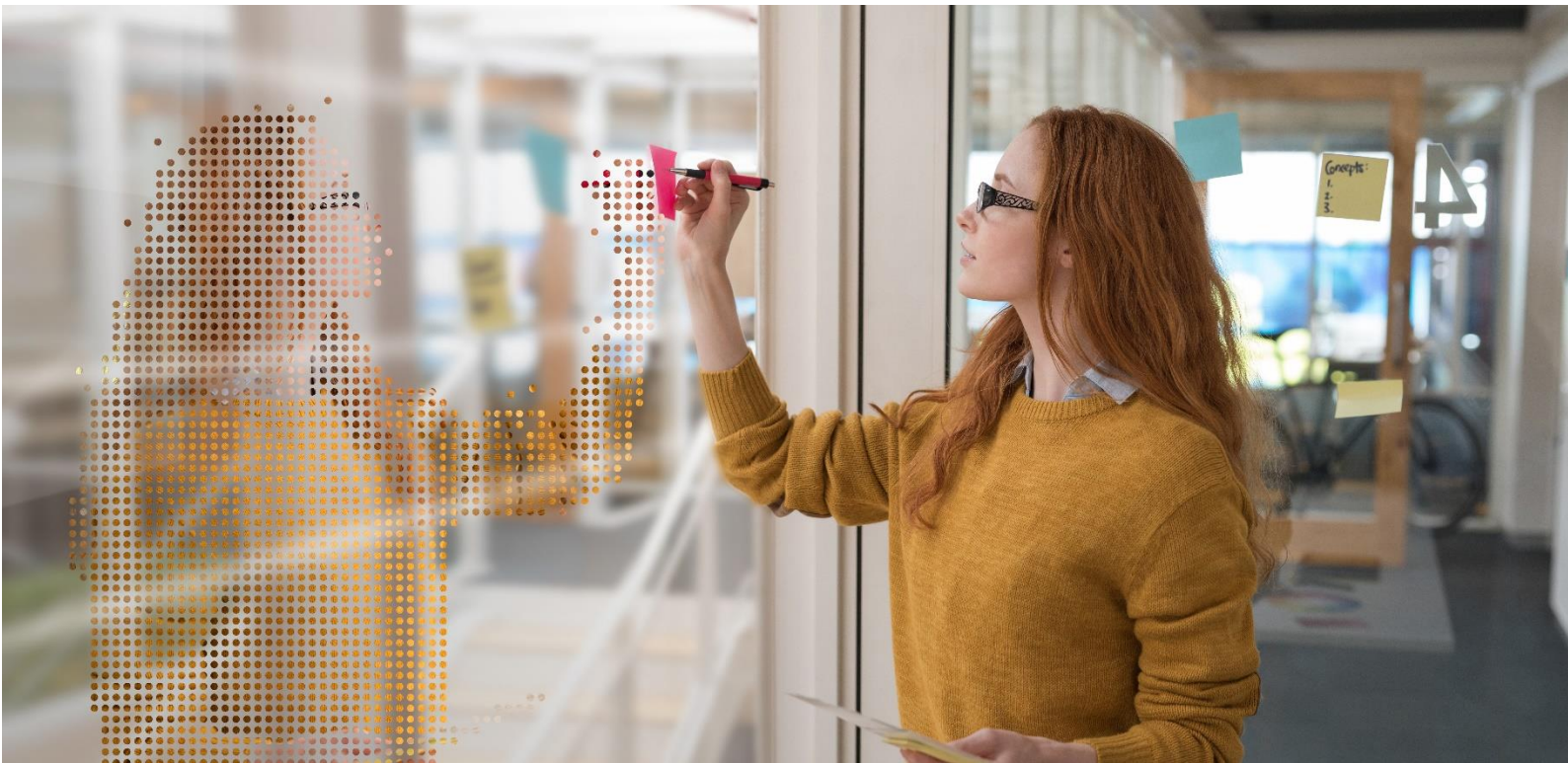
2020-21 Pre-Budget Submission

Roche (Pharmaceuticals) Australia

January 2020



About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in *in-vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them antibiotics, antimalarials and cancer medicines. Roche has been recognised as the leading healthcare company in the Dow Jones Sustainability Indices for ten consecutive years.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2018 employed more than 90,000 people worldwide. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. Roche invests around 11.4 billion US Dollars each year in research and development worldwide, including over AUD 44 million in pharmaceuticals in Australia.

