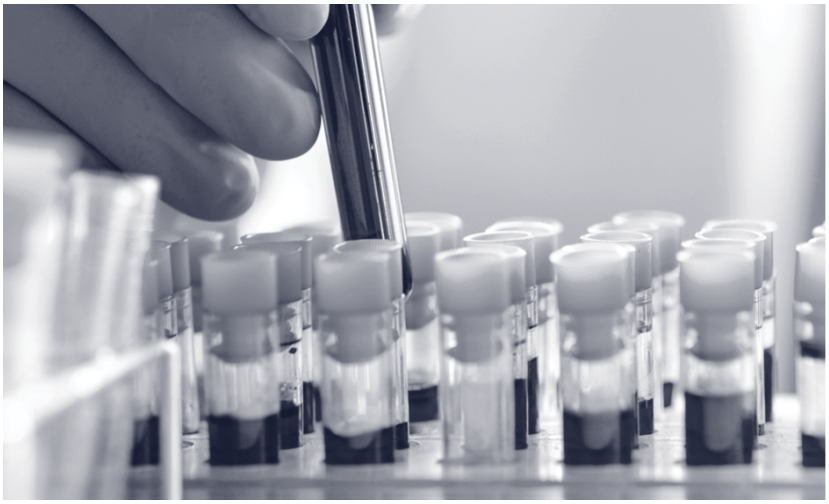
PATHOLOGY TECHNOLOGY -> DIRECT AND INDIRECT IMPACT -> VALUE



Diagnostics was the unsung hero in my story. **It was testing that guided my diagnosis**, my treatment and survival. Early Detection became my lifeline and without that, I wouldn't be here and about to become a dad.

Hugo, colon and testicular cancer survivor

OPTIMISING THE UTILISATION OF SCARCE HEALTHCARE RESOURCES FOR HEART FAILURE: NT-PROBNP



~1 in 2 patients die within 5 years of diagnoses

More than **102,000 people** report to have heart failure in Australia, but this figure may be significantly higher

$2.68 BILLION
is spent each year on the management of heart failure

BURDEN OF DISEASE

Heart failure is a condition that occurs when the heart begins to function less effectively at pumping blood around the body [24]. It can occur suddenly (acute) but usually develops slowly (chronic) as the heart gradually becomes weaker [25]. Symptoms can include breathlessness, fatigue, and swollen ankles or legs [26].

More than 102,000 people are living with heart failure in Australia. Aboriginal and Torres Strait Islander people are three times more likely to be diagnosed than non-Indigenous people. Older individuals and people of lower socioeconomic status are also at an increased risk [25].

Diagnosis of heart failure is often delayed, with most patients receiving their first diagnosis after being hospitalised [27, 28]. General practitioners (GPs) face significant challenges in diagnosis as there is no single test to confirm (or rule out) heart failure. Instead, a combination of tests is recommended including an echocardiogram (echos), physical examination and blood chemistry assessments [26, 29]. Around 25%–35% of people with suspected but uncertain heart failure have heart failure [30, 31]. This means a significant number of people are being incorrectly diagnosed and are receiving suboptimal care, resulting in the inefficient use of scarce healthcare resources [32].

Echos are used to show how blood flows through the heart and heart valves and are used to confirm the diagnosis of heart failure [33]. Unfortunately, long wait times and the location of echo centres can also make accessing these services difficult, particularly for Aboriginal and Torres Strait Islander people and those living in rural areas [34, 35]. Given this potential delay, GPs often refer their patients to specialists (cardiologists) or the emergency department (ED) [29].

Despite efforts to improve quality of life and survival, heart failure has poor patient outcomes. Around 50% of people with heart failure die within 5 years of diagnosis, worse than many cancers [36]. Combined, heart

failure and cardiomyopathy contributed to 15% of all deaths in Australia in 2021 [25].

As the population continues to age, the number of people living with heart failure is likely to increase, demanding additional resources for detection and treatment [36]. An estimated $2.68 billion per year is currently spent on the management of heart failure [36]. Improving the time to diagnosis and subsequent initiation of treatment, along with quickly ruling out heart failure in the primary care setting, will help reduce this huge financial cost and improve patient outcomes [37-41].

THE INNOVATION

NT-proBNP is a fast and accessible test that allows GPs to accurately rule out heart failure [26, 42]. It consists of a blood test that measures the protein N-terminal pro-b-type natriuretic peptide (NT-proBNP), produced when the muscles of the heart are stretched [43]. The test is performed via laboratory analysis, which provides a result in 3 days. However, there is also a POC test that returns a result in only 12 minutes [44].

NT-proBNP is currently funded in public hospitals and used in the ED and, because of this, many public patients are referred to the ED by their GP. This avoids the longer wait time for an echo in the primary care setting and out of pocket costs for patients accessing it through their GP or specialist. The test therefore has potential for significant benefit in reducing the unnecessary use of echos and visits to ED if made available to GPs [26, 40]. The test is recommended by Australian heart failure guidelines and is both recommended and widely available in the primary care setting in the UK [26, 45]. However, in Australia, access to NT-proBNP in the GP setting is not yet available despite the test being approved for use in Australia since at least 2003. [46].

THE IMPACT

Access to NT-proBNP in the GP setting can speed up the process of diagnosing or ruling out heart failure. Instead of referring patients with suspected or uncertain heart failure to the ED, a GP can carry out their own investigation to rule out the condition and shift their focus to more appropriate use of services and referrals [26]. A reduction in unnecessary echos for people who are found to not have heart failure, ED visits and subsequent hospitalisations from ED visits is expected to lead to a reduction in spending for the Government on these services, while reducing demand on the ED.

Patients with suspected or uncertain heart failure can also experience a positive impact. Not having to miss work for a visit to the ED and avoiding the out of pocket costs for unnecessary echos can result in significant cost savings. Family and friends, who often accompany patients to the hospital, will also benefit by not missing out on their potential earnings. In a workforce already facing shortages this takes a significant toll on businesses, the services they can provide and their ability to remain open. Moreover, this reduction in income loss can contribute to a boost in Government revenue through taxation.

NT-proBNP can improve time to diagnosis, leading to earlier treatment initiation. This could improve long term patient outcomes, reduce early death, and offer the broader population the advantages of a more efficient healthcare system [27, 28, 45]. Conservatively this extrapolation was excluded from the model.

Although difficult to quantify, a reduction in unnecessary investigations such as referral for echo also reduces CO2 emissions. This is important when considering the environmental impacts of healthcare [47].

At present value, if NT-proBNP had been made available in the GP setting one year post TGA registration in 2003, an estimated **$5.9 BILLION** in benefits would have been created in Australia over the past 20 years

DIRECT

HOSPITAL COSTS

$4.0 B

22,569 HOSPITALISATIONS PER YEAR

saved by the government on hospitalisation costs over the past 20 years due to a reduced need for subsequent hospital admissions.

ED ADMISSION COSTS

$1.8 B

64,117 ADMISSIONS PER YEAR

saved by the Government on ED admission costs over the past 20 years due to fewer admissions involving patients with suspected but uncertain heart failure.

OUT-OF-POCKET EXPENSES

$5.3 M

7,155 PEOPLE PER YEAR

in out-of-pocket costs saved by some patients over the past 20 years by reducing the need for unnecessary echos.

INDIRECT

PUBLIC REVENUE

$20.5 M

23,376 TAXPAYERS PER YEAR

in increased tax revenue for the Government over the past 20 years due to fewer patients with suspected or uncertain heart failure being referred to the ED.

PRODUCTIVITY

$71.5 M

23,376 PEOPLE PER YEAR

in income/savings for patients over the past 20 years with suspected or uncertain heart failure and their family/friends as they avoid missing work to go to the ED.

Source: Calculated from [29, 48-53]
Notes: Direct and indirect cost savings were estimated based on the incremental benefit of having access to NT-proBNP in the GP setting, instead of only in the ED. Australian data sources were used where available to estimate the cost savings that could have been incurred if a person could access NT-proBNP in the GP instead of the ED. Cost savings over one year were extrapolated to 20 years post TGA registration.

THE VALUE

The Australian healthcare system has yet to fully recognise the broader value of tests, such as NT-proBNP.

Introducing NT-proBNP testing at the GP level benefits patients as well as their families. For many patients, particularly those living rurally or of older age, travelling to the ED or to an echo appointment can be challenging. Providing a diagnostic test in the community setting improves equity of access and allows more patients to be tested efficiently.

Broadening the diagnostic capabilities of GPs can lead to resource optimisation, as patients no longer need to visit the ED. This shift can alleviate pressure on an already overwhelmed hospital system. Moreover, some patients may no longer require an echo.

Direct and indirect costs can therefore be reduced, improving efficiency as time to diagnosis decreases, and, for some patients, heart failure is ruled out. This means GPs can carry out more appropriate lines of investigation in a timely manner, improving patient care, and ensuring guidelines for early diagnosis and treatment are met.

The intangible value of knowing through a faster time to diagnosis, not captured in this analysis, can reduce stress, enhancing mental wellbeing and fostering a patient centric approach to care. Such timely insights empower both patients and their healthcare professionals to make better-informed choices regarding subsequent examinations and treatments.

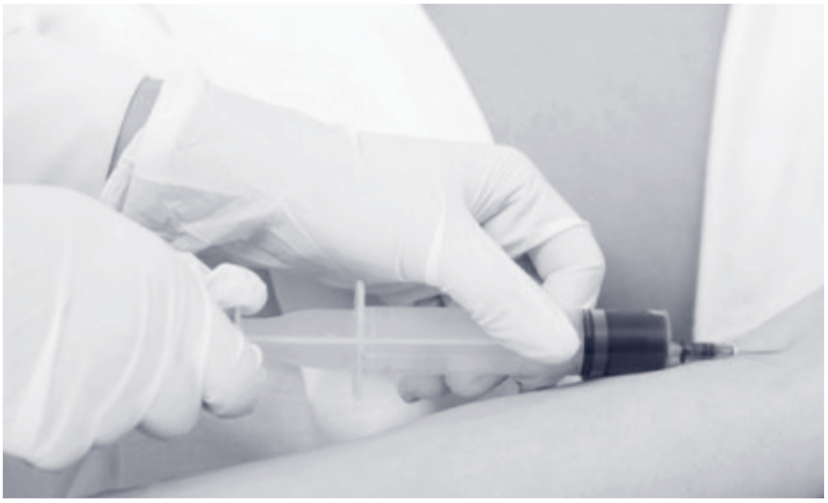
Comparable countries to Australia, such as the UK, have already acknowledged these manifold benefits and have made NT-proBNP available in the GP setting. If access to NT-proBNP is delayed further and the broader benefits are not recognised, it means a potential loss of approximately $300 million in value annually, a loss that impacts patients, their friends/families, and the Government.

REALISING THE VALUE

Realising the Full Value Fountain with an Accelerated Funding Model

Earlier detection of at risk populations allows for more targeted care, streamlining the finite resources of our healthcare system. Technology, such as NT-proBNP testing requested in GP settings, is a strong candidate for an accelerated access funding model, as described in this report. Approved through the TGA as safe and effective, and readily adopted and funded in similar jurisdictions, the provision of accelerated funding for this test in a setting closer to the needs of the patient and their front-line health professionals would allow for the full Value Fountain of this technology to be realised. This model ultimately relieves growing pressure on our medical system while still allowing for HTA processes to be undertaken. The relatively small cost outlay would greatly reduce the subsequent cost burden this report demonstrates when nothing is done throughout the long wait period between TGA registration and MBS listing.

