9th July 2021
IHPA Secretariat
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Dear IHPA Secretariat,

RE: Independent Hospital Pricing Authority (IHPA) Consultation Paper on the Pricing Framework for Australian Public Hospital Services 2022-23

I write on behalf of the Australian Genomics Health Alliance (Australian Genomics), an Australian Government initiative supporting genomic research and its translation into clinical practice. Through broad engagement and a national collaborative approach, we achieve two key objectives: to improve the efficiency, reach and timeliness of genomic research projects, and to support Commonwealth State and Territory Health Departments in the implementation of genomics research outcomes by refining and communicating evidence to inform policy development. Australian Genomics engages with current and emerging government policy and priorities to identify gaps and opportunities, to support policy and action for integrating genomic technologies into the health system. By interfacing with consumers, governments, industry and global genomics initiatives, Australian Genomics drives change and growth in the sector.

We thank you for the opportunity to provide a response to this consultation paper. Our response specifically addresses consultation question "***What evidence is there to support increased costs for genetic services…?"***

Evidence to support increased costs for genetics services:

- The 2017 Australian Health Genetics / Genomics Survey 2017 reported approximately 1700 whole exome and genome germline and somatic diagnostic tests were undertaken in the 2016 financial year[1]. By 2019, the number of genetic / genomic tests performed by public laboratories had grown to 4000 (personal communication).
- The Genetic and Genomic Health in Victoria 2021 strategic plan reported a 50% increase in demand for genetics services from 2011 to 2016[2].
- The number of neonatal intensive care unit (NICU) referrals per year to the **Victorian Clinical Genetics Services** almost doubled from 2007 to 2015. The increase in referrals was accompanied by an increase in confirmed diagnoses from 21% to 53%, due to the increased application of genetic and genomic technologies for diagnosing genetic conditions[3].
- **Monash Genetics** reported a 58% increase in new referrals from 2015 to 2018, with an accompanying 20% increase in review consultations. Whole exome sequencing requests have increased by 42% every year and the complexity of cases has increased, leading to greater time spent on each referral and increased costs of tests ordered for each patient[4].

- **Genetic Health Queensland** has experienced a 22% increase in referrals from the 2018 to 2020 financial year and demand on the genetics service increased 53% from 2012 to 2017 (unpublished data, personal communication).
- Between 2012 and 2020, annual referrals to the **Adult Genetics Unit in Adelaide South Australia** have increased by 150%; the number of individuals who had diagnostic genetic testing for suspected familial cancer increased by 130%, and the number of individuals who had diagnostic genetic testing for a suspected non-cancer genetic condition increased 100% (unpublished data, personal communication).
- From 2012 to 2020, **Genetic Services of Western Australia** has seen a 275% increase in the demand for services with a correlating 45% increase in tests requested. In addition to the number of tests requested the complexity of the tests requested has consistently grown through this period as well (unpublished data, personal communication).
- Since the 2015/2016 financial year, the number of clinical tests performed by the **Peter MacCallum Cancer Centre** Molecular Pathology laboratory has increased by 60% (unpublished data, personal communication).
- There is also variation across Australian States and Territories in the clinical geneticist and genetic counsellor workforce, with Victoria better resourced than other states in both professions[4].
- Research funded genomic testing may play a significant role in the increase in referrals and testing. This is likely to impact service delivery and is also not a sustainable approach to funding genetics tests or clinical services. As genomic research programs increasingly identify people at higher risk of developing genetic conditions it will put the health system at under pressure if capacity is not increased.
- Many health professionals convey financial constraints in ordering the genetic and genomic tests that they feel are appropriate to deliver the necessary standard of health care for their patients.
- Existing testing rates under-represent the rates that would be appropriate if clinical utility and cost-effectiveness evidence were applied across patient cohorts due to aspects such as financial constraints, degree of genomic literacy, and access to testing.
- Increasing demand for genetics services is reported at the same time as increasing Australian-specific published evidence becomes available on the clinical utility and economic value of genetic and genomic testing [5,6,7,8] (see the Australian Genomics website for more relevant publications). As Australian Genomics cancer and rare disease flagships complete recruitment and publish data, it is expected that incorporation into standard care of genomic testing for more conditions will be sought.
- An Australian Genomics study on the use of ultra-rapid exome sequencing for critically ill infants reported several case studies which demonstrate the clinical impact of genomic testing and/or genetic diagnoses for individual cases. In the study, genomic testing led to significant changes in clinical course, such as redirection to palliative care, avoidance of planned invasive tests (lung

biopsy), a change in a treatment to avoid damage to other organs, and recommendation for organ transplant[9] (see Table 2).

