Frequently Asked Questions (FAQs) About Infant Botulism

1. What is infant botulism?

Infant botulism is the infectious (intestinal) form of botulism, which results when swallowed spores of a particular bacterium (*Clostridium botulinum*) colonize the baby's large intestine and produce botulinum toxin in it. Botulinum toxin causes weakness and loss of muscle tone because it blocks the nerve ending's ability to signal the linked muscle to contract. The illness often begins with constipation but is usually first noticed as difficulty feeding (sucking and swallowing), a weak and altered cry and diminished facial expression.

2. How does infant botulism differ from foodborne botulism?

In infant botulism the swallowed botulism spores activate and produce botulinum toxin inside the baby's large intestine. In foodborne botulism the botulism spores activate in the food and produce botulinum toxin. Older children and adults get foodborne botulism by eating the food in which the botulism bacteria have produced botulinum toxin.

3. How does a baby get infant botulism?

A baby contracts ("gets") infant botulism by swallowing the botulism spores at a moment in time when the baby's large intestine is vulnerable to spore germination and toxin production. Medical science does not yet understand all the factors that make a baby susceptible to botulism spore germination. Honey is the one identified and avoidable source of botulinum spores. By a process of exclusion (testing over the years of hundreds of foods, beverages and other items placed in infants' mouths with negative results), it was concluded that most infant botulism patients acquired their spores by swallowing microscopic dust particles that carry the spores.

4. My infant was fed a commercial product containing honey (e.g. cereal with honey baked in), should I be worried about infant botulism?

Please refer to the American Academy of Pediatrics best practice guidelines regarding feeding solids to infants (<u>AAP Best Practice Guidelines regarding infant feeding and nutrition</u>).

Many foods and commercial products contain honey, and the honey is included in a variety of ways. Because the details of each manufacturing process vary, CDPH is unable to comment on the likelihood that the honey-containing food product may contain viable *C. botulinum* spores.

CDPH continues to recommend <u>not</u> feeding honey and honey-containing products to infants under the age of one.

5. I know that honey is not a safe food for babies. Is it ok for a breastfeeding mother to eat honey? Can botulism be transmitted in my breast milk? Should I continue to breastfeed my infant through his/her illness with infant botulism? Yes, it is ok for a breastfeeding mother to eat honey. Botulism is not transmitted by breast milk. The Infant Botulism Treatment and Prevention Program recommends continuing breast feeding or the feeding of expressed breast milk during the illness and recovery from infant botulism.

As always, thorough hand washing practices should be strictly adhered to, especially in households where honey is regularly consumed by family members and other caregivers. Doing so will help prevent having honey on surfaces that may come into contact with the infant's mouth.

Although the bacterial spores that cause infant botulism are known to occasionally be present in honey, even if a mother was to eat botulism spores in honey, the spores are far too large to pass through her body and into breast milk. Also, botulinum toxin does not pass into breast milk. For this and other reasons, breast milk is not a source of the bacterial spores or the toxin that cause infant botulism.

As stated in the patient management section of our website, breast milk constitutes optimal nutrition for infants, and mothers should be encouraged and supported in their efforts to continue breastfeeding through their infant's illness and recovery.

For a more thorough discussion of breastfeeding and infant botulism, please refer to the Prevention section below.

6. How is infant botulism treated?

Infant botulism is treated with meticulous supportive care with special attention to feeding and breathing needs. In the United States the orphan drug BabyBIG® is also used to shorten hospital stay and reduce complications.

7. What is BabyBIG[®]?

The orphan drug BabyBIG® is human-derived botulism antitoxin that was approved (licensed) by the U.S. Food and Drug Administration (FDA) for the treatment of infant botulism on October 23, 2003. Use of BabyBIG® significantly reduces the length of hospital stay and associated hospital costs in patients with infant botulism.

