World Marrow Donor Association	Rapid Alert Adverse Reaction Clinical Alert			
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ADVERSE REACTION CLINICAL ALERT

The WMDA Serious Product Events and Adverse Reactions (SPEAR) committee was informed of the following serious adverse reaction resulting in a recipient death and determined that a WMDA global alert is warranted to optimize recipient safety:

This recipient experienced a cardiac arrest following double cord blood unit (CBU) infusion and was not able to be resuscitated. The recipient was a 39 year-old male with a history of hyperlipidemia, hypertension (HTN), and accelerated phase chronic myeloid leukemia, who underwent a double CBU transplant on 19 March 2013. Historically, the patient had had episodes of chest pain that led to a cardiac catheterization in 2006, reportedly without clear evidence of coronary artery disease.

The recipient received a fully ablative preparation regimen (1200cGy TBI, 60 mg/kg x 2d cyclophosphamide (Cy), rabbit ATG). During the 2nd dose of Cy, the patient developed atrial fibrillation requiring 3 drugs for control of rapid ventricular response, including an amiodarone drip; he received only 85% of the planned dose of Cy as a result.

On 19 March 2013, the recipient received CBU #1 (red cell replete, ABO type B+ [recipient: type O]). CBU #1, 105 ml in volume, was contained in 2 halves. The 1st half of CBU #1 was thawed at the bedside and administered as an IV infusion over 5 minutes. The recipient developed nausea, abdominal cramping, HTN, and low back and flank pain, treated with morphine, furosemide, lorazepam, and ondansetron. The urine was observed at this time to be clear without visible heme. The 2nd half of CBU #1 was then thawed and administered as an IV infusion over 5 minutes. The patient then developed hypoxemia with oxygen desaturation to the 80's treated with 50% O_2 by Venti-Mask; O_2 saturation improved to 100%.

The recipient was felt to be sufficiently recovered from the 1st unit to go ahead with the infusion of the 2nd unit. CBU #2 (red cell replete, ABO type O+, 75 ml in 1 bag) was then thawed and administered as an IV infusion over 5 minutes. Shortly after administration, the patient developed progressive dyspnea and O_2 desaturation despite oxygen supplementation. The recipient required evaluation and intervention by the rapid response team, culminating in intubation. The patient was then readied for the ICU, but there was a 90 minute delay due to the lack of an available ICU bed.

The patient was given a total of 80 mg IV furosemide in the interim but had no response. Upon arrival at the ICU, a Foley catheter was placed with no urine in the bladder and no urine output. About 45 minutes after ICU transfer, the recipient suffered a cardiac arrest and was unable to be resuscitated. Labs from the peri-ICU transfer time showed a potassium of 7.6, which was treated with glucose and insulin; of note, the lab reported gross hemolysis in a blood specimen for electrolytes obtained around the time of the initial rapid response team evaluation and canceled that test because the specimen was thought not to be a valid collection.

We are informing the WMDA Community of this reaction to ensure awareness that two large volume RBC-replete CBUs given by the thaw and infuse method in the context of a patient with prior cardiac risk factors was associated in this case with a fatal outcome. We suggest that you consider this adverse reaction in the context of your patients' cases in deciding on the optimal methodology for CBU administration.