

Baxa Corporation

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**Enteral Feeding Misconnections**

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Technical Paper

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Review of enteral feeding tube to IV line misconnections  
and a proposed solution for neonatal nutrition.

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## Abstract

The recognition that IV and non-IV drugs should be administered in separate devices is supported by documentation of wrong route medication errors in medical journal articles dating back to the late 1960's. The problem of misconnections, particularly enteral and breast milk being injected intravenously into neonates, still happens to this day despite warnings from virtually every affiliated professional and regulatory agency. Baxa Corporation and VIASYS MedSystems have collaborated to develop the first comprehensive pediatric enteral feeding system that cannot be connected to IV lines. This paper concludes that hospitals should do a top-to-bottom assessment of whether their systems can absolutely prevent non-IV fluid tubing from being misconnected to IV lines and take the appropriate measures to correct any deficiencies.

## Introduction

Journal articles dating back to the late 1960's and early 1970's discuss the issue of wrong-route medication errors. In the years since, many articles have been written on medical errors related to tubing misconnections. The Institute for Safe Medication Practices<sup>1</sup>, for example, has written about oral – IV misconnections more than a dozen times since its inception in 1994. ISMP and other organizations have long advocated the use of non-luer connectors for administration of any non-parenteral drugs in order to prevent the possibility of an IV infusion of a non-sterile medication. Advocates for a new standard for enteral feeding include the Joint Commission on Hospital Accreditation (Joint Commission), which audits health-systems for compliance to best practices, and the National Health Service (NHS) in the UK.

## Background

Historically, the gastric tubes used for neonatal and pediatric enteral nutrition support and oral liquid medication administration have incorporated luer fittings to allow hypodermic syringes to access the tube. Although safer non-luer tip 'oral' syringes were available, their oral tips could not mate with the tubes' luer connections. Worse yet, when a gastric tube was in place, a luer-tipped syringe was required for oral liquid medication and feeding administration. This scenario made it impossible to avoid the potentially devastating hazard of misconnection of a luer-tipped syringe or bag tubing containing a non-IV fluid to a parenteral intravenous access line.<sup>2-9</sup>

Most facilities continue to use feeding tubes with luer connections because caregivers use stock hypodermic syringes to prepare and deliver enteral feeds. Further complicating the risk of misconnection is that the most common syringe-driver 'smart pumps' used in neonatal intensive care units are programmed to recognize only the brand and size of standard hypodermic syringes.

Using standard hypodermic syringes and readily available syringe pumps is easy and cost effective. However, this solution presents misconnection risks at every step of the process.<sup>10</sup> To reduce the risk, some facilities have started adding large orange stickers to the syringes and tubes. These components are then considered 'safe' simply because they are orange. The tragic reality is that the risk of a potential misconnection remains as long as there are luer compatible connection points.

Over the past three decades, a number of manufacturers have attempted to address the issue of wrong-route administration through adapters, non-standard connectors and other individual product designs. The challenge to creating a safe enteral feeding solution is this lack of standards for the desired components. With the exception of the step connector (commonly referred to as a 'Christmas tree' connector) used at the distal end of many adult feeding sets, there is no enteral standard for manufacturers to design their products to meet.

Without a defined standard that would prevent adaptation or modification for luer compatibility at all connection points for enteral feeding, it is difficult for manufacturers to create complementary products that they do not manufacture. For example, the companies that make the feeding tubes do not necessarily manufacture the enteral feeding pump sets, or the feeding formula container. Therefore, one manufacturer's connection solution may not fit with another's.

The optimal response to the patient safety risk must account for all of the potential points of failure in the process. Any comprehensive solution must prevent practitioners from making a misconnection by adapting accessories to fit an inappropriate connection through force, or any other creative mechanism. There has not been a precedent for such a solution in the past because none of the pump, container and tubing combinations that are currently on the market are designed to administer only enteral feedings.

## **Regulatory and Professional Organization Responses**

Every national professional and regulatory organization involved in this issue agrees that the problem of enteral misconnections is far too common and must be solved. This position is the logical response to decades of literature documenting the risks and impact of errors, some of which are summarized in the references. Every alert cited represents just a fraction of the actual number of tragic and near tragic events that have occurred with misconnections.

Prominent organizations that have positions on the enteral to intravenous misconnection issue are noted below.

**ASPEN (American Society for Parenteral and Enteral Nutrition)** has published standards for specialized nutrition support in hospitalized pediatric patients that consider the dangers of oral to IV misconnections.<sup>10</sup> Among their recommendations is the development of a dedicated nutrition support team to coordinate service delivery among departments and professional groups. This 'nutrition support service' would be charged with developing "...performance improvement mechanisms to initiate policy, procedure, and/or protocol changes that enhance the safety and efficacy of parenteral and enteral nutrition with the goal of improving patient outcomes."<sup>11</sup>

The FDA (**U.S. Food and Drug Administration**) assembled an advisory board to establish and publish guidelines for safe enteral feeding. The first meeting was in October 2006 in Washington DC. Some of the organizations that participated included the FDA, Joint Commission, USP, ISMP, ASPEN, ECRI, Premier Inc., Sharp, Baxa Corp., VIASYS Inc. and the MD Anderson Medical Center.

The ISMP (**Institute for Safe Medication Practices**) has written about oral to IV misconnections more than a dozen times since its inception in 1994.<sup>12-16</sup> ISMP is among the many organizations that have long advocated the use of non-luer connectors for administration of any non-parenteral drugs in order to prevent the possibility of an IV infusion of a non-sterile medication.

