RISK ALERT

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A Risk Management Newsletter for Hospital Authority Healthcare Professionals

Warfarin, a vitamin K antagonist, has been the only orally available anticoagulant for over 60 years. However, in the past few years, several direct oral anticoagulants have become available for prophylaxis and/or treatment of thromboembolism. These new compounds directly inhibit thrombin (e.g. dabigatran) or activated factor X (FXa) (e.g. apixaban, rivaroxaban). Compared with warfarin, they have a predictable dose-response with much less drug-drug and food-drug interactions. Moreover, they can be given orally in fixed doses once or twice daily, and do not require laboratory monitoring in most patients.

Like warfarin, the major adverse event of these new oral anticoagulants is bleeding. Although the risks of major bleeding related to these new drugs have reported to be similar or even lower than warfarin, there are no approved antidotes to reverse their effects when the ability of blood to coagulate has to be restored.

In the Hospital Authority Drug Formulary, dabigatran, rivaroxaban and apixaban have been listed as self-financed items. While dabigatran and rivaroxaban are included as special drugs for primary prevention of venous thromboembolism in adult patients undergoing total hip or knee replacement surgery, rivaroxaban can be used for treatment of deep vein thrombosis/pulmonary embolism in patients with intolerance or contraindication to warfarin.

Although these new anticoagulants are welcome by clinicians and patients alike, the rapid increase use in clinical practice has created new challenge and risks at the frontline level. From 4Q 2013 to 3Q 2014, two of the eight SUEs related to the use of oral anticoagulant involved the new drugs. Dual use and double entry of anticoagulants had been reported highlighting the fact that frontline staff may not be familiar with these drugs. With more new anticoagulant agents currently under development and are expected to be available for clinical use in the near future, more problems and confusions may arise. Clinical staff should therefore be vigilant about these newer classes of oral anticoagulants and understand that they are high alert medications. The same principles on medication safety as with other conventional anticoagulants should be followed!

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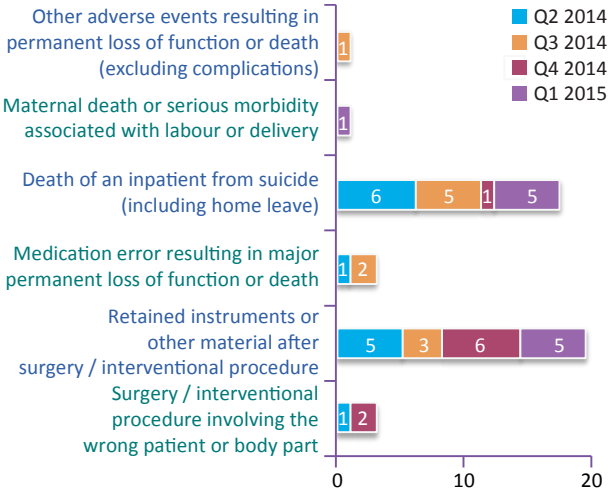
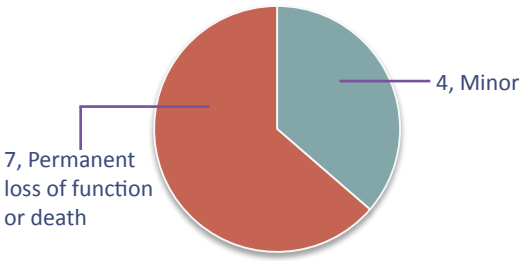
- *Statistic on medication incidents*

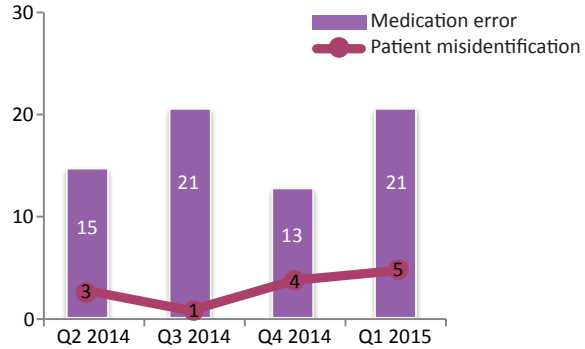
Distribution of SEs in the last four quarters



