Botulism Guide for Health Care Professionals

This information requires knowledgeable interpretation and is intended primarily for use by health care workers and facilities/organizations providing health care including pharmacies, hospitals, long-term care homes, community-based health care service providers and pre-hospital emergency services.

Public Health Division
Ministry of Health and Long-Term Care
August 2013

Ontario

AT A GLANCE

A Quick Response Guide to Botulism

Botulism – The treatment of botulism is guided by clinical diagnosis

The initial diagnosis of botulism should be based on a history of recent exposure, consistent clinical symptoms and elimination of other illnesses in the differential. **Treatment should not wait for laboratory confirmation.** All treatment and management decisions should be made based on clinical diagnosis.

Initial Presentation and Evaluation of signs and symptoms

There are several clinically distinct forms of botulism. ***All forms produce the same neurological signs and symptoms of symmetrical cranial nerve palsies followed by descending, symmetric flaccid paralysis of voluntary muscles,*** which may progress to respiratory compromise and death. Additional symptoms (e.g., gastrointestinal signs in foodborne cases) may also be seen in some forms.
Read more on the disease on page 2

Reading the section on ***Differential Diagnosis*** and the referenced articles will assist with making the diagnosis of botulism – you will find this on page 3

Place a request for Botulinum Antitoxin (BAT) or BabyBIG®

Ministry of Health and Long-Term Care (ministry) staff will arrange for the shipment of BAT. Information on ordering BAT and BabyBIG (BabyBIG has a different ordering process) is on page 5

Laboratory Diagnosis and Specimen Collection

Clinical specimens must be obtained prior to administering treatment with botulinum antitoxin. Call the Botulism Reference Service (BRS) for Canada to make arrangements for transporting suspect food and clinical specimens to Ottawa for laboratory analysis; contact information for further details and mailing information is on page 7

Notify your local public health unit

Botulism should be reported even if it is only suspected and has not yet been confirmed. Information on the suspected food item should also be provided during the call.

Contact the ministry with follow-up patient information

After treating the patient, call the ministry with information specified on page 7

The full document, Botulism Guide for Health Care Professionals is at: www.Ontario.ca/botulism

Titre en français : *Guide sur le botulisme pour les professionnels de la santé*

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Botulism

The initial diagnosis of botulism should be based on a history of recent exposure, consistent clinical symptoms, and elimination of other illnesses in the differential. **Treatment should not wait for laboratory confirmation.** All treatment and management decisions should be based on clinical diagnosis.

i) Initial Presentation and Evaluation

There are several clinically distinct forms of botulism. All forms produce the same neurological signs and symptoms of symmetrical cranial nerve palsies followed by descending, symmetric flaccid paralysis of voluntary muscles, which may progress to respiratory compromise and death.[1] Additional symptoms (e.g., gastrointestinal signs in foodborne cases) may also be seen in some forms.

Initially symptoms of **foodborne botulism** may include nausea, vomiting, abdominal cramps or diarrhea. Dry mouth, blurred vision, and diplopia are usually the earliest neurologic symptoms followed by dysphonia, dysarthria, dysphagia, and peripheral muscle weakness. These symptoms may extend to a descending symmetrical flaccid paralysis in an alert afebrile person. Constipation is a common symptom later in presentation. **Wound botulism** produces the same symptoms as foodborne botulism, except that gastrointestinal symptoms (vomiting and/or diarrhea) do not occur and neurological symptoms may take longer (up to two weeks) to appear. The earliest and most frequently observed symptom of **infant botulism** is constipation followed by lethargy, poor feeding, ptosis, difficulty swallowing, hypotonia and generalized weakness (floppy baby) including a weak cry.

Additional information assisting clinical diagnosis for infant botulism is available at the Infant Botulism Treatment and Prevention Program at **http://www.infantbotulism.org/.**

The symptoms observed in **adult intestinal colonization botulism** are similar to foodborne botulism. The clinical manifestation of **iatrogenic botulism** is similar to the characteristic findings seen in classic foodborne botulism, although nausea and vomiting are not typically present. Although **inhalational botulism** is not a naturally occurring disease, the syndrome was described once among laboratory workers in 1962, with symptoms resembling those of foodborne botulism. Please see *Appendix 1 Botulism: Clinical Description* for additional information on symptoms and incubation period.

