Medical Device Governance in a Pandemic:
A Chest Drain Modification to Prevent Transmission of COVID-19

Purpose

This report describes the approach taken by the MDU to address medical device governance and provide assurance for the safety and effectiveness of a modification to a medical device.

Background

The unmet need in a pandemic

Aerosol Generating Procedures (AGPs) carry an increased risk of viral transmission as they produce airborne particles (defined as particles <10µm) of respiratory secretions. Early in the COVID-19 pandemic, respiratory physicians raised concerns about the possibility of aerosol generation through chest drains and their Emergency Medicine colleagues proposed an in-house solution (antiviral filter modification) to address this problem. The Chief of Medicine, recognising the need for appropriate clinical governance around use of modified medical devices, asked the MDU to review this proposal and provide a solution to address medical device governance.

Device Governance and liability

A healthcare institution modifying a medical device in a way in which the manufacturer hadn't intended becomes responsible for the safety and effectiveness of the device and, as such, carries the legal liability as if it had manufactured the device. There is currently a full exemption from the UK medical device regulations for devices modified in-house for use on patients within the same legal entity (i.e., health board). However, robust systems are required to provide assurance for clinical governance and ensure device safety and effectiveness is in line with applicable medical device regulations. The accepted way to demonstrate this is to ensure that design, manufacture and surveillance of modified devices is undertaken under an appropriate Quality Management System (QMS). The internationally accepted QMS for the design and manufacture of medical devices is ISO 13485.

Methodology

Evaluation of aerosol generation and filter technology

The MDU used a multichannel particle counter in a controlled environment to establish the extent to which a bubbling chest drain is a potential source of aerosolised particles. They also demonstrated that the dispersion of particles of all sizes was prevented for a range of clinically significant flow rates by using a simple anti-viral filter modification[1].

Modification of a medical device under a QMS

The MDU's engineering team introduced the chest drain filter modification into clinical use under their certified and externally audited ISO 13485 QMS, producing a comprehensive set of controlled technical documents and records to demonstrate compliance with relevant international standards, best practice and to provide evidence that the modification is safe and effective:

- P070-DOC-002 Commercially Available Device Review: Report to establish that an in-house modification is justified.

- P070-SPE-001 User Requirements Specification: Design input from clinical stakeholders listed below.
- Records of verification activities (x18) to provide evidence that the technical requirements have been met, including bench top testing for pressure, air leaks and mechanical robustness.
- P070-DWG-001 ET Connector, P070-DWG-002 Tube, P070-DWG-003 ET Connector & Tube Assembly and P070-WI-001 Filter Connector Assembly: Production Specifications for the modification verified to satisfy technical requirements and applicable safety and performance requirements from the medical device regulations. The design is shown in Figure 1 and comprises a Teleflex Humid-Vent anti-viral filter connected to the Chest Drain via a bespoke connector, developed in-house.
- P070-TRP-001 - Risk Management Report: Demonstrates that the risks have been assessed, evaluated and controlled in accordance with ISO 14971 - Application of risk management to medical devices. Input from clinical stakeholders listed below. Records of Risk assessment, evaluation and control (x17).
- Records of verification and validation (x6) for manufacturing and inspection processes including preparation and packaging using aseptic techniques developed in conjunction with the Radionuclide Dispensary team.
- P070-IFU-001: Validated Instructions for Use (IFU) for the device modification.
- P070-LBL-001 Filter Connector Assy Label and P070-LBL-002 Wire Seal Label: Labels for
- Record of clinical validation via a simulation.
- P070-DOC-001 Product Release Declaration: formal approval for deployment in clinical practice
- Records of post deployment surveillance planning (x4) and results of ongoing monitoring for incidents or new information (risks, etc.) pertinent to the safety and effectiveness of the device.