Roche has been present in Australia for more than 60 years and is represented by three divisions: Roche Pharmaceuticals; Roche Diagnostics and Roche Diabetes Care. In Australia, Roche Pharmaceuticals employs over 350 people who are dedicated to the clinical development, registration, sales, marketing and distribution of innovative pharmaceutical medicines. Australian patients have access to around 42 Roche medicines, and the company is the leading provider of cancer medicines in Australia by sales.

For more information, please visit www.roche-australia.com.

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Executive Summary

The Australian Government has an unprecedented opportunity to transform healthcare, utilising the latest innovations to meet patient needs. With a high-quality universal healthcare system, an internationally renowned research sector comprised of world leading expertise in genomics and biotechnology, and investments in data and e-health, Australia is well placed to take advantage of Personalised Healthcare (PHC). PHC is a growing approach to healthcare which utilises patient-level health data generated in various settings to individualise patient care. PHC brings together the capacity of digital technologies (such as data analytics and artificial intelligence) together with advances in biosciences (such as genomics) to provide insights into the patient's lifestyle, environment and genes. These insights are then used to tailor healthcare to that individual patient, improving outcomes.

The PHC approach also encompasses precision medicines which include many innovative treatments such as targeted cancer medicines, cell therapies such as chimeric antigen receptor T cells (CAR-T), gene therapies and even gene editing using CRISPR- Cas9. Leading the implementation of PHC provides Australia with an opportunity to deliver more efficient care and better patient and caregiver outcomes. Additionally, investing in PHC represents a significant opportunity to create future healthcare sustainability by increasing the focus on disease prevention, growing the economy and creating more jobs.

The benefits of PHC and the technologies which underpin this approach to healthcare are already being realised. With a coordinated strategy that leverages Australia's existing Australia could be a world leader in PHC and maximise its many benefits which include improving health outcomes, health system sustainability, economic growth and job creation.

PHC technologies are having, and will continue to have, a transformational impact on healthcare, but are already posing policy challenges. These technologies are evolving at an exponential rate which is outstripping the capacity for responses by Government. For example, many of these technologies are challenging the definition of value, and the approach to evaluating it, used in existing health technology assessment (HTA) processes which underpin reimbursement or funding decisions.

For Australia to reap the benefits of PHC, it is essential that the Government commits to immediate action to create well balanced, well informed and cohesive policy settings that incentivise PHC. The critical first step to achieve this is to resource a collaborative and comprehensive policy development process that integrates and builds on existing initiatives in genomics, medicines, research and data. This policy needs to incorporate early input from a broad range of stakeholders, including industry, to capture expertise and insights into the individual technologies and international best practice.

In addition to the benefits of PHC, Government investment in a comprehensive PHC policy will ensure that Australian patients are able to have timely access to more targeted and effective treatments from among the latest available innovative therapies.

The Australian Government has an opportunity to address this policy gap as a matter of urgency in the 2020-21 Budget. With a large number of PHC technologies already available, a commitment to dedicate Government resources to a PHC strategic plan will ensure the benefits of PHC are not lost to Australia.

Recommendations

1. Develop a publicly available strategic plan with priority actions agreed by stakeholders to implement adoption of PHC in Australia, led by a dedicated Section within the Department of Health;
2. Commit to a review of the existing HTA processes and approaches for genomic tests and emerging technologies to ensure they are suitable for evaluating complex, personalised care models;
3. Better align HTA assessment and funding decisions at the Commonwealth and State Government levels to ensure equity of access; and
4. Strengthen the translational component of Government funded research in PHC, including genomics, to ensure research findings are embedded into routine clinical practice.

Current Environment

PHC is, and will continue to be, a key enabler of better health outcomes. Better health for Australians is integral to the ongoing economic prosperity of the country, through higher workforce participation, and enabling Australians to lead longer, more productive lives. In the 2020-21 Budget the Government can shift PHC policy settings to meet the health needs of our growing and ageing population as health technology innovation increases. Roche supports the Medicines Australia Pre-Budget submission calling for the offsets policy to be removed for new Pharmaceutical Benefits Scheme (PBS) listings.

Access to new medicines and health technologies are increasingly being delivered as integrated patient-focused solutions through PHC. Roche is a world leading innovator in PHC, with technologies such as the latest genomic tests to enable diseases to be targeted with precision medicines. Access to these genomic tests and targeted medicines may currently include clinical trials and some public funding, but often the pathways to funding are not clear.