[1] Sobel, J., 'Botulism', *Clinical Infectious Diseases*, 2005, Vol. 41(8), pp. 1167-73.

ii) Differential Diagnosis

Differential diagnosis of botulism can be challenging because the symptoms mimic those of other diseases, especially diseases characterized by muscle weakness.

Botulism in adults must be differentiated from diseases such as the following: Guillain-Barré syndrome (GBS) (including the Miller Fisher variant of GBS), Myasthenia gravis, Lambert-Eaton myasthenic syndrome (LEMS), stroke or central nervous system (CNS) mass lesion, toxic exposures (organophosphates, atropine, carbon monoxide, or aminoglycosides), tick paralysis, paralytic shellfish poisoning, and puffer fish ingestion.[2]

Botulism in infants must be differentiated from diseases such as the following: sepsis, meningitis, electrolyte-mineral imbalance, Reye's syndrome, congenital myopathy, Werdnig-Hoffman disease, and Leigh disease.[3]

iii) Laboratory Diagnosis

Laboratory testing to confirm the initial diagnosis can take at least 72 hours to complete and involves demonstrating the presence of botulinum toxin in serum, feces, gastric contents, vomitus or the implicated food; demonstrating toxicity to mice; or isolating *C. botulinum* from fecal specimens. In wound botulism, *C. botulinum* may be isolated from a wound specimen.

For further information on the collection and transportation of suitable suspect food and clinical specimens please see *Appendix 2, Suitable Specimen Collection and Transportation*. More information regarding the process for sending samples to the BRS Laboratory can be found in Health Canada's Botulism – Guide for Healthcare Professionals, August 2012 at http://www.hc-sc.gc.ca/fn-an/alt_formats/pdf/legislation/guide-ld/botulism-botulisme-prof-eng.pdf

If botulism is suspected please contact the Botulism Reference Service (BRS) for Canada at **(613) 957-0902** (Monday to Friday; 8:30 a.m. – 4:30 p.m.) or at **(613) 296-1139** (after hours, weekends and holidays). BRS will provide direction on the collection and transportation of suspect food and clinical specimens to Ottawa for laboratory testing. **Clinical specimens must be obtained prior to administering treatment with botulinum antitoxin.**

[2] Anderson, I.B., & Kim-Katz, S.Y., 'Botulism: Diagnosis and Management in the United States: A clinical and epidemiologic review', *Annals of Internal Medicine*, 1998, Vol. 120(3), pp. 221-228.
[3] Ibid.

iv) Antitoxin use and clinical management

Supportive care combined with the rapid administration of botulinum antitoxin is crucial to successful management of botulism. Advice on the most up-to-date treatment should be sought from a clinical expert.

For all types of botulism, accessibility to respiratory support is essential. For wound and foodborne botulism, **Botulinum Antitoxin (BAT)** is available for treatment. The BAT product currently available in Ontario is Botulism Antitoxin Behring (BAB®). BAB® is obtained from horses immunised with the toxins of *C. botulinum* Types A, B and E. The antibodies react specifically with and neutralise circulating botulism toxins (i.e., neurotoxin that is not already bound to neurons). One vial of BAB® should be administered to adults and children ≥ 1 year of age, as soon as possible, on the basis of clinical diagnosis and without awaiting laboratory confirmation. Antitoxin is effective in reducing the severity of symptoms, if administered early in the course of the disease; however, it will not reverse established paralysis.[4]

Please refer to the product monograph for **Botulism Antitoxin Behring®** for further dosage and administration details.

Note: *The recommendation for considering the use of equine antitoxin when BabyBIG® is not available would need to be handled on a case by case basis.*

Botulism Immune Globulin, Intravenous (BIG-IV); (BabyBIG®), is a preparation of human-derived botulinum antitoxin antibodies indicated in the treatment of infant botulism caused by toxin type A or B for babies up to one year of age.[5] BabyBIG® should be administered as a single intravenous infusion as soon as the clinical diagnosis of infant botulism is made. Please refer to the product monograph for BabyBIG® for further dosage and administration details.

Antitoxin prophylaxis for individuals who do not display symptoms consistent with botulism is not recommended due to the risk of serum sickness and hypersensitivity reactions associated with antitoxin administration. For wound botulism, in addition to antitoxin, the wound should be debrided and/or drainage established, and appropriate antibiotics (e.g. penicillin) administered. Attempts may be made to remove contaminated food still in the gut by inducing vomiting or by using enemas.

