PATIENT SAFETY ISSUE:
Hypodermic Syringe Tip Caps

Occasionally, hypodermic syringes are inappropriately used for oral administration of medication. In these cases, the tip cap, if inadvertently left on the syringe, may constitute a choking hazard. The elimination of the tip cap from the hypodermic syringe thus eliminates the risk that in the event a hypodermic syringe is incorrectly used for oral medication delivery, no choking hazard will exist. (see illustration)

There are two major classes of syringes used in healthcare: hypodermic and oral-dosing. The hypodermic syringe is designed for use with a needle, plastic cannula or IV port for parenteral (non-oral) administration of medication. The oral syringe is specifically designed to deliver oral medications. Unlike the hypodermic syringe, the tip design of the oral syringe precludes connection to a needle or other device, and may be graduated in teaspoons.

A tip cap is a small plastic component that covers the syringe tip if the syringe is supplied without a needle. Tip caps for hypodermic syringes are typically small, translucent, and may be similar in color to the syringe. Tip caps for oral syringes are more easily distinguished from the syringe body by larger size and/or contrasting color. Oral syringe tip caps also are specifically designed to protect the tip of the syringe after medication has been withdrawn into the syringe prior to administration. Most oral syringe tip caps are extremely difficult to dislodge when pressing on the syringe plunger, yet they pull off conveniently for medication administration.

Occasionally, hypodermic syringes are inappropriately used for oral administration of medication. In these cases, the tip cap, if inadvertently left on the syringe, may constitute a choking hazard. Because of this risk, BD (Becton, Dickinson and Co.) has decided to eliminate tip caps from all of its hypodermic syringes without needles or plastic cannulas. The removal of the tip cap from the hypodermic syringe thus eliminates the risk that in the event a hypodermic syringe is incorrectly used for oral medication delivery, no choking hazard will exist.

The importance of syringes in pediatric medication use. Giving the right dose is critical to ensuring the safest possible use of any prescribed medication. This is particularly important in the treatment of infants and children, who are more sensitive than adults to many drugs, and who may respond differently or with different side effects to prescription or over-the-counter medication.

For that reason, syringes and other dosing instruments are critical in helping a professional or non-professional caregiver, such as a parent, to provide the precise dosage of oral medication that comes as a liquid or suspension to a small child. Syringes are especially convenient for infants or very sick children who cannot drink from a cup. A syringe has easy-to-read graduations, and the design makes it possible to squirt the medication to the back or side of the child’s mouth where it is less likely to spill out. Syringes also offer a convenient, accurate way to store individual dosages so that, for example, the parent or primary caregiver can measure the dosage and leave the pre-filled syringe
for a babysitter or some other less experienced
caregiver to administer at the appropriate
time. Until the decision by BD to remove the
tip caps from its hypodermic syringes, most
syringes—hypodermic and oral—have included
tip caps. Originally designed by BD to assist in the
manufacturing process, syringe tip caps have come
to take on uses in healthcare professionals’ syringe-
handling procedures for which they were never
intended, and for which they are not fully adequate
since they are not reliable sterile barriers.

While hypodermic syringes can technically be
used for administration of oral medications,
the tip cap that is usually supplied with such
syringes is dangerous if it is not removed prior to
administration. (See above photo comparing a
BD oral syringe with a BD hypodermic syringe.)
If the tip cap is accidentally dispensed into a child’s
mouth with the medication, it could become
lodged in the child’s throat, thus becoming a
potentially serious or even life-threatening choking
hazard. Similarly, choking may occur if the tip cap
is not appropriately discarded, and a child finds the
small tip cap and puts it into the mouth. Clearly,
the risk associated with inadvertent access to the
tip caps of hypodermic syringes by children far
outweighs any possible benefit derived from
pre-assembled tip caps in practical use. At the
same time, BD recognizes the clinical needs served
by a sterile cap. BD will offer a separate, sterile,
single-use cap. BD will cease attaching tip caps to
its hypodermic syringes, sold without needles or
plastic cannulas in 2003.

Human error with the use of syringes and syringe
caps. The removal of tip caps from hypodermic
syringes by BD is intended to accomplish what
the Institute of Medicine (IOM) has referred to
as the prevention of medical errors (in this case
by preventing an inadvertent choking hazard) by
making it “harder for people to do something
wrong and easier for them to do it right.”

In 1999, a widely heralded, broadly publicized
IOM report, “To Err Is Human,” documented
the extent and impact of preventable medical
errors taking place in American hospitals each
year. Medical errors were defined by the IOM as
“the failure of a planned action to be completed
as intended or the use of a wrong plan to achieve
an aim.” Among the types of errors identified
were those relating to improper administration of
medication. Using data from two major studies, the
IOM found that deaths from preventable medical
ers in hospitals were found to nearly match the
number of deaths, collectively, caused by motor-
vehicle accidents, breast cancer and AIDS annually.
One of the report’s main conclusions was that
the majority of medical errors did not result from
recklessness, but from “conditions that lead people
to make mistakes or fail to prevent them.” Thus,
the report concluded, the best way to reduce
medical errors is to alter these conditions to make
errors less likely.

