



REDUCING ORAL MEDICATION WRONG-ROUTE ADMINISTRATIONS AND MISCONNECTIONS

An overview of best practices for reducing the incidence of oral/enteral syringe misconnections



OVERVIEW

Delivering patient medications via the right route is fundamental to patient safety, and one of the five rights of medication administration.¹ Despite improvements in provider education and hospital policies, misconnections continue to occur. Part I of this Technical Paper details the challenges, costs and anatomy of oral and enteral syringe misconnections. Part II discusses the approach Baxa Corporation takes to the safe development and use of oral and enteral syringes to maintain patient safety.

PART I: ORAL WRONG-ROUTE CHALLENGES, REGULATIONS AND BEST PRACTICE SOLUTIONS

MISCONNECTIONS AND PATIENT SAFETY

Despite the Five Rights of Medication Safety checklist, medication errors do occur. One study estimated that medication errors in the United States resulted in the deaths of about 7,000 patients per year.² These represent the most egregious mistakes and exclude the number of patients who survived to endure physical suffering and anxiety. The number of errors grows larger still when incidents that did not result in adverse effects—and therefore may not have been reported—are considered. Hence, the incidence of wrong-route administration errors remains a continuing concern.

A review of medication-error reports to the United States Federal Drug Administration (FDA) concluded that wrong-route accidents made up 12 percent of fatal medication errors over a five-year period.³ These accidents were the third-most common type of administration error. Among the reported deaths were those relating to oral and enteral products administered intravenously.

ORAL AND ENTERAL TO PARENTERAL MISCONNECTIONS

Once a parenteral syringe is filled with an oral substance, a momentary distraction can lead to its connection to an IV line and subsequent administration.⁴ What's unsettling about these wrong-route errors is that most of these incidents involve knowledgeable staff who inadvertently deliver oral substances via the wrong route or access port.⁵

1 <http://www.ismp.org/Newsletters/acutecare/articles/19990407.asp>

2 Phillips DP, Christenfeld N, Glynn LM. Increase in US medication-error deaths between 1983 and 1993. Research letter. *Lancet* 1998; 351: 643.

3 Phillips J, Beam S, Brinker A, Holquist C, Honig P, et al. "Retrospective analysis of mortalities associated with medication errors." *American Journal of Health-System Pharmacy*. 2001; vol: 58, Issue 19: 1835-1841.

4 Hurst, M., "Oral medication dispensers in clinical research." *Journal of Clinical Research Best Practices*, September 2006, http://www.firstclinical.com/journal/2006/0609_Oral_Dispensers.pdf. Last accessed: 04-15-10.

5 "Oral syringes: A crucial and economical risk-reduction strategy that has not been fully utilized," *Nurse Advise-ERR, ISMP Medication Safety Alert*, Vol: 8, Iss: 4, April 2010.

The problem has prompted the FDA to issue warnings to protect against the intravenous delivery of oral medications prepared in parenteral syringes.⁶ However, several recent oral/enteral to parenteral misconnections show that the problem persists.

1. A premature infant in Spain died when "...an intermittent feeding prepared in a parenteral syringe was administered intravenously instead of via a nasogastric tube."⁷
2. "A pharmacy dispensed ni**MOD**ipine capsules to nursing units, unaware that these were being used for patients who couldn't swallow. In one instance, a nurse softened the gelatin capsule in hot water and subsequently withdrew the medication into a parenteral syringe. In the chaos of the day, the dose was administered intravenously instead of via the feeding tube."⁸ The error resulted in the patient's death.
3. A 15 mg dose of VERSED (midazolam) syrup along with 650 mg of TYLENOL (acetaminophen) intended for oral administration were "withdrawn into a parenteral syringe and [mistakenly] administered intravenously to an 11-year-old child..."⁹ The patient recovered.
4. A new graduate nurse drew yogurt into a parenteral syringe intending to administer it via an enteral tube to treat diarrhea. The nurse accidentally delivered it via IV through a PICC line.¹⁰ The patient outcome was not reported.
5. A 17-month-old girl mistakenly received an injection of barium sulfate to her central venous line, which was mistaken for her gastrostomy tube.¹¹ Following corrective actions, the patient was discharged in stable condition four days later.

