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Blood Bag Temperature Monitoring System

Shokoufeh AALAEI[a], Shahram AMINI[b], Mohammad Reza KERAMATI[c], Hadi SHAHRAKI[d], Ameen ABU-HANNA[e] , and Saeed ESLAMI[f,a,e1]
Mashhad University of Medical Sciences, Mashhad, Iran:
[a]*Student Research Committee, Department of Medical Informatics, School of Medicine,*
[b]*Department of Anaesthesiology, School of Medicine*
[c]*Department of Pathology, School of Medicine*
[f]*Pharmaceutical Research Center, School of Pharmacy*
[d]*Department of Electrical Engineering, Faculty of Engineering, University of Birjand, Birjand, Iran*
[e]*Department of Medical Informatics, University of Amsterdam, Amsterdam, The Netherlands*

Abstract. Storage and transportation of red blood cells (RBCs) outside the standard temperature range as defined by guidelines can lead to hemolysis. One of the main factors believed to cause hemolysis is temperature.Infusion of the corrupted RBCs leads to haemolytic reactions which are severe and life-threatening. We developed a temperature monitoring system to monitor temperature changes of each blood bag during storage and transportation. The main objective of the present study was evaluating the accuracy of the temperature monitoring system and studying its feasibility. Validating the system relied on accurate digital thermometers that latch on a blood bag. To evaluate the feasibility, a case study was performed on 20 RBC bags transported from hospital blood bank to the cardiac surgery intensive care unit and the heart operating room. The results indicated that 12% of 25605 recorded temperatures (per minute) were outside the standard range. Minimum and maximum temperatures were 0.5℃ and 16℃ that were below and above the standard, respectively. The system was shown to be easily handled by users. The system is capable to alarm when a blood bag's temperature is outside the standard temperature and prevents blood corruption. This system can be used as a decision support system in blood transfusion services to improve storage and transportation conditions of the blood bags.

Keywords. Transfusion, hemolysis, temperature change, temperature monitoring system, decision support system

Introduction

Blood transfusion can save many patients' lives and has many clinical benefits, but it's not without risk. According to the 2012 annual SHOT report that covers the UK nine people out of 2466 have lost their lives due to blood transfusions. Compared with similar findings in 2011, there was an increase of about 12.5% [1]. Most cohort studies showed transfusion can cause adverse patient outcomes; including death, organ failure progression, infection and prolonged hospital stay [2]. Acute and delayed hemolytic

[1]Corresponding Author.

reactions are one of the deadly reactions caused by blood transfusions and their occurrence should be prevented as much as possible [1].

One of the main factors that cause hemolysis is temperature [3]. Storage and transportation of RBCs outside the specific defined temperatures leads to hemolysis via blood biochemical changes [4]. Infusion of these RBCs can be fatal due to severe symptoms that may occur [5].In order to preserve the quality of RBCs, they should be kept at a specified temperature range during storage and transportation [6, 7]. The use of a proper refrigerator with interior temperature between 1℃ to 6℃ is essential for storage. Also based on European and American guidelines, temperature of RBCs during transportation must be kept between 1℃ to 10℃ [8-10].

Concern about blood products' temperature begins when they are dispatched from the blood bank to different wards within the hospital and placed out of refrigerator in ambient temperature for an undetermined length of time. According to the 30-minutes rule, if a blood product is placed out of refrigerator longer than 30 minutes it must be taken out of use cycle [11]. But it is hard to determine the length of time that they were placed in out-of-range temperatures. The limited blood supply doesn't allow discarding them without confirming their length of stay outside the standard temperature.

In recent years, there has been an increasing interest in using temperature-sensitive indicators to address the problem of temperature monitoring during storage and transportation. Two types of these indicators are available for this purpose. Type 1 is a temperature indicator that determines if a bag's temperature has exceeded a defined maximum. Type 2 is a time-temperature indicator that determines the length of time in which a bag's temperature has exceeded a defined maximum. None of these indicator types can continuously record temperature changes and also control for the minimum temperature. We hence designed a device that is attached to a blood bag and continuously monitor temperature during storage and transportation and record them on embedded memory.

This study aimed to test the accuracy of the new temperature monitoring system and evaluate its feasibility during storage and transportation for RBCs transported from the hospital blood bank to the cardiac surgical intensive care unit (CSICU) and the heart operating room.

