Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

Mr Guy Davies
HM Assistant Coroner
Cornwall & the Isles of Scilly Coroner's Area
[redacted]

[redacted]

7 May 2024

Dear Mr Davies,

Regulation 28 report relating to the death of Ian Jacka (DOD 15/06/2022)

Thank you for your Regulation 28 Report relating to the death of Ian Jack (DOD 15/06/2022) which was received on 2 January 2024. I would like to offer my sincere condolences to Mr Jacka's family on their tragic loss.

Following receipt of the Regulation 28 Report we have considered the points of concern raised regarding the use of the Cook Airway Exchange (CAE) catheter, manufactured by Cook Medical, with the Manujet III manufactured by VMB.

Firstly, it may be helpful to provide background information relating to the Medicines and Healthcare products Regulatory Agency (MHRA) and the work we carry out. The MHRA is the executive Agency of the Department of Health and Social Care that acts on behalf of the Ministers to protect and promote public health and patient safety by ensuring that medicines and healthcare products can be used safely and meet appropriate standards of safety, quality, performance, and effectiveness. Medical devices such as these must comply with the medical device regulatory requirements and be CE or UKCA marked which is certified by notified bodies or approved bodies.

When an adverse incident involving a medical device is reported to the MHRA, we liaise with the manufacturer of the medical device(s) and request that they investigate and test the device(s). The MHRA assesses the balance of risks and benefits of devices, throughout their use in clinical practice, through the collection of information and assessment of any potential risks. This may be followed, when necessary, with communications and regulatory action to minimise those risks.

The Regulation 28 report concerns an incident that occurred on the 6 June 2022 at Derriford Hospital where a CAE catheter was used with a Manujet III, which is a manually controlled oxygen delivery system, to facilitate airway exchange in a complex polytrauma patient undergoing complex spinal surgery.

It is understood that prior to surgery there were several unsuccessful attempts to intubate. However, an oral endotracheal tube (ETT) was successfully placed and subsequently replaced with an armoured ETT for the duration of the operation. At the end of the surgery the CAE Catheter was used to aid the replacement of the armoured ETT for a more flexible critical care ETT. There were several unsuccessful attempts to insert the replacement ETT resulting in the patient experiencing oxygen desaturation. Therefore, jet ventilation was performed with Manujet III using the CAE Catheter. Subsequently, the patient experienced subcutaneous emphysema and cardiac arrest. As result of this event and the additional time needed to establish an alternative secure airway (i.e. cricothyroidotomy), the patient experienced hypoxic brain damage and died several days later.

We were initially informed of this incident on 22 March 2023 through a Yellow Card report from a healthcare professional and also received a report from Cook Medical. However, no report was received directly from Derriford Hospital. Additionally, no product was returned to Cook Medical for evaluation. We informed Cook and requested they investigate the reported incident.

Cook Medical investigated and concluded that the cause of the failure could be associated with an unintended use error. They indicate the device was used in a patient with a difficult airway, the catheter was over-inserted, and jet ventilation may not have been used in a manner consistent with the instructions for use (IFU). We note the difference in opinion with the medical team around over insertion.

We have received no other incident reports within the last 10 years where an issue occurred with AEC and jet ventilation being used together during endotracheal intubation.

Please see our response to the matters of concern raised below.

(1) The Inquest found that the use of the ManuJet III Ventilator with Cook Airway Exchange Catheter (AEC) likely contributed to Ian's death. This finding was based primarily on the evidence of the NHS investigation. It was found that the second use of the jet resulted in significantly increased airway pressure which caused tension pneumothoraxes and massive subcutaneous emphysema.

In this incident the CAE Catheter was initially being used with the Manujet III during an endotracheal tube (ETT) exchange. Endotracheal intubation involves a tube being placed through the mouth or nose into the windpipe. The incident describes multiple failed attempts at intubation indicating this was a difficult airway. However, the Cook airway exchange is intended for uncomplicated atraumatic endotracheal tube exchange where a ventilatory device may be used at any time during the procedure by using the Rapi-Fit Adaptor provided with the device. The IFUs provided with the device note that;

"Use of a high-pressure oxygen source should only be considered if the patient has a sufficient egression of the insufflated gas volume."

This incident describes that;
".. *having removed the armoured tube, the team were unable to insert the flexible tube despite repeated attempts. Ian then started to desaturate due to lack of oxygen. The Consultant Anaesthetist proceeded to jet ventilate Ian using a ManuJet III Ventilator with Cook Airway Exchange Catheter*."

The Manujet III can be used electively for microlaryngoscopy, rigid bronchoscopy, to assist a difficult fibreoptic intubation or during a predicted difficult extubation. However, the IFU states the intended use of the device is to provide transtracheal ventilation, in specific emergency situations. The IFUs specifies two types of emergency use with one including a lifesaving manoeuvre in the "cannot intubate – cannot ventilate " situation for oxygenation to avoid severe desaturation of the patient. Transtracheal ventilation is achieved in conjunction with a transtracheal catheter, placed percutaneously into the trachea or using cricothyrotomy device inserted through the cricothyroid membrane. The second specified emergency use is for prehospital use if there is a partial obstruction of the upper airway. The IFUs indicate that in emergency situations the transtracheal jet ventilation (TTJV) has fewer complications and is faster and simpler as a surgical cricothyrotomy. The Manujet III is sold in a kit including Jet Ventilation Catheters.

