

# BC RSV Immunoprophylaxis Program

## ADMINISTRATIVE MANUAL AND DECISION SUPPORT TOOL

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While every attempt has been made to ensure that the information contained herein is clinically accurate and current, the BC RSV Immunoprophylaxis Program acknowledges that this information may change over time as evidence becomes available.  
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## MANDATE & VISION STATEMENT

The BC RSV Immunoprophylaxis Program (“the RSV Program” / “the Program”) is a Provincial Health Services Authority program whose mandate is to determine eligibility for funded RSV immunoprophylaxis and administer doses to those so identified; and to promote health education aimed at reducing RSV hospital admission.

The Program’s Eligibility criteria are evidence-based, centered in clinical rationale, and reviewed annually.

## PURPOSE OF THIS MANUAL / DECISION SUPPORT TOOL

This manual primarily exists to elaborate on BC’s RSV Program and on the guidelines for enrolment. As the Program is evidence based, details regarding eligibility for RSV immunoprophylaxis and clinic practice may be subject to minor change, and therefore this annually updated manual keeps BC’s clinics apprised.

As a decision support tool this resource also provides an evidence-based guide regarding the administration of immunoprophylaxis for RSV, as well as the enrolment of high-risk infants into BC’s RSV Program. When making clinical decisions this tool is to be used in conjunction with clinical judgment, available evidence, discussion with colleagues, and consideration of client needs and preferences.

## STRUCTURE

The RSV Program’s **EXECUTIVE COMMITTEE** comprises:

- The Chair of the Advisory Committee;
- The Children’s & Women’s Pharmacy Coordinator;
- The Program Administrative Director;
- The Program Medical Director; and
- The Provincial Clinic Coordinator.

The **ADVISORY COMMITTEE** comprises:

- A Chair, elected by the Advisory Committee in three-year terms;
- All RSV Program Executive Committee members (listed above);
- Applicable paediatric subspecialty representatives when available, e.g.:
  - Cardiology,
  - Immunology,
  - Infectious Diseases,
  - Neonatology, and
  - Respirology
- Two nursing representatives of the RSV Clinics; and
- Representatives of each BC Health Authority.

The **ADJUDICATION PANEL** comprises:

- Three Program-aligned physicians; and
- A fourth alternate member.

Further information regarding the structure of the RSV Program and its members can be found in the program Terms of Reference in Appendix V.i and the contact lists in Appendices V.ii/V.iii.

### **INFORMATION SHARING AND RELATIONSHIP WITH BC'S HEALTH AUTHORITIES**

An Information Sharing Plan (ISP) has been completed by the RSV Program in consultation with:

- The Information Privacy Offices of the Fraser Health Authority;
- The Interior Health Authority;
- The Northern Health Authority;
- The Provincial Health Services Authority;
- The Vancouver Coastal Health Authority; and
- The Vancouver Island Health Authority.

The approved ISP forms part of - and is subject to the terms and conditions of - the General Health Information Sharing Agreement (GHISA).

### **ARMS-LENGTH RELATIONSHIPS**

In support of the RSV Program mandate and in alignment with the Canadian Paediatric Society (CPS) recommendations, no member of the Program's Advisory Committee or of the Adjudicator Panel shall have either a real, potential, nor perceived Conflict of Interest (as defined in the glossary on pages 19-20).

This preserves the objectivity and credibility of the guidelines and the RSV administration processes. For greater clarity, no one with a relationship or interest in a pharmaceutical vendor that manufactures palivizumab shall participate in the development of the guidelines or in the adjudication process.

## APPLYING FOR ENROLMENT

- Assess for Program eligibility (as per the Eligibility Criteria on Page 06)
- Discuss risks and benefits with the family
- Complete the RSV Program's Application Form and submit to RSV Desk, either via:
  - Email: [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca) (preferred method).
  - Fax: 604-875-2879 or toll-free 1-877-625-7555.

## PROTOCOL FOR APPLYING

- Email applications should only be sent from secure hospital/Health Authority addresses. Requests originating outside of secure locations must be faxed.
- Application Forms must include supporting clinical rationale.
- If the patient is in hospital after 01-Nov-2016, the discharge date may be estimated.
- Final approval of all applications is dependent on at least one signature from a health care professional on a faxed completed Authorization for Treatment Form.

## ADJUDICATIONS OF APPLICANTS NOT MEETING AUTOMATIC ELIGIBILITY

An adjudication occurs when an enrolment request (i.e., an Application Form) is submitted for a high-risk infant who does not meet the criteria for automatic eligibility.

## WHEN SUBMITTING AN APPLICATION FOR ADJUDICATION

Applications for adjudication may be made prior to discussion with the family.

To submit an application for adjudication:

- Fill out and submit Application Form and Authorization for Treatment Form as normal.
- Attach up-to-date relevant medical records.
- Attach a supporting letter from either an Infectious Disease Specialist, a Neonatologist, or a Respiriologist. If a supporting letter cannot be obtained due to limited accessibility to a specialist in one of the above fields, this should be clearly stated on the Application Form.
- Describe the applicant's specific medical illness detailing the clinical rationale for the application. Provide sufficient clinical details as it relates to the applicant and the risk for severe RSV disease.
- Briefly and specifically describe the general health of the applicant, especially with respect to respiratory conditions. Mention any medications they are taking.

## PANEL STRUCTURE & PRACTICE

- Adjudication will be conducted by a panel of three physicians and resolved with a majority vote.
- The panel will have the capacity for a fourth alternate, for in the event of an absence in the panel.
- Adjudicators will have no real, potential, nor perceived conflict of interest (as defined in the glossary on pages 19-20).
- No adjudicator may adjudicate their own patients, and must recuse themselves from the panel of three with respect to that case.

## ADJUDICATION PROCESS AND GUIDELINES

- Adjudications will be processed based on receipt of a fully completed Application Form and supporting clinical rationale.
- Although adjudications may be processed without evidence of consent, for final approval, completed Application Forms and Authorization for Treatment Forms are still required. Telephone consent is acceptable if necessary.

*[continued on following page]*

- Nearly all second-season requests will be adjudicated. First-season requests for complex infants without significant prematurity, chronic lung disease, or significant congenital heart disease will still require adjudication.
- Adjudications will generally be processed within five working days. The adjudication process will be audited in real-time for time-to-response, and each variance will be pursued and reported.
- Infants with significant congenital heart disease will not require adjudication for their first year as long as the application is supported by their cardiologist, with adequate documentation.

### FORMS AND REPORT-BACK

The forms included in this manual are mandatory, each providing a benefit to the patient or to the Program's ability to collect long-term data. This enables outcome review, without which the Program cannot function, and ensures that consent has been obtained by a person responsible and to facilitate parental consent for audit and follow up.

The forms for parents (in Appendices III.ii–III.iv) should be given to any parent whose child is identified at high risk for RSV infection this season.