Several alerts and guidelines have recently
been published by the U.S. Food and Drug
Administration (FDA), the Institute for Safe
Medication Practices (ISMP) and other healthcare
organizations to help eliminate hazards and
prevent medication errors associated with the
use of syringes to dispense oral medication:

- Choking is possible if a syringe tip cap
  is inadvertently left on the syringe during
  administration. In November 1994, the American
  Pharmaceutical Association (APhA) and the
  ISMP alerted healthcare professionals of several
cases in which children choked on hypodermic
syringe tip caps when the caregiver failed to
remove the syringe tip cap before administering
the medication. The tip caps did not prevent the
medication from flowing into the syringe from the container, but flew off and became lodged in the child’s airway. Because such problems are more likely with hypodermic syringes, ISMP urged practitioners to tell patients to use only measuring cups or oral syringes when giving liquids. Unfortunately, warnings from ISMP and the FDA website letter to physicians and pharmacists have not been adequate to prevent the use of hypodermic syringes for the delivery of oral medications.

An August 22, 2001 safety alert from ISMP described another such case. A tip cap from a hypodermic syringe being used for delivery of oral medication was overlooked by the parent and was accidentally ingested by a young child causing asphyxiation.

The ISMP also has reported serious, and sometimes fatal errors, where oral medications stored in traditional hypodermic syringes have been mistaken for hypodermic syringes filled with medication intended for parenteral (non-oral, e.g., intravenous) administration, and the oral medication was inadvertently administered parenterally resulting in death of the patient.\(^5\)

Finally, under no circumstance should children be allowed to play with a syringe (or any of its components, including an appropriate and necessary tip cap). Syringe tip caps and other syringe components present a choking hazard if improperly discarded. An ISMP Medication Safety Alert\(^6\) points out that the small tip caps are similar in size to many children’s toy pieces. Syringe tip caps have often been found in the bed covers or on bedside tables within easy reach of a child, notes the ISMP alert. Furthermore, children have access to discarded caps in the trash can or some other disposal container and, as every parent knows, have no aversion to putting things from the trash in their mouths. In this alert, ISMP asked healthcare professionals and lay caregivers to remove and safely discard the tip caps of syringes before administering medication in order to prevent accidental ingestion and asphyxiation by children finding these caps. The FDA has also issued a recent alert to healthcare professionals regarding the proper use of syringes for dispensing oral medications. The alert directs healthcare professionals to provide appropriate instructions to parents and caregivers in the use of syringes and tip caps. The FDA states that instruction should be provided in three distinct ways: orally; in written form; and with a practice demonstration to ensure caregiver understanding.\(^7\)

**BD’s efforts to prevent errors specifically related to the syringe tip cap.** In light of the evolving information being made available about the hazards associated with the inappropriate use of hypodermic syringes for the delivery of oral medications, BD has taken three key steps over the past year in an effort to reduce the risks associated with hypodermic syringe tip caps:

- On October 10, 2001, BD issued a safety alert to more than 150,000 healthcare professionals advising clinicians of the risk of the tip cap coming off in the patient’s mouth, should the tip cap be left on while medication is administered orally. The letter urged healthcare professionals not to use hypodermic syringes for the administration of oral medications, and to discourage their use by patients and patients’ families. The letter stated clearly that if a clinician advises a parent to deliver oral medication via syringes, only oral syringes should be used.

- BD has increased the visibility of tip caps for hypodermic syringes. As described above, while oral syringe tip caps are usually colored/tinted and shaped for visibility, hypodermic syringe tip caps have traditionally been small, translucent and inconspicuous, similar in color to the
syringe body. In January 2002, BD changed its hypodermic syringe tip caps from clear to blue to make them more visible, and thereby less likely to be mistaken for a permanent part of the syringe.

- And now, in 2003, BD will become the first major syringe manufacturer to re-engineer its hypodermic syringes to remove syringe tip caps altogether, thus eliminating completely the risk of pre-assembled tip caps on hypodermic syringes from becoming choking hazards.

“This was the right thing to do,” says Carole M. Lannon, MD, MPH, Associate Professor of Pediatrics, University of North Carolina School of Medicine. “The possibility of children experiencing life-threatening problems with the inhalation of syringe tip caps was simply too great to tolerate without an equally compelling reason to continue to include tip caps with the hypodermic syringe,” adds Lannon. According to Kenneth B. Kassler-Taub, M.D, Vice President of Medical Affairs for BD Medical Systems, “We determined that the presence or absence of the tip caps did not affect the sterility or performance of the syringe, and we made this change as the best way to help both patients and those physicians and family members who care for them. Consequently, BD will also continue to serve the needs of the healthcare community by separately providing sterile, individually packaged, single-use tip caps for those applications that require temporary capping of the hypodermic syringe in a sterile manner.”

References:

1. Safety Alert, Becton, Dickinson and Company (BD), October 10, 2001

2. Ibid.


For more information about pediatric patient safety, visit: www.ahrq.gov/consumer/20tipkid.htm