The Manujet III is a manually operated device and the IFUs indicate the user must adjust the ventilation pressure and ventilation frequency properly to achieve balanced ventilation. Additionally, the IFUs have safety instructions which include that:
"*The user must ensure that expiration takes place via the upper airways. A total obstruction is a contra-indication for the use of Manujet III with Jet Ventilation Catheter. If another way of securing the airway is not possible and expiration is not assured, ventilation frequency should be reduced to 3 strokes per minute to avoid barotrauma. This can be sufficient as a life-saving manoeuvre in case of a total upper airway obstruction."*

(2) Had the ManuJet III not been used to provide oxygenation during airway exchange it is unlikely that the scenario would have deteriorated to cardiac arrest so rapidly.

Please see answer to question 1

(3) It was found at Inquest that the outcome would have been different if the ventilator had incorporated an adjustable pressure limiting valve, allowing control of the flow pressure. This is not possible with the ManuJet. The ManuJet does not have automated pressure sensing capabilities to it which will reduce or cease delivery if it senses the pressure in the airway being too high.

The Manujet III is a manually operated device and the IFUs instruct the user to:
"*Adjust the desired ventilation pressure by turning the pressure regulator knob clockwise. Start with the lowest pressure (0 bar/psi) and afterwards increase this pressure slowly under ventilation and clinical control of chest movements. The adjusted ventilation pressure is displayed on the gauge. Push the pressure regulator knob for locking. To re-adjust the pressure, pull the pressure regulator knob and adjust to the desired pressure."*

The Manujet III IFU does indicate there is a maximum operation pressure of 4 bar (58 psi) and the pressure regulator and gauge ensure that the maximum operation pressure of 4 bar (58 psi) is not exceeded.

(4) The Inquest conclusion supported the finding in the NHS Investigation that the design of the Cook AEC is flawed and that it needs to be redesigned and in addition requires markings or a colour change at the maximal depth of 26cm. The Inquest found that there had been no over-insertion in Ian's case, but the risk of over insertion was noted by clinicians.

The Cook AEC IFUs clearly indicate it is only intended for uncomplicated atraumatic endotracheal tube exchange. Additionally, Manujet III can be used electively for specified types of intubations, however the IFUs state its intended is for transtracheal ventilation for lifesaving manoeuvres e.g., "cannot intubate – cannot ventilate " for oxygenation, to avoid severe desaturation of the patient.

It is also worth noting the IFU for the CAE Catheter warns *to avoid barotrauma by ensuring the tip of the CAE Catheter is, " always above the carina, preferably 2-3 cm*". It also instructs users to;
"*Properly position the CAE Catheter within the endotracheal tube by aligning the appropriate centimeter mark on the CAE Catheter with the corresponding centimeter mark on the endotracheal tube. This placement is determined by visualising the indicated centimeter length of the endotracheal tube, in place, as shown on the surface scale. (For example, an endotracheal tube that has been shortened to 24cm should have the 24cm marker of the CAE Catheter aligned at the 24cm mark of the endotracheal tube.)"*

In response to the suggested colour changes at a maximal depth of 26cm, variation in patient anatomy would mean that a maximal depth marking of 26cm may not be suitable for every patient (i.e. to position the catheter 2-3 cm above the carina). Also producing colour on a plastic catheter may introduce other risks. Furthermore, it is widely accepted the use of colour can introduce confusion due to the potential diversity amongst manufacturers leading to errors in use, and therefore is not recommended.

(5) Following the NHS investigation into Ian's death, Derriford Hospital have prohibited the use of jet ventilation via the Cook AEC outside of ENT and thoracic surgery without the use of a rigid bronchoscope. The hospital has removed ManuJet ventilators from theatres (apart from ENT and thoracic surgery).

Please see answer to question 1

In conclusion, this incident describes the use of the Cook Airway Exchange (CAE) Catheter, manufactured by Cook Medical, and Manujet III ventilator manufactured by VBM. However, the CAE Catheter is not intended for complicated airways. Additionally, the IFUs for the Manujet III ventilator indicate it can be used electively for specified types of intubations. However, it is intended to be used via transtracheal ventilation for lifesaving manoeuvres e.g., "cannot intubate – cannot ventilate " for oxygenation, to avoid severe desaturation of the patient.

We keep the safe and effective use of medical devices, including airway exchange catheters and manual jet ventilators, under continual review. We will further consider the issues raised in the report and will raise them with the manufacturer of these devices.

We would request the manufacturers are provided with a copy of the Regulation 28 Report or agreement that we can provide them with a copy of the Regulation 28 report directly. Additionally, we will work with the manufacturers of these devices to explore if any further action including any further risk communication and/or provision of information is required to help prevent any future recurrence of this issue.

Our guidance on Managing Medical Devices is about the use and management of medical devices. This indicates that instructions may need to be written locally to cover whole systems where devices are used together with other devices. If healthcare organisations draft their own instructions to supplement the manufacturer's instructions, consider consulting the manufacturer/supplier on their accuracy and suitability, before issue. Further information can be found in the Managing Medical Devices guidance available online at https://www.gov.uk/government/publications/managing-medical-devices.

Should you have any further questions, please do not hesitate to contact me.

Yours sincerely,

[redacted]

[redacted]
Chief Executive
Medicines and Healthcare products Regulatory Agency
[redacted]