

LCQ14: Treatment and prevention of breast cancer

Following is a question by the Hon Nixie Lam and a written reply by the Secretary for Health, Professor Lo Chung-mau, in the Legislative Council today (May 14):

Question:

According to government information, breast cancer is the most common cancer among females in Hong Kong, and new cases of breast cancer accounted for 28.6 per cent of all new cancer cases among females in 2022. Among them, HER2 (i.e. human epidermal growth factor receptor 2) low-expression metastatic breast cancer (HER2-low breast cancer) poses a great threat to the lives of patients as it is highly malignant and prone to relapse and metastasis. It is learnt that with advancement in medical technology, the classification of testing results of HER2 has been updated from two (i.e. "positive" and 'negative') to three categories (i.e. with the addition of "low-expression") in the medical guidelines of various places so as to provide precision treatment for patients with HER2 breast cancer. However, there are views pointing out that the existing HER2 testing reports of the Hospital Authority (HA) have not indicated the category of low-expression, nor has HA provided the relevant education to patients, rendering them unable to know their actual condition in a timely manner and thereby missing the golden period of early treatment. In this connection, will the Government inform this Council:

(1) whether it knows if HA will expeditiously review the classification of the existing HER2 testing reports to clearly indicate the testing result of low expression of HER2, while at the same time providing the relevant patient education, so as to ensure that they fully understand the clinical findings, thereby expeditiously receiving the appropriate treatment protocol; if HA will, of the timetable; if not, the reasons for that;

(2) whether it knows if HA will consider including drugs targeting HER2-low breast cancer into the safety net for application by patients suffering from that cancer and streamlining the vetting and approval process, so as to enhance the efficiency of vetting and approval of safety net drugs; if HA will, of the timetable; if not, the reasons for that; and

(3) whether the Government has currently formulated public education programmes for different groups of people to raise their awareness of breast cancer screening, including whether it has provided systematic online information and promoted on social media platforms; if so, of the details; if not, the reasons for that?

Reply:

President,

The Government attaches great importance to cancer prevention and control work. In 2001, the Government established the Cancer Coordinating Committee to formulate strategies on cancer prevention and control, and to steer the direction of work covering cancer prevention and screening, surveillance, research and treatment, etc.

The Government promulgated the Hong Kong Cancer Strategy (Cancer Strategy) in 2019 with a view to reducing the cancer burden of the local population and improving the quality of life and survivorship of cancer patients through setting work priorities and directions. The directions laid down in the Cancer Strategy include reducing risk factors leading to cancer and providing evidence-based screening, seeking early detection and diagnosis, offering timely and effective treatment, strengthening survivorship support to cancer survivors, providing palliative and end-of-life care, investing in technology, enhancing the collaboration among relevant bureaux, government departments, the Hospital Authority (HA), community organisations and civil society, as well as enhancing surveillance and research capabilities. The goal is to better prevent and control various cancers through these directions.

As for breast cancer screening, based on the recommendations of the Cancer Expert Working Group on Cancer Prevention and Screening under the Cancer Coordinating Committee, the Government adopts a risk-based approach for breast cancer screening and launched the Phase I of the Breast Cancer Screening Pilot Programme (BCSPP) in 2021. In collaboration with non-governmental organisations through a public-private partnership, the Government is now preparing for the Phase II of the BCSPP to provide subsidised breast cancer screening services to women being categorised as high risk of developing breast cancer (viz. carriers of certain germline mutations and/or presence of strong family history of breast cancer/ovarian cancer). The Phase II programme is expected to be launched around the second quarter of 2025. Relevant details will be announced in due course.

The reply, in consultation with the Department of Health (DH), the Primary Healthcare Commission (PHC Commission) and the HA, to the question raised by the Hon Nixie Lam is as follows:

(1) According to the data from the Hong Kong Cancer Registry, there were a total of 5 182 new cases of female breast cancer in 2022, of which 1 002 were Human Epidermal Growth Factor Receptor 2 (HER2) positive cases.

At present, the HER2 test performed by the HA consists of immunochemistry (IHC) and genetic testing (in situ hybridisation (ISH)). IHC testing results are scored as follows:

- (i) 0 (no staining, or ≤ 10 per cent of tumor cells show faint or weak membrane staining);
- (ii) 1+ (>10 per cent of tumor cells show faint/barely visible incomplete membrane staining);
- (iii) 2+ (>10 per cent of tumor cells show weak to moderate complete membrane staining (circumferential staining), or ≤ 10 per cent of tumor cells show strong complete membrane staining); or

(iv) 3+ (>10 per cent of tumor cells show strong complete membrane staining).

HER2 immunostaining scores of 0 and 1+ are interpreted as negative for HER2 testing, a score of 2+ as inconclusive, and a score of 3+ as positive. If the HER2 test result is inconclusive (i.e. the immunostaining score is 2+), the hospital will further perform HER2 gene in situ hybridisation testing for the patient to confirm whether there is an amplification of the HER2 gene. If the relevant test shows amplification, the patient's HER2 test result will be classified as positive; whereas if there is no amplification, it will be classified as negative.