8. How soon after BabyBIG® treatment can my child be immunized?

The infant should have good to full recovery of muscle strength and tone before immunizations resume. In addition, most live-virus vaccines (i.e., measles, mumps,

rubella and varicella) will need to be delayed until 6 months after BabyBIG® treatment because the antibodies in BabyBIG® may interfere with the effectiveness of the vaccine. The live-virus vaccine for rotavirus, RotaTeq® and Rotatrix® should also be delayed until sustained return of normal bowel function after BabyBIG® treatment. Although current data suggest that administration of intravenous immunoglobulin products such as BabyBIG® will not interfere with the efficacy of oral rotavirus vaccines¹, patients with infant botulism **should not** receive the rotavirus vaccine because of the slowed intestinal motility that results from infant botulism.

Accordingly, any of the recommended doses of the rotavirus vaccine (RotaTeq[®] or Rotarix[®]) that were not given to the infant before treatment with BabyBIG[®] should be delayed. Because the other live-virus vaccines (i.e., measles, mumps, rubella and varicella) are normally first given at one year of age, only those infant botulism patients who were 6 months of age or older when they were treated with BabyBIG[®] will need delayed immunization with these vaccines.

9. Are there any long-term consequences of infant botulism?

In the absence of serious hospital-acquired complications, no. The prognosis for infant botulism patients is for full and complete recovery. Recovery results from regrowth of the nerve endings that then are able to signal the muscles to contract. Botulinum toxin does not penetrate into the brain, and so infant botulism patients retain all the intelligence, athletic ability, musical ability, sense of humor and orneriness with which they were born.

10. Can my baby get infant botulism again?

No. Infants treated with BabyBIG® will have a protective level of toxin-neutralizing antibody for at least six months following administration of the medicine. This feature allows sufficient time for elimination of *C. botulinum*, which has temporarily colonized the infant's intestine causing disease.

Since the disease of infant botulism was first recognized more than 40 years ago, there have been no instances of an infant acquiring the disease more than once. During this time more than 4400 cases of infant botulism are known to have occurred worldwide.

However, a few reports of "relapsing" infant botulism have been published during this time. Careful review of these case reports by our program's physicians indicates that these were cases in which the infant was discharged prematurely, before adequate recovery of strength needed to sustain feeding and breathing. For a further discussion of this topic please see the patient management section of our website under the For Physicians tab.

11. Will my next child be at increased risk for infant botulism?

No.

12. How should I handle my baby's diapers as he/she recovers from botulism?

It is known that patients with infant botulism excrete both *C. botulinum* toxin and organism in there feces for periods ranging from weeks to months after symptom onset. Consequently, scrupulous handwashing should be practiced after each diaper change. Soiled diapers should be quickly disposed of in an area where no other person or animal can come into contact with them. Persons with open cuts or wounds on their hands should wear gloves when changing diapers.

Because the patient may be excreting the toxin and organism for weeks to months, it is advisable to limit close contact with other small children during this time. This is to ensure that other children do not come into contact with fecal material from a leaky diaper. Any contact the patient has with other children in this time should be supervised by an adult.

C. botulinum is not part of the patient's normal flora (normal, healthy bacteria that live in our bodies) and will eventually stop being excreted in the infant's feces.

13. How can infant botulism be prevented?

The only known prevention measure for infant botulism is to avoid feeding honey to infants 12 months of age or less. Breastfeeding may slow the onset of illness if it develops.

14. How do I contact other families in my area whose children also had infant botulism?

There are two ways to do this: 1) call the IBTPP collect and ask for assistance, 2) visit Facebook page by searching infant botulism or visiting Infant Botulism Family Network Facebook page or 3) go to the Online Parents' Forum on our website (Infant Botulism Treatment and Prevention Program website, under the For Parents section) and follow the instructions there.

When to Avoid Honey

Honey is the one identified and avoidable food reservoir of *C. botulinum*, the bacterial spore that causes infant botulism. While most cases of infant botulism today are not caused by exposure to honey prior to illness, it is the only avoidable source of exposure to the bacteria. By a process of exclusion (testing over the years of hundreds of foods, beverages, and other items placed in infants' mouth with negative results), it was concluded that most infant botulism patients acquired their spores by swallowing microscopic dust particles on which the spores travel.