[4] Wenham, T., & Cohen, A., 'Botulism', *Continuing Education in Anaesthesia, Critical Care & Pain*, 2008, Vol. 8(1), pp. 21-25.
[5] Fox, C.K., Keet, C.A., & Strober, J.B., 'Recent advances in infant botulism', *Pediatric Neurology*, 2005, Vol. 32(3), pp. 149-154

Process for ordering Botulinum Antitoxin (BAT) or BabyBIG®

Before placing an order for Botulinum Antitoxin (BAT) or BabyBIG® it is essential that you read the following sections within this guide:

i) initial presentation and evaluation;
ii) differential diagnosis;
iii) laboratory diagnosis; and
iv) antitoxin use and clinical management.

Step 1 Place a request for Botulinum Antitoxin (BAT) or BabyBIG®

Placing a request for BAT

A limited supply of BAT is kept on-site at the Ontario Government Pharmaceutical and Medical Supply Services (OGPMSS). Ministry of Health and Long-Term Care (ministry) staff will arrange for the shipment of BAT. Advice on administration is detailed in the product monograph which accompanies BAT. The ministry staff will advise OGPMSS of the authorization. The physician's information (i.e., name, address and phone number) will be provided to OGPMSS and they will prepare for the delivery of BAT.

Contact the ministry to place a request for BAT:

- *During Regular Work Hours (8:30 a.m. – 4:30 p.m. Monday to Friday):* Call the Infectious Diseases Policy & Programs Section of the ministry's Public Health Division at (416) 327-7392 and request to speak with a staff member.
- *After-Hours, Weekends and Holidays:* Call the Spills Action Centre at (416) 325-3000 or 1-800-268-6060 and request to speak with the Public Health Division on-call person.

Please provide ministry staff taking the order with:

a) the name of the physician to whom the antitoxin should be sent
b) the address to which the antitoxin should be sent
c) the physician's contact telephone number
d) the name of the public health unit in whose geographic jurisdiction the hospital is located.

Please see Appendix 3 for summary of process for ordering BAT or BabyBIG®

Placing a request to access BabyBIG®

BabyBIG® is not approved for sale in Canada and can only be accessed from the Infant Botulism Treatment and Prevention Programs (IBTPP) at the California Department of Public Health (CDPH) by placing a request with Health Canada through the Special Access Programme (SAP). The SAP will then authorize the CDPH to ship BabyBIG® to the hospital. The receiving hospital is responsible for paying the required fee to CDPH for BabyBIG®, as well as paying the transportation cost for BabyBIG® from California. The ministry will reimburse these costs upon receipt of the invoice. *The Special Access Request Form A* can be downloaded from Health Canada's website at http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapf1_pasf1-eng.php. Additional information on BabyBIG® can be obtained at the IBTPP website at http://infantbotulism.org/.

Place a request for BabyBIG® via Health Canada's SAP:

- *During Regular Work Hours (8:30 a.m. – 4:30 p.m. Monday to Friday)*: The physician should fax the completed *The Special Access Request Form A* to the SAP at **(613) 941-3194**. To avoid delays all sections of the form should be completed accurately. It is recommended to follow up with a phone call to (613) 941-2108.

- *After-Hours, Weekends and Holidays*: The physician should call the SAP on-call officer at **(613) 941-2108 (press 0)**. The attending physician should be prepared to provide the information required on the *The Special Access Request Form A* to the on-call officer. On the next business day the physician should fax the completed *The Special Access Request Form A* to the SAP at **(613) 941-3194**.

Call on-call physician at IBTPP to discuss the patient's clinical situation:

- *Anytime, 24 hours a day, 7 days a week*: Access to BabyBIG® is authorized only by one of the IBTPP on-call physicians. The patient's attending physician must call the IBTPP on-call physician at **1-510-231-7600** to discuss the clinical situation before BabyBIG® can be shipped.

Notify the ministry of the request for BabyBIG® from Health Canada:

- *During Regular Work Hours (8:30 a.m. – 4:30 p.m. Monday to Friday)*: Call the Infectious Diseases Policy & Programs Section of the ministry's Public Health Division at **(416) 327-7392** and request to speak with a staff member.