Forms related to the application process and patient tracking are in Appendix II. The program requires standard reporting on all infants receiving palivizumab throughout the RSV Season and at season end. All forms can be either sent by email to [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca), or by fax at 604-875-286 or toll free at 1-877-625-7555. The health care professional should also document palivizumab information as per organization policy.

Please submit applications as soon as feasible. RSV Program forms include the following:

Form	Timeline of submission	Purpose
Application Form	Prior to enrolment	Confirms eligibility
Authorization for Treatment Form	Prior to enrolment	Confirms informed consent
Hospitalization Data Form	Each time patient is hospitalized throughout RSV season	To report respiratory admissions
Patient Log	End of each clinic	Facilitates tracking/inventory

### SEASON DURATION

RSV-related illness normally has a consistent November-March trend. The RSV Executive Committee determines the commencement date for RSV immunoprophylaxis annually.

The 2016/17 RSV Season (i.e., dosing of RSV immunoprophylaxis) will begin on November 14 and ends the following March 31 with the following exceptions:

- Infants may receive one dose in the first two weeks of April if they meet all of the following criteria:
  - Discharged home for first time between April 01-April 14; AND
  - Otherwise automatically eligible for palivizumab due to prematurity/chronic lung disease; and
  - Under 35 weeks gestational age (GA) at birth.
- Clinics in the NHA have an adjusted season schedule (as detailed below and in Appendix I.V).

### INFANTS RESIDING IN NORTHERN HEALTH REGIONS

The RSV season in northern BC usually starts and ends later. To reflect this, the executive committee acknowledges some differences for clinics in the Northern Health Authority. In these areas the season start date will be three weeks later than other regions, and the season end date is one month later (on April 30). No palivizumab will be given after that time.

Infants 29-34 weeks GA age at birth who reside in NHA regions will be awarded 20 Risk Factor points for discharge in March / 10 points for discharge in April (instead of 10 points / 0 points, in other BC regions).

## ELIGIBILITY CRITERIA

Palivizumab is not recommended or funded for prevention of health care-associated RSV disease (i.e., in-hospital outbreaks or transmission), nor for the treatment of RSV illness.

There are two avenues to meet eligibility for enrolment:

- The infant has a pre-approved indication (as detailed below); or
- An application for adjudication is approved by the adjudicator panel.

## MAXIMUM AGE FOR CONSIDERATION FOR PALIVIZUMAB

No one born prior to 01-Nov-2014 will be eligible, regardless of their clinical condition. Most children 2+ years of age have antibodies to RSV, and within this population there is no evidence of benefit.

## PRE-APPROVED INDICATIONS

The following infants will automatically be eligible for prophylaxis:

- Ex-premature infants with Bronchopulmonary Dysplasia / Chronic Lung Disease (i.e., O<sub>2</sub> or CPAP at > 28 days) and born on or after 01-Nov-2015 and requiring continuous O<sub>2</sub> on or after 01-Jul-2016 due to chronic lung disease (i.e., O<sub>2</sub>- or CPAP-dependent at 28 days of age or 36 weeks corrected age)
- Infants born at < 29 weeks GA and discharged home on or after 01-Sep-2016
- Infants born between 29 weeks to 34<sup>6/7</sup> weeks GA without Bronchopulmonary Dysplasia and discharged home on or after 01-Oct-2016 and with a risk factor score of ≥ 42 points
- Infants requiring home respiratory support (e.g., home O<sub>2</sub>, CPAP, tracheostomy) on or after 01-Nov-2016 and born on or after 01-Nov-2014
- Hemodynamically significant congenital heart disease AND born on or after 01-Nov-2015 (i.e., less than 1 year of age on 01-Nov-2016)<sup>1</sup>
- Multiple of an approved child and under 35 weeks GA at birth and born on or after 01-Nov-2015 (i.e., < 1 year age at season start)

## INDICATIONS REQUIRING ADJUDICATION

Infants with the following conditions require adjudication (may not be an exhaustive list):

- Progressive neuromuscular disease and inability to clear secretions and DoB on/after 01-Nov-2014
- Severe immunodeficiency (i.e., stem cell transplantation, infant ALL/AML, infant brain tumor intensive protocol, SCIDS, ICE protocol) and born on or after 01-Nov-2014
- Significant cardiopulmonary disability (i.e., pulmonary hypertension, pulmonary hypertensions, severe Bronchopulmonary Dysplasia, symptomatic Cystic Fibrosis, cardiac palliation, other) and DoB on or after 01-Nov-2014
- Trisomy 21 without significant congenital heart disease and discharged on or after 01-Sep-2016 and risk factors

### NOTE:

- The presence or absence of risk factors is relevant to all adjudication requests.
- Infants under 2 years of age on 01-Nov-2016 who are on home oxygen or home ventilation, remain automatically eligible.
- Applications for infants with congenital heart disease should be supported by the infant's cardiologist (include the physician's name) as well as details on the type of heart disease, date of surgery/ surgeries, medications, or other medical support. Please describe this clinical reasoning on the Application Form.

<sup>1</sup> NOTE: The application for such infants must be supported by their cardiologist with clinical details

**RISK FACTORS**

- Birth weight  $\leq$  10<sup>th</sup> percentile for GA at birth: ..... 8 points
- Discharged home in December, January, or February<sup>2</sup>: ..... 20 points
- Discharged home in November or March<sup>2</sup>: ..... 10 points
- Female not receiving human milk<sup>3</sup>, or Male (all): ..... 8 points
- GA age at birth = 29-30<sup>6/7</sup> weeks: ..... 10 points
- Infants residing in a remote residence  
(i.e., > 100 km by ground transport to nearest hospital able to provide paediatric care): ..... 10 points
- $\geq$  2 smokers in the household<sup>4</sup>: ..... 8 points
- $\geq$  6 people residing in the household (including applicant and multiples of applicant): ..... 12 points
- Infants residing in a remote location<sup>5</sup>: ..... 10 points
- Other child < 5 years old living in the same household (not including multiples of applicant): . 14 points
- Regular attendance at home or facility-based group (in first 3 months after discharge)<sup>6</sup>: ..... 22 points

For premature infants 29-34<sup>6/7</sup> weeks of age with no chronic lung disease, the RSV Program will continue to apply a risk scale that cumulatively scores risk factors, and will again require a minimum of 42 points to meet eligibility.

<sup>2</sup> For infants residing in Northern Health regions, **20 points** are awarded for discharge in March; **10 points** for discharge in April.

<sup>3</sup> "Receiving breast milk": Refers to any regular consumption of human milk, including by bottle.

<sup>4</sup> Exposure to cigarette smoke is contra-indicated for all infants.

<sup>5</sup> "Remote Location": Refers to 100 km OR 1 hour by ground transport to nearest hospital/point of care.

<sup>6</sup> Day care is strongly discouraged in the first year, especially in those at increased risk.

