Probiotic sepsis in infants under 2 years of age

CANADIAN PAEDIATRIC SURVEILLANCE PROGRAM
2305 St. Laurent Blvd. Ottawa, ON K1G 4J8
Tel: 613-526-9397, ext. 239
Fax: 613-526-3332
cpsp@cps.ca
www.cpsp.cps.ca

REPORTING INFORMATION (To be completed by the CPSP)	
Report number:	
Month of reporting:	
Province:	
Today's date:	

Please complete the following sections for the case identified above. If the information asked for below is not readily available, please leave it blank. Strict confidentiality of information will be assured.

CASE DEFINITION FOR PROBIOTIC SEPSIS IN INFANTS UNDER 2 YEARS OF AGE

Report any patient under 2 years of age (up to their 2nd birthday) meeting **ALL four** of the following criteria of probiotic sepsis:

1) Receiving a probiotic
2) Presents with systemic signs or symptoms of infection (e.g., temperature instability, apnea/bradycardia, hypotension, lethargy, or feeding intolerance)
3) Blood culture confirms the presence of one or more micro-organisms representing a probiotic strain*
4) Requires clinical intervention (e.g., initiation or escalation of antimicrobial therapy).

Exclusion criteria

- Blood culture confirming the presence of a strain of *Streptococcus* (but report ***salivarius or thermophilus)***
- Positive culture of a probiotic strain from non-sterile fluid, such as endotracheal aspirate
- Positive culture of a probiotic strain from cerebrospinal fluid, peritoneal fluid, or urine
- Probiotic bacteremia without clinical or laboratory signs of sepsis

* **Examples of possible probiotic strains that could cause probiotic sepsis:**

- ***Lactobacillus:*** *rueteri, rhamnosus, acidophilus, helveticus, paracasei, delbrueckii subsp. bulgaricus, plantarum*
- ***Bifidobacterium:*** *longum, lactis, animalis, bifidum, breve*
- ***Streptococcus:*** *salivarius, thermophilus*
- ***Saccharomyces:*** *boulardii*
- ***Pediococcus:*** *pentosaceus*

The above list is not exhaustive and includes only common probiotic strains. **Report positive blood cultures for all strains of *Lactobacillus, Bifidobacterium, Saccharomyces, and Pediococcus*, as well as *Streptococcus salivarius or thermophilus.***

SECTION 1 – PATIENT INFORMATION

1.1. Month/year of birth: _____ /_____
MM YYYY

1.2. Gestational age at birth (weeks): _____

1.3. Sex assigned at birth: ❍ Male ❍ Female ❍ Intersex ❍ Unknown

SECTION 2 – PROBIOTIC SEPSIS

2.1 Full name of probiotic organism: _____

2.2 Age of patient at time of probiotic-positive blood culture: ____ days OR ____ weeks OR ____ months

SECTION 3 – PROBIOTIC PRODUCT

3.1 Was the patient's probiotic history known to the reporting physician at the time of diagnosis? ❍ Yes ❍ No

3.2 What was the name of the probiotic product given to the patient: _____ ❍ Unknown

3.2.1 Provide the labelled strength and manufacturer of the probiotic: _____ ❍ Unknown

3.3 Probiotic dose: _____ ❍ Unknown Frequency of administration: _____ ❍ Unknown

3.4 At what age was the probiotic started?

❍ ≤ 2 weeks ❍ > 1 month to 3 months ❍ > 6 months to 12 months
❍ > 2 weeks to 1 month ❍ > 3 months to 6 months ❍ > 1 year to < 2 years

3.5 Regularity of probiotic use since initiation: ❍ Daily ❍ Weekly ❍ Intermittently (multiple start/stop dates)
❍ Never been on regular dosing of probiotic ❍ Unknown

3.6 How long had the patient been using the probiotic prior to this episode of sepsis?
❍ < 7 days ❍ > 1 week to 4 weeks ❍ > 4 weeks to 2 months ❍ > 2 months to 6 months ❍ Unknown

3.7 Is the patient on, or has the patient been on, any other probiotics?
❍ Yes, currently ❍ Yes, previously ❍ No ❍ Unknown

3.8 Indication for the use of the probiotic product: (Select all that apply)

❑ Congenital heart disease
❑ Chronic reliance on respiratory support
❑ Diarrhea related to antibiotic use
❑ Diarrhea unrelated to antibiotic use
❑ Inflammatory bowel disease (IBD)
❑ Eczema
❑ Parents'/caregivers' preference
❑ Prevention of necrotizing enterocolitis or late-onset sepsis in preterm infant
❑ Other, specify: _____
❑ Unknown

3.9 Pre-existing diagnoses or conditions: (Select all that apply)

❑ Chronic lung disease (e.g., bronchopulmonary dysplasia)
❑ Congenital heart disease
❑ Diagnosis of immunodeficiency
❑ Eczema
❑ Intestinal complications (necrotizing enterocolitis, intestinal perforation, short gut, IBD)
❑ Presence of central intravenous catheter since at least 72 hours before the culture of the probiotic organism
❑ Prematurity (born at < 37 weeks gestation)
❑ Surgery performed within 7 days prior to the positive blood culture
❑ Use of systemic steroids
❑ Other, specify: _____
❑ None