Beyond the toll such errors take on patients and their families, healthcare professionals dedicated to positive patient outcomes also suffer—and not just emotionally.

According to a study done by The CNA Insurance Companies, lawsuits resulting from wrong route errors are very costly. Specifically over a 10-year period (1997-2007):

- The average paid indemnity for wrong-route administration claims was \$214,250 per case.¹²
- Wrong-route medication error claims represented the highest average paid indemnity and accounted for 25 percent of total amounts awarded.¹³

⁶ FDA Patient Safety News, "Never Use Parenteral Syringes for Oral Medications," Show #94, January 2010, <http://www.accessdata.fda.gov/psn/transcript.cfm?show=94>. Last accessed: 04-12-10.

⁷ Institute for Safe Medication Practices, "Oral Syringes: A crucial and economical risk-reduction strategy that has not been fully utilized," October 22, 2009 issue, <http://www.ismp.org/Newsletters/acutecare/articles/20091022.asp>. Last accessed: 04-12-10.

⁸ Ibid.

⁹ Ibid.

¹⁰ "Oral syringes: A crucial and economical risk-reduction strategy that has not been fully utilized," *Nurse Advise-ERR*, ISMP Medication Safety Alert, Vol: 8, Iss: 4, April 2010.

¹¹ Soghoian, S., Hoffman, R. and Nelson, L, "Unintentional i.v. injection of barium sulfate in a child." *AJHP*. May 1, 2010, Vol 67. pp. 734-736.

¹² CNA Healthpro Nurse Claims Study, "An analysis of claims with risk management recommendations 1997-2007", April 2009, p. 20, see "Closed Claims with Paid Indemnity of ≥ \$10,000". Document available at:

www.nso.com/pdfs/db/rnclaimstudy.pdf?fileName=rnclaimstudy.pdf&folder=pdfs/db&isLiveStr=Y&refID=rnclaim. Last accessed: 04-12-10.

In response to the human and financial costs, legislative bodies, physicians and medical organizations have developed best practices to lower the incidence of wrong-route administration errors.

REGULATORY TRENDS AND BEST PRACTICE RECOMMENDATIONS

Currently, luer connectors are common on many different types of medical tubing. This creates the potential for oral and enteral syringes to be connected to tubing designed to give access to other parts of the body besides the digestive tract. Such improper connections can result in enteral feed or oral medication being delivered into the lungs or veins, causing severe injury or even patient death.

Consequently, The European Committee for Standardization, the US FDA, the Association for the Advancement of Medical Instrumentation and the International Organization for Standardization (ISO) are all working on small-bore connector standards. The goal is to prevent intravenous (IV), urethral/urinary, dialysis and other tubing systems from being connected to each other accidentally. The ISO standard in particular (ISO 80369) is currently in draft form and projected to be finalized in 2010.

In anticipation of these changes, some states have passed legislation to incorporate ISO standards when they become available.

For example, California enacted Assembly Bill 818. In a letter to hospitals, the California Department of Public Health¹⁴ outlined a key provision of the bill:

- A prohibition on the use of intravenous connections or enteral feeding connections that would fit into a connection port other than the type they were intended to mate with.

The Institute for Safe Medication Practices (ISMP)^{15,16} 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.

In January 2009, the American Society for Parenteral and Enteral Nutrition (ASPEN)¹⁷ published a special report, "Enteral Nutrition Practice Recommendations," detailing the recommendations of a professional task force for balancing the clinical benefits of enteral nutrition therapy against the known associated risks. Among its recommendations for preventing enteral misconnections are:

¹³ Ibid.

