Possible risk of injury following EpiPen Jr injection

If you keep an EpiPen Jr (epinephrine) auto-injector on hand in case a child has a severe allergic reaction, you need to know about the risk of injury to the child if he or she moves while the needle is under the skin. An EpiPen Jr auto-injector is a disposable automatic injection device filled with 1 dose of epinephrine. The dose is delivered when the orange tip is pressed against a child’s outer thigh until it “clicks” then held there for 10 seconds. Prompt treatment of severe allergic reactions in the home and community can be lifesaving and has resulted in better survival rates and fewer long-term effects. Most often, auto-injectors are used successfully without complications. But two children recently sustained injuries when the EpiPen Jr was used.

A 4-year-old boy at daycare had an allergic reaction. The staff gave him an injection of epinephrine using an EpiPen Jr. The child was standing, and a daycare staff member was standing behind him for support. Another staff member held the child’s leg and gave the injection. The child kicked while getting the injection, so the needle moved while under the skin, leaving a cut along his leg. Believing the device had not been held in place long enough to give the drug (for the recommended 10 seconds), the staff member attempted to reinject the child using the same needle. This resulted in a second cut (Figure 1) when the child tried to get away again. The child’s symptoms improved without additional epinephrine. The two 3-inch cuts were closed with nonabsorbable sutures and tissue adhesive. X-ray imaging and inspection of the needle showed that the needle had bent, which likely prevented the needle cover from locking back in place when the needle was initially kicked free by the child (Figure 2).

In a very similar case, a 3-year-old boy having an allergic reaction while at daycare was given a dose of EpiPen Jr in his outer thigh. The child jerked his leg and got a 1½ inch cut on his leg. The daycare worker then restrained the child with her body weight and attempted to reinject the medication using the same EpiPen Jr, holding the device in place for 10 seconds to ensure the drug had been fully delivered. The child was taken to the emergency department, where his symptoms improved without additional medicine. The cut was repaired with eight nonabsorbable sutures.

These cases highlight features of the EpiPen Jr and adult EpiPen design and instructions for use that contributed to the injuries. The instructions direct the user to push the EpiPen firmly against the outer thigh, holding it in place for approximately 10 seconds (www.ismp.org/se?id=399). The needle stays under the skin until the EpiPen is pulled away from the thigh (http://youtu.be/0SzkO4-a3NM). Because of this, people may believe it takes 10 seconds for the medicine to be injected. However, the average time needed to inject the epinephrine is much shorter, less than 3 seconds in most cases.1 The instructions do not explain that the EpiPen should only be used once and should never be reinserted even if it comes out of the skin in less than 10 seconds. The instructions for EpiPen Jr also do not mention the need to restrain a child or the risk of injury if the child moves.

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SAFETY TIPS

- Dial-up, then push the button. If you have diabetes and take insulin using an insulin pen, you may be one of many who are not using the pen correctly. Many insulin pens have a dial on one end of the pen to “dial-up the dose” (Figure 1, top). That same end has a button that needs to be pushed so the dose can be delivered (Figure 1, bottom). We recently learned that some individuals were dialing the dose correctly but then, after inserting the needle under the skin, they dialed the dose back down to zero believing that would deliver the dose. Instead of dialing down the dose, they should have pushed the button to deliver the dialed dose of insulin. Without pushing the button, the dose of insulin was never given. This resulted in high blood sugar (glucose) levels in those individuals. The errors were discovered by their doctors, nurses, or diabetic education—continued on page 2—EpiPen Jr >
> EpiPen Jr—continued from page 1

With the availability of a newer epinephrine device, the Auvi-Q (epinephrine) auto-injector, the risk of this type of injury is less likely to occur. The Auvi-Q auto-injector delivers the medicine quickly, and the needle retracts automatically in less than 1 second (http://youtu.be/H6JZCUlicK8). There is little risk of needle injury since the needle retracts so quickly and there is zero risk once the needle is back in the device.

Here’s what you can do: Be sure to restrain a child when using an epinephrine auto-injector to prevent movement during the injection. This is particularly important for the EpiPen Jr and other similar epinephrine auto-injectors that recommend that the needle remain in place for at least 10 seconds. If the needle is dislodged, reinsertion should never be attempted. If it was in place for at least 3 seconds, it is likely that the full dose of epinephrine was injected. It is important to seek medical attention after administering a dose of epinephrine because another dose may be needed but should be determined by emergency medical professionals. This information should be relayed to caregivers, daycare workers, teachers, and anyone else who might administer epinephrine to a child.

ISMP thanks Julie Brown, MDCM, MPH, of Seattle Children’s Hospital for providing the contents of this article based on errors that happened outside the facility in which she works.

