Medicines & Healthcare products Regulatory Agency

MHRA

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Mr Kevin McLoughlin
Senior Coroner
for the County of West Yorkshire
(Eastern District)
71 Northgate
Wakefield WF1 3BS

[redacted]

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18 November 2021

Dear Mr McLoughlin

Regulation 28: Inquest to investigate the death of Mary Land

We acknowledge your Regulation 28 prevention of future death report, received by MHRA on 29 September 2021 relating to the conclusions of the inquest investigating the death of Mary Land at Pinderfields Hospital, Wakefield and your concern included in report that consideration should be given to a design change for the devices and connectors within breathing circuits.

You copied us into the report for information as the UK medical device regulator. I have taken the opportunity to provide you with some supporting information below, before providing comments to your matters of concern.

As you may be aware, the Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and Social Care and is responsible for the regulation of medical devices and medicinal products.

One of the MHRA's responsibilities is to collect, analyse, monitor and act on information relating to safety concerns from a range of data sources including reports of adverse incidents involving medical devices.

Patient safety is our highest priority and we encourage everyone to report safety concerns to the MHRA through our Yellow Card scheme. It is mandatory for manufacturers of medical devices to report incidents where the device is suspected or known to have contributed to the adverse event to MHRA.

When an adverse incident occurs and is reported either to the manufacturer directly or via Yellow Card, the manufacturer is responsible for carrying out any investigation required and informing MHRA of their findings. We evaluate and view all incidents in the context of other reports and data sources to determine if there is a potential safety signal for investigation and whether further action is needed.

Where necessary and when the Agency's criteria have been demonstrated and agreed to have been met, we will issue safety messages to health and care organisations, patients, and the public.

Manufacturers of medical devices considering a design change are expected to follow the principles set out in BS EN ISO 14971:2019 *Medical devices. Application of risk management to medical devices*. Each design feature should be methodically considered in terms of the hazards and risks it could introduce and then a process of analysis, evaluating and mitigation should be conducted to reduce any residual risk to be a low as reasonably practicable.

This approach aims to ensure that any unintended new risks associated with the design of the device itself are appropriately managed and minimised, however it may not be possible to identify all potential unintended consequences in advance of the device being used in the intended use scenario. The risk management process is therefore an ongoing one throughout the product lifecycle.

Manufacturers should demonstrate how their devices meet the relevant Designated/Harmonized Standards. If they have not applied these standards, then they must provide a description of the solutions adopted to fulfil the requirements which apply to the devices. This information should be included within their technical documentation for the devices.

Under the current UK medical device regulations manufacturers should inform and seek approval from their Notified Body of certain changes to the device or of the quality system. The requirements differ depending upon the route taken for conformity assessment however the guiding principle is that any change which could affect conformity with the essential requirements should be notified and approved prior to the updated device being placed on the market or put into service.

An evidence base exists across a range of types of devices supporting a proposition that when users of devices are not familiar with the device or there is a change in design or handling technique this can also contribute to errors and lead to patient harm. Healthcare professionals operating and monitoring the use of devices need to be supported with training and clear protocols on correct and safe device use.

Action undertaken by MHRA to date

On receipt of the regulation 28 letter we conducted a search of our database of reported adverse incidents to confirm whether the incident had been reported by Philips Respironics in line with the requirements set out in UK MDR 2002. The incident had not been reported.

We instructed Philips to report this incident to MHRA which they have now done. They informed us that the initial focus of investigation was on the BiPAP ventilator but following the inquest, the connection tubing and face masks are now being investigated. We requested they provide all available information established during their investigation to date. Their investigation has not been completed and a final investigation report has not yet been provided to MHRA. We have assessed the following facts may be relevant to future actions:

- The Philips devices involved in this incident were a Trilogy EVO BiPAP machine and a AF541 face mask. The AF541 has been in the market since August 2016 and the Trilogy EVO was launched in the UK market in August 2019.
- The elbow connection point of the AF541 and all masks manufactured by Philips conform to requirements of BS EN ISO 5356-1 2004 Conical Connectors. This is not the latest version of the standard.
- A clear guard filter manufactured by Intersurgical was fitted between AF541 elbow and the tubing. The inclusion of a filter in the breathing circuit is not supported by Philips. MHRA has asked Phillips to investigate the potential impact on the performance of the breathing circuit of using the filter.
- The hospital report to Philips stated that the filter was used in accordance with recommendations during the pandemic provided by the British Thoracic Society. We have confirmed with the Society

that specific guidance regarding the use of filters was introduced during the COVID-19 pandemic response. This was in collaboration with NICE.
- Philips has confirmed that the Trilogy EVO device has alarms to detect a disconnected circuit and the hospital has confirmed that the device alarm did sound during this incident. MHRA has requested more information about the incident from the hospital.

We have reviewed the current versions of ISO standards for connectors used within breathing circuits: BS EN ISO 5356-1:2015 and BS EN ISO 5356-2:2012.

BS EN ISO 5356-1:2015 defines the dimensions and test methods for cone and socket connections for breathing circuit components. The purpose of the standard is to ensure interchangeability between components from different manufacturers whilst maintaining a secure connection and at the same time enabling connection and disconnection by the operator. To minimise the risk of accidental disconnection the standard recommends a “latched” socket, also defined within the standard.

BS EN ISO 5356-2:2012 defines “Screw-threaded weight-bearing connectors” which are intended for mounting heavy or fragile components of a breathing circuit.

In October 2021 we conducted stakeholder engagement with the Association of Respiratory Nurses in order to seek qualitative feedback on the use of breathing masks, tubing and filters and the means of connecting them to make a complete breathing circuit. In summary they stated that, connections between masks and hoses are universal and all push-fit allowing for compatibility between the various manufacturer’s equipment. If the connection became a screw-thread style, then the ability to change the consumable components, when required and when in situ, would be more difficult. It could cause components to seize up, making quick changes difficult. This could put in place a further risk, when a patient is dependent on therapy, and a quick mask/hose change is needed. They also acknowledged that the risk of disconnection is no more than patients removing masks themselves. The hoses and masks fitting do not often come apart when fitted correctly.

Further action to be undertaken by MHRA

By the end of November 2021:
- Agree with Philips Respironics their investigation plan and a regular schedule for updates to be provided to MHRA, ensuring it is concluded in line with their regulatory obligations and any corrective actions identified are conducted. This includes ensuring they assess the impact of the connection design and the inclusion of the filter within the breathing circuit on the disconnection event and patient harm and measures to minimise this risk in the future
- Engage with Philips Respironics regarding maintaining compliance to the latest version of relevant and Designated or Harmonised Standards
- Contact the British Thoracic Society and NICE to agree a time to discuss updating the published guidance relating to the management of COVID-19 patients to ensure that health care professionals prescribing and setting up breathing circuits and the inclusion of filters are in accordance the breathing system device manufacturers’ instructions.

Ongoing:
- Continue to assess incoming data which identifies a new safety signal with these types of devices and take action when required.

Conclusion

Pending the conclusion of the actions detailed above, we will continue to monitor our reports and if further evidence should emerge we will review and take any necessary action.

Yours sincerely

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Chief Safety Officer

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