- *After-Hours, Weekends and Holidays*: The attending physician should call the Spills Action Centre at **(416) 325-3000** or **1-800-268-6060** and request to speak with the Public Health Division on-call person.

Please see Appendix 3 for summary of process for ordering BAT or BabyBIG®

Step 2 — Collect and make arrangements for transporting suspect food and clinical specimens to Ottawa for laboratory analysis

Call the Botulism Reference Service (BRS) for Canada to make arrangements for transporting suspect food and clinical specimens to Ottawa for laboratory analysis:

- *During Regular Work Hours (8:30 a.m. – 4:30 p.m. Monday to Friday)*: Call the BRS office at **(613) 957-0902** prior to sending suspect food and clinical specimens to Ottawa for laboratory analysis.
- *After-Hours, Weekends and Holidays*: Call the BRS cell phone at **(613) 296-1139** to make arrangements for transporting suspect food and clinical specimens to Ottawa for laboratory analysis.

Please see *Appendix 2 Suitable Specimen Collection and Transportation* for basic information on the collection and transportation of suitable suspect food and clinical specimens.

Samples should be sent by courier to:
(do not use Canada Post)

Dr. John W. Austin or Mr. Greg Sanders
Botulism Reference Service
Health Canada
Room 456, Sir Frederick G. Banting Building
251 Sir Frederick Banting Driveway
Tunney's Pasture, PL2204E
Ottawa, ON, K1A 0K9

Step 3 — Notify your local public health unit immediately.

Botulism is a reportable disease in Ontario under the *Health Protection and Promotion Act (HPPA)* and must be reported immediately to the local medical officer of health by telephone. The disease should be reported even if it is only suspected and has not yet been confirmed. Information on the suspected food item should also be provided during the call.

Step 4 — Contact the ministry with follow-up patient information.

After treating patient, please contact the ministry during regular business hours at **(416) 327-7392** and request to speak with a staff member from the Infectious Diseases Policy & Programs Section.

This information will be provided to the Health Canada Special Access Programme (SAP) to obtain BAT for future use.

Please provide ministry staff with the:

a) patient's initials
b) date of birth
c) sex
d) indication for use
e) dosage and duration
f) quantity used
g) date administered.

Reference List

The information provided is subject to change. The information was collated from the following sources:

1) Anderson, I.B., & Kim-Katz, S.Y. (1998) Botulism: Diagnosis and Management in the United States: A clinical and epidemiologic review, *Annals of Internal Medicine*, Vol. 120(3), pp. 221-228

2) Centers for Disease Control and Prevention, [Online], Available: http://www.cdc.gov/nczved/divisions/dfbmd/diseases/botulism

3) Engelkirk, P.G. and Duben-Engelkirk, J.L. (2008) *Laboratory diagnosis of infectious diseases: Essentials of diagnostic microbiology*, Lippincott Williams & Wilkins.

4) Fox, C.K., Keet, C.A., & Strober, J.B. (2005) Recent advances in infant botulism, *Pediatric Neurology*, Vol. 32(3), pp. 149-154

5) Health Canada (2013). *Special Access Request Form A*. Retrieved from http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index_e.html

6) Health Canada. (2012). *Botulism – Guide for Healthcare Professionals.* Retrieved from http://www.hc-sc.gc.ca/fn-an/alt_formats/pdf/legislation/guide-ld/botulism-botulisme-prof-eng.pdf

7) Heymann, D. (2008) *Control of Communicable Diseases Manual*, 19th Edition, American Public Health Association: Washington D.C.

8) *Infant Botulism Treatment and Prevention Program*, [Online], Available: http://www.infantbotulism.org/

9) Shapiro, R.L., Hatheway, C., & Swerdlow, D.L. (1998). Botulism in the United States: A clinical and epidemiologic review, *Annals of Internal Medicine* 129 (3), pp. 221-228

10) Sobel, J., (2005). 'Botulism', *Clinical Infectious Diseases*, 41(8): 1167-73

11) Wenham, T., & Cohen, A. (2008) Botulism, *Continuing Education in Anaesthesia, Critical Care & Pain*, Vol. 8(1), pp. 21-25.

