NHS
Blood and Transplant

CC4140 - VALIDATION AND PILOT OF NEW SHORT JOURNEY CONTAINERS

CLOSE OUT REPORT

9th March 2015

Background

There are currently two container systems used by NHSBT to transport blood and blood products to hospitals, the Clinimed system, which is used for short journeys of less than 2.5 hours, and the va-Q-tec container, which is used for journeys in excess of 2.5 hours.

NHSBT were out of contract with the supplier Clinimed and went to the market with SPN368 to find a short journey container system which would enable journeys of up to 3 hours for product temperatures, 4℃ +/- 2℃, 22℃ +/- 2℃ and a 6 hour journey time for products at -30℃. A solution was found from the supplier va-Q-tec and this was validated for the required journey times.

Due to the fact that there will be only one supplier of transport containers to NHSBT for the delivery of blood and blood products to hospitals, these will now be referred to as 'Short Journey Containers' and 'Long Journey Containers' rather than just 'va-Q-tec Containers'.

The original change control, CC/4140, was opened to include the validation according to VAL631, and the pilot, which was to take place at Cambridge NHSBT supplying all of the local hospitals. However, it became clear during the course of the work to carry out the required validations, and during discussions with Quality Assurance (QA), that it would be easier to remove the pilot from CC/4140 and open a further change control, CC/5366, to cover the pilot and implementation at Cambridge in accordance with the national roll out covered under an umbrella change control of CC/5111.

Container Solution

Following a full procurement process, the supplier va-Q-tec provided a solution which was acceptable to NHSBT and met the requirements of SPN368. The container was much more lightweight than the existing va-Q-tec container and used the same temperature stabilisation material and dry ice currently in use in NHSBT. The solution is currently available in two sizes. The small container holds 1-6 red cell or platelet components, but is not suitable for the carriage of frozen products due to its size. The medium container holds 7-15 red cells or platelet components and 1-10 frozen components. However, it may be necessary to transport one unit in a medium container, so this would also need to be tested (Phase 4 validation below).

Validations

VAL631 was used to carry out the validations on all product temperatures for a three hour journey time. The validations were carried out on prototype containers at Newcastle NHSBT under CC/4140.

Phase 1 of the validation was completed to ensure the three hour journey time was met for red cell and platelet components and the six hour journey time was met for frozen components, at ambient temperatures of -5℃ and +35℃.

Phase 2 of the validation replicated Phase 1 but the ambient temperatures were set at -10℃ and +40℃ to discover the time it wou ld take the container to fail. This phase of the validation has yet to be completed due to time and resource constraints and will be covered under a further change control CC/5434 later in 2015.

During the Phase 1 validation it became clear that there may be the potential that the container could exceed the 3 hour journey time for red cell and platelet components if extra temperature stabilisation material was used. At this point VAL631 was amended to include this as Phase 3 of the validation.

Also, during the Phase 1 validation, one unit in a medium sized container for red cells and platelets at an ambient temperature of +35℃ failed the three hour journey time. It was essential that NHSBT had the ability to transport one product in a medium sized container and VAL 631 was amended to include this scenario as Phase 4 for both red cell and platelet components with extra temperature stabilisation material. This was successfully validated for single units in Phase 4.

Validation Results

Phase 1

Phase 1 of the validation covered the three hour journey time for red cell and platelet components, 4℃ +/- 2℃ and 22℃ +/- 2℃ res pectively, at ambient temperatures of -5℃ and +35℃ with 1 and 6 units in a small container and 7 and 15 units in a medium container plus the minimum of 1 unit in a medium container. For -30℃ components, 1 and 10 units were p laced in a medium container to achieve a 6 hour journey time. The manufacturer's recommendations for the use of the temperature stabilisation material were used.

All combinations tested passed the validation apart from one unit of red cells and one unit of platelets at +35℃ in the medium con tainer. The results are attached to the change control record. This meant further testing of the medium container to meet the specified journey time in these scenarios in Phase 4 (see below).

Phase 2

Phase 2 of the validation replicated phase 1 but with ambient temperatures of

-10℃ and +40℃. This phase of the validation was not carried out due to time and resource constraints and is now to be covered in CC/5434.