UNLOCKING BETTER PREGNANCY OUTCOMES WHILE REDUCING HEALTHCARE EXPENDITURE: THE PRE-ECLAMPSIA RATIO TEST



Pre eclampsia can be **LIFE TREATENING**

Pre eclampsia is the **most common** serious medical complication of pregnancy

Affects 3% of pregnancies each year

Early diagnosis and monitoring are crucial to keep the mother and baby safe

BURDEN OF DISEASE

Pre-eclampsia (PE) is a potentially serious complication of pregnancy, that affects approximately 3% of pregnancies in Australia [54]. The cause of PE remains unclear [55]. However, women at high risk of PE during pregnancy are more likely to have high blood pressure, chronic kidney disease, are over 40 years of age, or have a high body mass index [54]. Aboriginal and Torres Strait Islander women are also more likely to experience PE, with 3.4% of mothers in 2020 having PE [56].

Beyond its common symptoms such as high blood pressure and protein in the urine, there are a range of other warning signs like headaches, changes in vision, and abdominal pain [57]. When left undiagnosed or inadequately monitored, PE can result in eclampsia (seizures), strokes, and HELLP syndrome (haemolysis, elevated liver enzymes and low platelets), which can be life threatening for both the mother and the unborn child [54, 57].

Given the threat of PE to both the mother and the unborn child, it is recommended that women diagnosed with high risk PE should be hospitalised, whereas those with low or moderate risk PE do not require hospitalisation. However, uncertainty in confirming the diagnosis, leads to unnecessary hospital admissions of women with low or moderate risk PE [58]. The current management of PE is therefore associated with significant healthcare costs [59, 60].

THE INNOVATION

The sFlt-1 / PlGF ratio test (PE ratio test) is the first automated test for identifying PE [58]. The PE ratio test in women with symptoms of PE can be used to rule out the condition or confirm the likelihood and severity of disease [57, 58, 61].

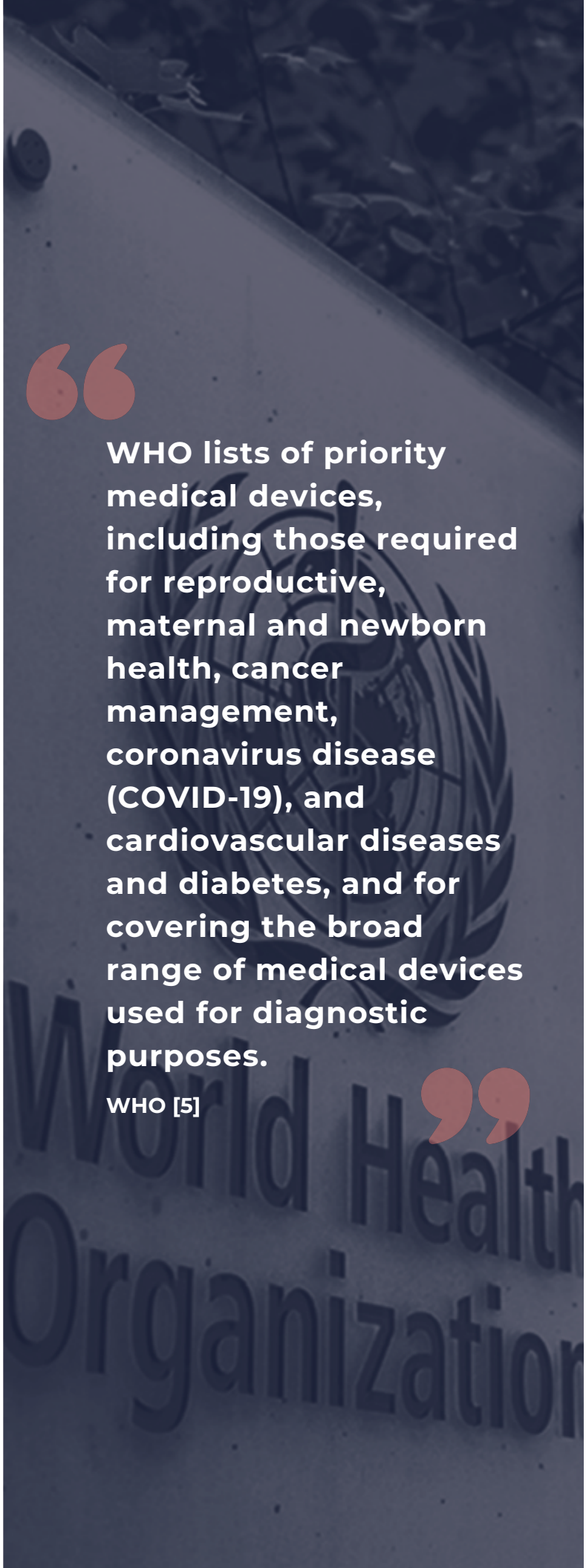
Where PE has been ruled out or they are at

low risk, women can be managed along the normal ante-natal pathway [57]. Women at moderate risk of PE can be managed through increased level of outpatient assessment, and women at high risk can be admitted to hospital for management [57].

Without the PE ratio test, women at risk need much more monitoring, including multiple tests (e.g. urine protein test, and full blood count), regular clinical check-ups, day care monitoring during pregnancy, and early hospital stays [57]. While the current standard used can help diagnose PE, none of them have the predictive capacity of the PE ratio test [58]. The UK have therefore recognised the benefit of this test and have already supported the use of the ratio test to rule in (diagnose) or rule out (exclude) PE [57]. The PE ratio test has been approved for use in Australia since 2011, however it has not yet been reimbursed.

THE IMPACT

Women who are eligible for testing include those with clinical signs and symptoms indicative of PE. The PE ratio test, when compared to existing standard tests in Australia, such as the urine protein test and full blood count, not only reduces costs but also enhances patient care. Notably, utilising the PE ratio test reduces hospital admissions by 20%. [58] For each person tested, the Government is projected to save an estimated $642 due to this decrease in hospitalisations. [58, 62-64]]



WHO lists of priority medical devices, including those required for reproductive, maternal and newborn health, cancer management, coronavirus disease (COVID-19), and cardiovascular diseases and diabetes, and for covering the broad range of medical devices used for diagnostic purposes.

WHO [5]

At present value, if the PE ratio test had been made available one year post TGA registration in 2011, it could have led to Government savings of over **$235.3 MILLION** from reduced hospital costs alone over the past 12 years.

HOSPITAL ADMISSIONS

$235 M
could have been saved due to reduced hospital admissions over the past 12 years.

Approximately 6000
women avoid a hospital admission each year[1]

BIRTHS

305.3 K
mothers having a baby in one year.

$642
saved per person who receives PE ratio testing[1-4]

TESTING

10%
of mothers are estimated to be eligible for testing due to clinical signs and symptoms indicative of PE.

Source: Calculated from 1. Vatish [58]; 2. Frusca [62]; 3. Ohkuchi [63]; 4.; 3. Ohkuchi [63]; 4. Schlembach [64]; 5. MSAC application 1706 [65]; 5. Australian Bureau of Statistics [66]; 6. Health and Welfare [67]; 5. MSAC application 1706 [65]; 5. Australian Bureau of Statistics [66]; 6. Health and Welfare [67]
Notes: The reduction in hospital admissions from Vatish [58] were used to estimate the potential savings in hospital admissions if the PE ratio test was adopted since 2012. Calculations on file.

THE VALUE

The delay in providing access to the PE ratio test in Australia means the broader value of the test is not being realised, especially when considering that the test was TGA approved in 2011. Not only does the PE ratio test enable more efficient resource utilisation — by reducing unnecessary hospital admissions and tests — it also represents an economic advantage for the Australian healthcare system. The test offers invaluable peace of mind by providing accurate and timely diagnoses, allowing expectant mothers and their families to make more informed decisions. It substantially reduces the risk of severe complications for both mothers and newborns, as they are able to receive appropriate treatment and monitoring at the right time, potentially saving lives. Its broader availability would also promote equity, benefiting women in rural and remote locations.

Until Australia provides funded access to the PE ratio test, estimated not to occur until at least 2025, the country will forgo the advantages that hold the potential to enhance individual wellbeing and the overall efficiency of the healthcare system.

REALISING THE VALUE

Multiple Lives Benefit from Accelerated Access Funding Model

During pregnancy Australia should be offering the gold standard of care to all. Decisions made affect two lives, with any complications in the critical developmental stages of the unborn child compounded throughout that child's lifetime. An accelerated access funding model would negate the years of increased risk and associated poor health progression of Australian mothers and their children experienced since this simple test was approved by the TGA but remains without an MBS listing. Yet another small cost outlay to bring Australia in line with other jurisdictions, while gaining considerable return on that investment across the breadth of the Value Fountain.

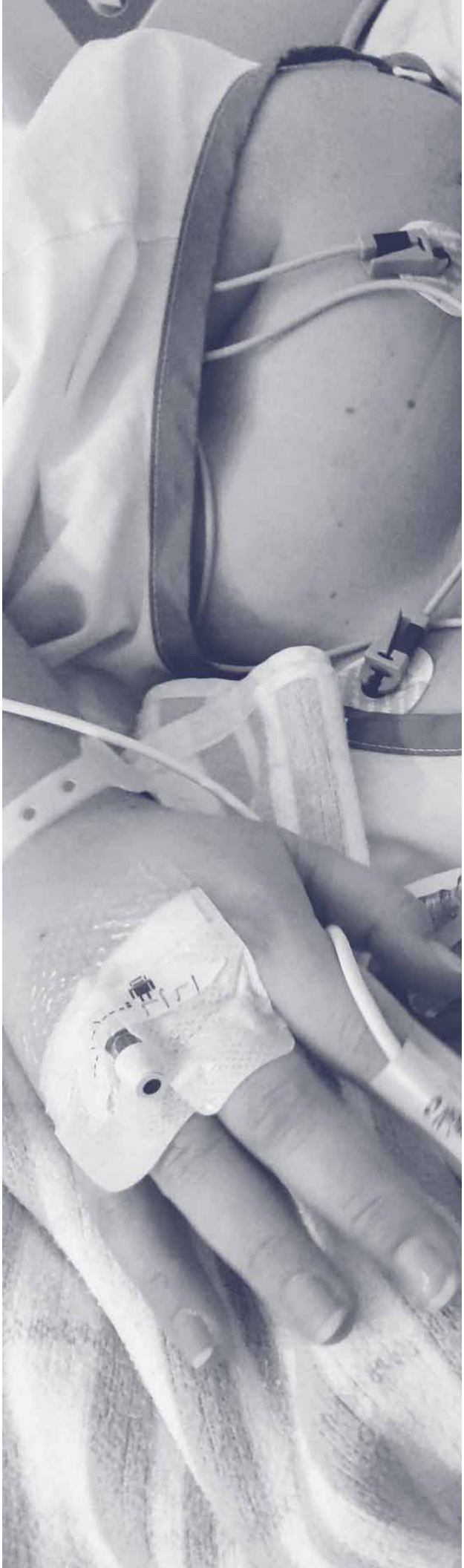
SARAH'S STORY

Sarah, a social worker, was pregnant with her first child when she found out she had PE. Sarah experienced high blood pressure from the beginning of her pregnancy, and so she had more regular appointments with her obstetrician, and many short stays in hospital to check her blood pressure.

Until around 30 weeks of pregnancy, Sarah's only symptom of hypertension was not accompanied by protein in her urine, and so PE was not considered. However, as the pregnancy progressed, she experienced additional symptoms including headaches, blurry vision, swelling, right shoulder pain, and carpal tunnel syndrome. Despite these symptoms and rapid weight gain, Sarah was reassured by her obstetrician at each appointment that she did not have PE. At 34 weeks, she listened to her intuition and went to the hospital, where she was diagnosed with PE and admitted for management of her blood pressure.

