NHS
Blood and Transplant

CC/5434 – TEMPERATURE EVALUATION OF SHORT JOURNEY TRANSPORT CONTAINERS/EXTENDED JOURNEY TIMES USING ADDITIONAL PHASE CHANGE MATERIAL

CLOSE OUT REPORT – **RED BLOOD CELLS ONLY**

6TH July 2017

Background

Short journey transport containers (SJCs) were introduced to NHSBT in 2015 following a tender process. The initial requirement was for the containers to meet a required journey time of three hours only. This time was achieved by using just two PCMs in the small container and three PCMs in the medium container for red blood cells.

During initial validation and following implementation, it was thought that if additional PCMs were added to the container during use, then there was a potential to extend the journey time. Ideally, this would match the current maximum journey times for the long journey containers (LJCs), although it was not entirely expected that the SJCs would or could achieve these results.

The LJCs were introduced in 2009/2010 and the fleet is ageing, reducing in quantity and requires expensive maintenance. The LJCs are almost three times the purchase cost of the SJCs and if there was the possibility that the journey time for SJCs could be extended, they could be used for some journeys in place of the LJCs and reduce both purchase and maintenance costs for NHSBT.

Initially, an informal evaluation took place to look at the potential of the containers when used with additional PCMs. Va-Q-tec, the manufacturer, was consulted and the view was that the journey time could be extended using the extra phase change material. The results of the evaluation looked promising and a formal validation was set up under CC/5434 using VAL979 to attempt to extend the journey time beyond the current three hours.

1. Validation – For Red Blood Cells Only

The validation took place at NHSBT Tooting in a test cabinet which replicated the ambient (external environmental) temperatures at both -5℃ and +35℃. To obtain a journey time of the existing three hours for red blood cells, there was a requirement for two PCMs in the small container, one at the bottom and one at the top, and three PCMs in the medium container, one at the bottom of the container and two at the top. The red blood cells were sandwiched in between the two layers of PCMs in a plastic liner. For the extended journey test, two PCMs were placed at the bottom of each container and two PCMs at the top with the units sandwiched between the layers in the plastic liner, the

addition of two extra PCMs for the small size container and one extra PCM for the medium size.

Both the small and medium sized containers were tested with minimum and maximum loads of 1 – 6 units and 7 – 15 units respectively at ambient temperatures of -5℃ and +35℃. A further test of on e unit only in the medium sized container was also carried out at both of the ambient temperatures above.

From the outset of the validation, the results achieved were minimal with variations in temperature results across the probes. A meeting was convened with the NHSBT validation team and va-Q-tec to investigate. It was found, following advice from va-Q-tec and evaluation work carried out by the team, the testing practices were different to those which took place during the original validations. The team found that the placing of the probes for this validation was actually on the very edge of the pack and the probes were not providing an optimal reading of the surface temperature of the units and therefore the probes needed to be moved to a slightly different position in order to read the surface temperature correctly.

It also emerged from the investigations and evaluation work, that it was possible to achieve better temperature control, if the units were packed in a certain way, that is the red blood cell units were stacked in the containers with the ports folded.

Following this investigative work, VAL979 was amended to reflect the positioning of the probes on the units and the packing permutations which could extend the journey times for these containers. The validation was re-started with the new version of the validation protocol.

2. Validation Results

2.1 Small Short Journey Container – One Unit Red Blood Cells at -5℃

The validation results show that the container achieved a maximum time of 23 hours and 45 minutes and a minimum time of 22 hours and 0 minutes, achieving an extended journey time above three hours and therefore passed the requirements of the test.

2.2 Small Short Journey Container – Six Units Red Blood Cells at -5℃

The validation results show that the container achieved a maximum time of 22 hours and 35 minutes and a minimum time of 17 hours and 20 minutes, achieving an extended journey time above three hours and therefore passed the requirements of the test.

2.3 Small Short Journey Container – One Unit Red Blood Cells at +35℃

The validation results show that the container achieved a maximum time of 15 hours and 25 minutes and a minimum time of 14 hours and 50 minutes, achieving an extended journey time above three hours and therefore passed the requirements of the test.

2.4 Small Short Journey Container – Six Units Red Blood Cells +35℃

The validation results show that the container achieved a maximum time of 9 hours and 30 minutes and a minimum time of 7 hours and 5 minutes, achieving an extended journey time above three hours and therefore passed the requirements of the test.

2.5 Medium Short Journey Container – Seven Units Red Blood Cells at -5℃

The validation results show that the container achieved a maximum time of 23 hours and 40 minutes and a minimum time of 15 hours and 5 minutes, achieving an extended journey time above three hours and therefore passed the requirements of the test.

2.6 Medium Short Journey Container – Fifteen Units Red Blood Cells at -5℃

The validation results show that the container achieved a maximum time of 22 hours and 25 minutes and a minimum time of 18 hours and 20 minutes, achieving an extended journey time above three hours and therefore passed the requirements of the test.

2.7 Medium Short Journey Container – Seven Units Red Blood Cells at +35℃

Following initial erratic results for this test, it was found that even with extra PCMs, the container was failing to maintain the three hour specification with at least one or two probes falling short of the required time. The tests were carried out again to check the equipment, but still failed. The tests were then carried out at Cambridge to check consistency and continued to fail. It was decided to carry out this test at a maximum ambient temperature of +30℃ and a deviation was raised in the change control record.

