NHS
Blood and Transplant

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

CLOSE OUT REPORT – **PLATELETS ONLY**

28th April 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 three PCMs for platelets.

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 extend the journey time beyond the current three hours. The maximum journey time that could be achieved for platelets would be 8 hours because of the requirement for agitation.

1. Validation – For Platelets 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 platelets, there was a requirement for three PCMs, one at the bottom of the container and two at the top. The platelets 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 the container and two PCMs on top with the platelets sandwiched between the layers in a plastic liner, the addition of one extra PCM.

Both the small and medium sized containers were tested with minimum and maximum loads of 1 – 6 units and 7 – 15 units respectively at both 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, that 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 platelet concentrate 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 platelets which are stacked on top of one another in the container remained within the required 20℃ - 24℃ f or a longer period of time, which could result in longer journey times.

Following this investigative work, VAL979 was amended to reflect the positioning of the probes on the platelet 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 Platelets at -5℃

The validation results show that the container achieved a maximum time of 15 hours and 45 minutes and a minimum time of 10 hours and 30 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 Platelets at -5℃

The validation results show that the container achieved a maximum time of 13 hours and 10 minutes and a minimum time of 10 hours and 5 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 Platelets at +35℃

The validation results show that the container achieved a maximum time of 10 hours and 15 minutes and a minimum time of 8 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 Platelets at +35℃

The validation results show that the container achieved a maximum time of 15 hours and 0 minutes and a minimum time of 13 hours and 10 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 Platelets at -5℃

The validation results show that the container achieved a maximum time of 12 hours and 35 minutes and a minimum time of 8 hours and 50 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 Platelets at -5℃

The validation results show that the container achieved a maximum time of 10 hours and 55 minutes and a minimum time of 9 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 Platelets at +35℃

The validation results show that the container achieved a maximum time of 14 hours and 45 minutes and a minimum time of 11 hours and 35 minutes, achieving an extended journey time above three hours and therefore passed the requirements of the test.

2.8 Medium Short Journey Container – Fifteen Units Platelets at +35℃

The validation results show that the container achieved a maximum time of 16 hours and 40 minutes and a minimum time of 12 hours and 10 minutes, achieving an extended journey time above three hours and therefore passed the requirements of the test.

2.9 Medium Short Journey Container – One Unit Platelets at -5℃

The validation results show that the container achieved a maximum time of 13 hours and 30 minutes and a minimum time of 10 hours and 10 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 Platelets at +35℃

The validation results show that the container achieved a maximum time of 12 hours and 35 minutes and a minimum time of 8 hours and 50 minutes, achieving an extended journey time above three hours and therefore passed the requirements of the test.

Following analysis of the results, all tests passed the requirement to extend the journey time beyond three hours. The minimum time across all tests was 8 hours and 50 minutes and therefore it can be concluded that the maximum journey time was achieved for the use of SJCs of both sizes for the maximum and minimum capacities for the longest journey time possible of eight hours (due to the required for agitation) matching the longest time for LJCs.

The short journey transport containers will be recommended for use for the transportation of platelets using four PCMs for up to eight hours and this will be reflected in DAT48 in the next revision of the document.

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 beset with difficulties 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 outstanding results also meant that the expected completion time was extended. However, although this validation has been one of trial and error, the final achievement can provide NHSBT with further flexibility within their transport container fleet.

Conclusion

As suspected and following investigative and informal evaluation work, the short journey transport container has achieved the maximum journey time possible for platelets and equals that of the long journey transport container.

The container should now be authorised for use for longer journeys for platelets 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 results of this validation will provide potential benefits to NHSBT as the use of the long journey container can be reduced and replaced by the short journey container for the transport of platelets providing further flexibility within the fleet, and also reducing the costs of maintenance and purchase of new transport containers.

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