Public Health Guidance for the Management of Infant Botulism Notifications

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Please note that this document should be used in tandem with other Infant Botulism guidance.

Readers should not rely solely on the information contained with these guidance outputs. Guidance information is not intended to be a substitute for advice from other relevant sources including and not limited to, the advice from a health professional. Clinical judgement and discretion will be required in the interpretation and application of this guidance document. This guidance document is regularly reviewed based upon emerging evidence at national and international levels and national policy decisions. In tandem with this, the guidance will be formally reviewed on a three-year cycle.

HSE Public Health: National Health Protection Office
FSS Sláinte Poiblí: An Oifig Náisiúnta um Chosaint Sláinte

VERSION HISTORY

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1.0	**09/12/2025**	*De novo* guidance

Contents

Glossary of acronyms and abbreviations

BAT	Botulism antitoxin
CPHM	Consultant in Public Health Medicine
FSAI	Food Safety Authority of Ireland
HPRA	Health Products Regulatory Authority
IBTPP	Infant Botulism Treatment and Prevention Program
IMT	Incident Management Team
NCCS	National Cold Chain Service
NHPO	National Health Protection Office
UKHSA	UK Health Security Agency

1.0 Description

Botulism is a rare but serious illness caused by a neurotoxin, which results in difficulty breathing, muscle paralysis, and can be fatal. The neurotoxin is produced by the anaerobic spore-forming bacterium *Clostridium botulinum (or* less commonly *Clostridium butyricum* or *Clostridium baratii*). These bacteria can produce the toxin in food, wounds, and the intestines of infants. [1] There are eight neurotoxins (A-H). Illness in humans is usually caused by types A, B, or E, or rarely by F. All toxins block release of acetylcholine at the neuromuscular junction, which results in flaccid paralysis.

How does infant botulism differ from other types of botulism?

Infant botulism occurs only in children under 1 year of age. When classical botulism occurs in older children and adults, it is usually from consumption of pre-formed toxin or wound infection. Infant botulism, however, is due to intestinal colonisation from ingestion of spores or live bacteria, which the infant's underdeveloped stomach acid and bowel flora fail to eradicate. This allows neurotoxin production to occur in the bowel.

Types of botulism

Infant botulism	Bacterial colonisation of an infant's gut allowing neurotoxin production.
Food-borne botulism	Consumption of foods contaminated with pre-formed toxin. Commonly homemade foods that have been improperly canned, preserved, or fermented. Less commonly, contaminated store-bought foods.
Wound botulism	Bacterial wound infection in anaerobic conditions and toxin production. Traumatic injuries and intravenous drug use are risk factors.
Iatrogenic botulism	Rare complication of botulinum toxin injection e.g. for cosmetic purposes.
Adult intestinal toxaemia	Rare, but similar to infant botulism. Bacterial spores colonise the gut in adults and produce neurotoxin. Occurs with underlying gut conditions.

Epidemiology

Infant botulism is rare. Four cases have been reported in Ireland as of 2025. [2, 3] Approximately 150 -180 cases occur annually in the United States, and it is now the most common form of botulism in the US and Canada. [4] It has no epidemic potential.

Sources

C. botulinum exists naturally in the environment. In most cases of infant botulism, the source is not identified. Potential sources include honey or peanut butter ingestion, areas of soil or dust disturbance (such as building sites) and exposure to reptiles (especially terrapins). [5] International surveys have demonstrated that between 2% and 7% of honey samples contain *C. botulinum* spores.

Incubation Period

It is often impossible to determine when exposure occurs, and so incubation periods cannot be calculated reliably. An exposure interval of up to 30 days before symptom onset should be used to determine potential exposures. [6, 7]

Period of communicability

Infant botulism is not a contagious condition. However, be aware that other infants may have been exposed to the same source as an index case and should be monitored for symptoms.

