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**For Information**
**on 17 November 2014**

## Legislative Council Panel on Health Services

## Quality Management of Pathology Reports in Hospital Authority

### Purpose

This paper sets out the system in place in the Hospital Authority (HA) for the quality management of pathology reports. It also summarises the handling of a recent pathology report deviation incident at the United Christian Hospital (UCH) and the corresponding improvement measures.

### Pathology Reporting in HA

2. In HA, there are 22 hospitals with pathology departments or laboratories, providing the following services: Anatomical Pathology, Chemical Pathology, Clinical Microbiology, Haematology and Immunology. Pathologists diagnose diseases through an analysis of tissues, cells and body fluid samples. Pathology reports describe the histological findings and present the opinion of pathologists. The reports serve as one of the many tools for clinicians to make diagnosis. Clinicians have to consider the whole clinical scenario, for example, signs and symptoms of a patient, imaging results and many other investigations to develop a treatment plan that best addresses the particular situation of each patient. In a complex case, an interdisciplinary team comprising doctors from different specialties will be formed to determine the best treatment plan. As the accuracy of pathology reports has a direct bearing on the diagnosis of clinicians and hence patient safety, HA takes the quality management of pathology reports seriously.

3. The pathology service in HA is led by specialists who have to be accredited through a set of stringent requirements by the Hong Kong College of Pathologists and the Hong Kong Academy of Medicine. A full training programme covers six years of post-internship training in recognised training institutes. The specialist training is divided into two phases - an initial phase of basic training followed by another phase of higher training (the details of the requirements are in **Annex**).

4. Aside from the stringent training and accreditation requirements, HA has put in place mechanisms to safeguard the quality of pathology reports both at hospital and corporate levels.

***Hospital Level***

5. At hospital level, both the running of laboratories and the performance of individual pathologists are subject to independent quality assurance. All the anatomical pathology laboratories in HA have been accredited for medical testing through regular surveys and assessment by one of the following third-party authorities:

(a) the College of American Pathologists ;
(b) the Hong Kong Accreditation Service; and
(c) the National Association of Testing Authorities, Australia.

These authorities provide independent assurance of operational standards and technical competence of HA laboratories.

6. For assurance of quality, HA has also engaged external quality assurance programmes (EQAP) organised by the College of American Pathologists, the Royal College of Pathologists of Australasia and the Hong Kong College of Pathologists to assure the diagnostic accuracy of anatomical pathologists.

7. Apart from EQAP, pathology departments in HA also undertakes regular internal clinical audits. In accordance with the international standard, 1% of pathology reports in histopathology service are randomly selected for audit. As for high risk or complex cases, such as frozen section and renal biopsy, all cases will be audited. Individual hospitals review and discuss the audit findings at their regular management meetings with a view to sharing the learning points, keeping track on the quality of pathology reports and sustaining the vigilance level of pathologists.

***Corporate Level***

8. At corporate level, HA Head Office (HAHO) has set up specific coordinating committee to coordinate the quality assurance for each clinical specialty. The Coordinating Committee in Pathology establishes clinical standards for quality assurance, and identifies and

manages risk inherent to the specialty.

## Recent Incident in UCH

9. In respect of a recent incident concerning the pathology report deviation at UCH, HA has taken comprehensive follow-up actions in accordance with established procedures, including conducting a root cause analysis. The findings by an Independent Expert Panel (the Panel) appointed by UCH confirmed that the occurrence of the incident was mainly due to personal performance issue. The discrepancies made in the pathology reports were largely due to lapses of sustained vigilance of the pathologist concerned. The cases with discrepancies in the pathology reports were not generally considered difficult by pathologists and the majority of the discrepancies would not have been made by a vigilant pathologist. A brief account of the incident and the follow-up actions taken are set out in the ensuing paragraphs.

### *The Incident*

10. On 7 August 2014, UCH reported a pathology report deviation incident to HAHO. UCH discovered that a pathologist had issued three incorrect pathology reports with potential clinical impacts in a working meeting of the Department of Pathology (the Department) in late May 2014. UCH had taken immediate action to suspend the pathologist concerned from issuing pathology reports independently.

*(a) Review by UCH*

11. Upon discovery of the issue, the Department proactively reviewed a total of 2,153 pathology reports, which represented all reports issued independently by the pathologist concerned since her attainment of Fellowship and accreditation by the Hong Kong College of Pathologists and the Hong Kong Academy of Medicine. This retrospective peer review process was conducted by four senior pathologists of UCH.

12. During the course of the review exercise, immediate follow up actions on patient management were taken once report deviation requiring changes in treatment plans were identified. Pathologists informed individual case doctors to review the clinical management of affected patients simultaneously in the retrospective peer review process. Affected patients were contacted for their revised treatment plans and follow up appointments as appropriate.

13. The review, completed on 7 August 2014, had identified 118 cases (or 5.5% of the reports issued by the pathologist concerned) requiring revisions. 17 of these reports, or 0.8% of the total number of reports issued by the pathologist concerned, were found to be having significant discrepancies requiring changes in treatment plans. Among the 17 cases, two required major changes and the remaining 15 needed minor adjustments.

