For discussion
on 21 December 2015

LEGISLATIVE COUNCIL PANEL ON HEALTH SERVICES

Patient Safety Management in the Hospital Authority

PURPOSE

This paper briefs Members on the management of patient safety in the Hospital Authority (HA). It also summarises the handling of the recent incidents at the Tuen Mun Hospital (TMH), Pamela Youde Nethersole Hospital (PYNEH) and Queen Mary Hospital (QMH) and the corresponding improvement measures.

BACKGROUND

2. As advancement of medical sciences has made diagnostic and treatment procedures ever more sophisticated, modern healthcare is increasingly complex with inherent risks. The emergence of complications, side-effects and changing clinical conditions may also increase the risks involved in the treatment procedures.

3. HA places quality and safety as top priorities in the planning and running of its patient-centred services. It establishes governance structure, systems and procedures to ensure high clinical standards.

CLINICAL GOVERNANCE & SAFETY MANAGEMENT

4. Clinical governance is the system and collective measures through which healthcare organizations are accountable for continuously assuring and improving the quality and standards of their services. In this respect, HA has established a clinical governance structure under which clinical specialty leaders form Coordinating Committees (COC) to identify and address clinical risks. A coherent quality and risk management framework is embedded in the set of standards adopted through hospital accreditation activities.

Hospital Accreditation

5. HA has actively embarked on accreditation of public hospitals since 2009 using the model of the Australian Council of Healthcare Standards. Experience of the five pilot hospitals[1] suggested that hospital accreditation contributed to the fostering of patient safety culture and strengthening of quality management framework. HA is extending the accreditation programme to other hospitals.

Credentialing

6. HA has drawn up a framework for credentialing to verify the qualifications, clinical experience, professional training and other relevant professional attributes of healthcare professionals. HA has recently also established a central credentialing committee to assess and address credentialing needs for high risk procedures. In clinical departments, staff are assigned duties and responsibilities according to their experience and training.

QUALITY & SAFETY MEASURES IN MAJOR DOMAINS

7. HA has identified major domains for safety management through organization-wide risk assessment by making reference to international trends in quality and safety management. In each domain, systems and processes are in place to address specific quality and safety issues.

Medication Safety

8. To enhance medication safety, HA has implemented various measures which include, for example –

(a) In bedside administration of medications, HA practices standard procedures to verify patients' identity. For example, the nurse would verify the patient's name and check the patient's identification information on the wristband and Medication Administration Record;

(b) HA has put in place an integrated Advanced Incidents Reporting System (AIRS) to facilitate efficient reporting of

[1] The five pilot hospitals are the Caritas Medical Centre, Queen Elizabeth Hospital, PYNEH, QMH and TMH.

medication incidents by frontline healthcare workers. Information captured through AIRS enables the review of error patterns and study of particular risks;

(c) HA has implemented an electronic medication ordering system, namely the Outpatient Medication Order Entry system, in outpatient departments since 1995. Furthermore, HA has implemented Inpatient Medication Order Entry, which is an electronic ordering system, in acute inpatient hospitals since 2013. Electronic medication can minimize errors caused by transcription and facilitate the timely review of orders. Drug allergy history checking is also simplified; and

(d) The Medication Safety Committee leads regular executive medication safety rounds to enhance safety.

Surgical Safety

9. HA adopts and implements the "Surgical Safety Checklist" of the World Health Organization in all operating theatres. The checklist involves the "Time-out" process whereby the entire clinical team in the operation theatre takes an explicit moment of pause to check and verify the identity of the patient, go through the procedure to be performed and consider any anticipated critical events before undertaking an operation. This multidisciplinary approach facilitates communication of the clinical team and reduces the possibility of errors arising from miscommunication. HA also adopts mandatory surgical count by counting objects before, during, and after surgery to prevent incidents of retained material/instruments such as gauze and sponge.

Surgical Outcomes Monitoring and Improvement Programme

10. HA has implemented the Surgical Outcomes Monitoring and Improvement Programme (SOMIP) in all surgical departments since 2008. SOMIP is an organisation-wide and clinician-led quality improvement programme, which aims at monitoring major and ultra-major surgical outcomes. The SOMIP journey significantly enhances transparency of surgical outcome information. Staff fora and media workshop are arranged to drive accurate communication of findings with focus on actively sustained improvement efforts.

11. Clinical experts in HA follow up on the findings of SOMIP to identify and implement practical improvement measures. The mortality

rate of emergency surgery has significantly improved since the launch of this programme in 2008.

Infection Control

12. Healthcare-associated infections are one of the most common complications of patient care. In this respect, HA is prioritizing its efforts to reduce the burden of infections.

13. To tackle the multi-drug-resistant organisms (MDRO) in hospitals, HA has established a corporate wide electronic MDRO database since 2011 for surveillance, monitoring, risk communication and public disclosure. Methicillin-resistant Staphylococcus aureus (MRSA) is one of the MDRO causing infection in hospitalized patients. On top of the surveillance, the MRSA bacteremia rate has been selected as the Key Performance Indicator to drive improvement. HA has achieved an overall 25% reduction for MRSA bacteremia since 2007.