"... But then I heard a doctor say my name and that my urine was really high in protein and my heart sank. The obstetrician walked into our cubicle and said that I had preeclampsia."

During her 6-day hospital stay, Sarah's blood pressure remained difficult to manage despite increasing doses of medication, leading to a shift in focus from potentially sending her home to ensuring the baby remained in utero for as long as safely possible. That afternoon, she talked to her family about her fears surrounding PE and the "unpredictable spiral" it could take at any moment. Their wish was to have the baby as near to full term as possible, but knowing they had to be ready for anything.



The same evening unfolded with a midwife coming in to check her blood pressure. The midwife's panicked eyes and urgent exit to fetch a doctor confirmed Sarah's fears. The next thing she knew, the red emergency button was pressed, and she was surrounded by a medical emergency team. The atmosphere was tense as the team worked swiftly and efficiently, checking vitals, testing reflexes, and preparing medications. She could hear alarming phrases and see worried expressions as her blood pressure continued to rise despite the medication. She focused on breathing and praying, gripping her families hand for support. When the surgeon finally said it was time to meet her baby, everything became a blur of urgency and fear as her flight response kicked in, conflicting with the reality that surgery was the only safe option for both of them.

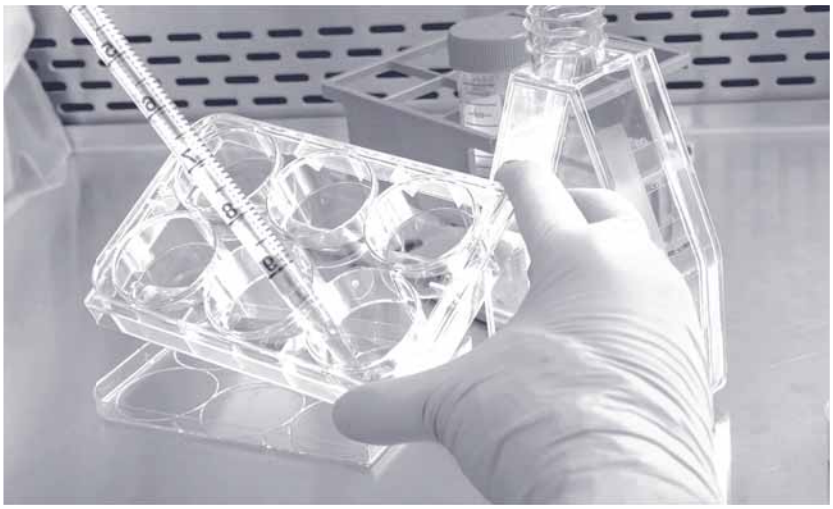
"I heard my blood pressure readings called out, and the anaesthetist say that it shouldn't be possible. I heard words like "urgent" and "emergency" and "now"."

Sarah later delivered her son by emergency C-section, and both Sarah and her son, spent a week in the Special Care Unit before being able to go home.

Sarah has since begun to heal, when she found stories like hers from people who understood how hard a traumatic birth can be on the brain and body. She now shares her own story to hep others around the world who have experienced PE.

"Preeclampsia is still considered an immediate risk and danger for 6 weeks after birth, but its impact on my brain and my body would last much longer than that... I walked away from [his] birth a different person to the one I was before it."

THE HIGH COST OF DELAYING ACCESS TO HRD TESTING FOR OVARIAN CANCER: HRD TESTING



1,734
People were diagnosed with ovarian cancer in 2021

46% of patients die within 5 years of being diagnosed

Homologous recombination deficiency (HRD) occurs in approximately 50% of women with ovarian cancer

BURDEN OF DISEASE

Ovarian cancer, often detected in women post-menopause, is diagnosed at an advanced stage in over 75% of cases [68]. Its symptoms, like bowel changes, indigestion, fatigue, weight changes, menstrual irregularities, and abdominal pain, can be subtle and are frequently overlooked or misinterpreted. [69, 70] Coupled with inadequate early detection and low awareness, ovarian cancer is notoriously known as the "silent killer" and "forgotten disease," leading to delayed treatment and worse patient outcomes. [69].

In Australia, ovarian cancer is the eighth most commonly diagnosed type of cancer for women, with an estimated 1,734 new cases in 2021 alone [71]. The 5-year relative survival for women with ovarian cancer in Australia is low at 46% [72]. Hereditary mutations in the homologous recombination repair pathway are one such risk factor.

The most important of these are *BRCA 1* and *BRCA 2*, which are well known to be associated with an increased risk and predisposition to hereditary ovarian cancer. [73, 74]

Advanced stage treatment typically involves surgery and chemotherapy. However, about 70% of these women experience a recurrence [75]. When the cancer returns, it can be difficult to treat. However, new medicines, such as Poly (ADP-ribose) polymerase inhibitors (PARPi) are now being used to help manage and treat newly diagnosed advanced ovarian cancer.

Until recently, only patients with a *BRCA* mutation were able to access PARP inhibitors. However, since the evolution of the HRD test, the PBAC have now recommended that women who are HRD positive (HRD+) and do not have a BRCA mutation (BRCA wild type [wt]) have access to potentially lifesaving treatments, offering them a renewed hope for survival and possibly a chance to be cured [73, 76].

THE INNOVATION

HRD testing uses a tumour sample to assess HRD positivity in newly diagnosed ovarian cancer patients [77]. HRD positive cancer cells hinder the cells' ability to repair damaged DNA. Because of this vulnerability, HRD+ cancer cells can die when treated with PARPi [78]. To test for this, a tumour sample is needed. This may be taken during surgery for ovarian cancer or by taking a small sample of the tumour (biopsy) for examination [77].

Before the availability of an HRD test, women who were HRD+ and did not carry the BRCA mutation had limited treatment options available to them to improve their survival outcomes. Despite this strong medical need, a recommendation for universal access to HRD testing by the MSAC was delayed, in part, due to the requirement to have a local testing capacity. Delaying access to funded testing significantly impacts women and their families.

A PARPi for women with HRD+ advanced ovarian cancer was TGA registered on March 1, 2021. However, multiple unexpected delays in the MSAC process, and concurrent NATA accreditation and TGA notification process delayed access to the HRD test. The NATA accreditation process was commenced by the Peter MacCallum Cancer Centre (PMCC) in September 2022. However, new TGA regulations for In Vitro Diagnostic (IVD) companion diagnostics, which took effect on February 1, 2020, meant the TGA was also involved in the laboratory accreditation process. When the PMCC HRD test was eventually NATA accredited in early 2023, it became the first complex molecular in-house IVD companion diagnostics to be evaluated concurrently by NATA and the TGA. NATA accreditation was received seven months after submission.

Following an initial rejection by the PBAC and the MSAC in July 2022, the delays in testing accreditation described above, led the PBAC to defer their recommendation of the PARPi treatment for use in eligible HRD+/BRCAwt ovarian cancer patients.

The decision was pending the outcome of the MSAC meeting for the HRD test on March 30, 2023. The meeting's outcome was eventually positive, with MSAC recommending the HRD test for use in March 2023. Consequently, PBAC pending NATA accreditation of the assay finally recommended the use of the PARPi treatment in eligible ovarian cancer patients four months later.

THE IMPACT

For patients with newly diagnosed HRD+/BRCAwt ovarian cancer, access to HRD testing and combination therapy can bring about life-changing benefits (9). The best available data was used to model the impact of access to HRD testing and combination therapy compared to current standard of care for newly diagnosed HRD+/BRCAwt ovarian cancer patients.

For the first time, these patients have access to a treatment that may improve survival and for some it may provide a cure. [76] This can reduce the need for palliative care while improving mental health and quality of life for patients and their families. Some patients may also return to work, increasing their income/savings while leading to increased tax revenue for the Government.

Carers, including friends and family also benefit from improved patient outcomes, with reduced social, emotional and economic burden. Without access to this treatment, patients with HRD+/BRCAwt ovarian cancer may continue to experience disease progression, losing their independence and ability to perform daily activities, relying more on their carers. [79]

Moreover, improved health outcome for patients with HRD+/BRCAwt ovarian cancer may increase productivity at work among friends and family who offer informal care. This leads to cost savings in annual revenue for employers. [80]

Compared to current standard of care, if access to HRD testing and combination therapy had been made available to newly diagnosed women with HRD+/BRCAwt ovarian cancer a year after suitable treatment was TGA registered, **88 LIVES** may have been saved between 2022 and 2023 and an estimated **$319.1 MILLION** in benefits could have been created in Australia over the two years.

DIRECT

PALLIATIVE CARE

$2.1 M

45 PATIENTS PER YEAR

saved over 2 years due to a reduction in palliative care needs. With access to HRD testing and combination therapy, some patients with HRD+/BRCAwt avoid death or are cured due to ovarian cancer.

INDIRECT

INFORMAL CARE

$3.0 M

13 CARERS PER YEAR

saved over 2 years in increased time for carers of people with HRD+/BRCAwt due to a reduced carer burden. This time saved was measured as an opportunity cost, signifying potential alternate uses based on the average hourly wage.

WELLBEING

$2.2 M

13 CARERS & 13 PATIENTS PER YEAR

saved over 2 years by patients and their carers in improved mental health due to an increase in patients avoiding progression. Calculated according to Australian Government Office of Impact Analysis guidelines for valuing injury, disease and disability. Total 12-month cost of mental health burden was $369,150 per patient and $727,040 per carer in 2023.

INDIRECT

PRODUCTIVITY

$919.7 K

6 PATIENTS PER YEAR

in increased income/savings over 2 years for patients with HRD+/BRCAwt due to an increased ability to work. When patients experience improved health outcomes as a result of combination therapy, those of working age may be able to return to work.

MORTALITY

$310.6 M

51 PATIENTS PER YEAR

saved over 2 years by the Government due to avoided deaths. The value of these lives was quantified using the Australian Government value of a statistical life year and estimated at $3.8 million per patient.

PUBLIC REVENUE

$177.2 K

6 TAXPAYERS PER YEAR

in increased tax revenue over 2 years for the Government. Improved health outcomes for some patients with HRD+/BRCAwt patients, may result in patients of working age working more productively or return to work. This, in turn, may reduce income loss while simultaneously increasing tax revenue.

EMPLOYER REVENUE

$160.9 K

8 EMPLOYERS PER YEAR

saved over 2 years by employers of carers. carers of patients that experience improved health outcomes are likely to be more productive while at work. This increased productivity (or presenteeism) was measured as a proportion of average wages earned by carers at their places of employment. On average, each employer was estimated to save $10,531.

Source: Calculated from: [77, 79-95]
Notes: Direct and indirect foregone savings were estimated based on the incremental benefit of having access to HRD testing in Australia, allowing BRCAwt HRD+ ovarian cancer patients to access treatment. Australian data sources were used where available to estimate the foregone savings that could have been avoided if patients had access to HRD testing. Foregone savings were measured over the two year period 2022-2023.

THE VALUE

The delay in providing access to HRD testing and PARPi to eligible ovarian cancer patients has had a profound impact. It has not just impacted patients, but also their friends, families and employers.

At its core, the most significant value of HRD testing is the potential to save lives. As mentioned previously, the delay in accessing HRD testing, and by extension, superior care over the two-year period, may lead to an estimated 88 women dying unnecessarily. Moreover, about 26 women needlessly experienced disease progression during this period, which may have been averted with timely care.

Furthermore, HRD testing also brings mental health benefits to patients, their families, and caregivers. Knowing that they have access to treatment that would have otherwise been inaccessible provides hope.

