Investigation Panel Report on Transfusion Reaction Event
Summary and Recommendations

Report summary

The Investigation Panel investigated into the events starting from the donation to transfusion of the contaminated blood unit to patient and the subsequent management. The Panel then made recommendations on how to minimize similar incidents. No culture documented red cell transfusion related bacteraemia or death have been reported for the last 10 years in HK. The standards at our Blood Transfusion Service and clinical management at Tuen Mun Hospital are observed to be very good. This very rare incident is indeed a sporadic case of contamination of a red cell unit by a common environmental cold-loving bacteria *Pseudomonas fluorescens*. The DNA fingerprint of the bacterial strains isolated from the blood culture of the deceased, the transfused red cell unit and one of the many strains found in the condensate specimens in the foam box containers with coolant used for transporting blood bags are identical. It is not possible to prove retrospectively the sequence of events leading to the contamination which happened one month ago. The possibilities could be, firstly, the environmental bacteria from the foam box contaminated the surface of the blood bag which might then enter through rare but possible microscopic defect with the facilitation of condensate formed during transportation; secondly, bacteria from condensates inside the blood bin or other environmental sources might have contaminated the hands of the phlebotomist who then contaminated the venepuncture site which allowed the bacteria to gain access into the blood bag. Since the bacteria can multiply to a huge number in red cell units even stored at 4 degree Celsius after a long period, it is important to ensure good aseptic technique during venepuncture and dryness of bags during storage and transportation. Manipulation of the tubings of the blood bags should be minimized. The HA and individual hospital guidelines for transfusion should be clarified to ensure that transfusions are only given if it is indicated, and is administered appropriately and closely monitored. The logistics of investigations for transfusion reactions must be clarified to avoid miscommunication. In the event of unexplained shock during transfusion, the patient should be treated empirically with one dose of broad spectrum antibiotic which is not continued unless investigations prove otherwise. A programme on auditing the management of transfusion reaction should be launched to ensure that the guidelines are complied. The track record of only one transfusion related septic death after 3,429,000 units of blood products were issued in the past ten years clearly showed that our Blood Transfusion Service has exceeded the international (FDA) standard of one death per

million of blood transfusion. No individual should be held responsible for the occurrence of such a rare incident.

Recommendations

Despite the effort of the panel, it is not possible to find out exactly what happened one month ago. Nevertheless, for risk reduction purposes, the panel makes recommendations based on the risk analysis at critical control points of the processes including communication, the findings on retrospective microbiological testing and the information in existing literature. All professionals involved in this investigation have followed the international standard and guidelines in their service. No individual should be held responsible for the occurrence of such a rare incident.

Blood donation, storage and transportation

1. Segregated sinks for handwashing and instrument cleansing should be provided in mobile blood donation vehicles.

2. Phlebotomists and nurses performing blood collection must ensure that the stipulated skin disinfection timing is registered by the use of a timing device such as a timer or stop clock.

3. Ensure that all blood bags tubings are dry and free of visible surface condensation prior to thermal sealing and milking by strippers. These procedures should be minimized.

4. Measures must be taken to minimize the amount of condensate in the blood unit transport containers or any storage sites. These containers must be regularly disinfected to reduce the environmental bacterial density so as to minimize the risk of contamination through inconspicuous pin hole defects in blood bag tubings which, in theory, may rarely arise from time to time but are undetectable.

5. Institute surveillance of discarded blood products by culture in order to generate contamination prevalence data to assist in preventing future similar incidents.

Blood transfusion and management of reactions

6. The HA and TMH guidelines on transfusion in terms of the indication for red cell transfusion, the responsibility and logistics of sending of donor blood units

for microbiological investigation during transfusion reactions should be clarified and promulgated to frontline health care workers. The exact indication for transfusion should be well documented on the blood request form of the Clinical Management System (CMS).

7. An auditing programme for transfusion reactions and their management according to HA guidelines should be considered. This would alert all medical doctors and nurses to follow these guidelines.

8. It is important that elective transfusion should preferably be instituted during the morning or early afternoon hours of normal working days and the rate of infusion should be complied.

9. Unexplained cause of shock and fever should be treated by one dose of broad spectrum antibiotic(s) with anti-pseudomonas coverage after taking blood culture from the patient. The antibiotic should be stopped once the investigations prove otherwise. It is also important NOT to abuse antibiotics by giving them to every patient who develop fever after transfusion since most of them do not have a transfusion-related infection unless there are other clinical indications. Clinicians should be aware of the possibility of anaphylactic reaction and septic reaction occurring at the same time especially when the initial blood investigations after the onset of shock suggest acute severe sepsis and the clinical progress could not be fully explained by anaphylaxis alone.

10. All blood products returned from patients with shock related to transfusion (or suspected septic transfusion reaction) must be examined by a Gram stain as soon as possible and if positive, a phone report must be sent to the clinician immediately.