Reference

Breast milk mix-ups at daycare facilities

Many breastfeeding mothers who return to work utilize daycare providers to care for their babies. Those who want to exclusively breastfeed their babies will need to plan for the transition ahead. In some circumstances the mother can come into the daycare facility to breastfeed at arranged times. However, many mothers do not have this option and have to provide pumped breast milk to the daycare facility to feed the baby. Unfortunately, errors have occurred.

Breast milk mix-ups

Surprisingly, cases of babies receiving the wrong breast milk at daycare facilities are not rare. A recent Internet search revealed six cases (Table 1, on page 3) highlighted in the media between 2010 and 2014 in which babies received another mother’s breast milk while in the care of a daycare provider. Additional stories were uncovered on various parenting forums. In all likelihood, there are more cases that have not been made public, or in some cases, never brought to the parents’ attention. However, as most parents would agree, the anxiety of learning your baby has ingested another mother’s milk can be significant.

Effects of mix-ups

Breast milk is not only an excellent source of nutrition for babies, it also contains important antibodies and other protective substances to help babies defend against illness. However, breast milk can also contain pathogens associated with dangerous diseases such as human immunodeficiency virus (HIV), cytomegalovirus (CMV), human T-lymphotropic virus (HTLV), hepatitis A, hepatitis B, and hepatitis C. Some sources suggest that breast milk can transmit these pathogens to babies, while other sources suggest the risk of transmission from the milk is very low. Specifically, transmission of HIV from breast milk is very low and has never been documented. The risk is considered low because chemicals present in breast milk act, together with time and cold temperature, to destroy HIV cells that may be present in breast milk. However, the Centers for Disease Control and Prevention (CDC) recommends treating breast milk the same as other bodily fluids (e.g., blood, urine) that may transmit diseases.

Aside from the risk of transmitting diseases from breast milk, there are other factors to consider if a baby receives the wrong breast milk. Breast milk may contain illicit drugs, alcohol, or prescription continued on page 3—Breast milk

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Categories who asked the individuals to demonstrate how they were taking their insulin.

Here’s what you can do: If you use an insulin pen, talk to your doctor, pharmacist, nurse, or diabetic educator about how to use the pen correctly. If a family member or other caregiver gives you your insulin, make sure they understand how to use the device as well.

Angeliq—not a birth control pill! Angeliq (drospirenone, estradiol) is a hormone-based medicine used to relieve the symptoms of menopause. Unfortunately, it has been wrongly prescribed as an oral contraceptive (birth control pill). In two cases, physicians provided women with samples of Angeliq to take as birth control. Both women took Angeliq for several months until the samples were finished. The mistakes were discovered when the women took prescriptions for further supplies of Angeliq to their pharmacies and referred to them as “birth control pills” (www.ismp.org/sc?id=330).

Angeliq has a number of similarities to birth control pills that might have played a role in the mix-ups. Angeliq comes in a 28-day package similar to how birth control pills are packaged. “Angeliq” also sounds like a woman’s name—many birth control pills also have female-sounding names such as Portia and Yasmin. In addition, the sample package of Angeliq does not have information pointing out that the medicine is used for symptoms of menopause. Most important, the hormones contained in Angeliq are similar to the ingredients in birth control pills: progestin and estrogen. However, the dose of progestin in Angeliq is less than that used in birth control pills, and the strength of the estrogen in Angeliq is also different from the strength used in birth control pills. So women using Angeliq instead of birth control pills could become pregnant. And that’s exactly what happened to a woman we heard from recently through our consumer error reporting program (www.consumermedsafety.org). Her doctor had given her Angeliq samples for continued on page 3—SAFETY TIPS
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and nonprescription medications that the mother has taken. These may cause problems for babies, particularly if they have never been exposed to these substances previously. Another consideration is the potential for bacterial contamination of the breast milk due to the normal flora of the mother or improper pumping and storage of the milk.

Causes of mix-ups

Studies that have investigated breast milk mix-ups have found that incorrectly labeled breast milk, difficult to read handwritten labels, mistaken identification of babies, and problems with the way milk is stored are the most common causes of breast milk mix-ups.6,7

Here’s what you can do: Discuss with your daycare provider the policies and procedures that are in place to prevent breast milk mix-ups. Be sure you are also comfortable with the process used for storing the milk and identifying the correct infant. Ideally, the breast milk will be stored at the daycare facility in labeled, separate storage bins in the refrigerator or freezer for each breastfed baby.

You can help to prevent mix-ups by clearly labeling the breast milk you provide for your baby. Consider these recommendations when labeling the breast milk:

- Use moisture-resistant ink to label the breast milk container.
- Include on the label your baby’s full name and date of birth, the date and time the milk was expressed, and the date and time the milk was thawed, if applicable.
- Print the label information or prepare a computer-generated label. Do not use cursive writing, which is more likely to be misinterpreted than printed information.
- Secure the label to the breast milk container. Be sure it cannot fall off.

