

Medication Safety Alerts

Kris Wichman and Sylvia Hyland

This column draws on US and Canadian experience and may include, with permission, material from the *ISMP Medication Safety Alert!*, a biweekly bulletin published by the Institute for Safe Medication Practices (ISMP), Huntingdon Valley, Pennsylvania.

INFLATION PORTS: RISK FOR MEDICATION ERRORS

The purpose of this article is to raise awareness of the risk for medication error-induced injuries associated with medical devices that have balloon inflation valves/ports. Such devices include tracheostomy tubes, endotracheal tubes, gastrostomy tubes, and Foley catheters. The connections for the balloon-inflation valves are designed to accommodate parenteral syringes (and therefore can also accommodate IV tubing). This interconnectivity may lead to inadvertent administration of a medication into a balloon, resulting in hyperinflation of the balloon and the potential for serious harm to the patient. The special feature below describes reports of such errors and includes pictures of the products to illustrate that the functionality of the balloon inflation valve is not necessarily intuitive and is not clearly identified on the product. Considering the complexity of care for many patients and the frequent requirement for multiple lines and tubing, it is not surprising that mishaps occur.

Device-related medication errors are of interest to pharmacists because they demonstrate that the risks within the medication-use system extend beyond the typical boundaries of pharmacist practice, yet pharmacists can have a role in minimizing such risks. For example, ensuring that oral medications are provided in oral syringes (never a parenteral syringe) can be one component in preventing inadvertent administration of medications into the inflation valves of medical devices. Other suggestions for preventing errors related to

balloon inflation valves are described in the special feature below.

The errors reported demonstrate the educational value of sharing information about preventable medication-related adverse events. Within hospitals, pharmacists can play a key advocacy role in ensuring that decisions about the purchase of medical devices include consideration of medication safety. Problems with medical devices emphasize the need for purchasing committees to have an understanding of failure mode and effects analysis (FMEA), an engineering process for evaluating products and their potential risks for error. Information from such processes can help in selecting products, lobbying for product improvement, and identifying education requirements for practitioners using the products.

Health care regulators and manufacturers must play a role in reducing risks with medical devices identified through error reports. Perhaps all manufacturers of devices with inflation valve/ports should be required by federal regulation to adopt a universal method for distinctly labelling the cuff inflation ports to differentiate them from IV ports. Ideally, product redesigns would eliminate interconnectivity or prevent hyperinflation of a balloon. Any such redesigns would also require FMEA considerations.

Practitioners can help spur action by continuing to report preventable adverse drug events to ISMP Canada's Voluntary Medication Incident and Near Miss Reporting Program (http://www.ismp-canada.org/err_report.htm), a component of the future Canadian Medication Incident Reporting and Prevention System (CMIRPS). Reporting of events can influence manufacturers and legislators to



take steps to research and mandate enhancements for medical devices.

SPECIAL FEATURE

The special feature presented below is an excerpt from the *ISMP Canada Safety Bulletin*, volume 4, issue 5, May 2004 (the complete bulletin is available online at <http://www.ismp-canada.org/download/ISMPCSB2004-05.pdf>).

Devices with Inflation Ports — Risk for Medication Error-induced Injuries

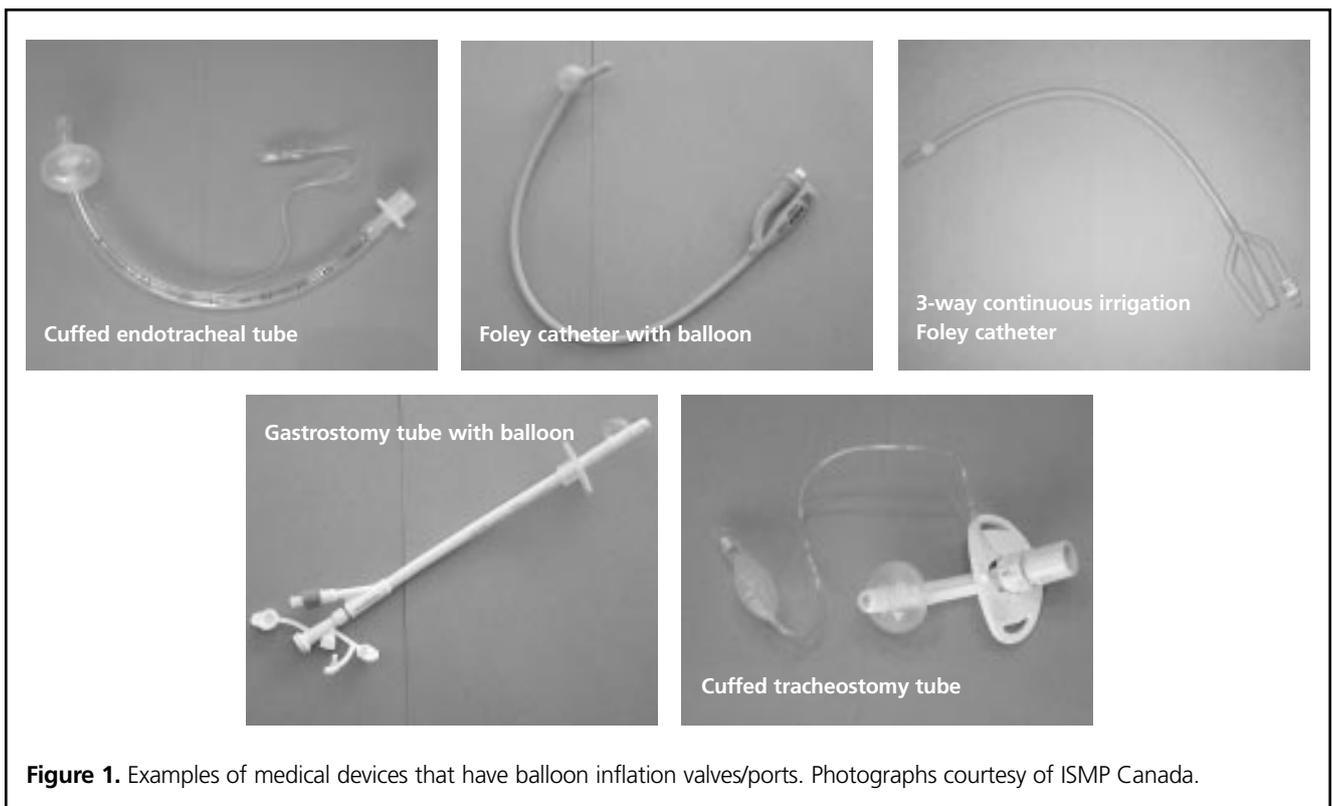
ISMP Canada has received correspondence from a Canadian hospital recommending safety improvements to medical devices with a “balloon inflation valve/port” also known as a “BLA”. The balloon inflation valve is used to inflate the cuff portion of a catheter (or tube) and the inflated cuff helps to ensure correct catheter placement during medical treatment of the patient. Such devices include tracheostomy tubes, endotracheal tubes, gastrostomy tubes and Foley catheters.