Consequence of SEs in Q1 2015



Distribution of SUEs in the last four quarters



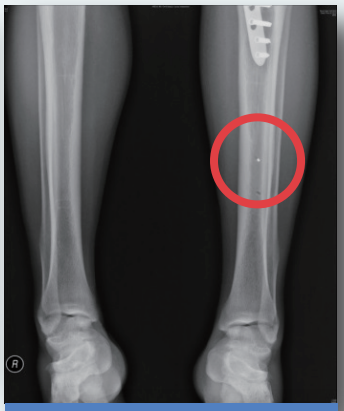
The updated SE and SUE Policy with a supplementary note and the Clinical Incident Management Manual have been implemented since 1 July 2015. To align with the government's practice, the new Chinese translation of Sentinel Event (SE) and Serious Untoward Events (SUE), 「醫療風險警示事件」and「重要風險事件」respectively, was also adopted. Both documents can be accessed at our webpage: http://qsdportal/psrm/Website/PSRM%20Website/index.html

Retained Instruments / Material

Retained tip of Stryker® pin

- The patient had high tibial osteotomy.
- Two pins (Stryker Ortho Lock Ex-pin 3mm) were used for temporary holding of trackers and were removed during the operation.
- The post-operation course was uneventful and the patient was discharged 5 days later.
- Followed up 17 days later, the patient had a routine X-ray of “left knee and long leg length”.
- The X-ray revealed a 2 – 3 mm metallic foreign body at the lower one third of the tibia, which was likely to be the tip of the pin used for holding the trackers.
- Removal of the foreign body was not advised after clinical assessment.

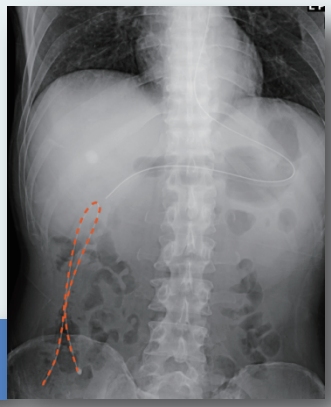
Stryker® pin was used during operation



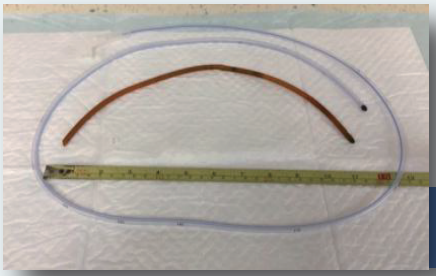
X-ray image revealed the broken tip of pin

Retained segment of feeding tube

- A patient required long-term tube feeding.
- Feeding tubes were changed when necessary.
- An abdominal X-ray taken for patient’s fever revealed a radio-opaque line in right lower quadrant.
- A 36 cm segment of silicone feeding tube was removed via colonoscopy uneventfully.



A segment of feeding tube was noted in a X-ray image



Removed segment of feeding tube

Contributing factor:

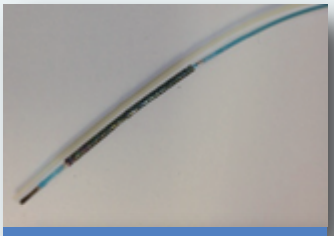
Failure to check the completeness of instrument upon removal.

Recommendations:

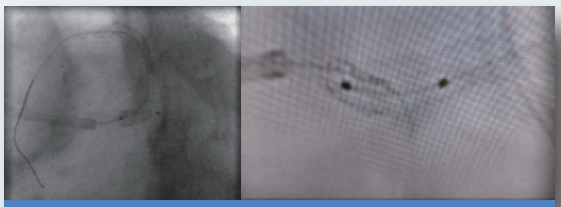
1. Inspect for completeness of instrument upon removal (e.g. checking the completeness of the used pin against other pins).
2. Examine by intra-operative X-ray whenever broken instrument in patient is suspected.

Must check completeness of instrument after use.

Retained coronary stent after percutaneous coronary intervention (PCI)



An unexpanded stent over catheter



Stent in-situ (Left: angiogram; Right: angiogram with use of stent boost function)

- A patient underwent PCI where deployment of three coronary drug-eluting stents was planned for improving blood flow in the coronary arteries.
- The patient deteriorated during the procedure and required use of inotrope and supplement oxygen.
- One of the stents could not be deployed to the intended site, thus it was retrieved with the whole stent delivery system.
- The cardiologist did not visualize the dislodged stent on angiogram because of heavy calcification of the coronary vessels.
- This was followed by the successful placement of the other two stents.
- On the next day, patient deteriorated and angiogram revealed a dislodged stent.
- A second PCI was performed uneventfully.
- The patient passed away on post-PCI day 6.