¹⁴ California Department of Public Health, Assembly Bill (AB) 818 (Hernandez, Chapter 476, Statutes of 2009), In a letter to hospitals and skilled nursing facilities dated November 19, 2009, AFL 09-41. Available at: <http://www.cdph.ca.gov/certlic/facilities/Documents/LNC-AFL-09-41.pdf>. Last accessed: 04-12-10.

¹⁵ Institute for Safe Medication Practices Medication Safety Alert. "Improvised drug delivery: A cause for concern." April 22, 2004 Issue. Available at: http://www.ismp.org/newsletters/acutecare/articles/20040422_2.asp. Last accesses: 05-12-10.

¹⁶ www.ismp.org.

¹⁷ Enteral Nutrition Practice Recommendations Task Force. "ASPEN Enteral Nutrition Practice Guidelines." *JPEN*. Jan. 26, 2009.

- Review currently used systems to assess practices that include the potential for misconnection, including nonstandard, rigged work-arounds (luer adapters, etc.).
- Do not modify or adapt IV or feeding devices because doing so may compromise the safety features incorporated into their design.
- Label or color-code feeding tubes and connectors, and educate staff about the labeling or color-coding process in the institution's enteral feeding system.
- Purchase and use oral syringes instead of luer lock syringes to draw up and deliver medications into the enteral feeding system. Include pharmacy department recommendations to ensure the correct syringe type, along with dispensing and proper labeling protocols.

Recommended Best Practices to Reduce the Risk of Oral Substance Misconnections

The pending ISO and legislative proceedings represent more stringent measures to be put into practice in the coming years. For the present, industry and trade organizations and other healthcare entities have taken action by developing and disseminating best practices to reduce medication errors.

Right-Route Considerations

Specialists writing in an issue of *Health Devices* suggest a dual approach to preventing misconnections.¹⁸ The first strategy is to adopt and implement administrative controls (policies) and work practices that lower the risk of wrong route errors.

An example of such a policy would be a prohibition against bringing enteral and parenteral medications simultaneously to a patient's bedside. By segregating the enteral and intravenous route substances, caregivers are less likely to confuse one for the other in their administration.

The second strategy is to adopt equipment and materials whose design "leaves the user with little or no choice but to make the correct connection."¹⁹ This "forcing function" recommendation has received widespread support.

As noted earlier, ISMP has found that the regular use of *oral syringes* to prepare and administer small-volume enteral liquids "is an effective and economical risk-reduction strategy that should be employed in all healthcare settings."²⁰

But what constitutes an "oral syringe?"

Some manufacturers sell dual-role syringes, whereby a common syringe can accept tips that mate with parenteral, luer, IV, enteral and oral connectors respectively. This design however, leaves open the potential for overworked, tired or improperly trained healthcare providers to accidentally switch tips, which may lead to a wrong-route administration incident. Moreover, in

¹⁸ "Preventing Misconnections of Lines and Cables," *Health Devices*, March 2006, Volume 35, Number 3, p. 84.

¹⁹ *Ibid*, p. 85.

²⁰ Institute for Safe Medication Practices, "Oral Syringes: A crucial and economical risk-reduction strategy that has not been fully utilized," October 22, 2009 issue, <http://www.ismp.org/Newsletters/acute/articles/20091022.asp>. Last accessed: 04-12-10.

situations where medications experience a change of custody from one medical specialist to another, confusion can occur regarding the correct route of administration. With this in mind, The Joint Commission recommends that providers "not purchase non-intravenous equipment that is equipped with connectors that can physically mate with a female IV luer-luer connector."²¹

In an extended treatise on Improving Medication Safety, England's Department of Health put forth a similar recommendation, stating that "Intravenous syringes should not be used to prepare or administer oral medicines. Oral syringes, whose tips are designed to be incompatible with luer-luer connectors, should always be used."²²

In the United States, the FDA concurs, recommending that providers never use a standard luer-luer syringe for oral medications or enteric feedings.²³

Taking these recommendations into account, pharmacists, hospital administrators and nurses can improve patient safety by adopting equipment designed specifically to lower the risk of wrong-route errors.