Appendix 1: Botulism – Clinical Description

Symptoms

Foodborne Botulism

Foodborne botulism is caused by the ingestion of food contaminated with preformed botulinum toxin and subsequent absorption of toxin through the gastrointestinal tract. Initially symptoms of foodborne botulism may include nausea, vomiting, abdominal cramps or diarrhea. Dry mouth, blurred vision, and diplopia are usually the earliest neurologic symptoms followed by dysphonia, dysarthria, dysphagia, and peripheral muscle weakness. These symptoms may extend to a descending symmetrical flaccid paralysis in an alert afebrile person. Constipation is a common symptom later in presentation.

Wound Botulism

Wound botulism is caused by toxin produced from a wound infected with the spores of *Clostridium botulinum*. The anaerobic conditions allow germination of the spores and production of toxin by vegetative bacteria that become systemically absorbed. This form of botulism produces the same symptoms as foodborne botulism, except that gastrointestinal symptoms (vomiting and/or diarrhea) do not occur and neurological symptoms may take longer (up to two weeks) to appear. Currently, the majority of wound botulism cases occur among injecting drug users who subcutaneously ("skin popping") inject street drugs contaminated with *C. botulinum* spores. Wound botulism may also occur following traumatic injury to an extremity, such as a compound fracture, laceration, puncture wound, gunshot wound, severe abrasion or crush injury. The presence of a wound is an important sign.

Infant Botulism

Infant botulism is caused by the ingestion of *Clostridium botulinum* spores, which then germinate in the intestine and produce bacteria that release toxin which is absorbed into the circulation. It affects infants under one year of age. The earliest and most frequently observed symptom is constipation followed by lethargy, poor feeding, ptosis, difficulty swallowing, hypotonia and generalized weakness (floppy baby) including a weak cry.

Adult Intestinal Colonization Botulism

Adult intestinal colonization botulism is a very rare kind of botulism that occurs among adults who have anatomical or physiological abnormalities of the gastrointestinal system (i.e., intestinal surgery, inflammatory bowel disease or recent antibiotic treatment). The pathogenesis of this type of botulism is similar to that of infant botulism. It is caused by the ingestion of *Clostridium botulinum* spores, which then germinate in the intestine and produce bacteria that release toxin which is absorbed into the circulation. The symptoms observed are similar to foodborne botulism.

Appendix 1: Botulism – Clinical Description

Iatrogenic Botulism

Iatrogenic botulism is caused by accidental overdose of botulinum toxin and has been reported in patients who have been treated with intramuscular injections of botulinum toxin for therapeutic or cosmetic reasons. Clinical manifestations are similar to other forms of botulism.

Inhalational Botulism

Inhalational botulism does not occur naturally. To date, only three human cases have been reported: this occurred in 1962 with veterinary laboratory technicians in Germany who were working with aerosolized botulinum toxin in animals. Symptoms occurred about 72 hours after exposure. This form of botulism is caused by inhalation of aerosolized preformed botulinum toxin with subsequent absorption through the lungs into the circulation.

Routes of Exposure

Botulism is caused by exposure to botulinum toxin. Humans can become infected by:

1) Oral

Consumption of toxin – **Foodborne botulism** is a severe intoxication resulting from ingestion of preformed toxin of the bacterium *C. botulinum* present in contaminated food.

Consumption of *C. botulinum* spores – **Infant botulism** and **Adult intestinal colonization botulism** results from ingestion of *C. botulinum* spores that then germinate in the colon, rather than by ingestion of preformed toxin.

2) Parenteral

Contamination of a tissue with *C. botulinum* spores – **Wound botulism** results from toxin produced from a wound infected with the spores of *C. botulinum*.

Contamination of a tissue with toxin – **Iatrogenic botulism** is the most recent man-made form of botulism that occurs due to infection of a large dose of toxin.

3) Inhalation

Inhalation of toxin – Inhalational botulism does not occur naturally, however, aerosolised toxin could be a potential route for infection as a result of deliberate release by bioterrorists.

Incubation Period

In foodborne botulism, symptoms generally begin 12 to 36 hours after eating a contaminated food, but can also occur as early as six hours or as late as 10 days. The incubation period of wound botulism is longer, averaging about 10 days. The incubation period of infant botulism and adult intestinal colonization botulism is unknown.