Clinical Presentation

Infants may present initially with non-specific features, such as constipation (often the first symptom), diarrhoea, weakness, weak cry or poor feeding. This can progress rapidly to weak suck, ptosis, loss of facial expression, reduced gag reflex, hypotonia and hyporeflexia. [8, 9]

Prevention

Reptiles should not be kept as pets where infants are present. Infants should not consume honey in the first year of life. Given the close association between infant botulism and honey consumption, the food safety agencies of most countries (including the Food Safety Authority of Ireland) have issued advice against adding honey to the food or drinks of children under one year of age. [10] Clothing worn on building sites or dusty environments should be changed before direct contact with infants.

Management

- Admission to Paediatric unit (isolation is not required).
- Report urgently to Public Health and speak with on-call Consultant in Public Health Medicine (CPHM) about any suspected case so that a thorough investigation and risk assessment can be undertaken.
- Handwashing is necessary following handling of soiled personal garments, including nappies.
- Early administration of botulism antitoxin (BAT) is essential and potentially lifesaving. **Administration of antitoxin should not be delayed pending laboratory results.**
- Infants also require a human-derived infant botulism immunoglobulin (BabyBIG®) which is only available from the Infant Botulism Treatment and Prevention Program (IBTPP) in California, USA. [11]

Public Health Response: On-Call Regional Consultant

- Support sourcing of BAT and BabyBIG in collaboration with the hospital treating the patient and the National Health Protection Office (NHPO).
- Obtain urgent full potential exposure history including food, animals and environmental sources.
- Determine if there could be linked cases or common exposures.
- Convene Incident Management Team (IMT). Members might include Public Health, Paediatrics, Microbiology, Environmental Health Officers, Food Safety Authority of Ireland, Health Products Regulatory Authority, Regional Veterinary Officer.
- Send warn and inform letters to others potentially exposed to source.
- Test potential sources for *C. botulinum* as outlined below.

Medication Procurement

Botulism Antitoxin (BAT)

- Botulinum antitoxin (BAT) is held by the National Cold Chain Service (NCCS). During working hours, contact should be made with NCCS customer services on vaccines@udd.ie. If requiring an emergency delivery out of hours, contact the on-call Consultant for the National Health Protection Office.
- Details of the product held and dosage required are here: US PI - March 2013

BabyBIG (Botulism Immune Globulin)

- If a baby is suspected of having botulism, they require BabyBIG, which cannot be held in Ireland. In the intervening time before it arrives, consideration could be given to a dose of BAT - consult product details above for dosage.
- BabyBIG is only available via consultation with physicians in The California Department of Public Health, who release the medicine as needed, after discussion with the child's treating physician. Stock cannot be held outside of

IBTPP. The 24/7 contact number is 001 (510) 231-7600. Website is http://www.infantbotulism.org

- Procurement of BabyBIG is the responsibility of the hospital treating the patient and the National Health Protection Office can give advice to the treating clinician on how to do this.
- If BabyBIG is required, it is an Exempt Medicinal Product and will require authorisation from the Health Products Regulatory Authority (HPRA). Emergency contacts for HPRA: https://www.hpra.ie/homepage/medicines/emergency-contact-details-medicines
- BabyBIG is very expensive (one dose costs approximately $69,300 USD) and the hospital administering it or the appropriate Regional Executive Officer must agree to pay for it. [12]

Testing

- Food items ingested e.g. honey, formula milk - involve Food Safety Authority of Ireland (FSAI)
- Medicines ingested e.g. probiotics - involve Health Products Regulatory Authority (HPRA)
- Animals, especially reptiles and terrapins - involve Regional Veterinary Officer
- Water sources e.g. private well - involve Environmental Health Officer

There are no laboratories in Ireland that can test for *C. botulinum*, so samples should be sent by courier to Colindale Laboratory (UKHSA, 61 Colindale Avenue, London, NW9 5EQ, UK). This can be arranged through the Public Health Laboratory at Cherry Orchard.

Management of Contacts or Similar Exposures

- Contacts without similar exposure need no action – there is no human-to-human transmission.

- Infants who have been exposed to the same potential source and who are displaying any symptoms as listed above or any concerning features should be brought for urgent medical review.

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