## ASSESSMENT

During a clinic day, perform a brief assessment of patient's health to identify any considerations or contraindications to RSV Immunoprophylaxis. Defer RSV Immunoprophylaxis when appropriate and according to the BC Guidelines for RSV Infection and Immunoprophylaxis (on Pages 4-7). It is the responsibility of the health care professional to assess benefit vs. risk of delaying Immunoprophylaxis.

### CONSIDERATIONS:

- A mild febrile illness, such as a mild upper respiratory infection, is not usually a reason to defer administration of palivizumab; withholding palivizumab entails a greater risk. However, a moderate or severe acute infection or febrile illness may warrant delaying the use of palivizumab.
- Administration of RSV Immunoprophylaxis to patients with thrombocytopenia or any coagulation disorder needs to be given with caution (refer to individual hospital policy). Use a fine gauge needle of appropriate length and apply firm pressure, without rubbing, for 5 minutes following injection.
- If a patient has started RSV Immunoprophylaxis, is readmitted to hospital for a condition other than RSV infection for a short period, and is due a routine dose, then one dose may be given.

### CONTRAINDICATIONS:

- Patients with known hypersensitivity to palivizumab or any of its excipients;
- Patients with known hypersensitivity to other humanized monoclonal antibodies;
- Patients who react with a severe hypersensitivity reaction (at which point administration of palivizumab should be permanently discontinued); and
- Hospitalized patients (i.e., only administer to outpatients and inpatients ready for discharge).

### TO NOTE:

- If further questions are needed to be addressed, contact the RSV Desk at [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca).
- During the clinic visit, the clinician will need to support parents' efforts to implement pain management techniques (see the pamphlet in Appendix III.ii).
- Since the monoclonal antibody is specific for RSV, palivizumab is not expected to interfere with the immune response to vaccines, including live viral vaccines. Therefore, routine immunizations may be given concurrently with palivizumab.

The below table shows an example of an assessment tool:

<p><b>1) Assess patient wellness – recent or current illnesses/surgery/hospital admissions</b> <i>Is your child well today? Has s/he been recently ill? Has s/he required surgery or been admitted to a hospital?</i></p>
<p><b>2) Identify and confirm allergies</b> <i>Does your child have any allergies? or My records indicate that your child is allergic to... or Have there been any additional reactions or changes?</i></p>
<p><b>3) Review current medication</b> <i>Is your child on any medications? Have there been any medication changes since his/her last visit?</i></p>
<p><b>4) Review recent vaccinations</b> <i>Has your child received any vaccines/needle injections in the last 24 hours?</i></p>
<p><b>5) Identify adverse reactions</b> <i>How did your child respond to his/her last injection? Any reactions noted?</i></p>
<p><b>6) Obtain child's weight</b></p> <ul style="list-style-type: none"> <li>• Consider utilizing a recent weight, within the last 48 hours, if done by a health care professional; ensure child was weighed naked / with dry diaper, depending on your policy.</li> <li>• Address concerns/questions that can be discussed while weighing the child.</li> </ul>

## CLIENT EDUCATION

Palivizumab must be administered on schedule throughout the season in order to maintain the serum concentration at a level sufficient to provide protection against RSV; while the infant may still experience morbidity due to RSV illness after receiving palivizumab, the effect is less severe.  
[continued on following page]



There are many ways to reduce a child's risk of contracting RSV. Discussing and reviewing these measures with the family/guardians is required. Communicating with parents the benefit of palivizumab in reducing RSV-associated illness and hospitalizations may also increase compliance.

Appendix III includes tips regarding how best to communicate with families and hand-outs for parents.

### CONSULTATION / OUT OF PROVINCE REFERRAL

The RSV Program liaises with similar programs in other provinces and territories. In the event that an infant whose health care is covered by another province requires dosage in BC, then, with the understanding that the home province would reimburse the RSV Program, the Program would provide doses as per the eligibility requirements of that infant's home province (regardless of whether they would be eligible for doses under the auspices of BC's guidelines).

All requests for dosage by the RSV Program must be forwarded to the RSV desk at [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca) for review. All referrals will be reviewed for eligibility. Only referrals that have received approval and that are issued a provincial registration number will be eligible to receive RSV Immunoprophylaxis.

There are two scenarios in which a patient from out-of-province may require a dose of palivizumab:

1. The patient is in a BC hospital (e.g., an infant in the NICU) and does not have prior approval in their home province or territory; and requires a dose of palivizumab prior to discharge home. The program will forward the referral to the patient's province or territory of residency. Once approval has been decided by the home province or territory, the program will notify the site of the approval.  
*NOTE: Eligibility criteria is decided by the patient's home province or territory, and may differ from BC's criteria.*
2. The patient has travelled to BC and has already been approved for RSV Immunoprophylaxis in their home province or territory. The RSV Program needs to be aware of such situations. The RSV Program will contact the clinic coordinator or appropriate liaison in the patient's home province, to obtain documentation of approved status prior to treatment. A copy of the approval will be sent to the clinic where palivizumab is to be given.

In either scenario, after the dose has been given, the providing clinic must notify the program with the following information, in order to recover vials from the patient's home province/territory:

- Name of patient
- Patient Weight
- Date dose was given
- Amount given (mg)
- Number of vials used
- Lot #
- Expiry date of vials

### DECISION-MAKING CRITERIA

An infant/child eligible for RSV immunoprophylaxis progresses through the following sequential steps.

1. Identification  
An infant or young child potentially eligible for RSV Immunoprophylaxis is identified.
2. Referral/Eligibility  
A referral is initiated and submitted to the RSV Program for review to confirm the paediatric patient's eligibility as per Program eligibility criteria. (See Appendix II for the Application and Authorization for Treatment forms, etc.)
3. Enrolment (consent and registering)  
The child's eligibility is confirmed by the RSV Program as per the BC guidelines (or otherwise approved by the RSV Program's Adjudication Panel) and the parents/legal guardians provide consent for RSV Immunoprophylaxis.
4. Provision of RSV Immunoprophylaxis (hospital/community based, in-patient and out-patient)  
The eligible child is registered and receives a reference number to obtain RSV Immunoprophylaxis.  
*[continued on following page]*

## 5. Tracking

Tracking of the eligible paediatric patient starts when they are first identified and continues until:

- They receive all of their appropriate doses, or
- The parents/legal guardians withdraw the patient's enrolment from the RSV Program.

### FOLLOW UP

Quality control and outcome evaluation are integral components of the RSV Program. The Program requires standard reporting related to all infants receiving palivizumab. Approximately one month after season end, all active clinics are required to connect with their patients' family/guardian to confirm whether any hospital readmission for respiratory illness occurred (as referenced on the bottom of the Patient Log). If an admission occurred, collect the appropriate information on the Hospitalization Data Form. These forms need to be emailed to [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca) or faxed to 604-875-2879.