Access to HRD testing also increases equity, ensuring more women have the chance to receive superior care. Regrettably, due to the delay in access to HRD testing, 377 women were denied access to PARPi over this two year period.

The failure to provide faster access to HRD testing has resulted in a loss of more than $319 million in benefits over two years. The foregone advantages ranges from hope and potential cure to the value of a life and improved equity for patients, their families, caregivers and employers.

REALISING THE VALUE

Recognising High Medical Benefit of HRD Testing for Accelerated Access Through a Diagnostics Expert Advisory Group

It is well-understood that current HTA processes are ill-equipped to keep pace with the rapidly evolving landscape of genomic-technology-driven healthcare. Ongoing clinical trials with novel indications for use for the suite of targeted treatments coming to market all rely on the use of diagnostic technology to identify appropriate patients and conditions. The inequity connected to out-of-pocket HRD testing required for access to specialised medicines highlights the urgent need for an Accelerated Access program overseen by a specialist Diagnostic Advisory Group. Centralising decision making through a core of experts will minimise delays for patients who often have very limited windows available to action life-saving care.

> **It's also vitally important that we make the best use of medicines and diagnostic technologies available to ensure better health outcomes for more Australians.**
>
> **The Hon Mark Butler MP [7]**

JACINTA'S STORY

Jacinta was about to turn 59 when she started experiencing symptoms. As is the case for many women, her initial symptoms - bloating and excess abdominal fluid, sudden weight gain (an increase in waist measurement of 10cm over the space of 2-3 weeks) and digestive issues, along with shoulder pain and frequent running injuries - were non-specific and misdiagnosed. Jacinta become more unwell, unable to get out of bed by herself, and was eventually referred for an abdominal ultrasound where she finally got a diagnosis and an answer for her symptoms.

"Once you're diagnosed everything is fine."

Jacinta underwent chemotherapy for nine weeks, followed by surgery and a further six weeks of chemotherapy. Although she responded well to surgery, the chemotherapy was gruelling and the cancer very aggressive, which meant Jacinta was running out of options. Genetic testing in Australia indicated that she was not *BRCA*+ and so an application for compassionate access to a PARPi treatment was not initially successful. Her specialist recommended she do further genetic testing on the tumour itself. This test was only available in the United States and would cost her $5000 but could potentially expand her treatment options.

"He said I need it to guide your treatment and if it doesn't bring any information then I don't have anything for you"

Jacinta chose to pay for the test and received a positive result for HRD. She was one of the 5 to 7% of patients with a somatic *BRCA* mutation. This result allowed her compassionate access to a new treatment and meant she could stop the chemotherapy, which had been so gruelling on her body and was failing to treat her cancer.

Jacinta, on her 60th birthday, post chemotherapy, post-surgery, while on the PARPi treatment

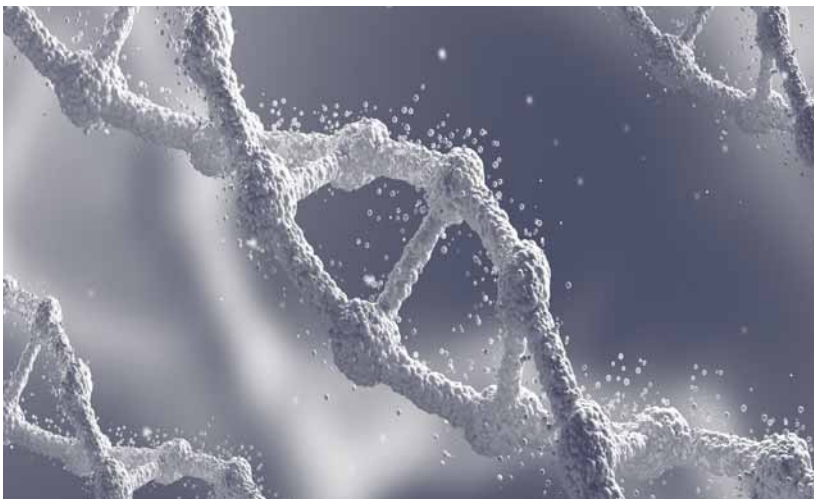
More than three years later, Jacinta has completed treatment and remains in remission; working, taking care of her family, travelling abroad for her son's wedding, and living her life. She strongly believes that her specialist's advice to do the HRD test and the subsequent access it provided her to a new treatment option was lifesaving.

"It (HRD testing and access to targeted treatment) absolutely saved my life. I've been able to return to work, care for my family, travel and hopefully I will long enough to become a grandmother!"

To ensure other women receive access to new, emerging, and potentially more effective treatment, Jacinta has continued to advocate for all patients to access HRD testing and new treatment options. To increase awareness of ovarian cancer Jacinta is involved with volunteering, podcasts, fundraising hikes, and commits her time to consumer advocacy for medical research grants to further advance the research.

"It's actually easy to save lots of women's lives in Australia. We can easily expand the HRD testing and access to a PARPi, and it's actually not that hard and we can do it. We should do it. That's my job, to try and support and encourage people to save women's lives every day. So, I feel how could you turn your back on that? I may not be well enough always to do that in the future, but I am well enough to do it now."

THE HIGH COST OF DELAYING ACCESS TO INNOVATIVE GENOMIC TESTS FOR CHILDREN AND NEWBORNS



1 in 17 people have a rare genetic disease in Australia

Before the introduction of WES/WGS, average wait to diagnosis was **6 years**

Yearly cost of raising a child with a genetic condition can be up to **$100,000 per person**

BURDEN OF DISEASE

Genetic conditions encompass a diverse range of diseases that include specific birth defects, chronic conditions, developmental challenges and sensory impairments. These conditions are caused by variations in an individual's DNA [96]. Some genetic conditions are individually rare but in Australia , one in 17 people will encounter a rare disease of genetic origin in their lifetime, with the majority being children [97, 98]. Alarmingly, genetic conditions are the primary factor of paediatric mortality in developed countries [99, 100].

These conditions can be complex, often requiring frequent, multi-disciplinary medical care and, in severe cases, immediate intensive care [12, 101]. While many genetic conditions lack a cure, prompt and appropriate treatment is crucial to enhance life quality and longevity [102].

Given their complex and rare nature, genetic conditions often lead to a 'diagnostic odyssey', where there is a prolonged delay in diagnosis or no diagnosis at all [103]. Before the introduction of whole exome sequencing (WES) and whole genome sequencing (WGS), patients waited on average six years for a diagnosis through the standard diagnostic pathway [103]. Often, patients remained undiagnosed and 38% of families consulted with at least six doctors before receiving a diagnosis [101, 103]. Such late or incorrect diagnoses lead to substantial financial, physical, and mental health burdens for the patient, their family, and the Government [97, 103]. For critically ill children, delayed or misdiagnoses can be fatal [97, 104]. The financial burden varies by disease, but annual costs for raising a child with a genetic condition can reach up to $100,000 per individual. Research has shown that these costs can be reduced with improvements in a child's intellectual functioning, facilitated by early diagnosis and targeted interventions. [105]

THE INNOVATION

WES involves reading and analysing specific parts (approximately 2%) of a person's DNA [106]. In Australia, WES was one of the first genome sequencing innovations available for children with suspected genetic conditions. Before the introduction of WES, standard of care testing (i.e., chromosome microarray or panels) only provided about 14% of these children with diagnosis. With WES, the number of children diagnosed increased to 52% and the average time taken to get a diagnosis has reduced from six years to approximately 6 months. [103]

An application to MSAC for the use of WES in children with suspected genetic conditions who remain undiagnosed after chromosomal microarray was initially made in 2016 [191]. However, in this period, developments in genomic sequencing resulted in the emergence of a more thorough test known as WGS, which has the capability to analyse a person's entire DNA [107]. WGS is less susceptible to technical distortions and blind spots and offers a superior diagnostic potential for genetic conditions compared to WES [192].

The lengthy delays by MSAC in funding WES resulted in WES not receiving a recommendation on its own. Instead, a few years subsequent to the initial WES application, WGS was incorporated [191].

Finally, five years post the original application, MSAC ultimately recommended the use of either WES or WGS in children with suspected genetic conditions [108].

Both WES and WGS help medical professionals identify and diagnose children with a genetic condition and play a crucial role in determining a personalised care plan [97, 109]. During this period, many children who could have benefitted from the use of WES or WGS were not able to access it. Without a confirmed diagnosis, they missed out on the opportunity for timely and targeted treatment/management plans as well as the value of knowing a diagnosis for parents to reduce stress and anxiety and enable them to plan for the future [101].

Similarly, while MSAC was in the process of evaluating WES/WGS, rapid whole genome sequencing (rWGS) emerged. Although rWGS diagnoses a comparable number of children as WES and WGS, its time to diagnosis is drastically reduced to an average of 2 weeks, and an impressive 2-3 days for ultra rWGS [12, 110, 111, 137]. This speed is particularly crucial in the Intensive Care Unit (ICU) environment, where time-sensitive decisions for critically ill infants and children can be life-saving [112]. Despite numerous studies demonstrating the benefits of rWGS, it has yet to be listed on the MBS [111, 112, 137].

THE IMPACT

WES/WGS

Providing access to WES and WGS increases the number of children diagnosed and significantly reduces the time to diagnosis for children with suspected genetic conditions [104, 119]. This provides benefits for patients, their families, and the Government. The original MSAC application was for WES and, consequently, the impacts have been modelled as such [191]. Nonetheless, it is important to note that since WGS possesses greater diagnostic capabilities, the modelled impacts might be even more substantial had it been available and used from the MSAC application submission in 2016 to 2020, the year WES and WGS was listed [192, 193].

Compared to the previous standard of care requiring several targeted genetic tests over an average of 6 years, WES can lead to savings for the Government through a reduction in the time to diagnosis, number of tests, specialist appointments and other procedures required [103, 109]. Families can also save on the out of pocket expenses associated with multiple tests and appointments [103, 123].

Knowing a child's diagnosis earlier is of immense value for families. This clarity offers insights into the disorder's cause, its potential progression, and the risks it might pose to other family members. [113] Armed with this knowledge, parents and clinicians can make well-informed choices about treatments and financial planning, reducing the associated cost of its management for families and the Government [109].

The emotional toll of a delayed diagnosis can result in mental health challenges for parents [114, 125]. Obtaining a timelier diagnosis can reduce this mental health and emotional burden [101, 125]. An earlier diagnosis with WES also allows some parents to return to work, increasing their earning potential [123].

Children with diagnosed genetic conditions have greater opportunities to access support services and special education. This provides long term value in allowing a child to reach their full potential and fostering inclusive and equitable access to education. [97]

Beyond the measurable benefits, WES brings countless intangible impacts to patients and the wider society, including better long term patient outcomes [194]. The increase in diagnosis of these rare, genetic conditions may also provide greater awareness and knowledge surrounding these disorders, leading to more research and better treatments or, even, a cure [195, 196].

At present value, if access to WES/WGS had been made available to all children with suspected genetic conditions when the application was submitted in 2016, an estimated **$158.9 MILLION*** in net benefits would have been created in Australia from 2016 to 2020 (the year it was listed).

5,709 additional patients diagnosed over 5 years compared with standard of care

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PRODUCTIVITY **$17.9 M**

in income/savings for parents of children with suspected genetic disorders over 5 years as they avoid missing work to attend appointments with their child due to earlier diagnoses.

OUT OF POCKET COSTS **$7.9 M**

in out-of-pocket costs saved by parents of children with suspected genetic disorders over 5 years due to an earlier diagnosis.

IMPROVED MENTAL HEALTH **$5.4 M**

saved by the Government over 5 years in reduced mental health service costs due to earlier diagnoses and the resulting improvement in the mental health of parents.