Table 1. Examples of mix-ups with breast milk at daycare facilities (2010-2014)

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2010</td>
<td>Bremerton Daycare, Bremerton, Washington</td>
<td>A 3-month-old child was mistakenly fed another mother’s breast milk</td>
</tr>
<tr>
<td>April 2010</td>
<td>Irving KinderCare, Irving, Texas</td>
<td>During the first week of daycare a baby was mistakenly fed another mother’s breast milk</td>
</tr>
<tr>
<td>September 2011</td>
<td>Kids R Kids Daycare, Pearland, Texas</td>
<td>A report published by the Texas Department of Family and Protective Services included an event in which a daycare caregiver failed to check the name on a breast milk bottle which was fed to the wrong child</td>
</tr>
<tr>
<td>June 2012</td>
<td>Bright Horizons Childrens Center, Washington University Family Learning Center, St. Louis, Missouri</td>
<td>The director of a daycare facility reported to the Missouri Department of Health that one infant at her facility was given another mother’s breast milk</td>
</tr>
<tr>
<td>March 2013</td>
<td>DaySpring Daycare &amp; Preschool Ministry, West Lafayette, Indiana</td>
<td>A daycare provider issued a public statement acknowledging an incident in which a child was accidently given a small amount of the wrong breast milk</td>
</tr>
<tr>
<td>April 2014</td>
<td>Willowcreek Academy Daycare Center, Gainsville, Florida</td>
<td>An infant received a bottle containing a combination of breast milk and whole milk that belonged to another infant in the same classroom</td>
</tr>
</tbody>
</table>

Here’s what you can do: Even when you receive samples from your doctor, it is safest to call the pharmacy where you fill other medicine prescriptions to let the pharmacist know about the samples. This way, the pharmacist can be sure there are no interactions between the sample medicines and any other medicines you take. When you do this, be sure to tell the pharmacist why you are taking the medicine. This will help uncover any possible errors, as a pharmacist would recognize that Angeliqu is not effective as a birth control pill.

Advice from FDA

6 tip-offs to rip-offs: Don’t fall for health fraud scams

If you are looking for a “miracle cure” or “alternative to medicine or surgery,” be cautious. For years, health products have been falsely marketed to people looking for easy solutions to difficult health problems. Use of these products can not only be a waste of money but they can also cause serious injury or even death.

A product is considered fraudulent by the US Food and Drug Administration (FDA) if it is promoted as being effective in treating a disease or health condition without scientific proof. Many fraudulent products claim to help you lose weight, enhance sexual performance or memory, or treat serious diseases such as cancer, diabetes, heart disease, arthritis, and Alzheimer’s. While they may sound promising, using these products can delay a person from getting a potentially life-saving treatment that is scientifically proven to work.

The FDA wants people to use caution and consider the following list of “6 tip-offs” that will help you identify product “rip-offs.”

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- Apply the label to the container in such a way that it would need to be viewed and considered when opening the breast milk container.
- Inspect the label for accuracy and complete information before providing the breast milk to the daycare provider.

What to do if your baby receives the wrong breast milk

If your baby receives another mother’s breast milk, ask the daycare provider how the milk was expressed and handled prior to giving it to your baby, and inform your child’s pediatrician. The CDC suggests that your child undergo a baseline HIV test as a precaution despite the low risk of being infected. Your child’s pediatrician will decide if baseline testing should also occur for other diseases such as hepatitis B, hepatitis C, and human T-cell lymphotropic virus (HTLV). Most babies are vaccinated against hepatitis B at birth.

References

5) Centers for Disease Control and Prevention. What to do if an infant or child is mistakenly fed another woman’s expressed breast milk. October 2009. Available at: www.ismp.org/sc?id=438

Advice from FDA

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1) One product does it all. Products that claim to cure a number of diseases or conditions are highly suspicious.
2) Personal testimonials. It is very easy to make up personal statements about a product. And these statements should not take the place of scientific evidence.
3) Quick fixes. Very few diseases or conditions can be treated in a few days.
4) “All natural.” Some natural ingredients may be harmful. And, FDA has found some natural products that contain high doses of prescription medicines which can be harmful.
5) “Miracle cure.” If a real cure for a serious disease were found, it would be widely reported and recommended by healthcare providers.
6) Conspiracy theories. Statements that the pharmaceutical industry and the government hide information about a miracle cure are just untrue. Statements like these are used to distract consumers from the obvious, commonsense questions about a miracle cure.

Here’s what you can do: Always check with your doctor, nurse, or pharmacist before trying any unproven product.