MDU Team - Roles and responsibilities

Project Manager – Planning, resourcing and risk management reporting.
Clinical Scientist – Particle detection experiments. Author of peer reviewed publication[1].
Clinical Engineer – Device development, verification, validation, manufacture and post deployment surveillance.
Mechanical Design Engineer – Device and manufacturing specifications.
Clinical Technologist (calibration) – Verification support for pressure, leak and mechanical robustness tests.
Clinical Technologists (manufacturing) – Manufacture of verification equipment.
Quality Manager – Compliance with MDU SOPs.
Head of Clinical Engineering – Authorisation for device deployment.
Audit Team – Ongoing audit of documentation for compliance with ISO 13485 and MDU SOPs.

Clinical Stakeholders

Consultant, Respiratory Medicine, QEUH
Consultant, Respiratory Medicine, GRI
Consultant, Respiratory Medicine, RAH
Clinical Fellow, Respiratory Medicine, QEUH
Clinical Nurse Specialist, Pleural Service, QEUH

Particle Testing

Health & Safety Practitioner, WGACH
Senior House Officer, Respiratory Medicine, QEUIH
Consultant, Respiratory Medicine x 2, QEUH

Principal Scientist at Institute of Occupational Medicine (IOM), Heriot-Watt University
Senior Lecturer, Civil and Environmental Engineering, University of Strathclyde
Quality manager, Surgical Materials Testing Laboratory (SMTL), Wales

Aseptic Manufacturing Support
Head of Radionuclide Dispensary, Old Western Infirmary Site
Production Manager, Radionuclide Dispensary, Old Western Infirmary Site

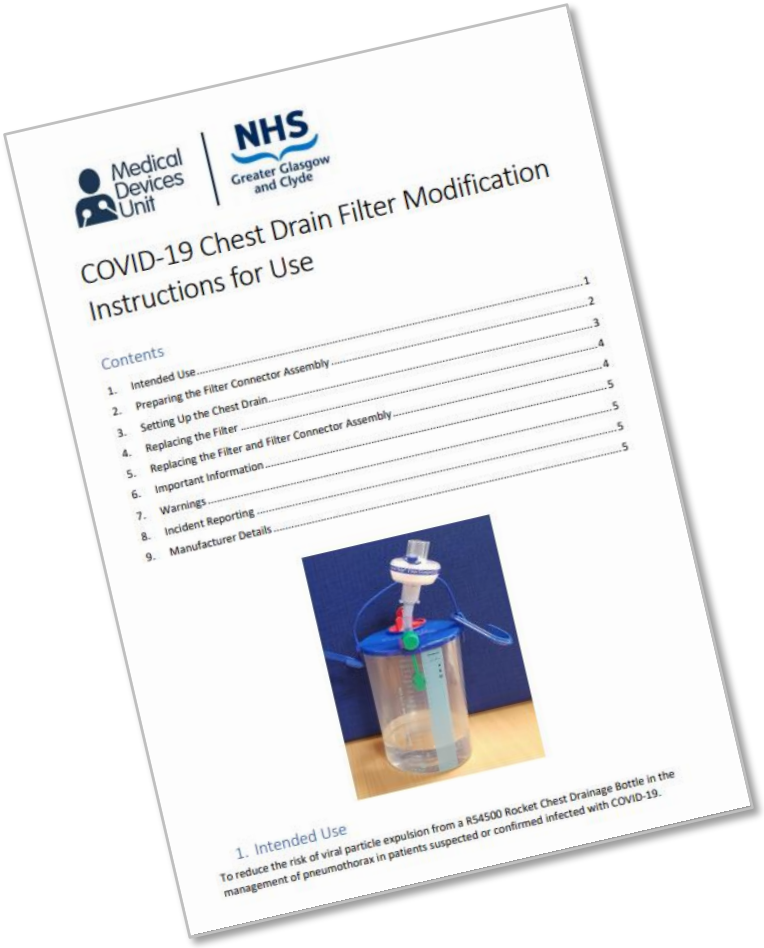

Figure 1: Instructions for Use

Outcome

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 the modification was formally approved for deployment in clinical practice. Over 100 packaged filter connectors have since been delivered for use in the Accident and Emergency departments and Acute Receiving Units.

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