In the case of enteral syringes, decision makers should consider updating their procurement requirements to specify the purchase of:

- Syringes designed and manufactured for oral or enteral-dedicated use only
- Syringes that incorporate tips that are incompatible with luer connectors

While the standardization upon oral or enteral-only syringes reduces the risk of wrong-route administration errors, this policy is not without its challenges.

Few manufacturers, for example, offer oral and enteral syringes in a full range of dose sizes. This forces procurement personnel to stock syringes from different manufacturers, which may carry different names and print colors. Such differences can lead to confusion among hospital staff who must exercise added diligence to reconcile any differences.

²¹ Joint Commission on Accreditation of Healthcare Organizations. Sentinel event alert: tubing misconnections—a persistent and potentially deadly occurrence. 2006;April 3;36. Available at: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_36.htm. Last accessed 04-12-10.

²² Dr. Smith, Jim, " Building a safer NHS for patients: IMPROVING MEDICATION SAFETY, Department of Health, 22 Jan 2004, p. 75. Available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4084961.pdf. Last accessed: 04-12-10.

²³ "More Patient Deaths from Luer Misconnections," *FDA Patient Safety News*: Show #68, October 2007, available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=68#5>. Last accesses: 04-12-10.

Right-Dose Considerations

It's commonly known that oral substances come in a wide array of colors. Thus it is essential that enteral/oral syringes incorporate design elements that promote the accurate reading of doses under multi-color conditions. Specifically, the color and resolution of syringe printing, as well as the color of the piston, can influence the accurate dosing of patient medications.

Figure 1 below compares the printing on two syringes. The syringe on the left shows printing that blends into the oral substance, making it difficult to read. Note that the black piston further compounds the problem by blending in with the oral substance to obscure the dose marking line.

By comparison, the syringe on the right in Figure 1 is markedly easier to read. Note that the blue printing contrasts against the liquid. Moreover, the use of a gray piston to clearly differentiates the dose marking line from the substance.

For oral doses of smaller sizes, e.g., 1mL, the use of syringes with high-resolution dosage gradations is preferred. Clearly marked and easily read graduations foster the accurate dosing of medications while relieving eye strain and added mental concentration among pharmacists, doctors and nurses.

Figure 2 contrasts the ease of reading the high-resolution syringe on the left/right versus the low-resolution syringe on the left/right.

Thus, the use of contrasting colors for syringe printing and pistons, along with high-resolution printing on small-dose syringes, collectively promote the accurate dosing of substances by hospital staff.

Availability Considerations

Ensuring the right dose is easier when the right tools are available. Even if prefilled oral doses from the inpatient pharmacy are provided in oral syringes, it is important that these specialty-purpose devices are available on nursing floors as well. This ensures the safety of extemporaneous oral dose preparation and administration.



Figure 1: Oral syringe printing directly affects the readability of dose scales.

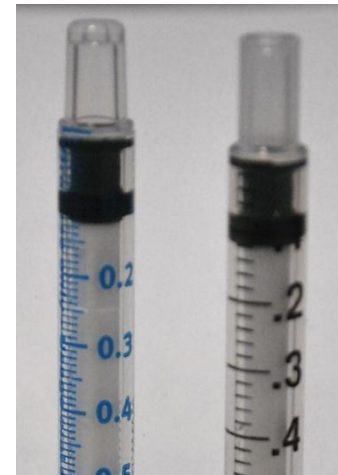


Figure 2: Oral syringe print resolution affects the readability of dose scales.

PART II: BAXA ORAL SYRINGES LEVERAGE BEST PRACTICES TO REDUCE MISCONNECTIONS

WHO WE ARE

For more than 35 years, Baxa Corporation has developed and manufactured safe and innovative oral and enteral delivery systems. Our products are used by health systems worldwide, making the Baxa name synonymous with the safest oral and enteral systems. Our first product – the ExactaMed® Oral Dispenser remains the industry standard for safe and accurate delivery of oral liquid drugs.