Australia has an internationally renowned healthcare system that is one of the most equitable and efficient in the world. Despite this, there are two trends which challenge the ability to maintain its world leading health outcomes in the future.[1] The first trend is the rapidly ageing population. Between 1996 and 2016, the number of people aged over 85 years almost doubled, with the associated costs of treating illness for this population likely to increase with 22% of the population projected to be aged 65 or older by 2056.[2,3] The second trend is the increase in chronic disease with around 50% of Australians in 2014-15 identifying as having one of 8 chronic diseases[4] which in 2015-16 were responsible for 37% of hospitalisations and 87% of deaths in 2016.[5,6]

To address these emerging health system challenges, CSIRO proposes shifting the healthcare system towards managing consumer health and well-being by adopting a preventative approach enabled by:

- Empowering consumers
- Addressing health inequity
- Unlocking the value of digitised data
- Supporting integrated and precision health solutions
- Integrating with the global sector[7]

Roche supports this vision for the future of healthcare and is aligned with the view of the World Economic Forum[8] that healthcare systems need to evolve to focus on prevention and wellness. Roche considers that central to this evolution is the development of evidence-based policies which address access and outcomes, recognise innovation and provide the right incentives.

PHC has the potential to reduce the impact of challenges from these health and demographic trends. For example, emerging challenges associated with increases in the number of dementia patients (a disease already costing Australia $14 billion annually)[9] may be addressed by developing PHC solutions which enable earlier diagnosis and treatments through target specific biomarkers of these diseases.

What is PHC?

Personalised healthcare (PHC) is a growing approach to healthcare which utilises patient-level health data being generated in various settings to inform the diagnosis, treatment, management and prevention of disease. This involves:

- generating and accessing deep and broad patient level data from multiple sources, including electronic health records, genomic testing, digital health technologies and advanced imaging;
- applying advanced analytics to derive meaningful insights into patients and their disease; and
- using these insights to discover, develop and deliver personalised care plans

Because the PHC approach focuses on personalising healthcare decisions, it also encompasses precision medicines which include many innovative treatments such as targeted cancer medicines, cell therapies such as chimeric antigen receptor T cells (CAR-T), gene therapies and editing genes using CRISPR-Cas9.

PHC represents a shift in how healthcare is provided as it allows care decisions to be tailored to each individual rather than providing care based on what is likely to work for the average patient population with that condition. Consequently, the patient is likely to have better outcomes.

The rate of innovation in this field is accelerating rapidly. This is driven by technologies which are able to generate large amounts of data (volume), from numerous sources (variety) at an increasing speed (velocity). These technologies coupled with increasing data analytical and storage capability are fuelling PHC growth. As a result, the opportunities and benefits of PHC through deeper clinical insights, better treatment options and more informed patient understanding will only increase over time.

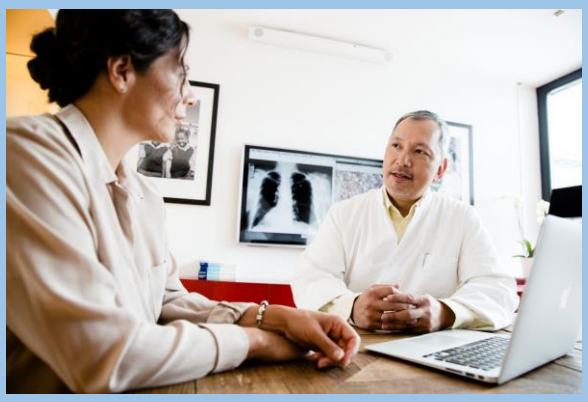
The technologies which support PHC are extensive and fall under the category of medicines, medical devices (including in-vitro diagnostics) and biologicals regulated by the Therapeutic Goods Administration.

Examples include:

- Genomic tests;
- Proteomic tests;
- Medicines targeted at specific biological molecules, including biomarkers, of disease;
- Immunotherapies;
- Cell treatments (such as CAR-T and stem cells);
- Gene editing (such as CRISPR-Cas9);
- Implanted devices which have a monitoring function such as implantable cardiac defibrillators;
- Wearable devices which transmit healthcare information;
- Artificial intelligence backed diagnostics which provide point of care testing (such as an app which can check for skin cancers); and
- Real-time monitoring of diseases like macular degeneration.

PHC incorporates precision medicine technologies such as genomics but is a broader term as it includes technologies such as wearables, apps and remote monitoring systems.

Many countries have already recognised the potential value of genomics, one of the most advanced disciplines of PHC. In particular, they are developing the infrastructure to sequence genomic samples from millions of individuals and store that information for cancers and rare diseases.