"HER2 low-expression" mentioned in the question refers to patients with a HER2 immunostaining score of IHC 1+ or a score of IHC 2+ with no amplification shown in in situ hybridisation testing. The HER2 Interpretation Guidelines (a set of international guidelines) were updated in September 2023. Although the new guidelines do not officially classify "HER2 low-expression" as a separate category, it is recommended that an annotation describing the result of "HER2 low-expression" (i.e. IHC 1+ or IHC 2+/ISH with no amplification) be included in the test report to enable physicians to better identify patients who may be suitable for a specific targeted therapy. The "multidisciplinary teams" for breast cancer at the oncology centres of the HA, consisting of oncologists, pathologists, radiologists, advanced practice nurses, etc, are discussing the implementation arrangements for the updated guidelines and will reach a consensus as soon as possible to implement the major updates under the Interpretation Guidelines in a gradual manner, while planning to add annotations to the test reports to explain the results of "HER2 low-expression". Currently, clinicians will determine, based on the test reports, whether patients are IHC 1+ or IHC 2+ with no ISH gene amplification, thereby providing patients with optimal follow-up.

(2) As the major provider of publicly-funded public healthcare services, the HA attaches great importance to providing optimal treatment for all patients (including cancer patients) while ensuring patients have equitable access to cost-effective drugs of proven safety and efficacy under the highly subsidised public healthcare system.

The HA has a mechanism in place to regularly evaluate new drugs as well as to review existing drugs on the HA Drug Formulary (HADF) and the coverage of the safety net (including the Samaritan Fund and Community Care Fund Medical Assistance Programmes). In assessing applications for new drugs to be included in the HADF and the coverage of the safety net, the HA follows an evidence-based approach, having regard to the safety, efficacy and cost-effectiveness, etc, of the drugs and other relevant considerations, including international recommendations and practices as well as views of professionals and patient groups, etc.

The HA will pay close attention to the latest scientific and clinical evidence of drugs suitable for treatment of various types of cancer (including "HER2 low -expression" breast cancer), with a view to providing cost-effective drugs of proven safety and efficacy as well as continuous optimal care to patients.

To shorten the lead time for introducing suitable new drugs to the HADF, the HA has simplified the application process for inclusion of new drugs in the HADF since the end of 2024. Clinicians and pharmaceutical companies can submit new drug applications directly to the Drug Advisory Committee. The frequency of prioritisation exercise for including new drugs in the safety net will also increase from twice a year to four times a year. With the implementation of the above new mechanisms, the HA has been actively optimising the procedures for introducing new drugs into the HADF, with the objective of reducing the time required for introducing new drugs with proven efficacy into the HADF or the coverage of the safety net by half, from the original 10 months to five months; and from 18 months to nine months respectively, so as to enable patients to have access to new drugs as soon as possible, and to obtain the subsidies under the safety net to alleviate the burden of drug expenses.

Besides, the Government and the HA will press ahead with the implementation of the fees and charges reform for public healthcare announced at the end of March this year, which aims to guide the public to make optimal use of healthcare resources through three aspects, namely reforming the subsidisation structure, reducing wastage and abuse, and enhancing healthcare protection. It also seeks to strengthen the healthcare protection on all fronts for patients who are "poor, acute, serious, critical". Such measures include enhancing the protection in terms of drugs and medical devices for critically ill patients (including cancer patients) through accelerating the introduction of more effective innovative drugs and medical devices to the HADF and the coverage of the safety net, with a view to ensuring that the limited healthcare resources can be directed in a more targeted manner to assist those patients most in need. This will thereby enhance the sustainability of the healthcare system and enable it to serve as a safety net for all.

(3) The DH has all along been promoting a healthy lifestyle, including avoidance of smoking and alcohol, healthy diet, regular physical activity and maintenance of a healthy body weight, as the primary strategy for preventing cancer and common non-communicable diseases.

The DH has all along attached importance to the public education of women's cancer (including breast cancer) and has been promoting breast cancer prevention and screening through various channels and media such as television, radio, websites, printed materials, newspapers, social media, online publicity and media interviews. Educational leaflets have been produced in many ethnic minority languages by the DH for ethnic minorities to comprehend the health information on breast cancer prevention and screening. In addition, the Cancer Online Resource Hub was launched in 2020 to provide the public with accurate and reliable health information relating to cancer.

Meanwhile, the District Health Centres (DHCs)/District Health Centre Expresses (DHCEs) under the PHC Commission in all districts across the city are actively assisting members of the public in formulating individualised Life Course Preventive Care Plan based on factors such as one's gender, age and family history. Life Course Preventive Care Plan is an evidence-based comprehensive health strategy that emphasises on prevention and personalised

needs and provides guidance on the health needs of citizens across different stages of life. DHCs/DHCEs may also provide members of the public with information related to breast cancer prevention and other women health education services according to their needs.

Starting from January 24, 2025, women's health services under the DH have been progressively integrated into the district health network of the PHC Commission, with the service points named Women Wellness Satellites (WWS). DHCs/DHCEs will identify women in need through basic health assessment and individual counselling, and arrange for them to receive women's health services at WWSs. WWSs will offer health assessment and counselling tailored to women's health conditions, breast cancer and cervical cancer screenings according to individual needs, as well as health education activities including talks on breast cancer prevention.