1. Cover Page containing the following information:
   • Hospital or Healthcare System name and address, city, state, URL.
     ◦ UC Irvine Health Medical Center, 101 The City Dr S, Orange, CA
     ◦ http://www.ucirvinehealth.org
   • Name, title, e-mail address and phone number for a contact person.
     ◦ Minh-Ha Tran, DO; minhhat1@uci.edu; 714-456-8925
   • Name, e-mail address and phone number of the contact person’s assistant, if applicable.
   • Title of application.
     ◦ Quality Improvement in Cardiopulmonary Bypass Surgery
   • Identify topical area(s) of focus in this application:
     ◦ patient safety
     ◦ quality improvement
     ◦ patient experience
   • Brief statement by an executive leader in support of the application.
     ◦

2. Executive Summary (limit 200 words)

Blood transfusion has been identified by Joint Commission and AABB (Advancing Transfusion and Cellular Therapies Worldwide) as a key area of focus in healthcare quality improvement. A blood conservation program in cardiac surgery was developed and implemented, resulting in significant improvements in intraoperative transfusions for patients undergoing cardiopulmonary bypass surgery.

3. Background and relevance of the problem being addressed and effort undertaken

Increasing scrutiny has been placed upon transfusion practices. Recognizing and reducing unnecessary transfusions addresses parallel goals of improving both quality and cost-effectiveness while reducing transfusion-associated risks. Furthermore, blood utilization in general is subject to significant heterogeneity in practice patterns. Cardiothoracic surgery, particularly procedures carried out under cardio-pulmonary bypass (CPB), have historically been resource-intense in terms of blood bank support. Extraordinary variability has also been observed in the application of blood resources during cardiac surgery.
In an observational cohort of 82,446 patients undergoing primary coronary artery bypass graft surgery with CPB support during calendar year 2008 at 408 sites in the US, rates of blood transfusion ranged from 7.8% to 92.8% for Red Blood Cells, 0% to 97.5% for Fresh Frozen Plasma, and 0.4% to 90.4% for platelets. The authors further found that this variability was independent of case mix. Data from UCI support historic intraoperative red cell transfusion rates for cardiopulmonary bypass surgery of 58% for procedures involving valve replacement and 64% for first-time (non-redo) CABG.

Recognizing the need for reducing transfusion risk among patients undergoing cardiac surgery supported by the cardiopulmonary bypass circuit, a multidisciplinary team was formed to initiate process improvement.

4. Describe the effort, including the scope, process, strategies and tactics utilized, challenges encountered and how they were addressed.

A multi-disciplinary task force was formed under the leadership of our Thoracic Surgery Chief. In addition to our cardiac surgeon, representation included cardiothoracic-anesthesiology, transfusion medicine, our chief perfusionist, and pharmacology.

A process-elucidation phase was initiated entailing literature review, multi-level discussions with all stakeholders, and intraoperative observation of numerous operations whereby opportunities for improvement were identified.

This process yielded hemodilution as a major contributor to intraoperative declines in hemoglobin that engender both transfusion risk and subsequent coagulopathy. A vicious cycle then develops culminating in increased intraoperative transfusion – particularly upon discontinuation of CPB (the ‘off-pump’ phase).

We divided the cardiac surgery procedure into phases of bypass (with bypass referring to the period where the patient is completely supported by the CPB pump). Sources of hemodilution during each phase are outlined in the following table.
<table>
<thead>
<tr>
<th>Pre-Pump</th>
<th>On-Pump</th>
<th>Off-Pump</th>
</tr>
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<tbody>
<tr>
<td>• IV fluid administration</td>
<td>• Cardiopulmonary circuit priming volume</td>
<td>• Crystalloids and washed red cells</td>
</tr>
<tr>
<td>• Suspension fluid for medications</td>
<td></td>
<td></td>
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</tbody>
</table>

IV – Intravenous

Administration of fluids and products during the off-pump phase generally reflects therapeutic directives aimed at addressing coagulopathy and bleeding associated with CPB.

Lowest-hanging fruit therefore came from pre- and on-pump sources of IV fluid. These were addressed by careful curtailment of anesthesiologist-driven pre-pump IV fluid administration and concentration of medications to minimal suspension volumes. Additionally, expert practice and evidence-based resources\(^3\) supported implementation of retrograde-autologous priming for blood conservation.