WHAT WE PRODUCE

Baxa products, systems and professional services encompass virtually every facet of compounding and dispensing fluid medications. These range from the most basic devices for oral unit dosing to syringe infusion, multi-source solution compounding, pharmacy automation and compliance training for professionals. From its inception, Baxa has focused on providing systems and services that improve patient safety through reinforcing best practices.

THE BAXA ADVANTAGE

Long before the best-practice recommendations described in this technical paper appeared, Baxa incorporated them into the design of its products. Specifically:

- Baxa Corporation’s ExactaMed Oral Dispensers are designed for oral use only to reduce the risk of misconnections. These dispensers:
 - Do not fit luer connections
 - Do not accept IV/parenteral tips
 - Do not actuate luer-access devices
 - Utilize visual indicators to distinguish from an IV syringe
 - Include clear labels which specify the appropriate route
- Baxa oral dispenser syringes utilize blue printing and a gray piston that is easier to read against a wide variety of oral substance colors and clearly distinguishes it from parenteral syringes.
- Baxa NeoThrive Enteral Syringes are designed for enteral use only to reduce the risk of misconnections. These these syringes:
 - Do not fit luer connections
 - Do not accept IV/parenteral tips

- Do not actuate luer-access devices
- DO use orange color-coding to differentiate them from IV syringes
- Baxa is the only company to offer a full line of oral and enteral syringe dosage sizes, from 1 mL to 60 mL, so pharmacies can standardize upon a single, safe and easy-to-use product line for non-IV medication deliveries. This simplifies procurement, inventory administration, staff training and daily product usage.
- Small-dose Baxa oral and enteral syringes use high-definition printing to facilitate proper dosing.
- All Baxa unit-dose products are chemically inert, DEHP, BPA and latex-free for added safety and stability.

Only Baxa provides a complete line of dedicated accessories to support the use of its oral and enteral syringes, including bottle adapters, filling adapters, connectors and tip caps.

SUMMARY

Despite advances in policies and device design, oral/enteral to IV/parenteral misconnections continue to occur. Such errors have led to patient deaths, leaving survivors to endure the hardships of recovery. Healthcare providers and caregivers also suffer emotional trauma following negative patient outcomes. Hospitals, clinics and other provider entities suffer financially as well, being subject to large settlements after an event.

Wrong-route errors can occur when oral medications are drawn into parenteral syringes, or when parenteral tips are mistakenly affixed to syringes intended for oral administration. Thus, the FDA, The Joint Commission, the United Kingdom's Department of Health, ASPEN and others have put forth recommendations to reduce the incidence of misconnections.

Best practices include the following actions:

- Adoption and use of oral and enteral syringe devices where the tips are incompatible with luer connections
- Avoidance of syringes that accept both parenteral/IV and enteral/oral tips
- Use of oral and enteral syringes printed with graduations that can be read easily against the rainbow of colors present in oral medications
- Use of a bullet gray piston to make it easier to read the dose marking line
- Use of small-dose oral and enteral syringes with high-resolution printing to facilitate easy and accurate dose reading by pharmacists, nurses and other caregivers

Baxa Corporation focuses on the development, manufacturing and marketing of dedicated oral and enteral devices. The company's syringes feature an enteral/oral-only tip that is incompatible with luer connections and does not accept parenteral/IV tips. The use of specialty printing and high-resolution graduations on small-dose syringes promotes their recognition as a non-IV device and assures accurate reading and dosing of all oral substances.

Collectively, these measures lower the risk of oral/enteral to IV/parenteral misconnections. By reducing the risk of wrong-route administration, health systems safeguard patients' safety while lowering their exposure to costly legal settlements.

TO LEARN MORE

To learn more about how Baxa oral and enteral solutions can help you lower your risk of wrong-route medication errors contact your Baxa representative today. Or visit www.baxa.com/exactamed and www.baxa.com/neothrive for details on specific products.