The Joint Commission (**Joint Commission on Accreditation of Healthcare Organizations, formerly JCAHO**) issued a Sentinel Event Alert on April 3, 2006 warning of the significant risk posed by 'tubing and catheter misconnection errors.'<sup>17</sup> The Joint Commission noted that at least six deaths were attributed to tubing misconnections and countless other near misses had likely occurred. The Alert strongly recommends that healthcare organizations not purchase non-intravenous equipment that integrates tubing connectors that can physically mate with a female luer IV line connector of any form. The Alert also clearly states that a standard luer syringe should 'never' be used for oral medications or enteral feedings. The final statement of the Alert urges product manufacturers to implement 'designed incompatibility' to prevent misconnections of tubes and catheters.

Furthermore, the Joint Commission's National Patient Safety Goals for 2008 will require facilities to demonstrate that they are actively working to eliminate the oral to IV misconnection risk before 2008 evaluation cycles.<sup>18</sup> The official release for these new goals is estimated to be in spring 2007.

The **Journal of Neonatal Nursing** published an article that detailed implementation of an enteral nutrition and medication administration system utilizing oral syringes in the NICU.<sup>19</sup> Among the study's conclusions were that, "...converting to oral syringe delivery of medications and enteral formulas utilizing enteral-only tubing eliminated the necessity for Luer-Lok IV tubing and syringes, thereby reducing the potential for wrong-route error."

**Premier Inc.** published a case study that documented the collaboration between Premier, member hospitals, VIASYS Inc. and Baxa Corporation to develop a new premature infant feeding system that will keep IV lines and feeding tubes from being accidentally connected.<sup>20</sup> More information on this system is included in the following section.

Finally, tubing misconnections are an issue worldwide. The **National Health Service** (London) – through their National Patient Safety Agency – issued a National Public Safety Alert on March 28, 2007 regarding the risks of misconnections.<sup>21</sup> The Alert was in response to 33 documented safety incidents involving oral liquids and IV administration between January 1, 2005 and May 31, 2006. This was after years of incidents that included multiple fatalities.

This enteral Alert summary was simple: "Enteral feeding systems should not contain parts that can be connected to intravenous syringes, nor have end connectors that can be connected to intravenous or other parenteral lines." The deadline for compliance with this Alert is September 30, 2007.

One consistent message resonates from all of the preceding organizations. The safest approach to eliminating the enteral to IV misconnection risk is to use a system that is wholly separate from all parenteral products and devices.

## **A Safe Solution**

The logical answer to preventing these wrong-route tragedies is a comprehensive, dedicated enteral system. Such a system would eliminate the potential for enteral-to-IV tubing misconnection.

In July 2006, VIASYS MedSystems launched the CORFLO™ Anti-IV Feeding System<sup>22</sup>. The system is designed to prevent inadvertent feeding into an intravenous line, injection of IV medication into the feeding port, and direct connections of the feeding set or NG tube to any standard luer lock or luer slip syringe. The proprietary connection on its feeding tube allows feeding only through the CORFLO Anti-IV feeding set to ensure that its use only for enteral feeding. The tube inlet port and medication flushing port also only accept standard oral syringe tips.

Baxa Corporation has provided specialty dispensers that prevent wrong-route administration since 1975. Their first product – a syringe designated for oral use only – featured a colored plunger and blue silkscreen print to distinguish them visually from hypodermic syringes. The dispensers' specialty tip would not fit into luer connectors and, when needleless connectors were introduced into the marketplace the Baxa devices were redesigned so that they would not actuate a luer-actuated valve (LAV). The Baxa product line now includes specialty syringes labeled for oral use only, enteral use only, topical use only and vaginal use to help prevent wrong-route administration errors. The syringes are complemented by a full line of accessories that accept only the Baxa non-luer tip.

The most recent of the Baxa specialty devices are syringes designed only for enteral feeding. These Exacta-Med® Enteral Syringes<sup>23</sup> feature bold orange screen print and striping to distinguish them from luer syringes and other devices. As with the Baxa oral dispensers, their unique tip cannot connect to a luer needle hub, or actuate a needleless IV connector. These syringes have been designed specifically to fit the VIASYS Anti-IV feeding sets to provide a dedicated system for neonatal enteral feeding. Offered in 20, 35 and 60 mL sizes, these syringes provide a safe choice for neonatal and pediatric intensive care applications where the majority of the oral and enteral doses are provided through a gastric tube.

The final component in closing the loop on enteral to IV misconnections is a dedicated enteral syringe pump – one that cannot be used for intravenous infusion applications. This specialty pump would sense that the dedicated enteral syringe is seated in its driver, preventing the opportunity for intravenous infusion of enteral nutrition. Several manufacturers are working on a solution that will provide this specialty drug delivery pump alternative.

A complete, dedicated enteral system incorporates three products designed specifically to prevent misconnections: the VIASYS Anti-IV feeding tube, the Baxa Exacta-Med Enteral syringes and a dedicated enteral pump. This system provides

neonatal and pediatric intensive care units with a way to eliminate enteral to IV misconnection errors.

## Conclusion

Tubing misconnections that have allowed enteral feedings and breast milk to be infused intravenously have injured and even killed adults and neonates for decades. The Baxa and VIASYS system is the only one *dedicated* to enteral feeding that would meet the NPSA and proposed 2008 Joint Commission standards to prevent wrong-route administrations. Now that a solution is available to address this issue, it is time for hospitals to do a top-to-bottom assessment of what dangers exist in their own institutions and implement a solution to prevent misconnections in neonatal and other critical care settings.

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