### INFORMED CONSENT

The health care professional will ensure that informed consent is obtained from parent/legal guardian for eligible paediatric patients. This is a mandatory step for approval to receive palivizumab from the RSV Program. To ensure consent is informed, it is essential for parents/legal guardians to have access to educational material regarding RSV Immunoprophylaxis and for them to understand this material. Refer to Appendix III for further information regarding how to discuss RSV Immunoprophylaxis with families.

### PROCEDURAL CHECKLIST

1. Obtain verbal consent, either via direct contact or telephone
2. Fill out and submit Authorization for Treatment Form (via [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca) or fax at 604-875-2879).
3. Obtain consent for end-of-season telephone follow-up (required for audit).

### NECESSARY COMPONENTS OF INFORMED CONSENT INCLUDE THE FOLLOWING:

- An explanation of RSV-related illness (including education on prevention measures);
- Identification of the drug (including administration requirements);
- A discussion of benefits versus risks (including potential side effects);
- Addressing of any family concerns; and
- Accommodation of language/literacy barriers and special needs.

### INTENDED OUTCOMES

RSV Immunoprophylaxis can reduce the hospitalization rate and severity of illness for the eligible infants. Palivizumab injections are generally well tolerated with minimal adverse effects. Overall the most common adverse events include rash, ear infection, runny nose, soreness around injection site, and fever. If these adverse effects occur they are generally minor and do not last for long periods.

### UNINTENDED OUTCOMES

- Anaphylaxis has rarely occurred. In the event of anaphylaxis be prepared to treat with epinephrine in appropriate paediatric dosage; follow employer policy for emergency treatment of anaphylaxis.  
To report any adverse reactions:
  1. Notify RSV Program directors.
  2. Report the adverse reaction to your local health authority after completing the Adverse Event Following Immunization (AEFI, i.e., case report form) found in Appendix IV.i.
- Suspected cold chain breaks should be reported immediately to the RSV desk at [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca). The RSV Program will forward details of the suspected cold chain break to the product manufacturer/distributor as soon as possible to determine product stability. The product should be quarantined until further direction is received. Refer to Appendix IV.ii for more details.

Palivizumab (PVZ), brand name Synagis<sup>®</sup>, a specific monoclonal antibody against RSV, has been demonstrated to decrease the likelihood of hospital admission due to RSV bronchiolitis in specific high-risk patient populations. It does not appear to prevent upper respiratory tract infection and may not prevent apneas associated with RSV in very young children. It is expensive and has not been shown to be cost effective, even in infants at moderately high risk. In Canada, each province creates eligibility guidelines for government funded RSV prophylaxis with PVZ.

## PRODUCT DETAILS

- A Humanized monoclonal antibody produced by recombinant DNA technology.
- PVZ is supplied as 50 mg vials of lyophilized powder, preservative-free.
- \* *NOTE:* palivizumab supplies may at a later date be provided in pre-reconstituted form. Should this happen mid-season, BC's RSV clinics will be notified of any changes and this publication will be updated accordingly.
- PVZ vials also contain glycine, histidine, and mannitol.
- PVZ vials must be kept refrigerated and stored between 2<sup>o</sup> C and 8<sup>o</sup> C in the original container. Do not freeze.
- The 50 mg vial is reconstituted with 0.6 mL sterile water. The resulting concentration is 100 mg/mL.
- The reconstituted solution must rest for 20 minutes prior to administration and is stable for three hours, at room temperature, after reconstitution.
- Cluster administration to several patients is standard in order to minimize wastage. Partially used vials should be shared between patients using standard aseptic techniques. Discard unused vial contents after three hours.
- PVZ is not expected to interfere with the immune response to vaccines, including live viral vaccines. Routine immunizations may be given concurrently with PVZ.

## CONTRAINDICATIONS

- Known hypersensitivity to PVZ or any of the additional components of the medication.
- Known hypersensitivity to other humanized monoclonal antibodies.

## PRECAUTIONS

- Anaphylaxis has rarely occurred; be prepared to treat with epinephrine in appropriate paediatric dosage as per individual agency policy.
- As with any intramuscular injection, use with caution on patients with thrombocytopenia or any coagulation disorder, or who are on anti-coagulation therapy. Use a fine gauge needle of appropriate length and apply firm pressure, without rubbing, for five minutes following injection.

Please see Appendix IV.ii which elaborates on how best to handle, store, and transport palivizumab.

## AUTONOMOUS RN ADMINISTRATION OF PALIVIZUMAB

The College of Registered Nurses includes palivizumab (PVZ) as a medication that RNs can autonomously administer (as seen in Scope of Practice on Page 18) without a client-specific order by a physician, to any patient that has been approved by the BC RSV Immunoprophylaxis Program. In order to be able to administer PVZ without a client-specific order two conditions must be met:

- 1) The registered nurse has the required competencies (as detailed on Page 18); and
- 2) The registered nurse's hospital or agency has approved the practice in their facility.

## DOSE

- Dosage calculation: patient weight (kg) X 15 mg/kg = mg to be administered.
- Round off dose to the nearest 5 mg.
- mg to be administered / 100 mg/mL = mL to be administered.
  - \* Example: If weight = 4.300 kg, then dosage to be administered is 64.5 mg. This is rounded to 65 mg. These 65 mg are contained in 0.65 mL.
- Dosage ceilings:
  - Infant with no cardiac disease and no CLD and premature  $\geq 29w$ .....Max. 3 doses
  - Infant with cardiac disease or with CLD or premature  $< 29w$ .....Max. 4 doses
- As a matter of policy, no PVZ will be administered to hospitalized infants unless and until they are ready for discharge.
- Multiples of enrolled children may only be given PVZ if they were born prematurely and are being discharged for the first time.
- Once a child is RSV+ (whether hospitalized/admitted or not), they are no longer eligible for dosing.
- Hospitals in other provinces will receive reimbursement for dosage of BC-residing patients only within the limits of the BC guidelines; and that reimbursements will be equivalent to the appropriate dosing regimen indicated by the guidelines indicated by the most current version of the RSV Program's Administrative Manual.
- For ambulatory patient care, it is strongly recommended that children receive their palivizumab doses from the central site in their region, through same-day, centralized, hospital-based outpatient clinics, in order to cluster dose and avoid wastage.

## INTERVALS AND DATES

For eligible infants discharged home before 14-Nov-2016 (or December 05, 2016 for infants in NHA regions), outpatient RSV clinics will commence that week.

- For eligible infants still in hospital on or after 14-Nov-2016, Dose 1 is ideally administered 1-3 days prior to discharge home; or up to 7 days if discharge date is certain (to allow for cluster dosing and to minimize wastage).
- Dose 2 is given 3-4 weeks after Dose 1.
- Any doses after dose 2 are administered at 4-5 week intervals (up to the prescribed dose amount).

The three-to-four dose regimen will continue to be applied, with the exception of qualifying children with cardiac conditions, who undergo repair under bypass and are discharged home up to 31 March 2017; infants in this group will receive a post-operative dose of PVZ once they are medically stable and ready for discharge, as long as they still qualify for PVZ prophylaxis, even if this is a fifth seasonal dose. This fifth dose will not require a separate adjudication.