*(b) Follow-up on the 17 cases*

14. UCH had offered all necessary examinations and treatments to the 17 affected cases. All patients are in stable conditions. HA will continue to monitor and follow up with their conditions.

*(c) Public Disclosure*

15. UCH informed the public of the incident and the planned actions to follow up the incidents through a press conference on 11 August 2014.

*(d) Independent Expert Panel*

16. UCH set up the Panel on 13 August 2014 to establish the factual account and investigate the causes of the incident, make recommendations to prevent future recurrence, and develop an action plan to enforce the recommendations.

17. The Panel comprises a senior pathologist in HA, the President of the Hong Kong College of Pathologists, a member of the Quality Assurance Subcommittee of the Coordinating Committee in Pathology, the Service Director (Quality & Safety) of Kowloon East Cluster, the Chief Manager (Patient Safety & Risk Management) of HAHO, and a HAHO member in the Coordinating Committee in Pathology.

18. The Panel confirmed the findings of the peer review set out in paragraph 13 above and agreed that appropriate follow up actions had been taken for the 17 cases requiring changes in treatment plan. Moreover, the Panel found no false-positive misdiagnosis that could cause unnecessary treatment to patients. Among the other 101 cases requiring revisions in the reports, there are seven cases involving deceased patients. The Panel confirmed that the causes of death in these cases were all due to their serious underlying diseases and were unrelated to any discrepancies in the pathology reports.

19. The Panel concluded that the occurrence of the incident was mainly due to personal performance issue involving the lapses of sustained vigilance in a task that requires a high level of attentiveness. Pathology diagnosis requires judgement and interpretation under conditions of high complexity and variability, sustained vigilance is a basic requirement for a pathologist to pay every effort to minimise errors and report accurately.

*Recommendations*

20. To prevent recurrence of any similar incidents, the Panel has made a number of recommendations. Apart from those related to the pathologist concerned, the recommendations include:

(a) An appropriate system should be enforced to monitor the performance of trainees; targeted coaching and training should be given to trainees with track record of unstable performance; the utmost importance of sustained vigilance should be emphasised to every trainee via various channels;

(b) Communication between the hospital management and the Department should be enhanced to improve the effectiveness of incident management; and

(c) A clear reporting line and review mechanism should be developed to strengthen coordination among departments involved and to enhance the efficiency of incident management process, particularly for incident that may have major impact on patient care.

**Improvements in the Quality Management System**

21. HA has accepted the recommendations of the Panel and UCH has taken a number of immediate measures after the announcement of the investigation report to enhance patient safety and to prevent the recurrence of a similar incident. The measures included implementing a mentoring system to provide one-on-one coaching and assistance to trainees, enhancing the case meeting mechanism between pathology and other clinical departments to review and discuss cases regularly, introducing the "Crew Resources Management" training to enhance

quality as well as strengthening the incident reporting mechanism.

22. UCH had also commenced human resources proceedings in accordance with prevailing HA human resources policy.

23. HA is committed to enhancing the quality management of pathology reports. With the enhancement measures introduced after the incident, together with the prevailing internal clinical audits, external quality assurance programmes and the standing quality management system already in place, HA will continue to pay every effort to ensure patient safety and prevent the recurrence of similar incident in the future.

Food and Health Bureau
Hospital Authority
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**Annex**

## Accreditation of Pathologists by the Hong Kong College of Pathologists and the Hong Kong Academy of Medicine

The training programmes of specialists follow the broad recommendations set forth by the Hong Kong Academy of Medicine (Academy). A full programme covers six years of post-internship training in recognised training institutes. Specialist training is divided into two phases - an initial phase of basic training followed by higher training. Total training time is six years, of which not less than three years are in basic training.

2. The basic (specialist) training is concerned with the acquisition of knowledge and basic skills, including bench work and operation of equipment. The emphasis is on education. Academic activities such as lectures, departmental and inter-departmental meetings, clinico-pathological conferences and journal clubs are prominent elements of basic training.

3. Practical skills are important in higher training. Diagnostic proficiency and laboratory and interpretive skills are sharpened. Trainees are expected to respond to clinical consultations, liaise with other clinicians and provide direct input in matters concerning patient management. Participation in clinical ward rounds and clinico-pathological meetings is considered an important part of training.

4. Completion of basic training is marked by the Membership Examination. The examination consists of written papers, practical and oral examinations. One of the papers includes questions on basic pathological sciences. The Fellowship Assessment is based on oral examination. In addition, one or more of the following may be required: written papers; a test of practical competence appropriate to the specialty; a dissertation; a suitable higher degree; a collection of refereed published papers with a critical commentary; or a casebook with a critical commentary.

5. Fellows of the Hong Kong College of Pathologists (the College) are recommended to the Academy by the College for admission as Fellows of the Academy. Fellowship in the Academy carries full formal recognition of specialist status in Hong Kong. A Fellow of the College

is entitled to use the designation "pathologist" in the professional context and on official documents. Fellow of the Hong Kong Academy of Medicine (Pathology) and Fellow of the Hong Kong College of Pathologists are both quotable qualifications. In practice, pathology specialists / pathologists in both public and private hospitals are issuing pathology reports independently.