14. Response system is in place to combat infectious disease crisis. In 2014 and 2015, HA activated the established system to manage the threat of Ebola Virus Disease and Middle East Respiratory Syndrome respectively. The system of response proves successful in managing risk to patient and staff.

Device Safety

15. The rapid development in medical research has resulted in the proliferation of new technologies in equipment and drugs. HA has set up a robust assessment mechanism, at both hospitals and corporate level, to support evidence-based decision making in the adoption of new technology.

At the hospital level

16. HA has built up, at the hospital level, a system of clinical governance whereby equipment with various levels of complexity will only be operated by staff with the corresponding experience and qualification. Furthermore, the clinical management teams will regularly conduct quality assurance activities such as mortality and morbidity meetings and clinical audits to ensure that any event affecting patient care would be looked into as appropriate.

17. The hospital administration systems support the clinical departments in the regular maintenance of equipment, including centrally coordinated programmes guiding the replacement of old or outdated equipment. The Central Sterile Supplies Departments have established protocols to ensure the sterilization of instruments is up to the specified standard.

At the corporate level

18. HA establishes the Central Technology Office under the Quality & Safety Division at HA Head Office (HAHO) to coordinate and align cross-departmental issues concerning medical equipment management using a risk-stratified approach. The HA Mechanism for the Safe Introduction of New Procedure / Technology was implemented in 2001 to review the safety and efficacy of new procedures and technologies before their introduction.

19. HA has also established the "Medical Equipment Safety Alert System" to facilitate prompt dissemination of hazard and alert notices involving medical equipment or devices.

Quality Management in Pathology

20. HA has implemented a corporate-wide barcode-based tracking and archiving system in all anatomical pathology laboratories to minimise identification errors. It also enhances traceability of specimens through an electronic information platform for continuous quality improvement.

CLINICAL INCIDENT MANAGEMENT

21. Similar to overseas experience, local clinical incidents were mainly caused by system and process factors rather than mere human errors. Recurrence of similar incidents can be minimized through improvements to the relevant systems and work procedures. Given the complex healthcare settings, it will be difficult for hospitals to attain zero incidents. That said, HA accords the highest priority to patient safety and will investigate each serious adverse event to identify the likely causes and the corresponding improvement measures.

22. Clinical incidents often have common root causes which can be identified, rectified and avoided. Incident reporting, therefore, can

enhance patient safety through facilitating continuous learning from past incidents occurring during the delivery of healthcare services.

Handling of Sentinel Events & Serious Untoward Events

23. HA started to roll out AIRS in 2004, initiated the Sentinel Event Policy in 2007 and implemented the revised Sentinel Event and Serious Untoward Events Policy (the Policy) in 2010.

24. Under the Policy, all public hospitals are required to report Sentinel Events (SEs) and Serious Untoward Events (SUEs) to HAHO via AIRS within 24 hours and handle them in accordance with established procedures. Through the arrangement, HA aims to minimize harm and provide necessary support to patients, family and staff, and encourage open disclosure of the incidents so that lessons could be learnt from the events to prevent similar medical incidents from happening in the future. The full list of medical events for reporting under the SE and SUE Policy is at **Annex**.

RECENT INCIDENTS

25. Recent incidents in TMH, PYNEH and QMH have aroused public interest. A brief account of the incidents and the follow-up actions taken are set out in the ensuing paragraphs.

Clinical Incident in TMH

26. In July 2015, TMH reported an incident on Alkaline Phosphatase (ALP) reference range deviation to HAHO. When an ALP analyser was installed at the Department of Clinical Pathology in TMH in August 2013, the ALP reference ranges of male and female patients for the age group of 60 or above were accidentally swapped. This was discovered on 6 July 2015 during the preparation of laboratory accreditation. TMH had rectified the reference ranges immediately.

27. Upon discovery of the incident, TMH reviewed a total of 9,443 reports, comprising 4,634 male patients and 4,809 female patients, and confirmed that none of the patients have been adversely affected by the incident. TMH informed the public of the incident and the follow-up actions through a press conference on 22 July 2015.

28. TMH set up an Independent Investigation Panel with participation of independent members and pathology experts. The Panel confirmed that the occurrence of the incident was mainly due to failure to detect transcription error. To prevent recurrence of similar incidents, the Panel recommended HA to:

(a) review the workflow to ensure independent entries of data fields by different members with subsequent reconciliation;

(b) document items that have been cross-checked and versions that have been amended;

(c) adopt steps of reconciliation between reference ranges of laboratory report and source documents; and

(d) better communicate to staff a standard operating procedure on cross-checking procedure.

29. The Panel also advised that, as a good practice, one should appoint multi-disciplinary project teams to monitor the installation and function test when major medical equipment system is installed, taking into consideration manpower, workload and project timeline.

