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Panel on Health Services

Meeting on 10 September 2021

Background brief on the Implementation of the Hong Kong Genome Project

Purpose

This paper provides background information and summarizes the major views and concerns expressed by members of the Panel on Health Services ("the Panel") on the Hong Kong Genome Project ("HKGP").

Background

2. Genome is the complete set of genetic material (i.e. DNA) found within a cell. Everyone's genome is unique. Apart from determining a person's physical characteristics, genome provides information why a person is prone to certain diseases and what treatment is more effective to that person. Genomic medicine uses genome data to support clinical treatment to bring the benefits of more precise diagnosis, avoiding unnecessary investigations, more personalized treatment, more prediction of disease development, more chances to explore new medicine and treatment, and more efficient ways to prevent diseases. There is an international trend to introduce large-scale genome sequencing projects for clinical and scientific advancement.

3. Pursuant to the announcement in the Chief Executive's 2017 Policy Address that a steering committee would be set up to lead the study on strategies for developing genomic medicine in Hong Kong, the Secretary for Food and Health appointed the Steering Committee on Genomic Medicine ("the Steering Committee") in December 2017. Three working groups were established under the Steering Committee, namely, the Working Group on Laboratory Network for Genetic Testing, the Working Group on Biobank and the Working Group on Hong Kong Genome Project.

4. It was announced in the Chief Executive's 2018 Policy Address that based on the preliminary recommendation of the Steering Committee that a large-scale genome sequencing project should be conducted in Hong Kong with a view to enhancing the clinical application and promoting innovative scientific research on genomic medicine, the Government would provide funding to introduce HKGP.

5. The Steering Committee submitted the Report on Strategic Development of Genomic Medicine in Hong Kong to the Administration in December 2019.[1] In May 2020, the Administration announced that it had accepted all the recommendations put forth by the Steering Committee, among which the $1.2 billion-budget HKGP was accorded the top priority.

6. To implement HKGP, the Hong Kong Genome Institute ("HKGI"), a private company limited by guarantee wholly owned by the Administration, was set up in May 2020 to coordinate the implementation of HKGP and drive the collaboration of existing infrastructure and expertise for maximum synergy and innovation.

7. HKGP aims to cover 20 000 cases and sequence around 40 000 to 50 000 genomes in six years. The pilot phase started in mid-2021 would cover 2 000 cases, focusing on patients and their family members with undiagnosed disorders and cancers with clinical clues linked to possible hereditary / genetic components. Three partnering centres at the Hong Kong Children's Hospital, Queen Mary Hospital and Prince of Wales Hospital will recruit patients with informed consent. Sequencing analysis results will be fed back to patients once available to aid diagnoses or clinical management.

Major views and concerns of members

8. At the Panel meetings held on 21 January 2019 and 12 June 2020, members discussed issues relating to HKGP. The major views and concerns expressed by members are summarized in the following paragraphs.

Scale of HKGP

9. Some members opined that more cases of undiagnosed disorders and cancers should be covered under HKGP for achieving the objective of enhancing clinical application of genomic medicine, in particular the diagnosis of uncommon disorders and the provision of more personalized treatment for cancer patients. In addition, the sample size or case selection for whole genome sequencing had to be of statistically significance to achieve the aim of enhancing

[1] The Report is available at the Food and Health Bureau's website at https://www.fhb.gov.hk/en/press_and_publications/otherinfo/200300_genomic/index.html.

genetic diagnosis of rare diseases. The Administration advised that the number of samples collected from each case might vary. It was estimated that the pilot phase of HKGP would sequence 4 000 to 5 000 genomes in total.

10. Noting that participation in HKGP would be by invitation, some members were concerned about the avenue for the general public to gain access to predisposition tests on carrier genes for certain diseases.

Funding and agent for the implementation of HKGP

11. There was a concern about the funding requirement for the implementation of HKGP. The Administration advised that $1.2 billion had been earmarked for the implementation of HKGP, which included a non-recurrent provision of $682 million to meet the project cost of HKGP and a subvention of about $87 million per year on average for six years starting from 2019-2020 to support the operation of HKGI.

12. Referring to a media report that the cost of sequencing a genome was about US$1,000, members sought elaboration about the use of the $1.2 billion. The Administration advised that HKGP aimed to cover 20 000 cases in two phases for a period of six years. Since some cases might involve two or more samples depending on the clinical and research needs, it was estimated that HKGP would sequence 40 000 to 50 000 genomes in total. A human genome contained approximately 3 billion deoxyribonucleic acid-sequence base pairs. The $1.2 billion would cover the cost of interpreting these enormous amounts of data. Participants who were referred by the Hospital Authority ("HA") and the Department of Health ("DH") for participation in HKGP would not be required to bear the expenditure arising from genome sequencing.

13. On the Administration's plan to task HKGI with the responsibility of coordinating the implementation of HKGP, questions were raised as to whether it was common in other places for the Government to set up an agent to deliver the genome projects. The Administration advised that the genome projects of Singapore and the United Kingdom were respectively led by an institute and a company set up by the governments concerned. The setting up of HKGI would enhance the flexibility and efficiency in the implementation of HKGP. The operation of HKGI would be bound by a Memorandum of Administrative Arrangement, which would incorporate important checks and balances to ensure transparency and public accountability of HKGI on the use of public fund.

14. There was also a concern as to how the Administration would strike a proper balance in the allocation of the finite public resources to promote the development of genomic medicine on the one hand, and on the other hand address the treatment needs of those patients with rare diseases and cancers who had to

purchase at their own expense those drugs which were proven to be of significant clinical benefits but were so expensive that HA did not provide them as part of its standard services.