Contributing factors:

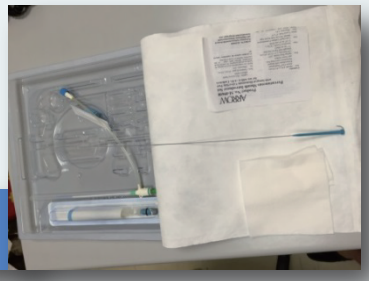
1. Insufficient vigilance.
2. Distraction by deterioration of patient's condition.
3. No explicit standard procedure to verify stent deployment.

Recommendations:

1. Enhance staff vigilance.
2. Strengthen staff training.
3. Establish a standard practice for staff guidance (e.g. examination of retrieved stent by two staff independently).
4. Use of alternative measure (e.g. stent boost function) to ensure proper stent deployment whenever necessary.

Retained guide wire

- A patient had a central venous catheter inserted in the operating theatre.
- The patient was well and discharged with regular follow up.
- Subsequent X-ray examination revealed a 40 cm guide wire.
- The guide wire was removed subsequently.



Central venous catheter inserted in OT

Contributing factors:

1. Lack of robust process to ensure correct counting of guide wires after use.
2. Lack of effective communication among the team members in correct counting and documentation on number of guide wires removed.

Recommendations:

1. Review the procedure and develop guidelines on the use of guide wires.
2. Delineate the roles and responsibilities of team members in procedural safety checking.

Retained gauze in vagina

A raytec gauze was packed in a patient's vagina during an operation.

Peri-operative nursing record: "Long R/G (raytec gauze) packed in vagina".

Doctor ordered "off vaginal packing" on post-operation day 1.

Nurse removed a plain gauze from the patient's vulva.

Discharged home..

The patient removed a raytec gauze from her vagina.

A raytec gauze was used for packing

Contributing factors:

1. Knowledge deficit in different types of gauze.
2. Unclear role delineation.

Recommendations:

1. Revise the "Preceptorship Program for Registered Nurse".
2. Develop a competency matrix for job delineation.

Maternal Death

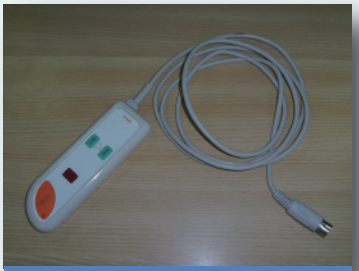
A maternal death due to HELLP syndrome was reported.

The clinical management was reviewed and found to be appropriate.

HELLP syndrome is a group of symptoms that occur in pregnant women who have

H – Hemolysis
EL – Elevated Liver enzymes
LP – Low platelet count

Patient Suicide



A call bell cord

In Q1 2015, a total of five patients (1 male and 4 female aged between 46 to 98) had committed suicide.

Two of them had underlying psychiatric illness.

Four committed suicide by jumping from height during home leave; the fifth, by strangulation with the cord of call bell.

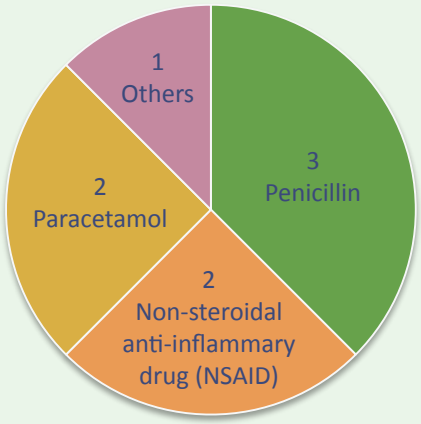
Overall assessment and management of these patients were considered appropriate.

