Commonwealth Government COVID-19 Response Enquiry

Submission on behalf of Kirby Institute, UNSW Sydney

About the Kirby Institute and our involvement in the COVID-19 response: The Kirby Institute at UNSW Sydney is an infectious diseases research centre with over 400 full-time equivalent staff, established in 1986 in response to the HIV epidemic. We have since become involved in a wide range of infectious diseases and had a major involvement in various aspects of the global, national and local response to the COVID-19 pandemic. Areas in which we were active include viral geno -and pheno-typing and characterisation, establishment of longitudinal cohorts to track the short and longer-term impact of infection, population surveillance, provision of point-of-care testing to Aboriginal and Torres Strait Islander communities in remote and regional settings, epidemiological analysis of the impact of interventions on case numbers and transmission and mathematical modelling to predict vaccine effectiveness. We can provide a full list of our publications on COVID-19 as needed. A number of our academic staff also served on national expert groups, both ongoing and ad hoc, that were asked to provide high level advice to government on various aspects of pandemic response.

Based on these various experiences, we offer the following recommendations to the review, with a primary focus on the role of research and its interface with governmental decision-making and program implementation.

1. **Establish open, expert-driven processes to compile and synthesise scientific evidence**:

What happened during the pandemic: Scientific evidence synthesized using widely agreed techniques is a key input for the development and implementation of health policy. A flood of scientific information emerged on key aspects of SARS-CoV-2, including occurrence, transmission, health outcomes, treatment and vaccine impact. Much of this information came in the form of preprints that had not been peer-reviewed. Evidence syntheses were undertaken by many organisations and individuals, including several resourced and set up by the Australian Government. Some of the publicly funded synthesis mechanisms were open and transparent, including the National COVID-19 Clinical Evidence Taskforce based at Monash University (see https://research.monash.edu/en/projects/national-covid-19-clinical-evidence-taskforce). Others such as the National COVID Health and Research Advisory (https://www.nhmrc.gov.au/about-us/leadership-and-governance/committees/national-covid-19-health-and-research-advisory-committee) operated in a much more constrained manner, with agendas and reports not made available beyond a very limited recipient list. Across the many initiatives there was massive duplication of effort as well as gaps and inconsistencies in the outputs of the various syntheses.

Recommendation for improvement: (a) Identify broad areas in which urgent evidence syntheses may be required in a pandemic emergency. (b) Designate transparent, resourced mechanisms for undertaking syntheses in these areas, potentially involving the new Australian Centre for Disease Control (ACDC) in collaboration with recognised experts (c) Publish in a

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publicly accessible forum regular updates on the agendas, methods and outcomes of the syntheses.

2. Minimise barriers to developing and accessing key data sets

What happened during the pandemic: There was an urgent need for a wide variety of real-time data sets to track the pandemic across the Australian population, monitor interventions and their impact, and predict the outcomes of policy options. There was also a need for integration across these diverse sets of data. Many of these data sets required new resources and collection processes. The governmental processes for determining methodologies and awarding contracts were often via professional consulting companies under broad service contracts, and not always subject to expert scrutiny, so may not have led to optimal systems and outcomes. Other issues included diverse approaches to collection and use of data across jurisdictions, restrictions on access to data sets that seemed to go well beyond the obvious requirements of individual privacy protection, and difficulties in linking the different datasets.

Recommendation for improvement: (a) Develop a data strategy, potentially via the ACDC, that designates broad areas in which urgent data collection would be required in a pandemic emergency. (b) Identify partnership arrangements, potentially coordinated by the ACDC, for developing protocols and procedures, with associated budgets, to address data collection. (c) As appropriate, undertake pilot projects to develop the proposed methods during inter-pandemic periods. (d) For each data set, make access available in real time to suitably qualified research groups, under conditions related to publication and other dissemination of findings. (e) Design an a-priori format that facilitates the integration of diverse datasets. We note that the Kirby Institute's long-term role in compiling and analysing national HIV data sets, with high-level community and government input into regular reporting and other forms of dissemination, provides a strong model for such arrangements.

