Doubling the 30-minute rule without compromising Red Blood Cells quality and safety

What is this research about?
Blood Operators, such as Canadian Blood Services, collect blood from donors with the goal to manufacture and distribute blood products to hospitals for use in patients in need. At Canadian Blood Services, red blood cell (RBC) units are the most common blood product distributed to hospitals. RBC units contain cells and biologicals that need to be stored under controlled temperature in order to maintain cell viability and limit bacterial growth. International regulatory agencies have established a “30-minute rule” to limit RBC exposure to uncontrolled temperatures during storage for up to 30 minutes to prevent contaminating bacteria from growing to lethal concentrations. In reality, it is not always possible to start a transfusion into a patient within 30 minutes, resulting in RBC wastage and potential delay of the transfusion. The economic impact of this rule is of importance. More than 9000 RBC units were disposed in England in 2008/2009 because they had been left out of controlled temperature. Similarly, 457 RBC units were discarded in the province of Ontario, Canada, in 2009 due to the 30-minute rule. The studies that led to the 30-minute rule were conducted in the 1970s, when blood products were stored in containers (glass bottles) with or without additive solutions that do not reflect current practices. The purpose of this two-year study was to document RBC unit exposure to room temperature and change in RBC quality and bacterial growth to establish if a link exists between these.

What did the researchers do?
Canadian Blood Services research clinic in Vancouver collected whole blood from healthy volunteer donors. RBC unit processing and storage were performed in accordance with Canadian Blood Services standard operating procedures. Groups of two ABO/Rh- matched, pooled, and split RBC units were used.

In Phase I of the study, RBC units (bacteria-free or inoculated with the bacteria Serratia liquefaciens and Serratia marcescens) were exposed to room temperature a single time for five hours or multiple times, each time for 30 minutes. Bacteria-free RBC units were quality tested following an in vitro panel of assays focusing on the RBC unit characteristics, metabolic changes and biomechanical lesion which was used to measure changes in RBC quality in control units and units exposed to room temperature. RBC units inoculated with bacteria were tested for bacterial growth using a standard microbial colony forming assay. RBC units core temperature was determined in mock RBC units which were stored and removed from storage in parallel with the testing units. Both internal and external temperatures were monitored using standard temperature loggers.

In Phase II, units inoculated with bacteria (Staphylococcus epidermidis, Escherichia coli, Yersinia enterocolitica and Serratia marcescens) were exposed multiple times to room temperature during their shelf life, each time for either 30 minutes or 60 minutes. RBC units were tested for bacterial growth and RBC core temperature was determined following protocols of Phase I.

In brief...
Once prepared for the hospital, red blood cells must be kept under refrigeration in order to maintain cell viability and limit bacterial growth until they are transfused into a patient. This study provides evidence that red blood cells can be exposed to room temperature for up to 60 minutes several times during their shelf life without compromising quality and safety of the product.
What did the researchers find?

- RBC unit core temperature ranged from 7.3 to 11.6°C during the 30-minute room temperature exposures.
- The time a RBC unit core temperature takes to reach 10°C varied from 22 to 55 minutes during 5-hour room temperature exposures.
- RBC quality was preserved after single or multiple room temperature exposures.
- Bacterial growth was not significantly increased in the first two hours of a 5-hour exposure of RBC units to room temperature.
- Statistically significant differences in bacterial growth were observed only after 2 h during the single 5h-exposure and between control and multiple 30 min-exposed units.
- Bacterial growth is not different between contaminated RBC units exposed to room temperature for 30 minutes or 60 minutes.

How can you use this research?

This study is aligned with other international studies also in support of the extension of the 30-minute rule. Blood Operators can use this research to make informed decisions when considering extension of the 30-minute rule. The researchers used the evidence to inform a proposal to extend the 30-minute rule for RBCs to 60 minutes. This would allow minimizing red blood cell discards, since units could be exposed to uncontrolled environments for a longer period of time, without compromising the quality or safety of red blood cell units for transfusion (i.e., improve CBS and hospital inventories). This proposal was submitted to the Canadian Standard Association (CSA) which concluded that no further RBC quality experimental work is required but that more repetitions of the bacterial experiments are necessary for final approval of the change to the CSA Standard. The proposal was also submitted to Canadian Blood Services Operations which is now under evaluation. These changes are expected to have an impact on Blood operators as it will change the time limitation for RBC exposure during production. More importantly it will reduce the wastage of RBC units by Hospitals without compromising the safety and efficacy of the product.

About the research team: Dr. Sandra Ramirez is a Development Scientist with Canadian Blood Services and Associate Professor in the department of Biochemistry, Microbiology and Immunology at the University of Ottawa. Dr. Eiad Kahwash is a Canadian Blood Services Medical Director located in Halifax. Dr. Yulia Lin is a Transfusion Medicine Specialist at Sunnybrook Health Sciences Centre. Dr. Jason Acker is the Associate Director, Development and Senior Scientist with Canadian Blood Services. Dr Acker is also Associate Professor in the Department of Laboratory Medicine and Pathology at the University of Alberta. Natasha McLaughlin, is a Project Manager working with Dr. Kahwash. Cherie Mastronardi and Adele Hansen are Project Leads in the Canadian Research and Development group. Heather Perkins, Yuntong Kou, Tracey Turner and Dilini Kumaran are Research Assistants at Canadian Blood Services netCAD laboratories. Mariam Taha is a PhD candidate with Dr. Ramirez. Dr Qi-Long Yi is senior biostatistician within the Epidemiology and Surveillance group of Canadian Blood Services.

This ResearchUnit is derived from the following publications:

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