Administration of PVZ for potentially eligible children who remain in hospital is not supported by the medical literature, and therefore is not supported by the RSV Program.

No doses are to be administered after 31 March 2017, unless the infant was premature (i.e., less than 35 weeks GA) at delivery and otherwise eligible and discharged within the first two weeks of April; these infants may receive a single dose of PVZ before going home.

#### PROCEDURE FOR ADMINISTERING

Administration of palivizumab for eligible children who remain in hospital is not supported by the RSV Program.

- Reconstitution of product is not recommended until a family has arrived for appointment.
- Palivizumab is administered via intramuscular route only. The preferred site for injection is the vastus lateralis. Maximum volume is 1 mL per site. Doses greater than 1 mL must be divided.

Monitor all children for 15-20 minutes after each dose to assess for hypersensitivity and/or anaphylaxis. If the family/guardian chooses not to remain under supervision after immunization, inform them of any signs or symptoms of anaphylaxis and instruct them to obtain immediate medical attention should symptoms occur. Refer to Page 11 for more product information.

Clinic instructions and provider expectations are detailed on the following page.

#### ROUTE

- PVZ is administered via the intramuscular route only. Preferred site for injection is the vastus lateralis.
- Maximum volume is 1 mL per site. Doses greater than 1 mL must be divided.

### CLINIC INSTRUCTIONS & PROVIDER EXPECTATIONS FOR PALIVIZUMAB ADMINISTRATION

Quality control and outcome evaluation are integral components of the RSV Program. As such, the Program requires standardized documentation and reporting. This requirement is part of official agreements between the PHSA and the Health Authorities.

The RSV Program has the following expectations of all sites administering government-funded PVZ:

- 1) Education on RSV, standard infection control measures, and the benefits and risks of PVZ are all part of the authorization process. Education pamphlets are available in Appendix III.
- 2) Program enrolment requires a fully completed Application Form, Program approval, and a signed and completed Authorization for Treatment Form.
  - For patients meeting pre-approved criteria, the Authorization for Treatment Form must be submitted with the Application Form.
  - For patients requiring adjudication, the Authorization for Treatment Form should be completed and submitted after approval has been received by the requesting health care professional.
- 3) Providers maintain accurate records of all doses given to each patient, using the Patient Log.
  - For patients who get their first dose while still in hospital, or who are transferred between sites, an up-to-date copy of the Patient Log will be forwarded to the clinic administering the remainder of the doses.
  - The sending site must confirm the receiving site has received the transfer information.
  - In every case where a patient transfer occurs and a dose of PVZ is administered, The RSV Desk at the Children's & Women's Pharmacy must be notified at [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca) or by fax at 604-875-2729.
  - At the end of every clinic day, copies of the Patient Log from every patient seen during that day must be submitted to the RSV Desk at [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca) or by fax to 604-875-2879 (for the purposes of quality control and outcome evaluation throughout the season).
- 4) Clinics stay in touch with their patients for the duration of the season and report any hospital admissions for respiratory illness to the RSV Program using the Hospitalization Data Form. At season end, a final contact is made with the family, documented on the Patient Log, and faxed to the RSV Program.
- 5) A completed Facsimile Cover Sheet must be used for **all** faxed Program communications.

#### WHEN ADMINISTERING

(as per BC Centre for Disease Control regarding administration of vaccines, etc.)

Document the following:

- Trade name of the product
- Disease(s) against which it protects
- Date given (day, month and year)
- Site and route of administration
- Lot number and expiry dates
- Name and title of person administering the vaccine

When a scheduled immunization is not given, record the following:

- The reason why the dose was not given
- The planned follow-up action.

Examples:

- Parent/guardian refusal
- Severe illness
- Contraindication to vaccine to be offered

Appendix IV.ii details handling of vaccines and other immunoprophylaxis with care.

Centralized RSV Clinics should be organized at sites expecting more than five patients annually. The purpose of the RSV Clinics is to maximize Program penetration and patient/family compliance with the immunoprophylaxis schedule, in order to achieve optimal results. It is recognized that attendance at a centralized clinic is not always possible due to distances involved so there are a limited number of physician offices or community health centres that see single patients.

### NOSOCOMIAL (HOSPITAL-ACQUIRED) INFECTIONS

RSV may be transmitted in the hospital setting and can cause serious disease in high-risk infants, though it is not as infectious as many other viruses. In high-risk hospitalized infants, the foremost means to prevent RSV disease is strict observance of infection control practices, including rapid means to identify and cohort RSV-infected infants. If an RSV outbreak is documented in a high-risk unit, accepted guidelines indicate that primary emphasis should be placed on proper infection control practices. There are no data supporting palivizumab (PVZ) use in controlling hospital outbreaks or for the treatment of established RSV.

### RSV DISEASE PREVENTION

Chronologic young age (i.e., below three months) is the single most important risk factor for RSV hospitalization.

General measures are the most effective way for preventing RSV Infection, as most admissions for RSV occur in previously healthy late pre-term and term infants who are not considered candidates for PVZ. Selection criteria to identify late pre-term and term infants at increased risk of RSV disease do not exist; no jurisdiction provides PVZ for this group. There is also a continued need for data regarding infants who currently do not qualify.

Parent education should be a core component of discharge teaching. Prevention of all respiratory viral infections, including RSV infection, includes careful hand washing, the use of alcohol based hand rubs, and avoidance of contagious settings such as child care centres and crowded public places (especially in the first six months). Breastfeeding and avoidance of exposure to tobacco smoke are also strongly recommended.

Guides for discussing RSV with parents and pamphlets for parents to take home are available in Appendix III.

### RSV PROGRAM QUALITY CONTROL

Quality control and outcome evaluation are essential components of the RSV Program. The information about PVZ administration and patient admissions required from the Clinics is at the core of the Program's outcome review, without which the Program cannot function.

The Program requires standard reporting related to all infants receiving PVZ:

- The Program requires a faxed Authorization for Treatment Form which includes additional consent for telephone follow-up as well as appropriate contact information, to facilitate audit at season end. Established clinics, physician offices, and other applicable points of care must co-operate with data collection.
- The information required from the RSV Clinics after each session is mandatory. **Fully** completed application/authorization forms expedite the request process and the delivery of the drug, and receipt of Patient Logs is required in order to activate the continuous supply of PVZ to the Clinics.

## VIAL SHARING

PVZ is an exceptionally expensive medication. The goal of the BC RSV Immunoprophylaxis Program is to provide palivizumab, to qualifying infants, with maximum efficiency.

As such, the RSV Program expects that PVZ will be administered in such a way as to maximize product utilization. RSV Clinics should be organized to provide clustered administration of PVZ to the largest number of patients possible. Vial sharing has been in place in BC and in most jurisdictions in Canada for many years, and is integral to the RSV Program.