TESTS, APPOINTMENTS AND OTHER COSTS **$3.0 M**

saved by the Government over 5 years on avoided unnecessary tests, appointments and other costs due to an earlier diagnosis.

VALUE OF KNOWING **$109.6 M**

saved by parents of children with suspected genetic disorders over 5 years due to more diagnoses being made and the information this provides to parents.

SUPPORT SERVICES **$15.2 M**

saved by the patient over 5 years due to improved access to support and special education services due to increased diagnoses.

Source: Calculated from [49, 103, 115, 118-121, 125-133]
Notes: Direct and indirect cost savings and benefits associated with access to WES/WGS were sourced from Australian data. Cost savings for each year were extrapolated to include the five years that WES/WGS was not available to patients through the MBS from date of application for consistency with other case studies.
*The net cost to the Government for WES/WGS compared to standard of care is $10.7 million. The net out of pocket cost to parents for WES/WGS compared to standard of care is $1.6 million. The cost is higher for WES/WGS due to the short time horizon.

RAPID WGS

Compared to WES/WGS, the introduction of rWGS has now enabled clinicians to diagnose rare genetic conditions in critically ill infants and children (collectively called children throughout this section) who require immediate and effective care [104]. Economic models based on real world clinical studies estimate cost savings for the Australian health system after implementing rWGS in the neonatal or paediatric ICU [110].

Diagnosing more patients earlier can eliminate the need for numerous tests, prevent unnecessary treatments and decrease the length of hospital admissions, significantly reducing Government hospital spending [110]. Reducing time spent in hospital also reduces the amount of time a parent spends in hospital away from work or alternative tasks [110, 197].

With rWGS, diagnosis can occur in less than 14 days [110]. A timely diagnosis maximises the opportunity to appropriately treat these critically ill patients and rapidly provide lifesaving treatment [100, 109]. Substantial cost savings are also incurred by the Government in lives saved [138].

Obtaining a precise diagnosis for a critically ill child not only provides valuable knowledge but also offers a sense of reassurance to parents [198]. It empowers them with crucial information about the disease, its origins, how it progresses, and the potential risks it poses to other family members [115]. The impact on a patient's family is also evident in the opportunity for cascade testing which facilitates decisions around reproduction and risk management. Increased diagnoses increase the opportunity for family members to be tested and diagnosed [115, 131].

Parents of critically ill children with suspected genetic conditions can experience improved welfare and mental wellbeing [109]. Reducing time to diagnosis increases a child's chance of receiving better care, alleviating the mental burden on parents associated with an uncertain diagnosis and treatment plan [109].

"...there is so much angst waiting for results and this is compounded by caring for a very sick child. Having the test come back quickly lifted an incredible weight and stress from our shoulders [115]."

As above, beyond the measurable benefits, rWGS brings countless positive impacts to patients and the wider society that cannot be adequately measured due to the lack of data available. Obtaining a diagnosis can also lead to palliation, ensuring a child is not suffering unnecessarily before they die [104, 129].

At present value, if rWGS had been made available to all patients that could benefit from it when the Acute Care Genomics Study had been established in 2018, an estimated **$370.6 MILLION** in net benefits would have been created in Australia over the past 5 years.

PRODUCTIVITY

$1.0 M

in income/savings for parents of critically ill infants and children with suspected genetic disorders over 5 years as they avoid missing work to stay in the ICU with their child due to earlier diagnoses.

CASCADE TESTING

$341.9 K

in savings for parents of critically ill infants and children with suspected genetic disorders over 5 years as they have the opportunity to be tested and risk manage for subsequent pregnancies.

AVOIDED DEATHS

$344.3 M

saved by the Government over 5 years due to the lives saved by earlier diagnosis enabling faster and better treatment.

HOSPITAL COSTS

$9.2 M

saved by the Government over 5 years on avoided unnecessary tests and treatments and reduced hospital length of stay due to earlier diagnoses.

VALUE OF KNOWING

$6.9 M

saved by parents of critically ill infants and children with suspected genetic disorders over 5 years due to more diagnoses being made and increased information provided.

IMPROVED MENTAL HEALTH

$8.8 M

saved by parents of critically ill infants and children over 5 years with improved wellbeing and mental health due to earlier diagnoses.

Compared to standard of care, 360 additional patients diagnosed over 5 years

Source: Calculated from [12, 48, 49, 104, 111, 113, 119, 135, 140-145]
Notes: Direct and indirect cost savings and benefits associated with access to rWGS were sourced from Australian data. Cost savings for each year were extrapolated to include the five years that rWGS was not available to all patients from when the Acute Care Genomics Study had been established.

THE VALUE

Delays in accessing new innovation such as WES/WGS leads to missed opportunities for cost savings and benefits that could otherwise be realised by patients, their families and the Government. Time is precious and responsiveness is critical for children with genetic disorders, as quicker and fewer tests can improve survival and quality of life.

Obtaining a diagnosis enables treatment personalisation, ensuring that children can receive the best possible care. The value of receiving a diagnosis for a child, particularly when seriously ill or after years of investigations and unanswered questions, is far-reaching. Knowing a diagnosis alleviates the mental burden on parents and helps them make informed decisions regarding their child's care. This includes enabling the difficult decisions surrounding palliative care, which can provide peace to families, relieve the suffering of a child and improve their quality of life. Alternatively, parents can hope for better treatment and long term outcomes for their child and plan for their future.

Diagnosing more children with rare, genetic disorders also promotes knowledge dissemination throughout a family with cascade testing. This not only aids in identifying and managing the condition in other family members but also informs family risk management and future pregnancies.

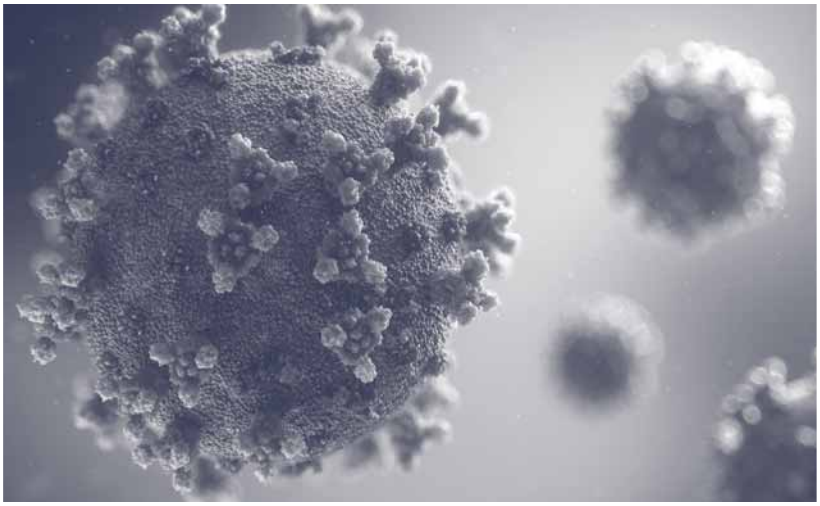
Advances in sequencing technologies like WES, WGS, and rWGS enhance diagnostic precision, yet slow adoption has cost $530 million. Accelerating access to these technologies is crucial for a healthcare system capable of effectively managing rare genetic disorders in children.

REALISING THE VALUE

Genomic Testing Better Understood and Implemented at Scale Through Diagnostics Expert Advisory Body (EAG)

Governments and Health Departments around the globe are coming face-to-face with the complexity of genomic testing, coupled with its rapidly accelerating development and links to underlying digital and artificial intelligence (AI) technology – a big ask among the rest of the complexity within the healthcare landscape. To effectively deploy this technology, at scale, in an equitable and affordable manner requires guidance from the subject matter experts currently supplying, delivering, and safeguarding our healthcare services – the pathology technology industry, pathology providers, digital and data infrastructure service providers, and specialist clinicians and service providers. Aligning with and extending existing EAG activities associated with Genomics Australia, or rolling up to a broader Diagnostic EAG with a continuing role of guiding policy and market access processes, will centralise decision-making and maximise opportunity to improve patient access in a targeted, safe, and cost-effective manner.

TOWARDS HEALTH EQUITY: COVID-19 POINT OF CARE



There have been **over 11.5 million COVID-19 infections** in Australia since the pandemic began

Over 22,700 **COVID deaths** between 2020 and 2023

3% of COVID-related hospitalisations require admission to the ICU

COVID-19 has cost the economy **$158 billion**

BURDEN OF DISEASE

The coronavirus disease of 2019 (COVID-19) was declared a worldwide pandemic in March 2020. Since then, multiple waves have infected over 11.5 million Australians and caused over 22,700 deaths [139].

COVID-19 is highly infectious and results in a wide range of symptoms. While many people experience mild symptoms, some can become seriously infected and are hospitalised. For patients who are hospitalised, 3% require admission to the ICU. [140] Older people and those with pre-existing medical conditions like cardiovascular disease have a higher risk of severe disease [139, 140]. First Nations people in remote communities, who experience a burden of disease that is 2.3 times the rate of non-Indigenous Australians, are also more likely to be affected by COVID-19 [141].

Extensive and rapid public health measures - such as contact tracing, physical distancing, testing and subsequent isolation - were employed as a response to the pandemic [140]. While these measures allowed Australia to avoid many of the worst effects of COVID-19 seen abroad, the pandemic still had, and continues to have, major impacts on the health and wellbeing of the community [142-144].

COVID-19 is estimated to have cost the economy $158 billion and a number of shortcomings in Australia's response to the pandemic have contributed to this huge cost [32]. Insufficient planning, inadequate infrastructure, and a lack of national coordination of public health measures reduced our capacity to respond in a timely and efficient manner. Further investment in these areas is critical to ensure the healthcare system is ready to face the challenges that the next pandemic will bring [142].

THE INNOVATIVE TECHNOLOGY

COVID-19 is a highly infectious disease that presents significant risks to First Nations people in rural, regional or remote communities. These communities are already at a higher risk of poor health due to a history of colonisation, multiple underlying conditions, limited access to medical facilities and challenges in isolating from others [145]. As laboratory services that test for COVID-19 can be hundreds of kilometres away for many of these communities, molecular POC testing is particularly beneficial. Molecular POC testing enables swabs to be tested for the virus within the health service by trained health care staff and provides an accurate result within 45 minutes [141]. Performing a Nucleic Acid Amplification Test to detect viruses, such as COVID-19, the technology can also be used to detect the presence of bacteria such as tuberculosis [145-147]. Molecular POC testing technologies aim to intervene at every stage of the disease to quickly and accurately identify infected patients [145-147]. This technology has played a key role in containing the multiple COVID-19 outbreaks in Australia [145-147].

The Aboriginal and Torres Strait Islander COVID-19 POC Testing Program was established in March 2020 as an immediate response to the pandemic. The Program was implemented under the governance of the National Aboriginal and Torres Strait Islander COVID-19 Advisory Group and led by The Kirby Institute University of New South Wales (NSW) and Flinders University International Centre for POC Testing. It involved molecular POC testing delivered within remote health clinics to First Nations communities, run by Aboriginal Community Controlled Health Services and state/territory health services [145, 146, 148]. The provision of molecular POC testing enabled COVID-19 to be identified, treated, and contained in a quick and accessible way to prevent widespread community transmission [145-147].