3. Minimise barriers for accessing biological specimens for analysis by suitably credentialled laboratories

What happened during the pandemic: A range of public and private laboratories at the jurisdictional level were the primary recipient of routine specimens collected for SARS-CoV-2 diagnosis. Specimens of public health importance were forwarded to designated laboratories at jurisdictional level, and hospitals had access to various specimens from admitted patients. Genomics surveillance networks were established to share information on viral sequences. Meanwhile, research laboratories around the country developed techniques of value on characterising circulating viral sub-types and strains and understanding their properties but did not always have access to relevant specimens in a timely manner. The limitations were often due to differences in both willingness and ability to share viral isolates, sometimes constrained by various pieces of legislation or their interpretation. Biobanking and specimen access procedures have been effectively established for some infectious agents, including HIV but were not available in real time for SARS-CoV-2.

Recommendation for improvement: (a) Establish biobanking arrangements that allow designated, pre-qualified public health, diagnostic and research laboratories to gain access to relevant specimens in real time, without compromising relevant public health functions. b) review the intent of acts that limited the safe sharing of viral swabs and isolates at jurisdictional and cross-jurisdictional level.

4. **Ensure that Australia makes optimal contributions to the search for therapeutic strategies**

What happened during the pandemic: The clinical trial response during the initial phase of the COVID-19 pandemic was disorganized and disconnected from the Australian health care system. Unlike what happened in the development of therapeutic guidelines for COVID-19, there was inadequate utilisation of Australia's considerable clinical infectious disease and clinical research expertise. Furthermore, a highly contentious issue that emerged with the pandemic was the choice of agents that should be considered for therapeutic trials and other forms of research into treatment. It was clear even at the time that some of the proposed agents were highly speculative (ivermectin, BCG and hydroxychloroquine for example), and that Australian clinical attention and resources should have been directed down pathways that were more likely to yield fruitful outcomes. However, multiple funding sources, some of them well outside the usual mechanisms for supporting therapeutic research, were quite influential in steering clinical sites and networks in these unhelpful directions. On the other hand, we missed the opportunity early in the pandemic to participate in some international trials of agents that had a better evidence base in their conception. The international REMAP-CAP network on treatment for community-acquired pneumonia had a strong Australian element to its leadership and was a substantial exception due to its well-established adaptive methodology and pre-approved clinical sites. Existing, externally-funded international networks with Australian sites, such as INSIGHT were under-utilised, while new and inevitably fragile networks were established at a time of extreme stress on the health care system. The relatively low number of cases in Australia through 2020 and early 2021 was of course a public health plus, but impacted local study enrolment and opportunities for Australian sites and patients to contribute to international studies were missed. This was subsequently addressed by the addition of Australian clinical research sites to the currently active global INSIGHT/STRIVE network (Strategies and Treatments for Respiratory Infections and Viral Emergencies) through MRFF funding in 2022 (https://clinicaltrials.gov/study/NCT05605093) but was too little too late.

Recommendation for improvement: (a) Establish a high-level technical group on priorities for clinical research in the time of pandemic emergencies with the ability to advise on both large-scale national initiatives, and opportunities for international trial participation. (b) Ensure participation in international pandemic preparedness clinical trial networks to enable rapid mobilisation of sites and patient recruitment. (c) Establish reciprocal agreements between regulatory and governance bodies for review and approval of protocols that transcend jurisdictional (state and international) boundaries. (d) Provide ongoing support for Australian involvement in the currently operating large scale pandemic preparedness networks (REMAP-CAP and STRIVE) to continue operations in inter-pandemic periods. (e) Support more Australian clinical sites that are prepared to follow the advice of the national strategic group referred to above to engage in research initiatives and embed research activities in daily clinical management.

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