A study by the RSV Program demonstrated that the greater the number of patients treated during a “clinic” day, the lower the cost for administering doses per mg delivered. For this reason, doses within BC Children’s Hospital and BC Women’s Hospital + Health Centre are coordinated as much as possible with scheduled outpatient clinic days in order to maximize effective utilization.

There are occasions when, due to clinical circumstances, doses must be administered outside of scheduled clinic days. It is encouraged, when possible, to coordinate other doses to maximize utilization.

Another important contribution to cost savings is the overfill in the 50 mg vials of palivizumab, which results in the ability to retrieve **55 mg (0.55 mL)** from each 50 mg vial when properly reconstituted.

An example of the savings using vial sharing on one typical day at BC Children’s Hospital is outlined below. This example is taken from a real day at BC Children’s Hospital and represents both the doses given in the outpatient clinic and doses given on an inpatient unit.

### EXAMPLE GIVEN

Total number of patients receiving a dose of PVZ = 13

Total number of mgs prescribed = 1232 mg

Total number of vials required to provide all doses with **no** vial sharing = 29 vials

Total cost to provide all doses with no vial sharing = \$21,750

Total number of vials required to provide all doses with vial sharing = 23 vials

Total cost to provide all doses with vial sharing = \$17,250

Amount of medication wasted with no vial sharing = **418 mg**

Cost savings with vial sharing for one clinic = **\$4,500**

### IS VIAL SHARING SAFE?

Vial sharing is practiced in many jurisdictions. The product monograph states that palivizumab is stable for 3 hours after reconstitution and up to 6 hours if reconstituted under strict aseptic conditions. If vials are always accessed using correct techniques, within 3 hours, then the risk of contamination is no greater than with single access.

### CLUSTER DOSING AND VIAL SHARING ON IN-PATIENT UNITS

In the majority of cases, the plan for a patient to be discharged home is known a few days ahead of time and can be coordinated with the outpatient clinic.

There are instances when discharge is sudden, or when an approval has been received late and a patient requires a dose immediately. In such cases there may be other eligible patients known to be going home within a short period of time. It is then possible to give more than one dose should doing so minimize wastage.

*[Vial sharing information continued on following page]*



**HOW TO DETERMINE THE MOST EFFICIENT USE OF PALIVIZUMAB**

The example below demonstrates how vial sharing and consideration of the **actual yield of 55 mg** from a 50 mg vial can maximize clinic efficiency.

**EXAMPLE GIVEN**

Wherein 3 patients require a dose of PVZ:

- Patient 1: 45 mg
- Patient 2: 95 mg
- Patient 3: 75 mg

The total amount of PVZ to be given is 215 mg. This can be obtained from sharing 4 vials due to known overfill in the 50 mg vials. This will eliminate the need to open a 5<sup>th</sup> vial, increasing the efficiency of PVZ use by 20%.

1. Reconstitute 4 vials x 55 mg/vial for a total of 220 mg of PVZ available. Label each vial with the time of reconstitution.
2. Coordinate the timing of each dose so that all of the PVZ is used within the 3-hour timeframe.
3. Withdraw the PVZ from each vial sequentially (i.e., use all contents of one vial before withdrawing from another vial). This reduces the number of times that a vial is accessed.
4. If there will be short delays between dosing each infant, then, to minimize the chance of contamination, store the vials in the medication fridge.
5. Discard unused PVZ after 3 hours.

## COLLEGE OF REGISTERED NURSES OF BRITISH COLUMBIA – LIMITS/CONDITIONS

Registered nurses who compound, dispense, or administer immunoprophylactic agents for the purpose of preventing respiratory syncytial virus infection must possess the competencies and followed decision support tools established by the PHSA.

RNs can autonomously administer PVZ to approved patients without a client specific order if they meet the College of Registered Nurses of British Columbia's (CRNBC) condition of practice and their employer policy supports and infrastructure are in place. Systems must be in place in outpatient clinics to manage anaphylaxis. It is recommended that there be a second RN available during the scheduled clinic time to provide assistance if possible.

The registered nurse must be familiar with the Core Nursing Competencies for RSV Immunoprophylaxis as outlined by the PHSA (as seen below).

Authorization for Treatment must be obtained from the parent or guardian prior to administration of palivizumab (PVZ). All health care providers administering PVZ must have the appropriate resources and plan in place to manage anaphylactic reactions or other potential adverse events.

### Core Nursing Practice Competencies for RSV Immunoprophylaxis

<b>KNOWLEDGE</b>	<ul style="list-style-type: none"> <li>• Demonstrates an understanding of the rationale &amp; benefit of RSV immunoprophylaxis</li> <li>• Demonstrates a general understanding of the immune system</li> <li>• Differentiates between passive &amp; active immunity</li> <li>• Explains how RSV immunoprophylaxis works using basic knowledge of the immune system</li> <li>• Demonstrates understanding of RSV immunization schedule &amp; Program eligibility criteria</li> <li>• Demonstrates an understanding of reporting responsibilities for adverse events/drug reactions (as per the Canadian Adverse Effects reporting system)</li> </ul>
<b>SKILL</b>	<ul style="list-style-type: none"> <li>• Applies knowledge of components/properties of RSV immunoprophylaxis for safe &amp; effective practice</li> <li>• Assesses clients' health status (&amp; immunization history); not unique in the sense that the assessment is required to evaluate whether to proceed with injection on that visit. (see "Judgment" section below)</li> <li>• Recognizes &amp; responds to the unique immunization needs within BC's RSV Program</li> <li>• Implements the BCCDC provincial guidelines when storing/handling/transporting immunizing agents</li> <li>• Prepares &amp; administers immunizing agents correctly</li> <li>• Provides education to client's family re: RSV, standard prevention precautions, &amp; post-immunization symptoms/care</li> </ul>
<b>JUDGMENT</b>	<ul style="list-style-type: none"> <li>• Anticipates, identifies, &amp; manages reactions following immunization</li> <li>• Determines need for appropriate referral to physician or NP</li> <li>• Documents information relevant to immunization in accordance with RSV Program guidelines &amp; institutional policies (including consent as per employer policy)</li> <li>• Determines need to postpone immunization (i.e., if child has been ill)</li> </ul>
<b>ATTITUDE</b>	<ul style="list-style-type: none"> <li>• Acts in accordance with legal &amp; high ethical standards</li> <li>• Respects individual choices &amp; beliefs</li> <li>• Demonstrates self-awareness of own beliefs, values, &amp; practice limitations</li> </ul>

### SCOPE OF PRACTICE

Under the Health Professions Act RNs can autonomously administer immunoprophylactic agents...

6(1)(l) in respect of a drug specified in Schedule I of the Drug Schedules Regulation, [including to]:

- (i) compound the drug,
- (ii) dispense the drug, or
- (iii) administer the drug by any method for the purpose of...