The California Department of Health Services (CDHS) prepared an informative brochure to increase awareness of avoiding feeding honey to infants under one year of age. The pamphlet is not copyrighted and CDHS encourages any and all interested parties to download, print, and distribute this brochure, available on our website (Infant Botulism Treatment and Prevention Program website).

Prevention

The only known prevention measure for infant botulism is to avoid feeding honey to infants 12 months of age or less. Breastfeeding may slow the onset of illness if it develops.

The role of breast-feeding and formula-feeding as factors possibly predisposing to the development of illness remains unsettled. All studies to date have identified an association between being breast-fed and being hospitalized for infant botulism²⁻⁸. This finding has resulted in one perspective that holds that breast-feeding predisposes to the development of illness ^{4,5,7}, whereas the other perspective holds that breast-feeding slows its onset sufficiently to permit hospitalization to occur^{2,3,9,10}. However, among hospitalized patients, the mean age at onset of infant botulism in formula-fed infants (7.6 weeks) was significantly younger and approximately half that of breast-fed infants (13.8 weeks). In addition, the fulminant-onset infant botulism patients who stopped breathing and died at home all were formula-fed. The relative susceptibility of formula-fed and breast-fed infants to the acquisition of infant botulism and the resultant severity of their disease may reflect differences in the availability of suitable ecologic niches in the intestinal flora for *C. botulinum*, differences in the availability of immune factors (such as lactoferrin and secretory IgA) contained in human milk but not in formula milk¹¹, or other differences not identified yet.

Honey is the one dietary reservoir of *C. botulinum* spores thus far definitely linked to infant botulism by both laboratory and epidemiologic evidence ^{8,12-19}. To date, 35 instances worldwide are known in which *C. botulinum* spores have been found in the actual honey fed to an affected infant before the onset of illness. In each instance, the toxin type (A or B) of the spores in the honey matched the toxin type (A or B) of the *C. botulinum* that caused the infant's illness; the probability that such perfect concordance occurred by chance is less than 1 in 10 billion. *C. botulinum* spores have been found in the honey from the United States, Argentina, Australia, Canada, China (Taiwan also), Denmark, Finland, Italy, Norway, Spain, Japan, and Central America ^{13-16,18-23}, but not in honey from the United Kingdom²⁴. For these reasons and because honey is not nutritionally essential, all major pediatric, public health, and honey industry agencies in the United States have joined in the recommendation that honey not be fed to infants. In 2000, several honey brands sold in the United States began to carry a warning to not feed honey to infants; an equivalent label first appeared on British honey in 1996.

Discussion of the possible role of corn syrup in infant botulism is necessitated by two reports. In 1982, the U.S. Food and Drug Administration (FDA) found *C. botulinum* type B spores in approximately 0.5 percent (5 of 961) of previously unopened retail samples of light and dark corn syrup²⁰; the manufacturer then made changes in the production process. In 1989, the CDC reported a 2-year epidemiologic study of U.S. cases from all states except California⁷. By subgrouping patients by age and using logistic regression modeling techniques, researchers were able to obtain a statistical association between

the triad of corn syrup exposure, breast-feeding, and an age of 2 months or older at onset^{7,25}.

In contrast to these reports, a 1988 Canadian survey found no *C. botulinum* spores in 43 corn syrup samples¹⁵. A 1991 FDA market survey of 738 syrup samples (354 of which were light corn syrup and 271 were dark corn syrup) concluded that none contained *C. botulinum* spores²⁶. In addition, a 1979 epidemiologic study that simply compared corn syrup exposure rates in 41 cases and 107 control infants identified feeding of corn syrup as a significant protective factor against the acquisition of type A infant botulism¹³. The explanation offered for the latter observation was that if a parent chose corn syrup as a sweetener for the infant, honey was unlikely to have been fed to the child as a second sweetener. Thus, on the basis of evidence presently available, corn syrup does not appear to be a source of *C. botulinum* spores or a risk factor for the acquisition of infant botulism.

It deserves emphasis that for most cases of infant botulism, no source of *C. botulinum* spores is ever identified, even circumstantially. In these cases, the illness probably was acquired by swallowing spores adherent to airborne microscopic (invisible) dust.

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