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Illumina Australia submission to the Commonwealth Government Covid-19 Response Inquiry.

Illumina¹ is a world leader in genomics. Our global mission is to improve human health by unlocking the power of the genome. To date, over 90% of all genomics data produced globally has been generated using Illumina Next Generation Sequencing and Array Genotyping technologies. In Microbial Genomics we have a strong record of innovation enabling novel microbial research, genomics-based surveillance of pathogens and antimicrobial resistance in public health agencies, as well applications in human health and infectious diseases.

We bring decades of collective expertise in microbial genetics and genomics acquired through years of experience working with key customers on implementation of genomics-based applications around the world. Our customers include key public health laboratories across Australia including the University of NSW, NSW Health Pathology, the Microbiological Diagnostic Unit Public Health Laboratory (MDU PHL), University of Sydney, Northern Territory Pathology and Queensland Health Forensic and Scientific Services (QHFSS).

Illumina has a strong footprint in Australia, including our partnership with the University of Melbourne and Invest Victoria to establish The Advanced Genomics Collaboration (TAGC). The TAGC enables multidisciplinary collaborations to use the power of genomics to create world-leading, commercially successful biomedical projects and businesses that make healthcare more effective, efficient and affordable for everyone.

Illumina Australia has been actively contributing to genomic public policy formation in Australia. For example, Illumina Australia's general manager is on the Australian government's Expert Advisory Group on the formation of Genomics Australia, and Illumina provided submissions to the review of Health Technology Assessment policy and methods and the recent government consultation on the RNA sector.

The thoughts and opinions expressed in this document are given through our unique lens as a global provider of genomic technology solutions to both researchers and public health scientists.

The role of genomics in the COVID-19 pandemic

The COVID-19 pandemic brought genomics to the forefront of public health surveillance, providing unprecedented speed and scale to the pandemic response. The technology generated invaluable insights that accelerated the globe's response to the COVID-19 pandemic, including the identification of the causative pathogen of COVID-19, SARS-COV-2² and creating genomic sequence information that underpinned the development of both IVD detection tests³ and mRNA vaccines⁴. Throughout the

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² CDC. CDC Museum COVID-19 timeline. Centers for Disease Control and Prevention.," 05 January 2022. https://www.cdc.gov/about/history/sars/timeline. [Accessed 28 September 2022]

³ Carter LJ, Garner LV, Smoot JW, et al. "Assay Techniques and Test Development for COVID-19 Diagnosis," ACS Cent Sci, vol. 6, no. 5, pp. 591-605, 2020.

⁴ FDA, "Commissioner O of the. FDA Approves First COVID-19 Vaccine," 23 August 2021. [Online]. Available: https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine#::text=Today%2C%20the%20U.S.%20Food%20and. [Accessed 5 October 2022].

pandemic, sequencing of the SARS-COV-2 genome enabled the identification of mutations and newstrains of the virus and informed public health management guidance and strategy⁵. Genomic technology has played a critical role in the global fight against COVID-19.

The COVID-19 pandemic accelerated the adoption of genomic technology in the public health management of other conditions such as influenzae⁶, and tuberculosis⁷. Additionally, research and development funding has been allocated to further expand the scope of genomic technologies in applications to environmental surveillance, biosecurity management, wastewater surveillance, and antimicrobial resistance surveillance.

Key observations from the pandemic in Australia:

With initial rapidly released MRFF-Coronavirus Research Response funding⁸ from the Australian Government, leading public health laboratories conducted critical research to develop and implement genomic technology to support the Australian population through the pandemic. The rapid realisation of funds put Australia in a strong position as it enabled the accelerated development of core genomic surveillance platforms that formed a strong foundation for informing routine activities throughout the pandemic. For example, funding enabled the development and national adoption of the Austrakka programme that helped achieve national real-time genomic surveillance of the SARS-COV-2⁹. While existing government initiatives such as this, helped to demonstrate the utility of genomic surveillance, this and other subsequent research has not been expanded into a clear, long-term national strategy for advancing viral genomic surveillance. This also creates uncertainty for business with regards to present and future technology investments.

Early access to national funding also sought to remedy the patchwork state of readiness across the country as significant variations in capacity and capability were observed in different jurisdictions. Some States pivoted their routine pathogen surveillance activities to SARS-COV-2 sequencing, repurposed technologies and developed new workflows to meet their state's needs, while other States without any capacity or capability relied on larger states for their genomic surveillance needs. This inequity of capability could be attributed to the state-based governance framework for genomic surveillance activities where the financial requirements for establishing genomic surveillance capabilities were out of reach for smaller States.

Owing to its nascent and often underappreciated contribution of genomics to the pandemic, we noted an absence of national procurement guidance, and insufficient engagement with industry to facilitate the incorporation of genomic technologies into the national pandemic response. This resulted in ad-hoc and sometimes opportunistic¹⁰ actions being carried out to secure the resources needed to diagnose

⁵ "A genomics-based approach to global public health surveillance," 2022 https://sapac.illumina.com/areas-of-interest/microbiology/public-health-surveillance/genomicsurveillance.html?scid=2022-225QR7416&catt=QR%20Code%20-%20Tradeshow%20-%20Brochure. [Accessed 13 December 2023].

⁶ Datta S, Budhauliya R, DasB, Chatterjee S, Veerm VV. "Next-generation sequencing in clinical virology: Discovery of new viruses," World J Virol., vol. 4, no. 3, pp. 265-276, 2015

⁷ WHO, "Use of targeted next-generation sequencing to detect drug-resistant tuberculosis," World Health Organisation, 2023

⁸ Australian Government Department of Health and Aged Care "Medical Research Future Fund Report on the Coronavirus Research Response," Australian Governmet Department of Health and Aged Care, 2023.