(iv) preventing disease using immunoprophylactic agents and post exposure chemoprophylactic agents.<sup>7</sup>

<sup>7</sup> CRNBC's "Scope of Practice for Registered Nurses": <https://www.crNBC.ca/Standards/Lists/StandardResources/433ScopeforRegisteredNurses.pdf>

## Active Immunity

An immune capacity produced within and by the host body. Naturally acquired active immunity occurs when the person is exposed to a live pathogen, develops the disease, and becomes immune as a result of the primary immune response. Artificially acquired active immunity can be induced by a vaccine, a substance that contains the antigen. A vaccine stimulates a primary response against the antigen without causing symptoms of the disease.

## Clinic

Any site where a patient receives a dose of palivizumab (PVZ), even if there is only one patient attending, and includes the child's home as well as a physician's office.

## Conflict of Interest (COI)

A Conflict of Interest occurs when there is a potential divergence between a person's personal interests and professional obligations, such that the public or patients might reasonably question whether the professional actions or decisions were influenced by personal gain, financial or otherwise. Personal interests may include business, commercial, or financial interests, as well as personal matters and career interests.

With respect to the RSV Program, a COI includes any relationship or interest with a pharmaceutical firm that makes palivizumab. Examples of such relationships or interests include:

- Membership on an advisory board or equivalent;
- Member of a Speaker Bureau;
- Payment from the pharmaceutical firm, including consulting fees, honoraria, salaries, etc.;
- Grants, industry-sponsored clinical trial, or other research funding;
- Holding a patent for a product that is marketed by the pharmaceutical firm;
- Investments; and/or
- Other relationships.

The Program's no-COI position is in alignment with the Canadian Paediatric Society (CPS) position statement, Preventing Hospitalizations for Respiratory Syncytial Virus Infection, which states the following recommendation:

*A panel of experts should be convened in each province or territory to review annually the palivizumab program guidelines and outcomes. People servicing on these panels should not have conflicts of interest, including research funding, participation in a speaker's bureau or financial links, with the pharmaceutical firm that makes palivizumab.<sup>8</sup>*

## Humanized monoclonal antibody

An antibody produced by a single clone of cells. As such, a monoclonal antibody is a single, pure type of antibody. Monoclonal antibodies can be made in large quantities in the laboratory and are the cornerstone of immunology.

## Immunoprophylaxis

- The prevention of disease by the production of active or passive immunity.
- The use of either vaccines or antibody-containing preparations to provide immune protection against a specific disease.

*[glossary continued on following page]*

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<sup>8</sup> Robinson, J, Le Saux, N, Canadian Paediatric Society, Infectious Diseases and Immunization Committee. [Preventing hospitalizations for respiratory syncytial virus infection](#). Paediatr Child Health 2015; 20(6):321-26.

### Passive Immunity

The transfer of active immunity, in the form of ready-made antibodies, from one individual to another. Passive immunity can occur naturally, when maternal antibodies are transferred to the fetus through the placenta, and can also be induced artificially. Artificially acquired passive immunity is a short-term immunization by the injection of antibodies, such as gamma globulin, which are not produced by the recipient's cells.

### Recombinant DNA technology

A series of procedures used to join together (recombine) DNA segments. A recombinant DNA molecule is constructed from segments of two or more different DNA molecules. Under certain conditions, a recombinant DNA molecule can enter a cell and replicate there, either on its own or after it has been integrated into a chromosome.

### Respiratory Syncytial Virus (RSV)

A major cause of respiratory illness in young children. RSV causes infection of the lungs and breathing passage, which may cause bronchiolitis or pneumonia. While most infants will only express mild respiratory symptoms, it can lead to other more serious illnesses in premature babies and infants/children with diseases that affect the heart, lungs, and immune system. RSV infections often occur in epidemics that last from late autumn through early spring. RSV is typically identified in nasal secretions, which can be collected with a nasal pharyngeal washing. RSV is highly contagious, and can be spread through droplets containing the virus when an individual coughs or sneezes. The virus can persist on surfaces for many hours and for over half an hour on skin.

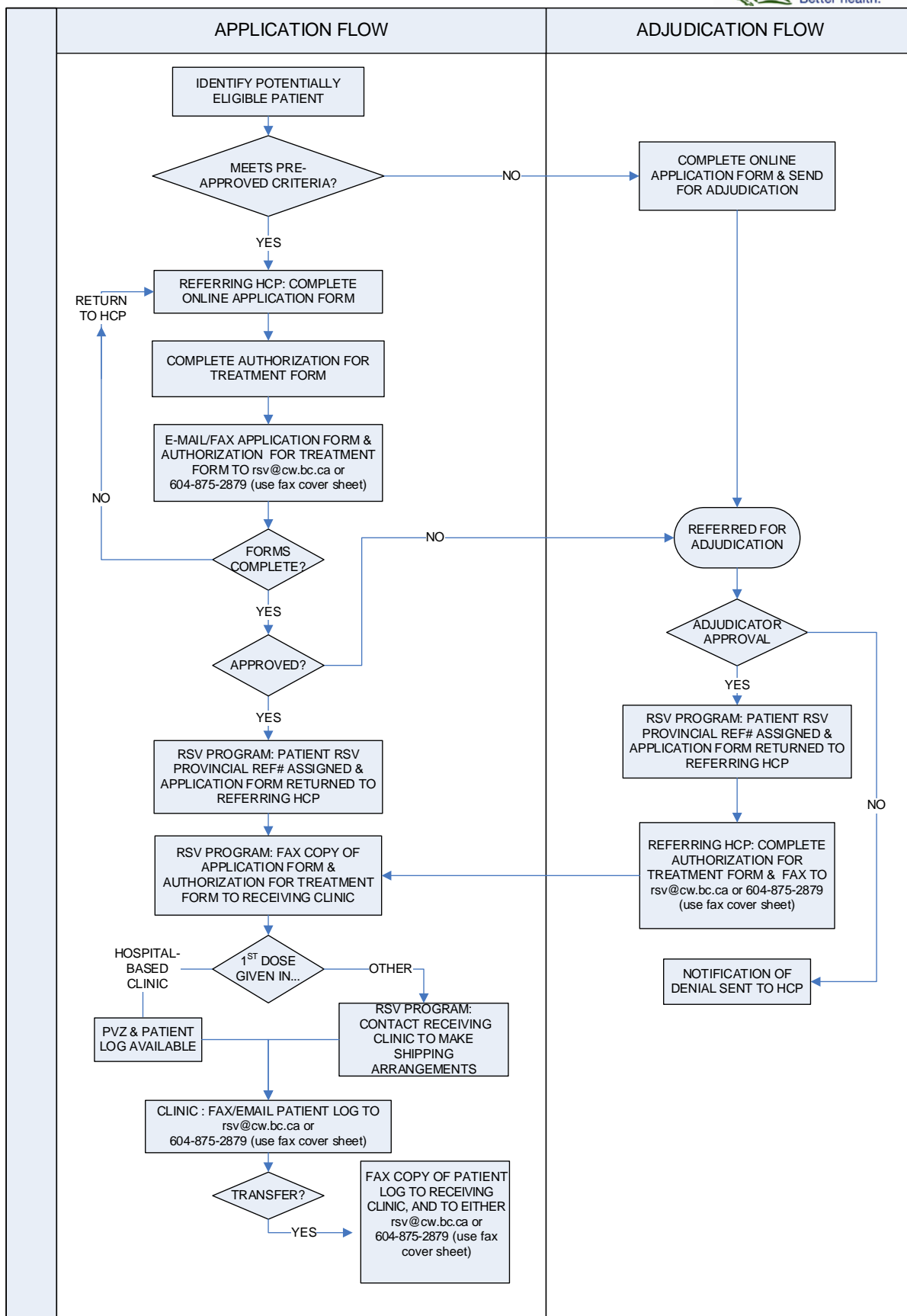
RSV infects almost all children by 2 years of age. While most infants will only express mild respiratory symptoms, RSV infection is responsible for most of the approximately 12,000 hospitalizations for respiratory illness per year in children younger than two years of age in Canada. In BC the RSV season typically lasts from November to April. The overwhelming majority of hospital admissions occur in term and late preterm infants with no pre-existing risk factors in the first year of life. Younger children are more likely to have a prolonged hospital admission and more likely to be admitted to the intensive care unit. Young infants with underlying cardiac or pulmonary disease are at highest risk of admission.