THE INNOVATION

An evaluation of the Aboriginal and Torres Strait Islander POC Testing Program demonstrated its effectiveness in delivering fast and accurate on-site molecular POC testing when rapid antigen tests were not yet available in Australia. Molecular POC testing enables swift initiation of public health interventions, including rapid community vaccination programs, to help prevent the potentially severe health impacts of COVID-19. [145] Without this testing program, people would have had to wait around 6 days for a result from a centralised laboratory. However, because the Program was funded in a timely fashion, the opportunity to identify positive cases was maximised, enabling effective contact tracing and breaking the link in transmission. It is estimated that in the first 40 days from the first case being identified, between 23,000 and 123,000 infections were averted as a direct result of the Program. [145]

Molecular POC testing also provided protection for those at particularly high risk of developing severe illness, by early identification of a positive case. It is estimated that at least 83,000 hospitalisations and 6,319 ICU admissions due to COVID-19 infection were avoided over 2 years because of POC testing, and around 16,875 medical evacuations were also likely to have been avoided. [145]

Prior to the implementation of molecular POC testing, some remote communities were chartering flights to transport swabs and symptomatic individuals to the nearest town to isolate while waiting on a test result. The prevention of this air travel through POC testing would have also significantly benefitted the environment through a reduction in carbon emissions. [145]

The implementation of the COVID-19 POC Testing Program in rural First Nations communities saved the Government between **$337 MILLION AND $1.8 BILLION** over the first 40 days following the identification of the first case of COVID-19.

INFECTIONS

Between 23,000 and 122,000 COVID-19 infections averted in the first 40 days following the identification of the first case of COVID-19

HOSPITALISATIONS

At least 4,564 hospitalisations due to COVID-19 infection averted in the first 40 days following the identification of the first case of COVID-19

ICU ADMISSIONS

At least 346 ICU admissions due to COVID-19 infection averted in the first 40 days following the identification of the first case of COVID-19

MEDIVACS

At least 924 medical evacuations due to COVID-19 infection averted in the first 40 days following the identification of the first case of COVID-19

Source: Department of Health and Aged Care [145]
Notes: Results are taken from the Department of Health and Aged Care 2022 report. The report did not account for the introduction of vaccination and rapid antigen testing and assumed 70-100% compliance with community lockdown. Deaths and other costs associated with non-hospitalised patients were not included in the calculations.

THE VALUE





The more infectious a disease, and the further away from centralised laboratory services a community, the more valuable POC testing becomes [145]. The provision of molecular POC testing during a global pandemic when the effects of a viral infection were largely unknown enabled communities to conduct testing within their health service where they otherwise would have had to rely on centralised laboratory services. The implementation of the POC Testing Program in a swift manner ensured that the true value of molecular POC testing was realised. Healthcare resources were utilised in the most efficient way possible and services were able to continue operating.

POC testing provided easy and equitable access of care to rural, regional, and remote populations vulnerable to the effects of COVID-19. The test enabled the protection of close contacts and rapid treatment for those who needed it. Positive cases and their close contacts were identified as early as possible, minimising transmission and keeping communities safe while avoiding substantial costs.

The Aboriginal and Torres Strait Islander POC Testing Program has also provided immeasurable value in the foundational infrastructure it has created. This model can be leveraged for future pandemic or outbreak responses that necessitate a quick and effective response to protect the community.

REALISING THE VALUE

Expanding the Impact of point of care (POC) COVID-19 Testing Through a National Diagnostics Strategy and Action Plan

The exceptional impact demonstrated by the effective and targeted use of POC COVID-19 testing does not have to be limited to emergency pandemic response plans. Lessons learned from this project can be recorded and applied throughout the country, coordinated through a National Diagnostic Strategy and Roadmap, and applied to a range of populations and healthcare needs. Such a plan can centralise and focus limited health resources and budgets and maximise the value that is offered through pathology technology. Centralising knowledge and response processes in this way helps to connect existing silos within our healthcare landscape, reducing wasteful repetition and expanding benefit to more patient populations.

SINGLE VISIT, LASTING CURE: HEPATITIS C POINT OF CARE TESTING

115,000 people live with chronic HCV, and **many are unaware that they have it**

A CURE is available for people diagnosed with HCV

Testing of HCV is declining

Between 2016-2030...
HCV could cost **$3.0 billion in direct health costs** and **$26.1 B in lost productivity and premature deaths**

BURDEN OF DISEASE

Hepatitis C (HCV) is a viral infection that affects the liver. HCV is spread through contact with infected blood. This can happen through sharing needles or syringes, or from unsafe medical procedures such as blood transfusions with unscreened blood products. [150] About 70% of people with HCV develop a chronic (long term) illness. The prolonged infection can lead to severe liver damage, including scarring (cirrhosis) and liver cancer, which can be life threatening. [150]

In Australia, over 115,000 people live with chronic HCV, with many unaware of their status [151]. In 2021 alone, Australia saw 7,487 new cases [152], with higher rates in rural and regional areas [152] and among the Aboriginal and Torres Strait Islander communities.

Although no vaccine exists for HCV, there are effective new treatments known as direct-acting anti-virals (DAAs). These treatments are available in Australia and can not only treat but cure the disease [150, 153].

With a curative treatment available, WHO has set a goal to eliminate HCV virus infection by 2030. However, Australia's ability to reach this goal is threatened by declines in HCV testing and treatment globally. The main obstacle to increasing HCV diagnosis and treatment is the current diagnostic process, which often requires approximately five visits and up to 4 weeks before receiving a diagnosis. This can result in many people being lost to follow-up. This problem is particularly pronounced in key target populations, such as people who inject drugs, individuals in prisons and Aboriginal and Torres Strait Islanders. [154]

If testing and treatment continues to decline, between 2016-2030, it could cost $3.01 billion in direct health costs (treatment, testing and disease management), and $26.14 billion in lost productivity and premature deaths [155].

THE INNOVATIVE TECHNOLOGY

Timely diagnosis and treatment of HCV is critical to achieve the WHO elimination goal [14]. Traditional testing pathways involve an HCV antibody test to confirm exposure and an HCV RNA test to detect active infection [154], thus requiring multiple visits before gaining a diagnosis. Recent advancements, and availability of finger-stick POC testing has changed clinical management, making it easier and faster to diagnose and treat patients. The HCV POC tests is accurate [156] and can detect an infection within one hour [154]. The test enables rapid diagnosis and treatment in a single visit, rather than in five visits with conventional testing methods. Patients being lost to follow up is therefore significantly reduced.

With the introduction to HCV POC tests, it has facilitated high HCV treatment uptake in needle and syringe programmes (78%) [157], medically supervised injecting rooms (89%) [158], mobile outreach models (74%) [159], and prisons (93%) [159].

THE IMPACT

Building on the success of the POC testing for COVID-19 implemented with remote Aboriginal and Torres Strait Islander communities (see COVID-19 case study), the National Australian HCV POC Testing Program was funded by the Australian Government. HCV POC testing was made available at sites with high-risk individuals, such as drug treatment clinics, needle and syringe programmes and prisons. The test as well as the cure was therefore brought to the person. [154]

In 2022, 5,733 POC tests were performed and 14% of people were identified as having a current HCV infection [154]. Within the program, it is estimated that 75% of those diagnosed were able to begin immediate treatment, , compared with the 26% to 60% initiation rate seen with conventional testing, which often occurs with a substantial delay [154, 160]. This rapid and efficient POC testing facilitated a broad reach, allowing a large number of individuals to be tested and treated swiftly, providing many with the opportunity for a cure [161]. As a result, it is estimated that the program saved approximately 9 to 29 additional lives, compared to conventional testing methods. These life-saving results and the associated costs were calculated using the best publicly available evidence and more comprehensive analyses are required to determine the full value of the program. Furthermore, while not factored into the cost savings, the average cost to identify patients and initiate HCV treatment via POC testing is estimated to be up to 35% less than that of traditional testing methods [162].

> We have a fantastic opportunity in Australia to eliminate hep C, but to mobilise all the **people with hep C and connect them to treatment and cure** is going to be a major challenge which requires significant resourcing."
>
> Stuart Loveday, CEO, Hepatitis NSW [164]

The implementation of the HCV POC Testing Program saved the Government between **$1.9 and $6.2 MILLION** over one year as a result of saving an additional **9 AND 29 LIVES.**

Compared to conventional testing methods, with access to the program it is estimated that between 9 and 29 HCV deaths were avoided in the one year

TESTS

5,733
HCV POC tests performed over one year across 41 sites

INFECTIONS

14% (713 PEOPLE)
of those treated had a current HCV infection[1]

TREATMENT

75% (535 PEOPLE)
initiated treatment in the program[1], compared to 26% to 60% with conventional testing methods[4]

CURE

Direct acting antivirals (DAAs) **can cure more than 95%** of people who are treated[2] **reducing the risk of death by 8%**[3]

Source: 1. Grebely [154]; 2. World Health Organization [163]; 3. Grebely [154]; 4. Yousafzai [160]
Notes: Results from the program conducted in 2022 Grebely [154], were used to estimate the impact of the number of additional lives saved compared to conventional testing methods. Grebely [154] reported that 535 people initiated treatment. Given DAAs cure at least 95% of people [163], and reduces the risk of death by 8%, it was estimated that approximately 44 deaths due to HCV were avoided because of the program. However, this mortality risk reduction might be overstated, as the HCV-afflicted demographic in the United States is generally older than that in Australia. Nevertheless, an estimate of lives saved using conventional testing was calculated by subtracting the expected number of people who would have initiated treatment without the HCV POC testing program from those saved by the program. The actual advantage of the program, in terms of lives saved, is estimated to be from nine to 29 lives compared to conventional testing. With the value of a statistical life year estimated at $227,000, the Government is conservatively projected to save the cost of one statistical life year for every additional life saved through this initiative. These calculations are based on the best evidence publicly available and strictly account for the savings related to the value of a statistical life. To fully understand the program's comprehensive value, a more detailed economic analysis is required.
Disclaimer: Only publicly available sources were used to develop the model. Kirby Institute were not involved in model development and involved in data interpretation only.

THE VALUE

There is a cure available for those diagnosed with HCV. However, to provide a cure for patients, it relies on detection of the infection. The value can thus only be realised with access to the HCV POC test as well as the program.

Traditional testing methods that are more widely available are resulting in a decline in testing rates as testing and treatment requires up to five visits, while the HCV POC testing program requires one. The POC testing program enables diagnosis and treatment in a single visit, allowing responsiveness to a positive result. Bringing the test to those most at risk and in hard to access areas - in prisons, and in the community such as needle exchange programmes - increases equity. Through a short duration, of the people tested, 14% had a current infection and 75% initiated treatment meaning that most can achieve a cure and can live longer and healthier lives.

For the value of this program to continue to be realised, appropriate funding is vital. Such investment not only holds the potential to save lives and enhance health outcomes but also brings us closer to achieving the WHO's goal of HCV elimination by 2030.

REALISING THE VALUE

A National Diagnostic Strategy and Action Plan can Strengthen Attempts to Eliminate HCV While Aligning Australia's Healthcare System with WHO Recommendations to Strengthen Diagnostic Capacity

This report demonstrates the excellent efforts to reduce HCV disease burden by testing and treating at-risk and traditionally hard to reach populations through POC technology, an activity that not only has immediate personal benefit, but significant society and healthcare system benefits ongoing. These activities are working towards the WHO goal of eliminating HCV by 2030. In February 2023, WHO also released a resolution urging Member States to establish national diagnostic strategies in recognition "that diagnostics are vital for the prevention, diagnosis, case management, monitoring and treatment of communicable, noncommunicable, neglected tropical and rare diseases, injuries and disabilities". Establishment of a National Diagnostics Strategy and Roadmap would align with WHO goals while increasing the sustainability of important initiatives such as those undertaken through the HCV POC testing activities.

