For Immediate Release

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KHOO TECK PUAT HOSPITAL (KTPH) APOLOGISES FOR ITS LABORATORY INCIDENT; IT WILL COMPENSATE AFFECTED PATIENTS, METE OUT DISCIPLINARY ACTIONS, AND IMPLEMENT CORRECTIVE ACTIONS AS RECOMMENDED BY THE NHG REVIEW COMMITTEE

1. The National Healthcare Group (NHG) Review Committee (NRC) has completed its independent investigation into the incident at the Khoo Teck Puat Hospital (KTPH)'s Department of Laboratory Medicine, Anatomic Pathology Section (APS). Its Human Epidermal Growth Factor Receptor 2 (HER2) immunohistochemistry (IHC) section had produced unusually high HER2 positive rates for KTPH's breast cancer patients. KTPH has since stopped all HER2 IHC testing services upon discovery of the error. The NRC reviewed the incident and also the IHC section's processes from 1 January 2012 to 26 October 2020.

2. The NRC has submitted its report to NHG GCEO Professor Philip Choo, the NHG Board Risk Committee and the Ministry of Health (MOH).

Causes and Discovery of the Lapse

3. The NRC, which comprised experts in various disciplines from the healthcare industry, found that the inaccurate HER2 positive rates were caused by a suboptimal HER2 staining protocol used by the HER2 IHC section. The suboptimal HER2 staining protocol was caused by human error when establishing the protocol. This led to over-staining of slides, which affected the interpretation of the slides, resulting in a higher than usual HER2 positive rate. The calibration error was not discovered due to a failure to conduct rigorous checks at the point when the protocol was established.

4. Investigations by the NRC revealed inadequacies in the KTPH HER2 IHC section's quality control. The deviation of HER2 positive rates from international benchmarks was noted earlier on during the laboratory's regular monitoring. The section checked the accuracy of reading of the slides and attributed the deviation to differences in patient population, and did not recheck the accuracy of the staining protocol. Staff from KTPH's HER2 IHC section failed to perform quality control checks properly, including monitoring and properly analysing the HER2 positive trend closely over time, which affected the interpretation of the over-stained slides and a delay in detection of the error.

5. The inadequate quality control and assurances contributed to the failure to detect the over-staining issue early, and over the years, when the tests were conducted.

6. In 2020, when the clinicians reviewing breast cancer cases noticed the higher than usual positive rate, an internal review was then conducted to follow up on the deviation.

Corrective Actions

7. The NRC has given its recommendations for improvement including Processes and Practices governing the use of Laboratory-Developed Tests; Quality Control and Assurances; Governance and Oversight; and Staff Training, Education and Professional Competencies. These recommendations seek to prevent future occurrence of similar incidents, and include:

- Proper selection of the correct assay optimisation protocol, and improving the checking process to confirm the selected protocol;
- Strengthening the Quality Control (QC) and Quality Assurance processes for the HER2 IHC section, and designating staff with expertise to oversee the programme;
- Close monitoring and auditing of processes and results using best industry practices and international benchmarking; and
- Retraining, re-educating and upgrading competencies to reinforce professional technical knowledge and skills.

8. NHG has formed an Implementation Committee to ensure that KTPH implements all the NRC recommendations and works towards closing the gaps identified. The NHG Review Committee has shared the findings and recommendations from the incident across all NHG institutions. It has heightened staff awareness and reinforced full adherence to the laboratory processes for patient safety and care.

Disciplinary Actions

9. With the completion of the NRC investigation, a Board of Inquiry (BOI) was set up to examine the roles, responsibilities and actions of specific staff involved, and upon completion of the BOI's deliberations, a Disciplinary Committee was convened by the NHG Board in March 2021 to recommend the appropriate actions to be taken. Five individuals, comprising both KTPH's management and staff, were identified for not adequately performing their duties and responsibilities, leading to the serious lapses. The penalties meted out against them included cessation of employment, financial penalty, and stern warning. Appropriate counselling, retraining and re-education are currently being conducted.

Apology and Patient Actions to Be Taken

10. Associate Professor Pek Wee Yang, Chairman Medical Board, KTPH said, "KTPH views this incident very seriously and we sincerely apologise for the lapses in our laboratory processes. We have reached out to all affected patients to offer our support, and we give the assurance that we will look into the appropriate compensation for each individual patient. We would also like to seek their understanding and patience as this process will take some time to complete. In addition, we will provide psychological counselling to these patients, where needed, during this period."

11. Associate Professor Pek added, “We are determined to set things right to regain the trust and confidence of our patients. We will expeditiously rectify all gaps in our processes in the laboratory. Moving forward, we will ensure strict adherence to industry’s best practices and international benchmarks.”

12. Professor Philip Choo, GCEO, NHG said, “On behalf of NHG, we deeply regret the incident. I would like to thank the NHG Review Committee (NRC) for its thorough review of the incident, and the recommendations made to improve KTPH laboratory’s systems and processes, as well as the NHG Implementation Committee for overseeing the action plans based on all the NRC’s recommendations. Patient care and safety will always remain our top priority.”

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