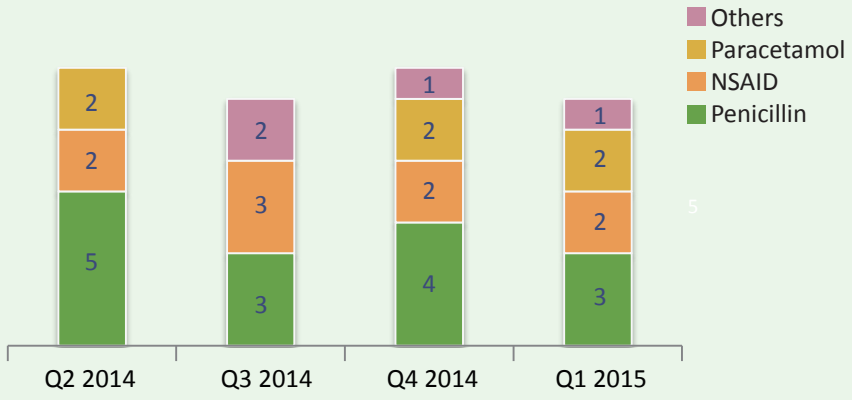
Serious Untoward Events

There were 26 SUEs reported in Q1 2015, of which 5 were patient misidentification and 21 were medication error.

Medication Error

There were 8 SUEs related to administration of known drug allergens. The drugs involved including paracetamol, penicillin/cephalosporin, NSAID and nifedipine.





Important notes:

Augmentin (amoxicillin and clavulanic acid) is a Penicillin.
DO NOT prescribe Augmentin to patient with known Penicillin allergy.

Case highlight:
A dose of oral phosphate mixture was given to a baby intravenously

- Nurses A and B intended to administer the following to a neonate:
  - Normal Saline (NS) in a 3ml syringe (for flushing);
  - Cefotaxime (light-yellow in color) in a 3ml syringe (capped with needle);
  - Oral phosphate solution in a 3ml sterile syringe (without needle and wrapped in a syringe bag).
- Nurse B flushed the intravenous access with NS and then administrated oral phosphate intravenously instead of cefotaxime.
- The incident was discovered when Nurse B, while discarding the used syringes, found 1.65ml light-yellow solution of cefotaxime remained in the syringe.
- The patient was stable afterwards. No adverse event was noted.

All medications were placed in kidney dish before administration

Contributing factors:

1. Use of sterile injection syringe for administration of oral medication in preterm patients.
2. Lapse of concentration during drug administration.

Recommendations:

1. Source for appropriate oral syringes which are not compatible for intravenous injection.
2. Reinforce clear labeling on syringes for all medications.
3. Use of colored labels to alert staff on the route of drug administration.

Patient Misidentification

Case highlight (1):
Two patients' computer tomography (CT) images were swapped

Currently, when Radiology Department received inpatient CT requests, registration of CT request form via Radiology Information System (RIS) is required. A RIS gum label will then be generated, which will be affixed onto the CT request form.

A sample of wrongly labelled CT request form

1

- Radiology Department received two CT abdomen requests with registrations done.
- Patient A's RIS label was affixed onto Patient B's CT request form and vice versa.

2

- Patients' identities were checked against the CT request forms but not the RIS label before CT scans.
- Thus, the CT images of Patients A and B were swapped in RIS and ePR.

3

- Both patients were discharged subsequently with follow up CTs arranged.
- The error was discovered during the follow up CT scan.

4

- Clinical management of both patients were not affected.

Contributing factors:

1. Failure of correct patient identification during the matching process.
2. Lack of consistent house-rule during the process of RIS registration.
3. Use of two labels of RIS and GCRS on the same CT request form which may cause wrong labelling.

Recommendations:

1. To reinforce the importance of correct patient identification at different juncture before CT scan.
2. To develop a house-rule for RIS registration and correct patient identification.
3. To perform regular audit on correct patient identification.
4. Explore with HAHO IT team on the possibility of generating a combined information sheet that could merge the information from GCRS and RIS.

Case highlight (2):
Entry of CT report to wrong patient's electronic Patient Record (ePR)

Radiologists currently use 2 independent systems, Film Reading System (FRS) and Radiology Information System (RIS), for reviewing films and writing reports respectively.

1

- Patient A had emergency CT abdomen.
- Patient B had CT abdomen at outpatient.

2

- The radiologist verbally informed the clinical team that patient A had pneumoperitoneum and subsequently emergency operation was performed.