3.10 How was the probiotic initiated?

❍ Prescribed by a physician in hospital
❍ Prescribed or recommended by a community physician
❍ Recommended by an allied healthcare provider (e.g., nurse, dietitian, pharmacist)
❍ Recommended by an alternative health practitioner (e.g., acupuncturist, naturopath)
❍ Given by parent/caregiver without medical advice
❍ Other, specify: _____
❍ Unknown

3.11 Where was the probiotic infection likely acquired (setting of exposure)?

❍ In hospital (admitted to hospital > 48 hours prior to onset of symptoms)
❍ At home
❍ Other, specify: _____
❍ Unknown

SECTION 4 – TESTS/LABORATORY INVESTIGATIONS

4.1 Was antibiotic sensitivity of the isolated probiotic organism performed? ❍ Yes ❍ No
If Yes, antibiotic sensitivity of the isolated probiotic organism: _____

4.2 Was genomic testing done for the isolated organism? ❍ Yes ❍ No

4.3 Were any other organisms isolated from blood within 7 days of isolating the probiotic organism?
❍ Yes ❍ No ❍ Not sure

SECTION 5 – SIGNS AND SYMPTOMS

5.1 Signs and symptoms that led to the blood culture: (Select all that apply)

- ❑ Abdominal distension
- ❑ Apnea (pauses in breathing)
- ❑ Fever or hypothermia
- ❑ Hypotension (low blood pressure)
- ❑ Irritability
- ❑ Lethargy
- ❑ Mottled or pale skin
- ❑ Poor feeding
- ❑ Prolonged capillary refill time
- ❑ Respiratory distress
- ❑ Tachypnea (rapid breathing)
- ❑ Increased work of breathing
- ❑ Vomiting
- ❑ Other, specify: _____

5.2 Laboratory findings suggestive of sepsis: (Select all that apply)

- ❑ Elevated C-reactive protein (CRP), highest level _____
- ❑ Leukocytosis, highest white blood cell (WBC) count _____
- ❑ Leukopenia, lowest neutrophil count _____
- ❑ Metabolic acidosis, lowest pH _____
- ❑ Elevated lactate, highest level _____
- ❑ Elevated procalcitonin, highest level _____
- ❑ Other, specify: _____

SECTION 6 – TREATMENT

6.1 Antimicrobial therapy: list the drugs used to treat the probiotic sepsis:

- ❑ Penicillin G or Ampicillin
- ❑ Clindamycin
- ❑ Carbapenem
- ❑ Gentamicin
- ❑ Cephalosporin
- ❑ Fluconazole
- ❑ Other, specify: _____

6.2 Total duration of antimicrobial therapy: _____ days (expected or planned duration if still under treatment)

6.3 Need for multiple drugs to treat probiotic sepsis: ❍ Yes ❍ No

6.4 Need for admission to hospital for probiotic sepsis: ❍ Yes ❍ No

If Yes, length of stay: _____days

6.5 Need to prolong hospitalization from a previous admission as a result of the probiotic sepsis? ❍ Yes ❍ No

If Yes, number of extra hospital days due to probiotic sepsis: _____

6.6 Need for admission to intensive care unit: ❍ Yes ❍ No

6.7 Need for intubation and mechanical ventilation, HFNC, or CPAP: ❍ Yes ❍ No ❍ Not applicable

6.8 Need for inotropes: ❍ Yes ❍ No ❍ Not applicable

SECTION 7 – OUTCOME

7.1 Outcome attributed to probiotic sepsis:

- ❍ Full recovery
- ❍ Recovery but with ongoing health problem(s), specify: _____
- ❍ Still recovering
- ❍ Disability, specify (if known): _____
- ❍ Death, specify if death was related to probiotic sepsis: ❍ Unlikely ❍ Possible ❍ Definite
- ❍ Unknown

SECTION 8 – REPORTING PHYSICIAN INFORMATION

8.1 Which one of the following best describes your practice?

- ❍ General paediatrician
- ❍ Paediatric infectious disease specialist
- ❍ Neonatologist
- ❍ Paediatric intensivist
- ❍ Other, specify: _____

8.2 Practice setting where you cared for this patient: (Select all that apply)

- ❍ Neonatal intensive care unit
- ❍ Hospital inpatient ward
- ❍ Emergency department
- ❍ Paediatric intensive care unit
- ❍ Outpatient clinic
- ❍ Other, specify: _____

8.3 First three digits of the postal code of your practice: ___ ___ ___

8.4 Are you willing to be contacted by the Canadian Paediatric Surveillance Program for further information on this questionnaire? ❍ Yes ❍ No

First name_____ Surname_____

Address_____

City_____ Province_____ Postal code_____

Telephone number_____ Fax number_____

E-mail_____ Date completed_____

Thank you for completing this form.

PS 11/2025