- The personal and familial value of genomic testing has been demonstrated from the perspectives of the Australian public and families experiencing genetic conditions across several studies led by Australian Genomics[10,11,12] (and unpublished data). One of the important findings of these studies was that increased familiarity with the likely benefits of genomic testing will increase demand and uptake of clinical genomics[10].

As evidence of clinical and patient utility grows, demand on genetics services is increasing.

Genetics services in Australia must be adequately resourced to provide the right test at the right time, equitable access and to ensure cost-effectiveness, clinical and patient utility, and patient safety:

- Consulted stakeholders in an NSW-led report on genetic counselling services in 2017 said that wait times for appointments with genetics services had increased to between six months to two years, depending on geographic location and urgency of the test[13].
- The benefits of genomic testing as a first line diagnostic test have been demonstrated:
    - An Australian Genomics Mitochondrial Flagship economic evaluation found that early access to testing saved 45% in costs relative to late testing, from a cost of $6760 per child tested early to $12,400 per child tested later[6].
    - An economic study for renal genetic conditions had similar findings; the costs associated with doing exome sequencing early were 50% less than performing the test later (manuscript under review).
    - An economic study investigating the impact of exome sequencing applied early in the diagnostic pathway for infants with suspected monogenic disorders resulted in three times more diagnoses at one third of the cost[14].
- One theme arising from focus groups from an Australian Genomics study on what matters to key stakeholders in clinical genomic testing was how having a confirmed genetic diagnosis can lead to better access to government supported services, such as the NDIS, interventional and educational programs (unpublished data, personal communication). These are additional downstream reasons why the healthcare system should be striving for timely, equitable access to genetic and genomic testing.
- There is a link between a lack of resourcing and patients' experience or clinical outcomes. A study on cancer genetics services indicated that long wait times resulted in an increase in no-show rates[15]. Reduced wait times for genetic counselling appointments and timely diagnostic pathways have been identified as a key to successful implementations (National Strategic Action Plan for Rare Diseases, Action 2.2.3) [16].

Evidence-based, cost-effective, and culturally sensitive genetic services need to be available to all in the population for whom they could be appropriate. However, the lack of a fit-for-purpose funding model for public patients is leading to an inequity of access to genetics services and the value they provide, which increases the risks that the gap in health outcomes for vulnerable populations will become wider.

<u>Challenges to accurately costing genetics services:</u>

- Australian Genomics partner and stakeholder organisations consistently report lack of clarity with respect to funding of genetics services through Activity Based Funding (ABF), and inappropriateness of codes for recording service events. Interpretation of codes also varies across States and Territories. This leads to at least two downstream issues:
  1) **services are not correctly or adequately funded for the services and tests they provide**
  2) **services are not able to accurately capture the costs for reliable evidence collection to inform future funding decisions.**
- There is uncertainty amongst genetics professionals about how the hospital costings department derives the actual costings, and what they include. Increased communication across stakeholder groups and co-designed costing studies could resolve these issues.
- Because some clinics are block funded, most costs relating to these clinics, including genetics specialists, genetic counselling, testing, and administration are likely to be recorded separately across medical information databases. Identifying and linking these data may serve to improve costing assessments.
- Cancellations and failure to attend events are not captured through any standard system across genetics services but impact upon service delivery data and capturing costs[4].

We understand that IHPA is keen to resolve these complicated, long-standing issues[17], which we strongly support as an immediate action, given the three-year time lag to enact funding reforms. It is recommended that costing studies occur in multiple jurisdictions to better understand the usage and cost of genetic and genomic tests in the delivery of care by clinical genetics services and other clinical services.

Australian Genomics, through its engagement with genetics services, other health professionals delivering genetic health care, and senior health managers in each jurisdiction (primarily through the National Implementation Committee), is well-placed to raise awareness of these issues and to support action and collaboration with key stakeholders to bring about change.

Recommended areas for immediate consideration:

Costing genetic counselling services:

- Genetic counselling services ensure the safety and quality of genomic testing. Equity of access to genetic counselling is critical for patient care and support (refer also to Pillar 2 of National Strategic Action Plan for Rare Diseases) [16].
- In 2021 the ABF price for outpatient service events provided by a clinical geneticist and genetic counsellor are currently $961 (code 20.08) and $232 (code 40.53), respectively. **The 40.53 code is a general medicine allied services code and is unlikely to cover the cost of a genetic counselling service event in most instances. It does not reflect the complexity of genetic counselling services**. For example, the preparatory work and clinical work-up done outside of the face-to-face consultations is often extensive and is predominantly done by genetic counsellors[13].
- Clinical geneticists also do significant preparatory work and clinical work-up outside of face-to-face consultations, and thus should be assessed at the same time as genetic counselling services to gain a comprehensive picture of the time spent on each patient, for example, reviewing medical literature, case discussions, and expert consultation for rare diseases.
- A 2017 census led by Australian Genomics confirmed that delivering services relating to genomic testing take more time than genetic testing. Clinical genetic counsellors reported that genomic testing added approximately 2.75 hours extra in total workload per patient, and clinical geneticists reported it added approximately 2.25 hours.
- A new, fit-for purpose Tier 2 class 40 code should be established, which has been a recommendation of the Human Genetics Society of Australia (HGSA) in previous years. Clarification is sought from IHPA as to the existing appropriate code for genetic counsellors to record their services in the meantime.
- In any re-costing of genetic counselling services, the expansion of genetic counselling delivery as a telehealth service should be considered at the same time. In some states and territories with remote, disperse populations, telehealth service delivery has been in place for some time and many genetics services were able to pivot into telehealth delivery during the COVID-19 pandemic.
- In considering costing for genetic counselling services, the impact of successful funding through the current MSAC application for a Medicare item number for genetic counselling should be considered.

Resourcing for Multidisciplinary Team (MDT) clinics and Molecular Tumor Boards:

- MDTs (and molecular tumor boards for cancer genetics services) ensure the safety and quality of genomics testing and provide opportunities for upskilling the genetics and non-genetics workforce. MDTs are considered best practice nationally and internationally.
- MDTs are an important part of the testing process (even if the test is requested by non-genetics professionals) and will be core business for clinical genetics services into the future. The time is

not funded and not captured by the pathology costs, which go to the testing lab and not the clinical services.

- However, MDTs are resource intensive and, without proper costing, our stakeholders report that they may not be able to continue in some settings. Proper costing studies could be quickly achieved and should be done with the contribution of data from genetics services, to allow these valuable services to continue.

Genomic test costs:

- The cost of most genetic tests cannot be covered by the funding levels set by ABF through the 20.08 (clinical genetics, $961) or 40.53 (general medicine allied service code, $232) codes.
- Genetic and genomic tests are funded through different sources, including Medicare, block funding or user pays models – as well as research and philanthropy, though these latter sources are not sustainable, nor appropriate, sources of funding for clinical service provision. IHPA should develop a comprehensive understanding of the landscape of current funding structures for genetic and genomic tests and incorporate this into any additional decisions about their funding. Australian Genomics is currently undertaking relevant projects, including the development a genetic/genomic test directory for Australia, as well as evaluating genetic and genomic tests available through Medicare. These projects, along with the 2017 RCPA report on genomic test volume and demand[1] could be important resources for IHPA.

<u>IHPA can ensure future preparedness for new genomic technology applications:</u>

- The value of incorporating pharmacogenomics in personalised healthcare, both to the individual and the healthcare system has been demonstrated. An estimated $1.4B could be saved each year in Australia by avoiding hospitalisations due to adverse drug events[18]. An Australian Genomics incubator project in 2021 will assess current evidence to develop recommendations for further research in this area and readiness for incorporation into healthcare. (The introduction of pharmacogenomics is relevant to the consultation question '*What pricing and funding approaches should be explored by IHPA for reducing avoidable and preventable hospitalisations?*'.)
- The Mackenzie's Mission Australian Reproductive Carrier Screening study may result in mainstreaming of pre-conception carrier screening. While there is an application currently being considered for funding the test through Medicare, other downstream genetics service impacts should be considered as the general population begins to take up screening tests. For example, there would be an increase overall in clinical genetics services workload (see also National Strategic Action Plan for Rare Diseases Action 2.3.1 regarding equitable access to peri-conception genetic testing and counselling) [16].
- There is increasing discussion and evidence collection relating to enhancing newborn bloodspot metabolic tests by incorporating tests involving genetic and genomic technologies. This is another area that could have vast implications for genetic service delivery.

- Australian Genomics conducted several studies on preparedness of health professionals to engage with new genomic technologies. Our national survey of medical specialists found that geneticists and genetic counsellors are essential in providing advice to other health professionals and are spending considerable time on education activity.

Recommendations:

- IHPA should work with genetics services, hospitals (costing departments) and health departments to ensure appropriate, clear, and standardised data collection about genetics service provision across jurisdictions.
- The planned costing studies and engagement with genetics services delayed in 2020 by the COVID-19 pandemic should be reinstated.
- A multi-year genetics costing study is needed to gain a true understanding of the increase demand for genetics services, given the evidence for rapidly increasing demands summarised in our submission.
- A new Tier 2 class 40 service category should be established for genetic counselling.

Sincerely,

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Lead
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