TIMELY DIAGNOSTICS, TANGIBLE SAVINGS: THE MULTIPLEX PCR TEST

An infection of the CNS can be **LIFE TREATENING**

Meningococcal disease and encephalitis are **common CNS infections** affecting children

Broad-spectrum antibiotics are often used until a diagnosis is confirmed

=

Increased risk of **antimicrobial resistance**

By 2050, antimicrobial resistance could cost the economy

$370 BILLION

BURDEN OF DISEASE

Infections in the brain and spinal cord (central nervous system [CNS] infections) can be caused by bacteria or viruses. In Australia, meningitis and encephalitis are the common CNS infections in children [165, 166]. These infections have affected more than 4,000 children in Australia over the past 10 years [167, 168]. They can be very serious, leading to an increased risk of death and long term complications, such as cognitive impairment (e.g., memory problems), seizures and loss of vision [169-171].

Prompt medical assessment and treatment for children are critical for survival [169-171]. Treatment must begin immediately with broad-spectrum antibiotics, and once the exact cause is determined, a more targeted therapy should be initiated [171].

To diagnose CNS infections, a sample of the cerebrospinal fluid (the fluid surrounding the brain and spinal cord) is taken for laboratory analysis [172].

However, traditional diagnostic methods require 1 to 3 days to determine the exact cause of infection. This delay means that broad-spectrum antibiotics or anti-virals are used for longer than needed, increasing the child's risk of adverse events, lengthening their hospital stay and accelerating the development of microbial resistance to antibiotics [166, 171]. While only one of many cases in which antibiotics are used, current projections indicate that antimicrobial resistance could cost the Australian healthcare system $370 million by 2050 [173].

Treatment options vary depending on the cause of infection, and the overall health of the child. On average, children with a CNS infection stay in the hospital for 6 days, and each day in hospital costs $1,816 [174, 175]. However, if the exact cause of infection is determined faster, children's health outcomes can be improved and both the length of stay in hospital and its costs can be reduced.

THE INNOVATION

As a countermeasure to the shortcomings of traditional diagnostic methods requiring long incubation times (1-3 days), the Multiplex Polymerase Chain Reaction Meningitis and Encephalitis Panel (multiplex PCR test) was developed [166]. The multiplex PCR test can effectively detect up to 14 potential pathogens of meningitis and encephalitis from a single cerebrospinal fluid sample within 1 hour [166, 171].

The utilisation of this rapid diagnostic tool can lead to significant benefits such as reduced broad-spectrum antibiotic usage, anti-viral usage, shorter hospital stays, and lower hospital costs [166, 171].

THE IMPACT

The effectiveness of the multiplex PCR test in children with CNS infection was compared to traditional diagnostic methods in patients in the Top End region of the Northern Territory, Australia. The impact of the multiplex PCR test in terms of reduction in hospital length of stay was assessed [166].

The impact, however, could be even more significant than that seen in the Northern Territory trial as the multiplex PCR test was not performed immediately after the cerebrospinal fluid was obtained [166]. Had the test been performed immediately, there would have been an even larger improvement in time to determine the exact cause and length of hospitalisation [166]. For example, a study conducted at Australian Capital Territory Pathology estimated that median turnaround time for the multiplex PCR test was 2.9 hours, compared to 21.1 hours for traditional laboratory testing [178].

> **Recognizing the critical role of rapid and accurate diagnostics** to combat antimicrobial resistance by **guiding the correct management** of infections, and the appropriate use of new and existing antimicrobials through improved antimicrobial stewardship and surveillance.
>
> WHO [5]

At present value, if the multiplex PCR test was utilised nationwide, it could lead to Government savings of over **$35.2 MILLION** from reduced hospital days alone over the next 10 years.

TIME TO DIAGNOSIS		Time to confirmatory diagnosis reduced from **6 to 2 days** [1]
ANTI-VIRAL DURATION		Duration of intravenous acilovir administration, which is nephrotoxic, was reduced by **11 hours** [3]
ANTIBIOTIC DURATION		Time using antibiotic treatment reduced from **3 to 2 days** [1]
TIME IN HOSPITAL		Hospital length of stay reduced from **5 to 3 days** [1]

IMPACT

Over 10 years **$35.2 M**
could be saved by the Government in reduced days in hospital [1-6]

~9,684 CNS Infections in children

One day in hospital with a CNS infection costs **$1,816**

19,367 days in hospital avoided with multiplex PCR test

Source: 1. O'Brien [166], 2. Evans [176], 3. IHACPA [174], 4. IHACPA [175], 5. Beaman [177], 6. Huppatz [168]
Notes: The number of days in hospital avoided in O'Brien [166] was used to estimate the total number of avoided days if the multiplex PCR test was adopted nationwide for next 10 years. Calculations on file.

THE VALUE

The impact of the multiplex PCR test is far-reaching. Instead of using broad-spectrum antibiotics or anti-virals, healthcare professionals can prescribe targeted treatments within one hour of collecting cerebrospinal fluid, increasing responsiveness. Children therefore receive access to the right treatment at the right time reducing the risk of death, illness and time spent in hospital while improving equity of care. With hospitalisation costs of $1,816 per day for CNS infected patients, utilisation of multiplex PCR tests could save the Government up to $35.2 million in hospital costs alone over the next 10 years while also significantly improving the welfare and experience of thousands of children [166, 168, 174-177].

Beyond the immediate value, the multiplex PCR test has long term advantages for children and their family. Giving the right treatment at the right time plays a critical role in the global fight against antibiotic resistance. Using targeted treatments more rapidly results in optimisation of current healthcare practices while ensuring antibiotics remain effective for future generations.

REALISING THE VALUE

Unlocking the Potential of Multiplex PCR Testing Through the Guidance of a Diagnostic Advisory Group and National Diagnostic Strategy and Roadmap

Technology advancements that disrupt status quo processes, such as the multiplex PCR test for CNS infections, can often face several hurdles for adoption due to the silos across cost centres and where value is realised. We can achieve a more holistic, sustainable, and economical approach to assessing innovation in pathology technology where the full Value Fountain of reduced hospital stays, support of antimicrobial stewardship practices, and equity of care across all populations are enshrined within a National Diagnostics Strategy and Roadmap, with implementation guided by a Diagnostics Expert Advisory Group.

SAVE LIVES WITH LESS BLOOD: POINT OF CARE COAGULATION TESTING

~ **1 in 5** patients receiving a massive transfusion die

Blood is a vital **natural resource** and is identified as one of the top over-utilised treatments

$1.2B
is spent each year on blood products associated hospital experiences

BURDEN OF DISEASE

During surgeries, organ transplantation, childbirth, or when there has been a car accident or other injury, there is a risk of heavy bleeding [179]. When a person bleeds heavily (known as a major haemorrhage), patients require administration of large volumes of blood [179]. Managing these events can be complex, and is life threatening for patients [180]. In Australia between 2011 and 2015, almost 1 in 5 patients receiving a massive transfusion did not survive [102].

Blood, a vital natural resource, forms the cornerstone of our healthcare system [181]. Blood is generously donated, and excessive blood use places a huge burden on health expenditures. Australian annual expenditure on blood products is staggering, exceeding $1.2 billion [181, 182]. Each unit of red blood cells costs around $412 [183]. Inclusive of hospital expenses, a single transfusion could cost over $1,000 per patient. [183]

Appropriate use of blood not only conserves this invaluable resource but also minimises health complications such as allergic reactions and the potential of disease transmission. With 29,000 donations made weekly in Australia, blood transfusion is a common therapeutic procedure, however it is frequently overused. Excessive blood usage and its impact on patient outcomes emphasise the importance of Patient Blood Management (PBM) programs, especially in a world where healthcare budgets are tightening as the population is ageing. [183]

THE INNOVATION

PBM is aimed at enhancing clinical outcomes by reducing unnecessary use of scarce blood supplies [184, 185]. POC coagulation tests are important in achieving the aims of PBM as the test provides detailed information in only 5 to 20 minutes, enabling fast and targeted treatment decisions [186]. In comparison, conventional coagulation tests offer limited information and targeted treatment decisions take between 40 to 60 minutes [186].

The World Health Organization strongly supports the adoption of POC coagulation tests as part of PBM, highlighting its ability to guide healthcare professionals in blood product selection, expedite outcomes, reduce reliance on donor products, and prioritise patient-centred care [185]. Although Australia pioneered this domain, its adoption of POC coagulation tests has been slow. Queensland and Western Australia have incorporated this technology into their care, but not all states have followed suit. One reason is that the POC coagulation tests are more expensive than conventional tests. While pathology budgets incur the full expense of these tests, the broader benefits and cost savings of faster and more detailed testing to the wider healthcare system are not accounted for within the pathology budget. POC coagulation tests have therefore not been consistently funded across states, despite the clear benefits to patients and the healthcare system as a whole.

THE IMPACT

The world's largest study on the impact of implementing a PBM program and adopting POC coagulation testing was conducted in Western Australia. The study included 600,000 patients admitted to Western Australia's four major adult hospitals between 2008 and 2014.

Over the six-year study period, the program was associated with healthcare system and resource savings with a significant reduction in the use of blood and long-term improvements in patient outcomes. [187]

If PBM, including access to POC coagulation testing, was adopted nationwide it could lead to Government savings of between **$1.4 AND $1.8 BILLION** over the next 10 years.

PBM IMPLEMENTATION		**$1.4 to 1.8 BILLION** could be saved on **transfusion administration, hospital and blood poduct costs** over 10 years if PBM, including access to visoelastic testing was adopted nationwide
BLOOD PRODUCT UTILISATION		**$324.9 MILLION** could be saved on **blood products** over 10 years if PBM, inculding access to POC coagulation testing was adopted nationwide
RED BLOOD CELLS		**41% reduction** in use of red blood cells
PLASMA		**47% reduction** in use of plasma cells
PLATELETS		**27% reduction** in use of platelets
TIME IN HOSPITAL		**15% reduction** in hospital length of stay
MORTALITY		**28% reduction** in hospital deaths
STROKE		**31% reduction** in number of strokes

Source: Leahy [187], IHACPA [175]
Notes: The findings from Leahy [187] included data on hospital admissions in four major hospitals in Western Australia and the cost savings over 6 years if PBM and POC coagulation testing is used. The cost savings calculated from Leahy [187] were then used to project potential savings if PBM were adopted nationwide for ten years. Calculations on file.

THE VALUE

The POC coagulation test as part of PBM has the potential to enhance healthcare delivery and optimise resources throughout Australia, moving beyond the specific states or hospitals that currently use it. With faster and more precise treatment decisions, the POC coagulation test not only improves patient health outcomes but also considerably reduces medical expenditures.

By facilitating faster and more precise treatment decisions there is a substantial decrease in the consumption of blood – a precious resource generously donated. This not only conserves the invaluable blood resource but also reduces the associated costs of transfusion administration. POC coagulation tests can provide a more responsive healthcare approach, underscoring its immense value in the broader context of hospital efficiency.

REALISING THE VALUE

POC Blood Coagulation Testing Clear Case for National Diagnostics Strategy and Roadmap

Finite healthcare budget and resources are a constant limiter to the quality of care on offer, which is why it is even more important to devise a National Diagnostics Strategy and Roadmap that can improve the utilisation of critical healthcare resources such as our nation's blood products. Such a plan can provide an umbrella understanding of the Value Fountain provided through the targeted use of pathology technology and overcome the silo of cost burden vs return on investment that routinely stymies national adoption.

It [diagnostics] enabled access to a targeted treatment option to manage and prevent metastases of a rare cancer and without this targeted treatment, I simply wouldn't be here.

I hope that other patients are educated and empowered to pursue diagnostic testing interventions and hope that, with increased funding and support and improved access, that the right treatments are available, for the right patient, at the right time.