2.8 Medium Short Journey Container – Fifteen Units Red Blood Cells at +35℃

This test too proved to be difficult and failed as above. The test was carried out again at Cambridge to check consistency but still failed. It was also decided to include this in the deviation and to test at +30℃.

2.9 Medium Short Journey Container – One Unit Red Blood Cells at -5℃

The validation results show that the container achieved a maximum time of 22 hours and 50 minutes and a minimum time of 21 hours and 55 minutes, achieving an extended journey time above three hours and therefore passed the requirements of the test.

2.10 Medium Short Journey Container – One Unit Red Blood Cells at +35℃

The validation results show that the container achieved a maximum time of 12 hours and 0 minutes and a minimum time of 10 hours and 50 minutes, achieving an extended journey time above three hours and therefore passed the requirements of the test.

CC/5434 – Temperature evaluation of short journey transport containers/extended journey times using additional phase change material.

2.11 Medium Short Journey Container – Seven Units Red Blood Cells at +30℃ – Deviation as above

The validation results show that the container achieved a time of 3 hours and matched the original journey time specification but with a lower ambient temperature.

2.12 Medium Short Journey Container – Fifteen Units Red Blood Cells at +30℃ – Deviation as above

The validation results show that the container achieved a time of 3 hours and matched the original journey time specification but with a lower ambient temperature.

3. Results Analysis and Recommendations for Use

3.1 Small Short Journey Container – Ambient Temperature -5℃ and +35℃

Following analysis of the results, all tests for the small containers passed the requirement to extend the journey time beyond three hours. The minimum time across all tests was 7 hours and 5 minutes and therefore it can be concluded that the maximum journey time achieved for the use of the small SJCs for the maximum and minimum capacities is 7 hours. This is two hours shorter than the maximum journey time achieved for the LJCs.

The small SJCs will be recommended for use for the transportation of red blood cells using four PCMs for up to seven hours and this will be reflected in DAT48 in the next revision of the document.

3.2 Medium Short Journey Container – Ambient Temperature of -5℃ and +35℃

Results analysis shows that all tests for red blood cells in the medium container at -5℃ passed the requirement to extend the journey time beyond three hours. The minimum time across these tests was 15 hours and 5 minutes.

Testing of one unit in the container achieved a minimum 10 hours and 50 minutes at +35℃. It can be concluded that one unit maintained temperature because of being totally surrounded by four PCMs.

The two other tests failed to extend the journey time even with extra PCMs and had difficulty maintaining the full three hours specification, originally a requirement of the procurement process. This led to the reduction of the maximum ambient to +30℃ and testing took place at Cambridge for these final two tests.

3.3 Medium Short Journey Container – Ambient Temperature of +30℃

Analysis of results show that the test for seven units and 15 units in the medium container at +30℃ only reached 3 hours. The results were

disappointing in that the ambient temperature range had been reduced by 5℃. The original specification required these containers to achieve a journey time of three hours at +35℃. The manufacturer has been informed in order to investigate the container performance.

To achieve operational consistency and reduce ambiguity, the medium short journey transport containers, will be recommended for use for the transportation of red blood cells at ambient of -5℃ to +30℃ using four PCMs for up to three hours only and this will also be reflected in the next revision of DAT48.

In the case of journey times above three hours for the transportation of red blood cells, the small short journey container should be used for loads or 6 units or less and the long journey container for loads of 6 units or more.

All data and summary tables have been reviewed by Quality Assurance and will be stored along with the completed validation protocol in the validation library at NHSBT Tooting.

Constraints

The validation work for this change control had been challenging from the outset. Apart from the differing results which were being achieved initially, there were problems with the data loggers, a new set had to be sent from Newcastle, and unavoidable staff absence which prolonged the validation beyond the expected completion time. The investigative and evaluation work that was required to achieve these results also meant that the expected completion time was extended. The medium container's performance at warm temperatures was extremely disappointing delaying the validation work further.

This validation has been one of trial and error, the final results can provide NHSBT and in particular hospitals who use the small SJC, with further flexibility within their transport container fleet when using the va-Q-tec small SJC for up to seven hours for transporting red blood cells.

The validation work however has reduced the ambient temperature range by 5℃ and only maintained the current transportation times of the medium SJC.

Conclusion

Following investigative and informal evaluation work, the small short journey transport container has achieved an extended journey time for red blood cells.

The small container should now be authorised for use for longer journeys for red blood cells reducing pressure on the ageing fleet of long journey containers. DAT48 will be updated to show the new journey time and the required packing permutations, which will also ensure a nationally consistent system of packing for these transport containers.

The medium container, however, will only be authorised for use for three hours for red blood cells. The container has in fact failed the original specification and therefore discussions will need to ensue with the manufacturer.

The results of this validation will still provide potential benefits to NHSBT despite the results for the medium container. The container has still provided outstanding results across all component types and will enhance the flexibility of NHSBT's container fleet and will further reduce the use of the long journey container. It has also enabled a consistent packing process which will be reflected in the next revision of DAT48.

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