Hospital Authority
22 January 2008

輸血反應事件的調查小組報告
摘要及建議

報告摘要

調查小組就此事件作出調查，已詳細審查全部過程，包括血液收集、輸注給有關病人，以至其後的處理等各個環節。小組亦作出了建議，以儘量減低類似事件再次發生。在過去十年，香港並無經細菌培殖證實之紅血球輸注引致細菌感染或死亡個案。據小組之調查觀察，輸血服務中心的輸血服務及屯門醫院的臨床處理均有很高的水平。這是一宗罕見的單一事件，涉及的血液被一種在環境中常見及嗜冷的「螢光假單胞菌」污染。從死者血液、涉及輸注的血液，和於置有冷卻劑的血包運送發泡膠箱內多個冷凝水樣本中找到的細菌中之一個樣本，均屬相同的脫氧核糖核酸指紋圖譜。但因事情發生在一個月前，小組無法事後重組血液在那個環節受到污染，只能推斷可能原因如下。於血液運送時，發泡膠箱內一些環境細菌透過冷凝水經血包上罕有但可能存在的非肉眼所能看到的微細裂縫進入血包；第二個可能性，是運送箱內冷凝水中的細菌或其他環境細菌，污染抽血人員手部，繼而把細菌帶到捐血者之抽血位置上，讓細菌有機會進入血包。雖然血液保存在攝氏 4 度中，但經過長時間的貯存，此類細菌仍有可能在血包內大量繁殖，因此抽血過程中的嚴謹消毒程序是十分重要，而血包在保存及運送時亦須保持乾爽，連繫血包的軟管亦應減少處理程序次數。醫管局及各醫院應釐清輸血指引，確保在必要的情況下才給予病人輸血，並要適當地進行及密切觀察病人輸血時的情況。調查不良輸血反應的各項運作亦須清晰，以避免溝通上的問題。一旦輸血期間病人出現原因不明的休克，醫生應根據經驗給予病人一劑量的廣譜抗生素，如調查後證實沒有細菌感染，應停止使用。此外，醫院應推行不良輸血反應處理審核計劃，以確保員工遵守指引。

根據以往的記錄，在過去十年內已使用的三百四十二萬九千包血液製品中，這是唯一與敗血性輸血反應有關的死亡事件，清楚顯示輸血服務中心是優於國際(FDA)標準的每一百萬宗輸血中有一人死亡。沒有任何人仕須為這宗罕見事件的發生而負責。

建議

儘管調查小組已盡很大努力，但亦無法確定一個月前的事情如何發生。雖然如此，為減低風險，小組根據過程中包括溝通在內的各個關鍵環節作出風險分析，加上隨後的微生物測試結果及現有的文獻資料，作出了一系列建議。小組認為，是次調查涉及的所有專業人員，在提供服務時均有遵照國際標準及部門服務指引，無人需對這宗罕見事件負責。

捐血、血液貯存及運送

1. 流動捐血車上應設有不同洗滌盆，分別用作洗手及清潔器具。

2. 負責收集血液的抽血人員及護士應使用計時工具，例如計時器或秒表，確保執行消毒皮膚的既定時間。

3. 血包軟管在加熱封口及切割前，應確保軟管乾爽及表面沒有可見的冷凝水，對軟管的處理程序次數亦應減至最少。

4. 應採取措施減少血液運送箱或任何貯存器的冷凝水，容器必須定期消毒，以減少環境中的細菌數量，從而減低細菌由血包軟管上極微細缺口進入血液的風險，此等缺口理論上極為罕有，亦不能用肉眼察覺。

5. 對棄置血液進行血液培養監察，以收集污染數據，協助防止類似事件再次發生。

輸血及不良反應的處理

6. 應釐清醫管局及屯門醫院的輸血指引，包括說明有需要輸血的情況、處理不良輸血反應時血液化驗的安排及責任，並向前線醫護人員發布。在需要輸血的情況下，應在臨床管理資訊系統的血液要求表上清楚列載需要輸血的具體原因。

7. 應考慮根據醫管局的指引，推行不良輸血反應及其處理的審核計劃，提醒醫生和護士遵守有關指引。

8. 非緊急的輸血程序應於一般工作日的早上或下午較早時間進行，亦須遵循既定的輸注速度。

9. 一旦病人在輸血期間出現原因不明的休克和發燒，在抽取病人血液作培養後，應給予一劑量可抗假單胞菌的廣譜抗生素作治療，經調查後如證實是其他情況，應立即停止使用。切勿濫用抗生素，不是每名輸血後發燒的病人都須使用抗生素，因多數都不是因輸血受到感染，除非病人還有其他臨床的原因。醫療人員應要留意，病人亦可能同時出現過敏反應及敗血性反應，特別是當病人休克，初步血液檢驗顯示急性嚴重敗血症，而且病況未能單以過敏反應解釋。

10. 病人因輸血(或懷疑敗血性輸血反應)休克而送還的所有血液製品，必須盡快使用革蘭氏染色法作測試，如結果屬陽性，必須立即致電向醫療人員報告。

醫院管理局
二 oo 八年一月二十二日