Australian Genomics Health Alliance

30th October, 2019

Mr Tim Murphy
General Manager
Blood Cancer Partnerships

Dear Mr Tim Murphy,

Submission on the National Action Plan for Blood Cancer

Given the vast challenges but significant opportunities identified in the recent State of the Nation: Blood Cancer in Australia report, we strongly support the development of the National Action Plan. As a key national stakeholder and driver in the implementation of genomics into the healthcare system, I am pleased to provide specific insights and perspectives on behalf of Australian Genomics in the following areas:

Perspectives on the Framework for the National Action Plan

The State of the Nation Report indicates that in most cases genetic/genomic testing for blood cancer patients is not funded, which results in low rates of testing (<30%). Enabling access to genomic testing so that it becomes integrated into standard of care for all patients with blood cancer should be the key priority of the Action Plan.

During the last four years Australian Genomics and the State Genomic initiatives have been navigating the challenge of implementation of genomic medicine in an environment where testing remains predominantly funded by research and philanthropy. There is MBS reimbursement for few genetic tests and no genomic tests to date, and there is limited funding by State Clinical Services. This is more pronounced in some states than others, demonstrating the current inequity.

The Australian Genomics research model involves providing recruited patients with the intervention of a clinically accredited genomic test or specialist research genomic test, in areas of significant un-met diagnostic need, for example for research participants with leukaemia. Importantly, the research design incorporates the collection of data on diagnostic utility and health economic evaluations, to inform policy, funding and change in clinical practice. The first genomic MSAC application[1] managed by Australian Genomics has recently been recommended for funding, and several more applications addressing different testing indications are in preparation.

The State genomics initiatives are State Government funded, and have lobbied State Departments of Health for funding. Evidence from the Melbourne Genomics Health Alliance clinical flagships resulted in a further $8.3M investment from the Victorian State Government for rare disease genomic testing and associated genetic counselling and clinical care in the 2017/2018 budget. Therefore, in the current funding environment, a combination of research, Federal and State-led progress is necessary to build evidence to transition toward fully funded genomic testing. A Blood Cancer Research Mission would

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be a key driver of implementation of genetic/genomic testing for patients with blood cancer. In the interim the Taskforce should consider other research funding options, such as through the MRFF Missions, to continue to gather evidence on the utility, impact, and appropriate implementation processes to support uptake into healthcare.

Increasing equity of access to standard care for blood cancer patients was identified as another key priority in the State of the Nation report. Increasing equity for genomic testing has been addressed through several aspects of the Australian Genomics program:

- Rigorously pursuing a national approach to recruitment for genomic testing within the research programs, despite the challenges that present to multisite research initiatives.
- Developing an inclusive and broad national network of researchers, diagnosticians and clinicians. A similar national network model should be considered for a national Blood Cancer Research Mission.
- An Australian Genomics national working group is investigating the current challenges to equity of access to clinical genomic testing across Australia.
- Mapping the Australian health workforce understanding of genomics, and evaluating what education could support mainstreaming of genomics in health.
- Ongoing education, engagement and involvement of patients and advocates in our research program, to improve public awareness and understanding of the benefits and implications of diagnostic genomics.

Australian Genomics will be willing to share experiences and resources with the Taskforce, should this be deemed valuable as the National Action Plan evolves.

Clinical trials and the proposed Right to Trial program will be facilitated by the timely finalisation of the Clinical Trials Governance Framework, which will support consistent national accreditation of Health Services undertaking Clinical Trials in Australia. This will be included in the National Safety and Quality Health Service Standards. The Framework is expected to speed up the research ethics and governance process for clinical trials, which has been identified as one of the major barriers to trial initiation and to attracting internationally sponsored trials[2]. The Taskforce should identify itself as a key stakeholder in this process, if it has not already done so.

Importantly, there needs to be recognition that the aspirational target of zero avoidable deaths must be underpinned by strong, supported and ongoing research. This is particularly so in the genomics space. We currently do not cure all patients that have access to therapies. This indicates that there is still much work to be done to understand the blood diseases and develop new effective therapeutic approaches. Delivered through a strong national framework, access to research must be increased and underpinned by robust research pipelines that are continually updated by contemporary therapeutic approaches. The NHMRC has historically been the main source of funding for this, but MRFF funding has made considerable investment in cancer to date, and agencies such as LFA should be encouraged to underpin this research in their strategy moving forward. Developing the

[2] Haas et al., The ethics approval process for multisite research studies in Australia: changes sought by the Australian Genomics initiative. MJA DOI: 10.5694/mja2.50397

international research mission as an identified priority should serve to open up access to international funding opportunities and research collaboration. Partnerships with industry could be a key driver of success of a Blood Cancer Mission and should be explored.