Appendix 2: Suitable Specimen Collection and Transportation

Food samples may include leftovers or unopened containers. When commercial foods are involved, it is important to retrieve the label, the manufacturer's lot number and codes embossed on the can or package.

Suitable clinical specimens for analyses include:

- Fecal samples (approximately 10 g),
- Enema fluid,
- Gastric contents (adjusted to approximately a pH of 6.0 with 1N NaOH, if possible),
- Serum (from 20 ml of blood collected before administration of antitoxin).
- When infant botulism is suspected, the essential material for analysis is the infant's feces. As constipation is a common symptom, the following samples may be submitted if necessary: soiled parts of diapers, a rectal swab, 2 ml of serum or a combination of samples may be submitted.

Specimens should be handled according to routine practices and additional precautions, and packaged for transport to the BRS. After collecting the sample, but prior to shipping, ensure that the sample is stored in the refrigerator at approximately 4°C. For safe shipment, the specimens must be in a watertight primary receptacle, in a watertight secondary container, with sufficient absorbent material between the two containers to absorb the entire contents of the primary receptacle. The preferred method of preserving the material during shipment is by cooling rather than freezing, i.e., by including commercial cooling packs in the parcel. After the specimen is shipped, inform BRS of the expected delivery time. In urgent cases, the parcels are picked up immediately upon arrival, usually at the airport.

Appendix 3: Process for ordering BAT or BabyBIG®

Before placing an order for Botulinum Antitoxin (BAT) or BabyBIG® it is essential that you read the following sections within this guide:

i) initial presentation and evaluation;
ii) differential diagnosis;
iii) laboratory diagnosis; and
iv) antitoxin use and clinical management.

Step 1

Place a request for Botulinum Antitoxin (BAT) or Botulism Immune Globulin, Intravenous (BIG-IV); (BabyBIG®)

Placing a request for BAT

Obtain botulinum antitoxin from the Ministry of Health and Long-Term Care's Public Health Division (PHD).

PHD will direct processing and delivery of the antitoxin

- During regular work hours: **(416) 327-7392**
- After-hours, weekends & holidays: **(416) 325-3000** or **1-800-268-6060**

Placing a request to access BabyBIG®

Place a request for BabyBIG® via Health Canada's Special Access Programme (SAP)

- During regular work hours: Complete Special Access Request Form and fax to **(613) 941-3194**
- After-hours, weekends & holidays: Call the SAP on-call officer at **(613) 941-2108 (press 0)**

Speak with an on-call physician at the Infant Botulism Treatment and Prevention Program at the California Department of Public Health

- Anytime, 24 hours a day, 7 days a week: **1-510-231-7600**

Notify the Ministry of Health and Long-Term Care's Public Health Division

- During regular work hours: **(416) 327-7392**
- After-hours, weekends & holidays: **(416) 325-3000** or **1-800-268-6060**

Step 2

Discuss specimen collection, transportation and clinical presentation of the suspect case with the Botulism Reference Service for Canada.

- During Regular Work Hours: **(613) 957-0902**
- After-hours, Weekends & Holidays: **(613) 296-1139**

Make arrangements for transporting clinical and food specimens for laboratory analysis to the Botulism Reference Laboratory in Ottawa.

Step3

Notify the local public health unit about suspect case of botulism without laboratory confirmation.

- If food is suspected as the cause, the suspect source should also be reported.

Step4

Provide after-treatment information to the ministry's Public Health Division on the amount of antitoxin administered and date administered.

- During regular work hours: **(416) 327-7392**

www.Ontario.ca/botulism Titre en français : *Guide sur le botulisme pour les professionnels de la santé*

Appendix 4: Important Telephone Numbers

Ministry of Health and Long-Term Care

Public Health Division

- (416) 327-7392
- (416) 325-3000 or 1-800-268-6060

Health Canada

Botulism Reference Service Office

- (613) 957-0902
- (613) 296-1139

Special Access Programme

- Fax Special Access Request Form A to (613) 941-3194
- (613) 941-2108 (press 0)

California Department of Public Health

Infant Botulism Treatment and Prevention Program

- 1-510-231-7600
- 1-510-231-7600

- During Regular Work Hours
  Monday to Friday (8:30 a.m. – 4:30 p.m.)
- After-Hours, Weekends and Holidays

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