The recommendation stems from a critical adverse medical event where medications were inadvertently delivered into the balloon inflation valve portion of a catheter instead of directly into the catheter itself. A case

report describing a similar error has been previously published.¹ In the published case, intravenous medications were infused into a balloon inflation valve of a tracheostomy tube. The balloon valve was mistaken for a central line IV port. As a result of hyperinflation of the cuff, the patient’s airway was obstructed causing respiratory arrest. An alert was provided to US hospitals in 2001, by ISMP US.²

As we consulted healthcare professionals in our research on this issue, we received descriptions of two additional incidents where ports connected to the cuff (or balloon) had been accessed in error to administer medications. In each of the cases the balloon expanded and caused harm to patients. This bulletin intends to raise awareness regarding the risk for error-induced injuries with balloon inflation valves. This bulletin will also be shared internationally in the hope of compelling manufacturers to make changes and that government authorities will mandate improvements to products with balloon inflation valves.

Balloon inflation valves are designed to meet ISO standards for accommodating connection with parenteral syringes used to inflate the cuff with saline or air. These same ISO standards are used by manufacturers of IV tubing and IV ports to accommodate connection with parenteral syringes. Human factors engineering specialists



warn us that the use of identical designs carries inherent risks for error-induced injuries. Because of the 'technology interconnectivity' the design invites human error and therefore warrants consideration of safeguards.

Photographs of several tube/catheter device products are included here [Figure 1] to illustrate that use of the inflation port is not intuitive, that manufacturers do not label the port, and in the minority of cases where they are labelled, the information is not prominent.

By marking pertinent information directly on a product, either with bold print on the port extension or by utilizing a non-removable label, the manufacturer could provide the user with a prompt, rather than requiring the user to rely entirely on memory or experience. Point of care information can be especially valuable for the novice healthcare professional, and for emergency situations where quick action is needed.

Improved labelling is not the complete remedy. The risk for error still exists if one can easily connect a syringe or IV tubing to an inflation port. Ideally, inflation and infusion should be absolutely incompatible. The interconnectivity should be removed through product redesign. In addition there may also be technological

strategies which could prevent hyperinflation of the balloon (cuff). Redesigns would need to be researched by human factors engineering experts.

References

1. Pope M. A mix-up of tubes. *Am J Nurs* 2002;102(4):23.
2. IV connection to tracheostomy cuff inflation port reflects larger problem. Huntingdon Valley (PA): Institute for Safe Medication Practices; c 2004. Available at: <http://www.ismp.org/msaarticles/connection.html>. Accessed 2004 Jun 1. Article also appeared in *ISMP Medication Safety Alert!*, issue of 2001 Nov 28.

Kris Wichman, BScPhm, FCSHP, is Project Leader for the Medication Safety Support Service, Institute for Safe Medication Practices Canada (ISMP Canada).

Sylvia Hyland, BScPhm, MHSc, is Vice-President of the Institute for Safe Medication Practices Canada (ISMP Canada). She is also a member of the Pharmacy Department at both Sunnybrook and Women's College Health Sciences Centre and University Health Network, Toronto, Ontario.

e-mail: info@ismp-canada.org

ISMP Canada home page: www.ismp-canada.org