15. The Administration advised that the introduction of HKGP would, among others, enhance the diagnostic rate and enable more targeted clinical management of uncommon genetic disorders and allow more personalized treatment for cancer patients. Separately, recurrent resources were provided for HA to expand the scope of the HA Drug Formulary. While patients who needed the self-financed drugs had to purchase them at their own expense, a safety net was in place (i.e. the Samaritan Fund and the Community Care Fund Medical Assistance Programme) to subsidize the drug expenses of patients with financial difficulties. With the introduction of measures to enhance the means-tested mechanism for the safety net in 2019, the Administration and HA would continue to study measures to alleviate the financial burden on patients' families arising from drug expenditure.

Data privacy

16. On the privacy-related issues arising from the access to the genomic and clinical data under HKGP, enquiries were made as to whether a regulatory framework or administrative measures would be put in place to protect patient privacy under HKGP and under what circumstances informed consent from participants would be sought and the parties responsible for approving data access requests. There was a particular concern about the privacy of the genomic and clinical data of patients with rare diseases, whom were small in case numbers and hence, could be easily identified. Concerns were also raised on whether the Administration and the Police would be empowered to access the genome data without the consent of the individuals concerned for law enforcement purposes.

17. The Administration advised that eligible patients (and their family members if necessary) would be invited to participate in HKGP on a voluntary basis after giving informed consent. Participants could withdraw from HKGP anytime if they wished to do so. Similar to the practice of some overseas genome projects, a secure database infrastructure platform would be established under HKGP and data access guidelines and protocols would be developed. With the informed consent of HKGP participants, researchers could only access the anonymized genomic and clinical data with the approval of the specific advisory committee and under an ethically approved research protocol. The Working Group on Hong Kong Genome Project set up under the Steering Committee would continue to examine issues relating to patient privacy under HKGP with reference to overseas practices. The view of the Privacy Commissioner for Personal Data in this regard would be consulted.

Clinical application

18. Enquiries were made on the estimated time required for HKGP to bring clinical benefits to patients and their families after starting to recruit patients for sequencing. The Administration advised that at present, genetic and genomic services of HA were mostly developed at the local level and on an independent basis by individual clinicians or hospitals according to the interest and expertise of the respective staff and local needs. The clinical genetic and genomic services provided by the two medical schools, such as that for hereditary breast and colorectal cancers, were funded by research grants or private grants and catered only for a limited number of patients. Apart from that, part of the demands for clinical genetic services had been met by the private sector. The implementation of HKGP would serve as a catalyst to enhance clinical application of genomic medicine to benefit patients and their families. For instance, international and local experience revealed that the diagnostic yield of uncommon diseases could be raised from around 10% up to around 30% to 40% by using whole genome sequencing. Along with HKGP, HA would implement its Strategic Service Framework for Genetic and Genomic Services which aimed to fill the current service gaps and set out a blueprint for its genetic and genomic services to help patients make informed decisions on their treatment and management.

Development of genome medicine

19. Concerns were raised over the sufficiency of local experts in the sphere of genomic medicine, and whether the development of genomic medicine in the long run would involve the controversial issue of human genome editing technology. According to the Administration, there were experts in genomic medicine or related field working in HA, DH and local universities. The implementation of HKGP would not only facilitate the enlargement of the talent pool, but also enhance the diagnostic rate of uncommon genetic disorders, enabling more targeted clinical management which ranged from targeted diagnostic testing, medication, surgical procedures, surveillance to lifestyle changes.

Collaboration on genome data analysis with other places

20. Referring to the genome studies conducted in the Mainland and other places on Chinese population, some members asked whether the application of genomic medicine could also be achieved by making use of the genome profiles developed under public genome infrastructure platform in the Mainland, or any collaborative studies could be conducted to achieve synergy and facilitate the development of a genome database of Chinese population. Some members asked whether the long-term goal of HKGP would go beyond benefiting patients in need but to gain a position in genomic medicine in the region. There was also an enquiry as to whether the Administration would accede to other places' request

to access HKGP's anonymized genome data of the local population for the carrying out of various studies and, if so, whether a fee would be charged.

21. The Administration advised that the transfer of domestic genome data to places outside the Mainland was not allowed under the laws of the Mainland. That said, it was expected that the implementation of HKGP would contribute to the enhancement of clinical application of genomic medicine, the development of genome profiles on Chinese population and relevant scientific exchanges with other places, including the Mainland. HKGP would also create synergies with the world-class biomedical technology and information and communications technology clusters established in the Hong Kong Science Park. Efforts had been and would continue to be made to maintain communication with other places where similar genome projects were being carried out, which included the Mainland, Singapore and some Western countries.

Relevant papers

22. A list of the relevant papers on the Legislative Council website is in the **Appendix**.

Council Business Division 4
Legislative Council Secretariat
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Appendix

List of relevant papers

Committee	Date of meeting	Paper
Panel on Health Services	16 October 2017 (Item IV)	Agenda Minutes
	15 October 2018 (Item III)	Agenda Minutes
	21 January 2019 (Item III)	Agenda Minutes Supplementary information provided by the Administration
	21 October 2019 (Item I)	Agenda Minutes
	12 June 2020 (Item III)	Agenda Minutes
	8 January 2021 (Item III)	Agenda
Council Meeting	5 May 2021	LCQ20: Policies and measures on rare diseases

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