1. Materials and Methods

According to a need assessment performed in the hospital, the monitoring temperature system was designed and developed by the authors. This system is equipped with an accurate thermometer sensor and a memory unit to save temperature in pre-specified time intervals when attached to the blood bag. One of the main features of this system is its connectivity to an external reader to display the recorded data in a graphical form and to save them in an external memory for computer use. In addition the system compares the recorded temperatures with the standard ranges and gives appropriate alarms. In order to test the accuracy of the system, we used different standard digital thermometers to be attached to the blood bag including one with the accuracy of ±0.3℃. For this purpose we used standard blood bags that were filled with water at different temperatures. Then we compared the standard digital thermometers recorded temperature with our system.

For evaluating the feasibility of the system, a case study was performed on 20 RBC bags transformed from the blood bank to the CSICU and heart operating room for

transfusion. Alarm capability of the device was disabled and only temperature of the blood in the bag during storage and transportation was saved on the embedded memory.

There were up to six stages of transportation and storage for each blood bag: transportation from blood bank to OR, storage in OR, transportation to CSICU if not used in OR, storage in CSICU, and finally transportation to blood bank if not used.

2. Results

We achieved ±0.5℃ accuracy for the temperature monitoring system. These systems recorded a total of 25605 measurements (one per minute) of data, of which12% were abnormal (out of range).Table 1 displays minimum, maximum and average of blood bag temperatures during storage and transportation.

Table 1. Minimum, maximum and average of blood bag temperature in degrees Celsius

	Blood Bank	Transportation	Operating Room	ICU
Minimum	3	1	1	0.5
Maximum	12.5	16	13	9
Average	4.4	5.3	4.5	3.5

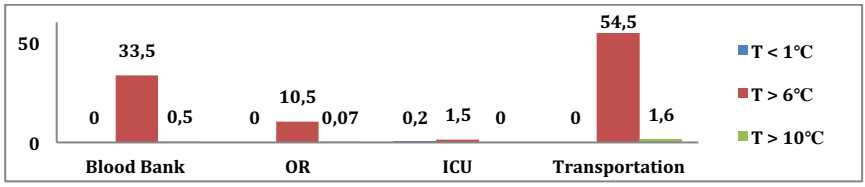

Figure 1. Percentage of abnormal data in different stages of storage and transportation

The results of the preliminary analysis assessed the percentage of abnormal data measurements in different stages (Figure 1). We were able to identify 7 cases out of 20 in which temperature was outside the 1℃ to 10℃ range and should be taken out of use cycle based on the 30 minutes rule. Other 13 out of 20 bags had exceeded defined temperature during storage. Our findings showed undesired fluctuations in blood bag temperatures in one domestic refrigerator due to its thermostat function. If the warning system of the designed device would have been activated, it would have announced critical conditions with appropriate timely alarms. We used a questionnaire to evaluate the users' satisfaction. The questionnaire was answered by 30 users. They were satisfied and found the system easy to handle. We did not record any issue for attaching and detaching the device from the blood bags and did not also have any gap in recording the bags' temperature and extreme values (below -10℃ and above 40℃).

3. Discussion

The results of this study showed that a considerable percentage of RBC bags have out-of-range temperatures during storage and transportation and it requires corrective action. Our designed and developed temperature monitoring system has hence the potential to improve the quality of blood bag storage and transformation, especially after utilization of alarms. Also feedback from staff showed that the device was easy to handle. The cost of the device (approximately $30) indicates it should be affordable especially in the coming years.

Our study has some limitations. First turning on the device before connecting to the bag or turning it off after separating it from the bag could cause the device to record ambient temperature; data cleaning techniques should be able to address this limitation. Second, like other temperature indicators this device can just provide surface temperature [12]. Despite these limitations, we found that this system can provide more information in comparison to standard temperature and time-temperature indicators due to its continuous monitoring and recording. For example results in one of the domestic refrigerators indicated regular fluctuation in blood bag temperatures during storage with 3℃ peak to peak amplitude. After preliminary analysis we found these fluctuations are due to the thermostat function. In addition we could measure and record the temperatures which were below the range. Below 1℃ temperature as important as above 6℃ for storing and transporting blood bags but none of the usual indicators can control for the minimum temperature.

Another main feature of the temperature monitoring system is its capability of remote monitoring. It can be connected wirelessly to a central system and a central system can monitor the temperature conditions and expiry date of a blood bag.

Further research should be done to investigate the utilization of this system as a decision support system in different blood services. In this way two types of alarms can be employed. These alarms can be used to declare critical conditions before and after blood corruption and prohibit the use of the corrupted blood bag.

4. References

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