Perspectives on patient reported outcomes

The value of patient reported outcomes is being increasingly recognised, particularly for establishing the natural history of disease, and the informative value this has on development, targeting and impact of new therapies. The State of the Nation report suggests that patient reported outcomes could be delivered through the My Health Record infrastructure. We have developed an online tool called CTRL, which enables research participants to manage their research consent choices, monitor and follow their progress through a study, communicate with the researchers and access sources of news and information. We are making this tool available to other research organisations, with an additional planned feature being a platform for patient self-reported outcomes. Research projects aligned with the Action Plan or initiated as part of the Blood Cancers Research Mission could build upon the CTRL prototype to fulfil proposed actions including developing real world evidence through patient reported outcomes, and the One-Stop Shop information portal.

Perspectives on the role private health insurance

In 2018, following the Parliamentary Joint Committee on Corporations and Financial Services Inquiry into the Life Insurance Industry, Australian Genomics developed a position statement on the use of Genomic Information in Life Insurance which is now available on the Australian Genomics website. This position statement supported the adoption of a nationally consistent approach to the use of genomic information by the insurance industry to ensure patients undertaking clinical testing and/or participating in research are not subject to discrimination in life insurance and related policies. The position statement called strongly for the Australian Government to regulate the use of genomic information by the Insurance industry and suggested the implementation of an interim moratorium pending adoption of a national regulatory approach.

Subsequent to the inquiry, the Financial Services Council (FSC) announced the introduction of a moratorium on the use of genetic results in life insurance from July 2019. Australian Genomics made a submission to the FSC's consultation on the proposed terms of the moratorium and also contributed to the Australian Genetic Non-Discrimination Working Group (AGNDWG)'s submission to the same consultation.

In 2019, once the final terms of the moratorium were announced by the FSC, the Australian Genomics position statement was updated to acknowledge the moratorium. Australian Genomics also worked with the FSC and other stakeholders, including the Human Genetics Society for Australasia (HGSA) and members of the AGNDWG, to develop a fact sheet that outlines consumers' rights and responsibilities in relation to genetic test results when applying for individually assessed life insurance (available on the FSC website, alongside the moratorium document (Standard 11)).

In addition, Australian Genomics has prepared consumer information on how genetic or genomic testing can impact insurance policies which is available on the genomicsinfo.org website and the consent documentation used by the Alliance's clinical flagship projects includes information about implications of testing for insurance and refers to the current moratorium.

Australian Genomics also continues to engage with the Australian Genetic Non-Discrimination Working Group which is keen to monitor the impact of the FSC moratorium and ensure that evidence is collected over the next three years to inform the 2022 review of its operation.

We have noted the State of the Nation report action to partner with Australian Genomics to continue to advocate for insurance regulation, and Australian Genomics will actively identify opportunities for collaborative effort in this area.

Perspectives on supporting Aboriginal and Torres Strait Islander patients and their families

Australian Genomics has invested significant effort in engaging with ATSI communities in genomic research, and this has been advanced through meaningful and productive partnerships with the National Centre for Indigenous Genomics and the Poche Centre for Indigenous Health, at the University of Sydney. The Taskforce should consider engaging with these and other stakeholders, such as the Wardliparinga Group at SAHMRI (led by Prof Alex Brown) to facilitate the Action Plan objectives by engaging with ATSI peoples for better health outcomes. QIMRB and Queensland Genomics Health Alliance have developed the Genomic Partnerships guidelines for working with ATSI populations in Queensland, the principals of which could be applied more broadly. Consultation with the ATSI advisory group to the Project Reference Group on Health Genomics (appointed by the Australian Health Ministers' Advisory Council) may be necessary for genomic research.

Perspectives on successful implementation and governance models

Australian Genomics has developed a strong and multidisciplinary governance structure, to provide guidance on strategy, consumer engagement, industry intersections and international activity. Further details on this structure can be found at australiangenomics.org.au.

Recently the Australian Health Ministers' Advisory Council (the advisory and support body to the COAG Health Council) appointed the Project Reference Group in Health Genomics, to oversee the implementation of the National Health Genomics Policy Framework. This model provides clear oversight of the actions of the Implementation Plan and ensures State and Territory buy in to genomics. This will also be critical to the success of the Blood Cancer Action Plan. As a research organisation we have been able to engage with Federal and State governments through the Project Reference Group to contribute to the Implementation Plan. Therefore, we suggest exploring a similar model of governance and oversight to be applied to a Blood Cancer Action Plan.

Thank you for the opportunity to provide a submission on the Action Plan.

Best regards,

Prof Kathryn North AC