Phase 3

Phase 3 of the validation replicated Phase 1 but with the addition of extra temperature stabilisation material above the manufacturers instructions. Although this phase of the validation produced some excellent results of additional journey times, there were some outlying probe temperatures and other problems associated with the validation equipment as well as the interpretation of the results.

Therefore, it was decided, in agreement with QA, that these results were not valid and the containers could not be put into use with these combinations of extra temperature stabilisation material until this phase of the validation could be repeated again at some point in the future under a separate change control (CC5434). The results are attached to the change control record.

Phase 4

Phase 4 of the validation covered one red cell or platelet component in a medium sized container with extra temperature stabilisation material above the manufacturer's instructions.

All combinations passed the three hour journey time and the use of a medium container with extra temperature stabilisation material with only one component can now be used. The results are attached to the change control record.

Interpretation of Results

When analysing the results, the validator drew up a table interpreting the results in a certain way. This was when all of the components within the container had reached the mid temperatue point e.g. Red Blood Cells 4℃ +/- 2℃, to when they first exceeded the temperature requi rement. This interpretation did achieve the 3 hour journey time that was required. This was more of a scientific approach

During analysis of the results by the change manager and Quality Assurance, interpretation was taken as the point when the container was placed into the controlled ambient temperature situation. This interpretation also resulted in achieving the three hour journey time. This added further variation in that some of the units could be at the lower end of their temperature specification, e.g. Red Blood Cells at 2℃, or at the higher end, e .g. Red Blood Cells at 6℃, and the containers still performed as expected, wit hin the three hour journey time range.

This provided a certain amount of tolerance around the three hour journey time and with further validation using the addition of extra phase change material, NHSBT has sourced a robust system.

Use of Container for Frozen Components

During validation, the container exceeded drastically the requirement to meet the six hour journey time for frozen components.

During discussion with operational users of the container, it was felt that a journey time of 11 hours for these components would be in line with operational requirements.

Therefore, after discussions with Quality Assurance and further analysis of the validation data, the containers were approved for use for an 11 hour journey time for frozen components only.

IQ Results

IQ testing was carried out on the prototype container at which time certain changes were made by the manufacturer to the outside belt and the closing mechanism to ensure that the components were secure and the mechanism was tamper proof. These reports are attached to the change control record.

Two fully manufactured containers, one of each size, were sent to Newcastle by the manufacturer for full IQ testing by QA. This testing was successfully completed in late 2014 and the results are attached to the change control record.

Change Controls

CC/4140

CC/4140 was opened to cover the IQ and temperature validation and pilot at Cambridge NHSBT. However, during the course of the complex work that was required to validate the containers, it became clear that the validation and pilot needed to be managed by separate change controls.

CC/5366

CC/5366 was opened to cover the pilot and implementation of the new short journey containers at NHSBT Cambridge. This is in accordance with CC/5111 and for the reasons stated above. CC/5366 can proceed once CC/5326 is completed.

CC/5111

CC/5111 is the national overarching change control for the full implementation of the new short journey containers into NHSBT. This will require all Hospital Services Managers to open a Change Control to cover implementation at their sites. CC/5366 was opened by the Cambridge Hospital Services Manager for this purpose.

CC5434
CC5434 has been opened to cover the Phase 2 & 3 of VAL631 later in 2015 to enable flexibility of the container fleet.

Conclusion
The sourcing, procurement and validation of a new transport container system to replace Clinimed has been a complex project for NHSBT in order to meet the stringent temperature control requirements and address the health & safety and handling issues which were prevalent during the implementation of the long journey containers.

The solution found has been validated to the requirements of the original specification and has subsequently met these requirements. However, it has been recognised that using the containers and the temperature stabilisation material in different combinations could produce a more flexible container for use within the organisation as regards journey times and further validations need to be carried out to ensure that NHSBT have obtained a solution which is safe, efficient and effective.

It is the recognition of the container's potential that has indeed made this project complex and with this in mind lessons have been learnt for future projects of this kind, certainly to ensure that the validation change control is carried out separately to the pilot and implementation.

The short journey container will be validated again in the future under separate change control (CC5434) at other ambient temperature ranges with different combinations of temperature stabilisation material to ensure that NHSBT has the full benefit of this piece of equipment.

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