In Australia, PHC can ensure patient health outcomes are maintained or improved, address healthcare sustainability challenges and provide opportunities for economic growth.[10,11] Advances in genomics and related laboratory tests have already brought great opportunities for improving health in cancer and rare diseases. In the longer term, there are significant opportunities for precision medicine to improve health outcomes for complex conditions such as diabetes and cardiovascular disease.[12]

An example of the benefits of adopting a PHC approach to cancer relates to new technologies such as large panel genomic tests which are able to be sequenced using next generation sequencing, enabling large amounts of genetic information contained in the patient's tumour to be analysed. In metastatic non-squamous non-small cell lung cancer, identification of the genetic drivers of tumour growth has unlocked high impact treatments for patients, greatly improving their prognosis and long-term outcomes.[13] Building on this identification of genetic drivers, the use of large panel genomic tests will make it easier in the future to identify multiple targets and new high impact treatments.

PHC-enabling technologies such as artificial intelligence, the Internet of Things and precision medicine are driving the Fourth Industrial Revolution.[14] As a pillar of the Fourth Industrial Revolution, PHC is characterised by a fusion of technologies that is blurring the lines between the physical, digital, and biological spheres.[15] How countries invest in, and deploy these powerful new technologies will shape the future.[16,17]

The opportunity of the Fourth Industrial Revolution leverages many of Australia's existing competitive strengths and economic imperatives leading to the creation of new markets, products and services.[18] As such, PHC and precision medicine are prominent strategic opportunities for Australia, with an estimated market for precision healthcare solutions in the Asia-Pacific generating annual revenues worth $30–50 billion within a decade. Furthermore, the market for precision medicine is growing quickly - it was valued at $43.98 billion USD in 2018 and is expected to grow to $86.25 billion USD by 2025.[19]

Given Australia's research strength in biotechnology and genomics, coupled with rich data from the public healthcare system, the Government is in a unique position to promote Australia as a leading provider of precision healthcare products and services to the region[20] and to benefit economically.

The Promise of PHC

Patient benefits

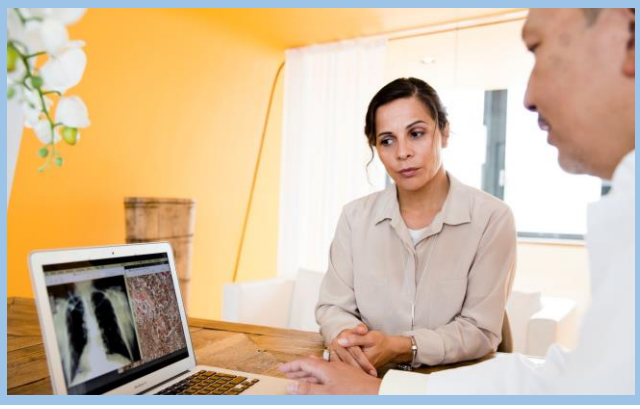
PHC has the potential to improve patient outcomes through:

- targeting treatments to the cause of the patient's disease;
- curing diseases following a single (or low number of) treatments;
- avoiding unnecessary or potentially harmful care;
- providing early diagnosis, enabling earlier initiation of treatment and reducing the harmful effects of untreated disease;
- broadening treatment options by repurposing available treatments or facilitating the discovery of new treatments;
- driving more targeted and efficient R&D thereby accelerating the discovery of effective therapies; and
- identifying early if a medical condition is not being adequately controlled through continuous monitoring of biological indicators of control, enabling earlier, more effective and potentially less costly medical intervention.

Health system benefits

PHC can support the sustainability of healthcare by:

- improving the efficiency of healthcare delivery;
- improving the quality and safety of healthcare by avoiding treatments that are less likely to work or may cause harm; and
- improving healthcare sustainability by offering cures (thereby avoiding life-long treatment), shifting systems from treating disease to preventing disease, minimising wastage (by using treatments more likely to work) and enabling and accelerating the development of treatments / interventions to address chronic diseases and those associated with an ageing population.



The need for a PHC Strategic Plan

The Australian Government has recognised the importance of health and digital technologies to the future of healthcare and developed key strategic documents that will facilitate the adoption of PHC. These include:

- The *National Health Genomics Policy Framework 2018-2021* which outlines the issues that need to be addressed to enable the uptake of genomics in clinical practice in Australia;
- *Australia's Long Term National Health Plan* which commits to implementing a 10 year plan for primary care, including access to and research relating to many PHC technologies. The Plan also establishes a *National Preventive Health Strategy* which includes genomics but would need to include other PHC technologies that facilitate screening and other tools to enable the early detection of disease; and
- The *National Digital Health Strategy* which provides a vision for how to expedite the development of Australia's digital health foundations in a coordinated manner across jurisdictions and the public and private sectors.

