Department of Health

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[redacted]

Mr J Pollard
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Dear Mr Pollard

Thank you for your letter following the inquest into the death of Brian Marks.

I was very sorry to hear of Mr Marks' death and wish to extend my sincere condolences to his family.

You explain that Mr Marks had Motor Neuron Disease and was fed and given medication via a PEJ (Percutaneous Endoscopic Jejunostomy) tube. During a stay in hospital Mr Marks' feeding tube appeared to malfunction.

The nurse who tried to replace the PEJ tube mistakenly believed that it was a PEG (Percutaneous Endoscopic Gastrostomy) tube. Whilst the two tubes are similar in appearance, the procedures for using them are very different. The PEJ tube could not be replaced because of the error and Mr Marks had then to be fed and medicated intravenously. The best protection against error of this kind is to ensure that the clinician concerned is fully aware of what he or she is doing. Regrettably, that does not appear to have happened in this case.

You have noted that the PEG and PEJ tubes are very similar in appearance and there is therefore a risk of confusion. You heard from witnesses at the inquest that a simple colour coding system could be implemented so that the tubes (including when in situ) could be immediately differentiated.

We have discussed your report with NHS England and the Medicines and Healthcare Products Regulatory Agency (MHRA).

Both organisations agree that feeding tubes look very similar and can therefore be confused with one another, potentially putting the patient at risk. However, the solution might not be as straightforward as it first appears.

There is a wide range of feeding tubes available, beyond PEJ/PEG, and the terminology used may not always be clear to practitioners. Further types of tubes are in use for purposes other than feeding. These tubes may also be used in different anatomical sites - for example, Percutaneous Endoscopic Sigmoid Colostomy (PEC) tubes are inserted into the colon and used for irrigation or anchoring the bowel.

Some tubes are licenced for use both in the stomach or small bowel. The position where the tube exits the body on the patient's abdomen does not automatically indicate where the tube is located within the gastrointestinal tract.

This means that even after correctly identifying the tube it would not be possible to reliably identify its position or function in the gastrointestinal tract.

Your suggestion of introducing a colour coding scheme has already been considered. Some experts in the field believe a suitable scheme could be helpful, although influencing manufacturers to change design to ensure easier visual distinction of their product is not always straightforward. Manufacturers cannot be compelled to make such changes where these are not part of internationally required design standards.

Medical products traded in the European Economic Area (EEA) are assessed before being placed on the market. To obtain the CE mark demonstrating approval for use, manufacturers must demonstrate that their product conforms to the relevant essential requirements of the *Medical Devices Directive 93/42/EC*, and does not compromise the safety of the patient or user when used as intended. This includes ensuring that risks from foreseeable misuse have been assessed and adequate controls implemented. The Directive does not however stipulate the control measures to be adopted. It may therefore be difficult to persuade manufacturers to make specific changes to their devices for only a single country in the current global market.

There are other potential problems in introducing the proposed colour coding. Many enteral feeding catheters (for feeding directly into the stomach, duodenum or jejunum) already use a colour code on the connector to indicate the diameter of the catheter. If further colour coding for PEG and PEJ tubes were to be implemented, this might provide scope for even more confusion.

Colour coding itself also causes problems for users with colour blindness or deficiencies in colour perception. For these people, colour coding may not help them to distinguish between devices and can therefore introduce new hazards.

There is also the likelihood that the colours introduced would not be specific to one group of devices, so that a reliance on colour coding could also introduce the potential for misconnections between different tubes. This issue was reported in the recently published U.S. Food and Drug Administration (FDA) guidance document, *'Reduce – and Report – Enteral Feeding Tube Misconnections'*.

This guidance advises that users *'shouldn't rely on colour coding to prevent misconnection because colours aren't always consistent or specific to device groups'*. The full document is available at:

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm234440.htm

A similar message was contained in an earlier Joint Commission Alert in 2006. Issue 36 of the Joint Commission's Sentinel Event Alert in 2006 stated that colour coding *'can lead users to rely on the colour coding rather than assuring a clear understanding of which tubes and catheters are connected correctly to which body inlets.'*

The full document is available from the following web address:

http://www.jointcommission.org/sentinel_event_alert_issue_36_tubing_misconnections%E2%80%94a_persistent_and_potentially_deadly_occurrence/

Although the introduction of further colour coding might not be the solution you had hoped for there are other steps that are being taken to minimise the risk of such confusion in future.

Many manufacturers use harmonised standards where they exist for a particular device because there is an assumption that products meeting these standards conform to the requirements of the *Medical Devices Directive 93/42/EC.*

MHRA will bring the issue of tube misidentification to the attention of the Standards Committees *(European Committee for Standardisation – CEN and International Organisation for Standardisation - ISO)* to consider if this issue should be addressed in the relevant standard. If this issue were to be included, it would help to bring about beneficial changes to the products by manufacturers.

MHRA publishes a document called *Managing Medical Devices,* providing guidance on factors to consider before purchase to help Trusts with this process. MHRA confirms its intention to include the risk of misidentification of similar devices in the next revision of this guide.

In addition, individual NHS Trusts can already take steps to minimise such risks. An opportunity arises during the procurement phase for devices, when NHS Trusts consider the usability of devices and whether the particular devices used within their healthcare organisation could be confused. Devices that have a lower risk of confusion should be identified and purchased. NHS Trusts should also consider further training of staff and development of local policies and documentation in minimising the risk to patients.

Lastly, I can confirm that NHS England is committed to working with other stakeholders, including the MHRA, on solutions to the risks you have identified in your report. They will keep you informed of progress.

I hope that this response is helpful and I am grateful to you for bringing the circumstances of Mr Marks' death to my attention.

Yours sincerely

TAMARA FINKELSTEIN