The use of intraoperative cell-salvage and antifibrinolytics were already in place at the time of our intervention. These modalities were continued based upon evidentiary and best-practice support.

5. Describe the results of the effort.

Data on blood utilization were obtained as part of an IRB-approved research project. Our intervention, which successfully reduced excess intraoperative volume exposure (hemodilution), resulted in improved hemoglobin levels throughout all phases of cardiac surgery.

Figure 1 reports data for first-time, non-redo Coronary Artery Bypass Graft (CABG) surgery and Figure 2 reports data for non-emergent valve replacement surgery.
Figure 1: First time, Non-Redo CABG. Delta hematocrit (Postimplementation minus Preimplementation). The unshaded boxes represent statistically significant changes. For example, the lowest-on pump hematocrit was 2.4% higher during the post-implementation period (transfusion of 1 unit of RBCs to an adult typically increases hematocrit by 3%).

Figure 2: Non-emergent valve replacement surgery. In this graph, the delta hematocrit (postimplementation minus preimplementation) is represented by the columns, mean hematocrit per period by the line graph. For example, the lowest on-pump hematocrit was 5.58% higher during the postimplementation period (transfusion of 1 unit of RBCs to an adult typically increases the hematocrit by 3%).

The improvement in hematocrit through reduced degrees of hemodilution
The overall benefit of our implementation resulted in reduced red cell transfusions during non-redo CABG surgery (Figure 3) and in non-emergent surgeries involving valve replacement (Figure 4).

Figure 3: Percent of cases between the preimplementation phase (n=72; solid black column) and postimplementation phase (n=64; unfilled column) in which any Red Blood Cell transfusions were administered during the off-pump phase (difference 20.6%, p=0.014).

Figure 4: Percent of cases between the preimplementation phase (n=38; solid black columns) and postimplementation phase (n=65; unfilled columns) in which red cells, plasma, or platelets were transfused during the off-pump period (all differences statistically significant).
6. Discuss the significance of the results. How do the results demonstrate outstanding achievement?

The outstanding nature of this achievement lies both in the teamwork and in the ultimate outcome. The teamwork relied upon expertise of individuals from a range of specialties thus making the total much greater than the sum of its parts. As a result, we were able to significantly reduce intraoperative transfusions for patients undergoing cardiopulmonary bypass surgery.

7. Describe sustainability and scaling of the achievements.

The sustainability of results was more recently assessed using a data extraction from our anesthesia information management system, Surgical Information Systems (SIS Systems, Alpharetta, GA).

All consecutive surgeries involving the cardiopulmonary circuit (with certain exclusions – ie, massive transfusion, aortic arch repair) for a 52-month period spanning the intervention were analyzed for intraoperative blood component use. The pre-intervention period included January 2011 to March 2012 (study months 1-15; n=112 cases); the post-implementation period April 2012 – April 2015 (study months 16-52; n=276 cases).

Statistical process control methodology was used to analyze trends in intraoperative blood transfusions. Monthly mean intraoperative transfusions, units per case, were as follows:

- **RBC (pre-post)**
  - 1.37 (SD 1.43) vs 0.59 (SD 1.10) units per case
  - Absolute difference 0.78; (95% CI, 0.47-1.07; p<0.001)
- **Plasma (pre-post)**
  - 1.62 (SD 2.39) vs 0.60 (SD 1.40) units per case
  - Absolute difference 1.02; (95% CI, 0.54-1.50; p<0.001)
- **Platelets (pre-post)**
  - 1.01 (SD 1.09) vs 0.60 (SD 1.08) units per case
  - Absolute difference 0.41; (95% CI, 0.17-0.65; p<0.001)
This analysis demonstrates that transfusion reductions have achieved sustained reductions between the pre- and post-implementation periods (See process control charts, Figures 5 a-c).

Figures 5a-c: Process control chart for improvement in RBC, Plasma, and Platelet transfusions. Vertical dotted lines represent implementation.

a) Red blood cell transfusions, monthly:

b) Plasma transfusions, monthly:
c) Platelet transfusions, monthly:

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References