3

- To prepare the written report of patient A, the radiologist retrieved the correct image from FRS.
- However, the radiologist wrongly retrieved patient B's record from RIS by scanning the barcode on the wrong CT request form.
- Therefore, CT report belonging to patient A was uploaded to the ePR of patient B.

4

- Patient B was admitted for the abnormal CT report.
- Surgeon reviewed the CT film and found no evidence of pneumoperitoneum.

5

- Clinical management of both patients were not affected.

Contributing factors:

1. Reports writing and images retrieving were operating under two separate systems.
2. Picking up a wrong CT request form for barcode scanning would lead to the wrong selection of patient for report writing.

Recommendations:

1. Improve work process design to restrict the reporting task under one patient's identity at a time.
2. Post up an eye-catching alert signage on top of the screen of both systems to keep Radiologists vigilant in patient identification.

Local Sharing

Two medication incidents related to the use of new anticoagulants

Case 1

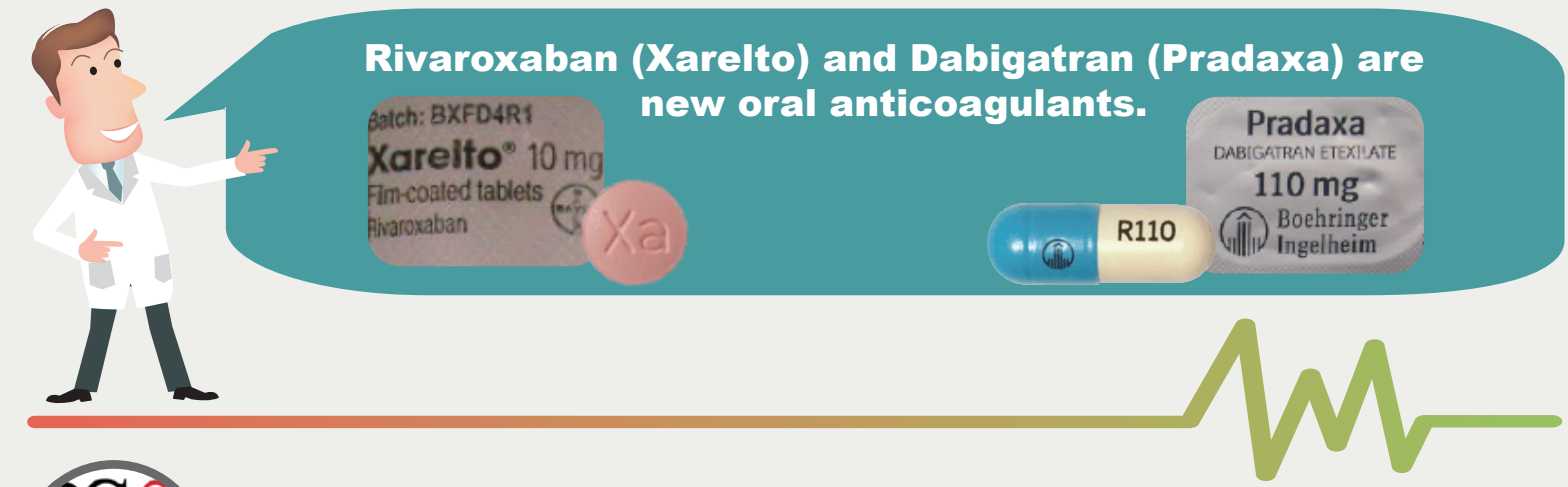
- Patient A was on rivaroxaban for atrial fibrillation.
- Doctor was unaware that Xarelto was the brand name of rivaroxaban and transcribed both rivaroxaban and Xarelto onto the Medication Administration Record (MAR).
- One extra dose of rivaroxaban was given to the patient.

Case 2

- Patient B was initially put on dabigatran which was replaced by warfarin during follow up.
- Doctor transcribed both warfarin and dabigatran onto the MAR according to ePR record.
- Both drugs were given to patient.

Learning points:

1. Increase the awareness and alertness of staff on the use of new anticoagulants.
2. Special attention should be paid to elderly, underweight or obese patients, especially those with renal or liver impaired function as new anticoagulants may cause more bleeding complications in this group of patients.



Statistic on medication incidents

Staff can access the latest statistics on clinical incidents, including medication incidents, at the following link:

http://qsdportal/psrm/Website/PSRM%20Website/incident.html

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