Medical Device Governance in a Pandemic: A Chest Drain Modification for Patients with Pneumothorax, Suspected or Confirmed Infected with COVID-19

Sarah Francis[1], Robin Sayer[1], Alistair Graham[1], Kay Pollock[2]

[1]Medical Devices Unit, Dept. of Clinical Physics & Bioengineering, NHS GG&C, West Glasgow Ambulatory Care Hospital

[2]Radionuclide Dispensary, Dept. of Clinical Physics & Bioengineering, NHS GG&C, Dumbarton Road

Introduction

Aerosol generating procedures (AGPs) carry an increased risk of viral transmission because they produce airborne particles of respiratory secretions. Following the coronavirus outbreak, there existed growing concern in the respiratory medicine community that viral transmission from patient to healthcare worker was a significant risk in pneumothorax related chest drain. In May of 2020 this concern was brought to the attention of the Medical Devices Unit (MDU) by respiratory consultants at the Queen Elizabeth University Hospital (QEUH).

Emerging literature revealed that anti-viral filters ordinarily used in breathing circuits were being modified for use in chest drains to reduce risk of transmission. However, there was little evidence of consideration for the safety of such off-label use of an existing medical device. In order to introduce a chest drain modification in local hospitals, it was necessary to meet NHS GG&C's requirements for medical device governance.

Aim

•To develop a technique to attach a viral filter to a chest drain container

•To gather the necessary technical documentation for release of the modification under the MDU's in-house ISO13485 certified Quality Management System (QMS)

Method

By consulting clinical stakeholders at the QEUH and reviewing general safety and performance requirements outlined in the EU 2017/745 Medical Device Regulations, a requirements specification was outlined.

A Failure Mode and Effects Analysis (FMEA) framework was then applied to risk assess the attachment of a breathing circuit filter to the outlet valve of a chest drain container.

By referring to the requirements specification and considering the identified risks, four different solutions were developed (Figure 1).

Figure 1: The four design solutions under consideration. Each connects a Teleflex Gibeck Humid-Vent Compact Filter to the outlet of a R54500 Rocket Blue Drainage Bottle System, using A) an endotracheal tube connector and a 5cm segment of endotracheal tubing; B) an endotracheal tube connector and a 5cm segment of chest drain tubing; C) a rubber adapter; D) a 2cm segment of chest drain tubing.

Each solution was tested for safety against a series of system requirements, including tests to identify:

•Air leaks in the circuit

•The strength of the new connections

•Pressure increases within the bottle

The latter was deemed to be of highest priority due to its clinical significance: pressure increases within the bottle could impede drainage from the patients' chest, potentially leading to a life threatening tension pneumothorax.

Figure 2 shows the set up for assessing pressure inside the container. The test was performed with no modification, with the filter modification, and then with a filter saturated with water.

Figure 2: To simulate a chest drain circuit, air was pumped into the bottle at 5l/min. The pressure gauge was used to record the pressure inside the bottle intermittently over a period of 24 hours (dry filter and control) and 1 hour (saturated filter) .

Test Results

Solution B passed all of the design acceptance tests and so was selected as the design of choice. A record of each of the performed tests is held on Redmine, the repository for the MDU's QMS.

For the pressure test, the maximum pressure increase over a 24 hour period due to the addition of the dry filter was 0.244cmH_2O.

For the saturated filter, the maximum increase in pressure was 1.885cmH_2O. This maximum pressure was recorded at the beginning of the test, and continually decreased over a period of 1 hour as the filter dried.

For both the dry and wet filter, the maximum pressure increase due to the modification was deemed to be clinically negligible, indicating that the likelihood of tension pneumothorax was sufficiently low.

These results, alongside supplementary testing conducted to assess the effectiveness of the viral filter at preventing the transmission of COVID-19, have been published in [1].

Product Assembly

Following the confirmation that the chosen solution was safe for use, an Instructions for Use document was produced which informs clinicians on preparing and using the chest drain modification.

In addition, the MDU liaised with colleagues at the Radionuclide Dispensary to assemble batches of connectors using aseptic techniques. The process was risk assessed, and additional tests were performed with a vacuum chamber to ensure that the packaging was air tight.

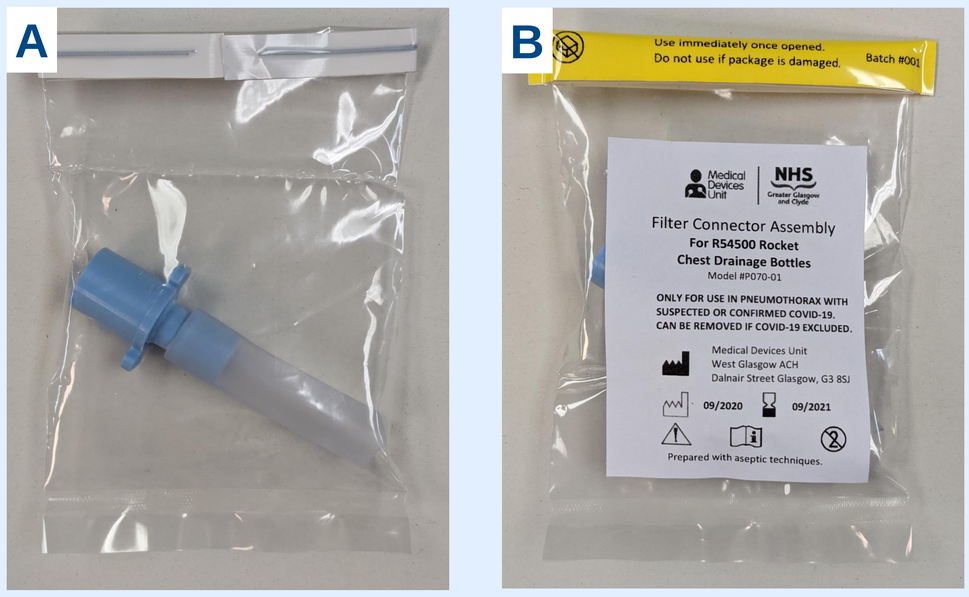

Figure 3: The product assembly (A) sealed and (B) labelled and ready for delivery.

Clinical Validation

Clinical validation was undertaken prior to release. Two respiratory clinical fellows were supplied with the Instructions for Use and asked to perform several tasks. They were then questioned and their set up was assessed. Alongside the results of the design acceptance tests, this process verified that the product was able to meet all of the user requirements.

Conclusion

With the filter modification proven safe for use and the necessary technical documentation gathered under the MDU's QMS, the Instructions for Use document was released and approved for use. Additionally, over 100 packaged filter connectors have been delivered to the QEUH for use in the Accident and Emergency department and the Acute Receiving Unit.

References

[1] Duffy C, Kidd A, Francis S, et al. Chest drain aerosol generation in COVID-19 and emission reduction using a simple anti-viral filter. BMJ Open Respiratory Research 2020; 7:e000710. doi: 10.1136/bmjresp-2020-000710