⁹ Seemann, T., Lane, C.R., Sherry, N.L. et al. "Tracking the COVID-19 pandemic in Australia using genomics.," Nat Commun, p. 4376, 2020.

^{10 &}quot;Ground breaking partnership delivers 10 million COVID-19 tests and equipment," Ministers Department of Health and Aged Care, 29 April 2020. [Online]. Available: https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/ground-breaking-partnership-delivers-10-million-covid-19-tests-and-equipment. [Accessed 13 December 2023].

and conduct genomic surveillance of COVID-19 samples. Establishing transparent procurement frameworks, would enable suppliers to enhance their agility in responding to sudden spikes in demand, enabling a more effective and coordinated pandemic response to safeguard public health.

We encourage the adoption of a concerted whole-of-government approach in managing future pandemics, and welcome the Australian Government's commitment to creating the Australian Centre for Disease Control to help provide national oversight into the management and response of future outbreaks/ pandemics¹¹.

While the Australian Government addressed demand for more health care workers by increasing funding for health workforce and training programmes through the National medical workforce strategy¹², we however, could not identify a specific strategy to address the acute shortage of workers with pathogen genomics expertise. The COVID-19 pandemic highlighted the shortage of appropriately trained workforce in pathogen genomics, which is in part being addressed by academic insitutes such as the University of Melbourne who have developed a bespoke Microcertification course in pathogen genomics that upskills the existing workforce¹³. Efforts like this must be supported and expanded.

The pandemic also highlighted a lack of an appropriately trained/educated workforce to provide the necessary capacity for increased demands during outbreaks.

Recommendations to consider for future pandemic management:

The threat of future outbreaks is ever present. Therefore to ensure Australia is better prepared for future outbreaks Illumina offers the following recommendations:

Ensure genomics remains a core pillar in future pandemic preparedness programmes.

The value of genomics to inform public health strategy was repeatedly demonstrated throughout the pandemic, and should remain at the forefront of public health surveillance. Incorporating genomics into plans for pandemic preparedness or communicable diseases e.g., the Australia Health Management Plan for Pandemic Influenza¹⁴ enables a proactive approach to monitoring, understanding, and responding to infectious diseases, significantly enhancing our ability to tackle and mitigate the impact of pandemics. Expanding access to pathogen sequencing will aid in creating a global pandemic early warning system by enhancing geographic coverage and catalysing efforts to detect new epidemics before they spread widely, and to monitor their transmission in real-time for a more targeted and precise response.

Pathogen sequencing will also contribute to research and development efforts for new vaccines, diagnostics, and treatments for current and emerging infectious diseases.

National governance of genomic implementation would ensure consistency and equitability in data creation and sharing.

¹¹ Australian Government, Statement of Intent Working toether to support the Australian Centre for Disease Control, Australian Government, 2023.

¹² Australian Government, Statement of Intent Working toether to support the Australian Centre for Disease Control, Australian Government, 2023

¹³ University of Melbourne, "Microbial Genomics," University of Melbourne, [Online]. Available: https://study.unimelb.edu.au/find/microcredentials/microbial-genomics-bioinformaticanalysis-basics/. [Accessed 13 Decebmer 2023].

 $^{^{14}}$ Australian Government, Department of Health "Australian Health Management Plan for Pandemic Influenza," 2019.

Recommendation 1: The Australian Government, like many others worldwide, should provide guidance on the use of genomics as critical infrastructure in pandemic preparedness programmes and establish transparent, nationally consistent, procurement and governance frameworks.

Establish multi-sector engagement forums to ensure supply of critical infrastructure

The Australian government should facilitate the establishment of multi-sector, multi-stakeholder fora to ensure holistic assessment of convergent critical technologies, including genomics, biological sensors, remote sensors, advanced computing (AI/ML), and robotics. In order to accelerate adoption and to facilitate cooperation among different stakeholders (academia, industry, end users) the government should establish a set of strategic policy and investment priorities with mid-term and long-term objectives for ensuring that Australia remains at the forefront of public health disease management.

Recommendation 2: The Australian Government facilitate more open multi-stakeholder fora to accelerate the adoption of emerging technologies in pandemic preparedness.

Increase investment in a skilled workforce to combat future outbreaks.

Federal investment in public health education has been reduced over the last decade, yet the COVID-19 pandemic clearly demonstrated the value of public health workforce in a health crisis. Designated Federal investment in training and education is needed to ensure that Australia has a workforce that is capable and ready to pivot in public health emergencies.

Recommendation 3: The Australian Government designate funding for essential capacity building in the public health genomics workforce.

Global cooperation and sharing of best practices

The global community learned from the last pandemic that we are interdependent, and we need to work together to effectively tackle the pandemic. We need to work together to expand genomic sequencing capacity by building capacity, providing technical support, learning from one another's experiences, and through building a shared platform of best practices. In Singapore for example, to complement clinical testing in monitoring the spread of COVID-19, the government conducted wastewater surveillance as the virus may be found in stools or respiratory discharges of infected individuals, including those with mild or no symptoms. The testing of wastewater provides an indication of COVID-19 transmission in the community.

Recommendation 4: Australia develop and foster closer cooperation with regional research institutions and other countries for better preparedness against future pandemics.

Illumina stands ready to work with the Australian government and its institutions to build on Australia's existing pandemic preparedness capabilities. We would be happy to discuss this further with the Committee.

For any questions please contact:

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