30. TMH has taken immediate measures to implement the recommendations to enhance patient safety. HA is working on an electronic platform for cross-checking entries of the laboratory reference ranges. The objective is to validate reference ranges automatically, instead of manually, to avoid transcription error.

Clinical Incident in PYNEH

31. On 24 August 2015, PYENH reported to HAHO an incident related to contaminated lung biopsy specimen resulting in the unnecessary surgical removal of part of the lung of a patient.

32. Two patients had CT-guided lung biopsy performed in the Department of Radiology in PYNEH on the same morning. Pathology reports confirmed both patients had the same type of lung cancer. On subsequent assessment, one patient was referred to the Department of Cardiothoracic Surgery in QMH for further management.

33. In QMH, this patient had surgical removal of the right lower lung lobe. Pathological examination of the excised lung tissue revealed

features of tuberculous infection instead of lung cancer. PYNEH confirmed that there was contamination of the patient specimen which led to the wrong diagnosis.

34. Subsequently, representatives of PYNEH met with the patient and family members to explain the incident and apologize. A media briefing was conducted to disclose the incident on 26 August 2015.

35. PYNEH set up an Independent Investigation Panel with participation of independent members and pathology experts. The Panel has interviewed the staff concerned, examined the workflows and reviewed the relevant documents, qualification of staff involved and manpower status on the day of the incident.

36. The Panel has concluded that problems in three processes are believed to have contributed to the contamination of the specimen, namely biopsy collection, tissue wrapping and embedding in the laboratory. To prevent recurrence of similar incidents, the Panel recommended HA to:

(a) ensure specimen bottle will not be used once the seal is broken or removed;

(b) eliminate the additional use of rinsing bottle for biopsy procedure;

(c) label the specimen bottle once it is designated to a patient;

(d) enhance the documentation of specimen nature and quantity;

(e) stagger the sequence of handling specimen of similar nature whenever possible;

(f) facilitate the ease of single use of forceps in tissue wrapping and embedding; and

(g) ensure adequate checking and traceability in laboratory, particularly in tissue wrapping and embedding procedures

37. PYNEH has subsequently met with the patient again to explain the report findings and expressed sincere apology to him. The hospital will continue to follow up on his clinical condition. PYNEH has taken measures to implement the recommendations to prevent the recurrence of

a similar incident. HA is working with COC Pathology and COC Radiology to take further improvement measures as appropriate.

Non-clinical Incident in QMH

38. In June and July 2015, six patients were found infected with mucormycosis at QMH. All these six patients were immunocompromised. Two of them passed away on 24 June and 14 July respectively. The patient cases have been referred to the Coroner to inquire into the causes of death. HA set up an Investigation Panel subsequently to determine the root cause of the contamination. In the course of investigation, samples from other laundry centres of HA have also been collected but none was tested positive for mucormycosis.

39. HA held press conference to inform the public of the incident and the follow-up actions on 20 July 2015 and the investigation report of the Panel on 6 August 2015 respectively.

40. The Panel confirmed that Shum Wan Laundry (SWL) was the source of the outbreak. There were major deficiencies in the physical environment and the general cleanliness that led to a heavy environment contamination of finished products and faulty disinfection by the laundry process.

41. To prevent recurrence of similar incidents, the Panel has recommended the following measures both on hospital and laundry aspects:

(a) to reinforce the checking of temperature sensors of the laundry equipment in all laundries;

(b) to enhance the monitoring work process in particular moisture control during drying and packing of patient linen items;

(c) to cease the use of starch power for ironing of patient linen items;

(d) to periodically and thoroughly clean, disinfect and de-dust facility environment and delivering vehicles. A clear segregation of used and clean linen should be put in place to prevent cross-contamination;

(e) to follow the “first-in-first-out” principle on linen consumption

and not to allow topping up; and

(f) to conduct periodic microbiological testing for linen items.

42. HA has taken follow up actions on the recommendations of the Panel and adopted immediate and longer term measures to tighten the linen quality control. The laundry service of SWL has been partly taken up by other HA laundries and partly contracted out to an outside vendor since late July 2015.

43. In addition, HA has formed separate task force to review the overall laundry management and to draw up a future mode of operation of laundry services, especially in SWL.

ADVICE SOUGHT

44. Members are invited to note the content of this paper.

Food and Health Bureau
Hospital Authority

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Annex

HA's Sentinel and Serious Untoward Events Policy

Sentinel Events

1. Surgery / interventional procedure involving the wrong patient or body part

2. Retained instruments or other material after surgery / interventional procedure

3. ABO incompatibility blood transfusion

4. Medication error resulting in major permanent loss of function or death

5. Intravascular gas embolism resulting in death or neurological damage

6. Death of an in-patient from suicide (including home leave)

7. Maternal death or serious morbidity associated with labour or delivery

8. Infant discharged to wrong family or infant abduction

9. Other adverse events resulting in permanent loss of function or death (excluding complications)

Serious Untoward Events

1. Medication error which could have led to death or permanent harm

2. Patient misidentification which could have led to death or permanent harm