Based on these strategies, plans and frameworks, it is clear that the range of PHC initiatives and policy issues are varied with diverse responsibility within different areas of the Department of Health, across

other Australian Government Departments (such as the Department of Industry and the Australian Digital Healthcare Agency (ADHA)), and across State and Territory Health Departments.

This fragmentation of responsibility for different PHC-related activities within the above strategies is problematic and could hamper the progress of Australia becoming a regionally and globally recognised centre of excellence for PHC. An excellent illustration of the current fragmentation between and within Government Departments relates to genomics. Of the seven groups within the Department of Health's portfolio, five have responsibility for different elements of genomics policy. To obtain a comprehensive picture of Departmental activities or position on genomics, stakeholders would need to approach individual Branches dispersed across over 12 Divisions to discuss policy issues on genomics. Other elements of genomics such as data issues are covered within the Department of Industry and the Australian Digital Healthcare Agency. This separation of activities, coordination and accountabilities for PHC policy is not efficient, risking duplication and inconsistencies in approaches and outcomes. It is also difficult for stakeholders to engage in any meaningful way on genomics policy, particularly as there is limited transparency of activities.

Therefore, there is a need to consolidate and centralise current initiatives through a single comprehensive PHC strategy. This strategy should encapsulate the range of activities by the Government on PHC and associated technologies such as genomic tests and matched targeted medicines, as well as other technologies (such as cellular and stem cell treatments and gene editing). It should also identify any gaps that need to be addressed.

Additionally, as the majority of current PHC policy and program activities are the remit of the Department of Health, it should be allocated accountability for coordinating and delivering on the PHC strategy. This would include providing transparency of key activities across the Australian Government through updates on PHC-related activities on the Department's website and providing a central contact point to coordinate all stakeholders. To do this, a dedicated Section in the Department of Health is required, comprising skills in project management and policy together with a comprehensive understanding of the healthcare system and emerging technologies. One priority focus for this new area would be to coordinate PHC activities across other Departments, including establishing Inter-Departmental Committees where these are required.

As a first step, an analysis of the implementation progress of existing Government policies, strategies and frameworks, such as the National Genomics Policy Framework 2018-2021 is required. Subsequently, gaps in activity across key areas such as health system connectedness and alignment of HTA for PHC technologies and data should be identified, leading to the development of an action plan to reduce hurdles and promote access to PHC technologies and associated targeted treatments for Australian patients. This review, gaps analysis and action plan should be delivered within 6 months of accountability being assigned to a new, or existing, dedicated Section.

Recommendation

- Develop a publicly available strategic plan with priority actions agreed by stakeholders to implement adoption of PHC in Australia, led by a dedicated Section within the Department of Health.

Reform Health Technology Assessment for PHC technologies

The current HTA system is not fit for purpose for many PHC-enabling health technologies and is no longer, on its own, sufficient to inform reimbursement decisions.

Some of the evidence issues faced relate to the following:

a) Clinical trial design is adapting to address the challenges of generating evidence for targeted treatments where the disease or molecular target is rare, where there is a need to test a treatment and companion diagnostic simultaneously or the therapeutic area is evolving rapidly. This is leading to a shift away from traditional randomised controlled trials to newer study designs e.g. 'basket' or 'umbrella' studies. As a result, direct evidence of comparative effectiveness and safety may not be available from the trial, requiring the use of observational studies and real world data to fill evidence gaps. This will require greater acceptance of uncertainty when reimbursement decisions are made to ensure timely access for patients and the implementation of more sophisticated risk-sharing mechanisms, likely involving the collection of real world data.

b) Diseases are now able to be better categorised and there may be currently available medicines which could be useful but are not subsidised or approved for marketing for the newly categorised disease. However, the current evidentiary hurdles and associated costs may present a barrier to sponsors applying to broaden the availability of repurposed medicines.

c) Curative or regenerative therapies that have a sustained effect for many years are becoming available and offering new opportunities for the treatment of disease and injury. These are associated with very high initial costs and benefits that accrue over a long time, often the lifetime of the patient. These benefits may not be captured over the duration of the trial, and therefore these treatments face significant challenges in demonstrating value within the current HTA framework. These treatments are also challenging the definition of value for decision-makers as 'value' in the context of a curative treatment is different to 'value' for life-long treatment. In the absence of a framework to consider 'value', determining a fair price for reimbursement for curative treatments can be challenging.