After all, patients deserve hope, confidence and most importantly, a shot at life.

– Emily, NUT Carcinoma

OVERVIEW OF CASE STUDIES

The innovation provided by pathology technology can be transformative, and timely access to such technologies can bring a vast array of benefits to the Government, patients, families, and the community. Value that could have been provided by NT -proBNP and the PE ratio test are still yet to be realised. Value brought by the HRD test as well as the WES and rWGS was delayed by many years due to the long HTA process.

		PERSONALISATION	RESOURCE OPTIMISTION	KNOWING	HOPE	CURE
TOTAL VALUE FOREGONE	NT-proBNP		✓	✓		
	PE RATIO TEST		✓	✓		
	HRD TEST	✓			✓	
	WES AND Rwgs	✓		✓	✓	
TOTAL VALUE GAINED	COVID POCT					
	HEP C POCT					✓
TOTAL POTENTIAL VALUE	POC COAGULATION TESTS		✓			
	PCR MULTIPLEX		✓			

"**Equitable access to safe, effective and quality assured diagnostics requires a comprehensive health-systems approach that addresses all stages of the value chain" - WHO [5]**

LIFE	RESPONSIVENESS	PREVENTION	KNOWLEDGE DISSEMINATION	EQUITY	COMMUNITY	EFFICIENCY
	✓			✓		✓
✓				✓		✓
✓		✓		✓		
	✓		✓			
	✓	✓		✓	✓	✓
✓	✓			✓	✓	
✓	✓			✓		✓
✓	✓			✓		✓

THE CALL TO ACTION: REALISE THE VALUE OF PATHOLOGY TECHNOLOGY

To continue to realise the broad value of pathology technology including those tests highlighted in this report, Australia should adopt a model for pathology technology that changes our core perspective.

Contributing to a Wellness Economy

The overarching vision is a healthier Australia firmly based on a Wellness Economy. With this foundation, future policy and funding decisions move us incrementally but purposefully towards this outcome. This vision firmly supports and is a key contributor to the Treasurer's Wellbeing Framework.

Establishment of Diagnostic Advisory Group

A multi-disciplinary advisory group that includes healthcare professionals and service providers, patient advocacy groups, industry bodies, and Government representatives. The group would advise on IVD-related health policy and funding, including the creation of a National Diagnostics Strategy and Roadmap, and adjudicate on high-medical value IVDs. They could also conduct periodic horizon scanning activities and potentially assist in identifying high-value Australian IVD innovations for accelerated local commercialisation initiatives to boost our sovereign capacity and support high-tech manufacturing. This group could also form the link between our major health strategies, such as the recently announced Australian Cancer Plan, and service providers, ensuring technology suppliers can develop and supply devices required to achieve our national healthcare goals.

Establishing a National Diagnostic Strategy and Roadmap

National leadership offers recognition for the critical role diagnostic tests and technology play in moving Australia to a wellness-based health economy. This position has many aspects, including the greater planned and funded use of diagnostic technologies such as genomics, proteomics, POC, and digital enablers (including AI). These technologies are advancing at speed, and current processes for funding and incorporation into routine healthcare are no longer fit for purpose. The rapidly changing nature of this sector demands a clear strategy and roadmap to ensure patient outcomes are improved and costs are reduced. These actions will set Australia on the road to a Wellbeing Economy.

It also brings us into alignment with the WHA recommendation for countries to establish a diagnostics strategy.

> **Consider the establishment of national diagnostics strategies, as part of their national health plans, that include regulation, assessment and management of diagnostics and development of integrated networks to tackle all diseases and medical challenges, avoiding current silos often observed**
>
> **WHO [5]**

Patient-Centred Strategic Elements to Support National Health Goals

Under the guidance of a Diagnostics Advisory Group, we could ensure our National Diagnostics Strategy and Roadmap (NDSR) had a strong patient-centric focus, encompassing the full Value Fountain as outlined in this report. Pathology technology is a keystone of our healthcare system – impacting almost every element of healthcare from diagnosis to prognosis. We must address the existing barriers to access if we are to secure the success of any other national healthcare priority. A brief overview of the priorities and key asks on the Department of Health and Aged Care demonstrate the clear need for a nationally coordinated approach that draws on the subject matter expertise of those currently supplying, delivering, and safeguarding our healthcare services.

Recent reports from Government, Patient Advocacy Groups, and Peak Bodies:

1. The Diagnostic Technology Sovereign Capability & Resilience National Action Plan identified the role of a NDSR as well as a legislated EAG to drive sustainable sovereign capability in key areas of the IVD sector.

2. The Intergenerational report acknowledges ""escalating health pressures, it will be important to ensure that the health system provides value for money. This requires a health system that innovates and prioritises funding a patient-centred and sustainable Australian healthcare system that delivers the best outcomes for communities

   This will require funding arrangements that continue to effectively invest in preventative health and evidence-based health care spending."

3. The Department of Health and Aged Care Capability Review identified a critical challenge to “increasing focus on preventative healthcare”, the “need to address inequities between different population groups” and “the need to improve the sustainability of the health system”. That same report acknowledged the need for the Department to be “on the front foot in terms of opportunities in the rise of personalised medicine, mRNA technology, digital technologies, the promise of artificial intelligence and the revolution in genomics” - all of which can be served through a NDSR and Diagnostic Advisory Group.

4. Rare Cancer’s Rarefication: Personalised medicine in the genomic revolution calls to ”progress a coordinated national genomics strategy, as well as the need to adequately prioritise research into genomic studies and precision oncology”. The same report calls for “a new pathway in our Health Technology Assessments that encompasses broader value measures”

5. CSIROs Strengthening Australia’s Pandemic Preparedness calls to “develop a diagnostics deployment strategy for scaling POC testing applications,” implement a diagnostics development program aimed at small and medium sized enterprises”, and to “Strengthen translational science to help bridge the gap between research, industry and the health system”

6. ATSE Tech-Readiness Health Report highlighted technology as a solution to improve equity of access to healthcare and called on Government to support “investment in improving pathways to commercialisation for Australian-developed medical technology”.

7. Cancer Australia Australian Cancer Plan highlights the need for preventative and early detection measures that rely on a streamlined process of funding evolution in genetic tests and technology that underpin these goals.

THE PATH FORWARD

In today's dynamic landscape of healthcare innovation, pathology technology stands as a beacon of promise, offering transformative potential for improving patient outcomes and advancing healthcare in Australia. It is a pivotal moment for the nation, where embracing this often under-valued facet of healthcare can take Australia from a nation primarily treating chronic diseases to a proactive healthcare society that pre-empts and manages illnesses before they take a firm grip. The discourse in this report presents an irrefutable case for the Australian federal Government to recognise the invaluable contribution of pathology technology and cultivate a comprehensive perspective.

Pathology technology cannot be confined as a budgetary line item in Australia's healthcare system. When harnessed with a clear purpose, it forms an essential cornerstone of our healthcare infrastructure with broad-reaching effect. Its significance is being recognised globally; the World Health Organization acknowledges pathology technology as one of the five most promising areas of innovation, and the recent World Health Assembly (WHA) is urging Member States to elevate the role of diagnostics in their healthcare approach.

Timely investment in pathology technology provides gains in healthcare system efficiency, advances in disease prevention, and optimisation of responses and resource management. This value transcends obvious fiscal gains; benefiting the Government, patients, families, and society at large. Timely investments in this space go beyond the pioneering of healthcare solutions; it’s an opportunity to fortify Australia's leadership position in an ever-evolving medical field.

Our current reimbursement pathways - complex and outmoded - struggle to keep pace with technological advancement. Fragmented funding structures, distributed across federal and state governments, foster inefficiency and impede the timely provision of innovative pathology technologies. Delayed access to these technologies has imposed a high cost that extends beyond dollars and cents. This report demonstrates over $7.0 billion has been forfeited due to delays in providing funded access to high-medical value technologies.

Consider, for instance, the delayed introduction of GP-requested NT-proBNP for suspected heart failure or the PE ratio test for pre-eclampsia. A staggering $5.9 billion could have been preserved by averting ED visits. Furthermore, timely access to the PE ratio test could have spared the Government another $235 million in reduced hospital admissions. Notably, the delay in providing access to WES/WGS meant that 1,068 additional children were left without a diagnosis, missing out on the vital support they and their families needed.

The Government's potential benefits from acknowledging the value of pathology technology are substantial. Programs such as COVID-19 and HCV POC testing exemplify the immense benefits of early detection and patient-centred testing. These advantages translate to a substantial value of at least $1.8 billion, potentially saving countless lives. For instance, compared to conventional testing methods, the HCV program using POC testing saved an estimated 8 lives within a single year.

Embracing the broader spectrum of innovative pathology technology, including the Multiplex Assay for CNS infections and the POC coagulation test, could yield over $1.8 million in avoided hospital costs over the coming decade. Pathology technology holds the key to superior resource utilisation, heightened healthcare efficiency, and improved patient health outcomes. The development of the "Value Fountain" concept underscores the untapped potential that must be harnessed when considering investments in this field.

The recent Intergenerational Report underscores the mounting cost pressures on healthcare expenditure, driven by an ageing population, increased rates of chronic disease, and the escalating demand for high-quality healthcare services. This juncture represents an opportune moment for Australia to pioneer a nationally consistent framework for comprehensively assessing technology's value in healthcare, including pathology technology.

Australia urgently requires a more comprehensive and inclusive approach that encapsulates the total value of pathology technology to patients, their families and to Government (both in terms of costs and lost productivity). In addition to HTA reform, the provision of an accelerated access program for high-medical value and promising innovative technologies is essential to curtail access delays.

A natural progression from this recognition is the development of an overarching Diagnostics Advisory Group to devise a pathology technology strategy for Australia – a NDSR. This comprehensive strategy should encompass a National Genomic Strategy (to replace the guidance that expired in 2021), digital health initiatives, including the strategic use of AI, POC testing, and a roadmap for innovative technology development, as recommended in the ADAPT Diagnostics Report [189].

As Australia stands at the threshold of transformative change in healthcare, pathology technology offers a wealth of opportunity. Through visionary leadership, innovative strategies, and judicious investments, we can unlock pathology technology's full spectrum of value, securing a brighter and healthier future for Australia.

But while Australia has changed a lot, Medicare hasn't changed much at all.

That same fee-for-service model that provided rebates to local doctors in 1984 is still largely intact, some forty years later.

And as the years have passed, it's started to show its age...

The case for reform is now urgent. We can't keep trying to treat 21st century Australia with 1980s Medicare.

The Hon Mark Butler MP [188]

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ABBREVIATIONS

AI	Artificial intelligence
ARTG	Australian Register of Therapeutic Goods
BNP	B-Type Natriuretic Peptide
CNS	Central nervous system
DAA	Direct-acting anti-virals
ED	Emergency department
GP	General practitioners
HCV	Hepatitis C
HRD	Homologous recombination deficiency
HTA	Health Technology Assessment
ICU	Intensive Care Unit
IVD	In Vitro Diagnostic
MBS	Medicare Benefits Scheme
MSAC	Medical Services Advisory Committee
NDSR	National Diagnostics Strategy and Roadmap
NHMRC	National Health and Medical Research Council
NSW	New South Wales
PBAC	Pharmaceutical Benefits Advisory Committee
PBM	Patient Blood Management
PE	Pre-eclampsia
PMCC	Peter MacCallum Cancer Centre
POC	Point of care
TGA	Therapeutic Goods Administration
WES	Whole exome sequencing
WGS	Whole genome sequencing
WHA	World Health Assembly
WHO	World Health Organization

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