d) Diagnostic technologies (such as comprehensive genomic profiling) which are able to diagnose multiple diseases, provide prognostic information and identify a number of treatment options to optimise clinical care for patients are becoming available. Unlike therapeutics, where the direct clinical effects are more easily demonstrated, diagnostics also provide information that indirectly informs clinical care, either eligibility for trials or clinical practice treatment options. However, the current HTA framework does not fully account for, or appropriately value, the full range of benefits offered by diagnostic technologies, resulting in inequitable access and forgone efficiency and effectiveness benefits for the healthcare system. Existing access pathways focus on a 'one test, one gene, one drug' assessment. This is not an optimal approach to the evaluation of genomic tests which can detect a large number of genetic mutations which can be linked to a number of different diseases and multiple therapeutic options.

e) In addition to the value issues raised under c) above, assessing 'value' using Quality Adjusted Life Years (QALY) does not include an assessment of value beyond the health gain and cost that is relevant for payers, patients and broader society. For example, comprehensive genomic profiling is able to provide value to clinicians by enabling the timely selection of appropriate therapies (or avoidance of inappropriate treatments) and identifying patients for clinical trials. For patients, families and caregivers, aside from clinical benefits, it may provide information that empowers the patient ('value of knowing') and allows them to take control of their care which can lead to better health outcomes. The current HTA framework adopts a healthcare system

perspective in defining value and in doing so could miss opportunities to adopt technologies that may lead to a more efficient, effective and affordable healthcare system.

Additionally, there needs to be better alignment of HTA assessment and funding decisions at the Commonwealth and State Government levels to ensure equity of access. For example, treatments such as CAR-T have been recommended for funding by the Medial Services Advisory Committee (MSAC) indicating universal public funding is recommended. However, only two States are able to provide CAR-T treatment meaning that in fact, the universality of an MSAC recommendation in the public system is being compromised.

A comprehensive and holistic review of the current HTA process and framework is required to ensure that PHC-enabling technologies are considered in a timely and pragmatic manner and that Australia continues to operate an equitable and efficient healthcare system that delivers world-class outcomes for patients.

Recommendation

- Commit to a review of the existing HTA processes and approaches for genomic tests and emerging technologies to ensure they are suitable for evaluating complex, personalised care models.
- Better align HTA assessment and funding decisions at the Commonwealth and State Government levels to ensure equity of access.

Translational PHC Research

The Australian Government has invested significantly in research into various areas of PHC, including genomics, through the Medical Research Future Fund (MRFF). Rapid translation of research findings into clinical practice is fundamental to more rapidly realise the benefits of PHC and ensures Government derives value from its significant MRFF investment. Consequently, a PHC strategy needs to include a commitment to strengthening the translational component of research activities. There are many options for this including:

a) Incentivising the development of translational strategies for research findings by providing access to funding through an abridged, simpler or expedited grants process for academics and clinicians;
b) Dedicating a portion of MRFF funds to research that involves collaborations between academics, clinicians and industry that focus on integrating PHC technologies into practice to embed Australia as a world-leading centre for PHC research;
c) Where research involves specific health technologies, the Department of Health expediting the pathways for their HTA evaluation following conclusion of the research;
d) Dedicating a portion of MRFF funds to clinical groups to develop clinical practice guidelines that assist translation of research into practice;
e) Embedding public reporting of translational research rates as key a performance indicator to the MRFF's reporting requirements and transparent reporting of translational research into a dedicated PHC Strategy;
f) Including translational research requirements and transparency of how the research was embedded into practice as a key component of a PHC Strategy; and

g) Dedicating a portion of MRFF funds to translating research on the re-purposing of precision medicines into clinical practice; given re-purposing of medicines is a priority under the MRFF.

Recommendation

- Strengthen the translational component of Government funded research in PHC, including genomics, to ensure research findings are embedded into routine clinical practice.

Conclusion

PHC can result in improved health outcomes, health system sustainability, economic growth and job creation. However, these opportunities and benefits can only be leveraged if we address the existing and emerging challenges in a coordinated, transparent, timely and collaborative manner. Roche's recommendations provide a guide for how we can consolidate and leverage existing efforts and investments to create an efficient structure that will serve to accelerate the realisation of PHC in Australia.

Roche is eager to partner with the Government to explore how the value of PHC can be captured, understood and recognised and how further investment in PHC can be realised – leading to a sustainable, healthier and more prosperous Australia.

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