### Vaccination

A type of immunoprophylaxis involving the injection of a killed microbe in order to stimulate the immune system against the microbe, thereby preventing disease.

*NOTE:* palivizumab is not a vaccine.

# RSV Program – Enrolment Flow Diagram



## BC RSV Immunoprophylaxis Program

### Guidelines by Comparison - Indications

Condition	BC 2014	AAP 2014	CPS 2015	BC 2016 (same practice as 2015)
Preterm infants without CLD born before 29w+0d GA	Up to 4 doses per season, if date of discharge after 01 Sep and GA at birth <29w	Recommended for infants born before 29w+0d gestation who are < 12 mos at start of RSV season.	Reasonable (but not essential) for infants born <30w+0d when <6 mos of age at start of RSV season,	Up to 4 doses per season, if date of discharge after 01 Sep and GA at birth <29w
Infants born after 29w+0d GA	Up to 3 doses per season, if date of discharge after 01 Oct AND have >41 points in the BC Risk Score	Not recommended for healthy infants born at 29w+0d GA or later.	PVZ should not be prescribed for infants after 30w+0d weeks.	Up to 3 doses per season, if date of discharge after 01 Oct AND have >41 points in the BC Risk Score
CLD - first year of life	CLD/BPD (defined as a need for oxygen or CPAP for more than 28 days) AND <12 mos at start of season AND on oxygen after 01 Jul	Recommended for CLD of prematurity defined as gestational age <32w+0d and a requirement for >21% O <sub>2</sub> for at least the first 28 days after birth.	CLD is defined as a need for oxygen at 36 weeks' GA who require ongoing diuretics, bronchodilators, steroids or supplemental oxygen. PVZ if <12 mos of age at start of RSV season.	Same as previous years. To be adjudicated if >12 mo age by 01 Nov
CLD - second year of life	[IBID]	Only if continue to require medical support (chronic corticosteroid therapy, supplemental oxygen, diuretic therapy) during 6-mo pe- riod prior to start of second RSV season.	Only indicated in the second year in those still on or weaned off of supplemental oxygen in the past 3 mos.	To be adjudicated if >12 mo age by 01 Nov
Significant pulmonary disability	Significant pulmonary disability (pulmonary hypertension, pulmonary malformations, severe BPD, progressive neuromuscular disease) AND <24 mos by 01 Nov			To be adjudicated
Upper airway obstruction, or chronic pulmonary disease other than CLD	Funded only if severe and after adjudication by single expert, if age <12 mos		Should not routinely be offered PVZ.	To be adjudicated
<24 mos of age on home oxygen for severe pulmonary disease	Funded after adjudication by single expert, if age <12 mos		Consider prophylaxis	Up to 4 doses per season if continous home O <sub>2</sub> /ventilation on or after 01 Nov 16 and DoB on or after 01 Nov 14
Hemodynamically significant CHD	PVZ if they are <24 mos of age at the start of RSV season AND have hemodynamically significant CHD on or after 01 Nov	May administer to <12 mos with acyanotic heart disease receiving medication to control congestive heart failure and will require cardiac surgical procedures; and infants with moderate to severe pulmonary hypertension. Infants with cyanotic heart defects in the first year of life, in consultation with a pediatric cardiologist.	PVZ if they are <12 mos of age at the start of RSV season. PVZ is not indicated during the second RSV season for infants with CHD	PVZ if <12 mos as of 01 Nov 16 AND hemodynamically significant CHD: i.e., acyanotic heart disease receiving medication to control CHF and requires cardiac surgical procedures; and infants with moderate to severe pulmonary hypertension. Infants with cyanotic heart defects in the first year of life, in consultation with a pediatric cardiologist.
CHD, special circumstances	Extra post operative dose after cardiac bypass.	Extra post operative dose after cardiac bypass. ECMO or transplant during RSV season AND <24 mos.		Extra post operative dose after cardiac bypass, ECMO or transplant during RSV season AND < 24 mos.

## BC RSV Immunoprophylaxis Program

### Guidelines by Comparison - Indications

Condition	BC 2014	AAP 2014	CPS 2015	BC 2016 (same practice as 2015)
CHD - Complex patients being carried over with single ventricle palliations and <24mo			PVZ if they are <12 mos of age at the start of RSV season. PVZ is not indicated during the second RSV season for infants with CHD	To be adjudicated
CHD clarification		PVZ not indicated: hemodynamically insignificant CHD(*), lesions adequately corrected by surgery unless requiring medication for CHF, mild cardiomyopathy not requiring medical therapy.		To be adjudicated if PVZ for any of these is requested
Cystic Fibrosis	If symptomatic and DoB after 01 Jan	Only if clinical evidence of CLD and/ or nutritional compromise in the first year of life. PVZ in second year only if severe lung disease or weight for length less than the 10th percentile.	Should not routinely be offered PVZ.	To be adjudicated
Trisomy 21	If hemodynamically significant CHD is not present, then approved only if date of discharge after 01 Oct and BC Risk Factor score	Only if with qualifying heart disease, CLD, airway clearance issues, or prematurity (<29 weeks, 0 days' gestation) is present.	Should not routinely be offered PVZ.	To be adjudicated
Neuromuscular disease and inability to clear secretions	By adjudication	Neuromuscular disease or congenital anomaly impairing ability to clear secretions from the upper airway because of ineffective cough may be considered for prophylaxis during the first year of life.		To be adjudicated
Solid organ or hematopoietic stem cell transplantation; and severely immunocompromised children <24 mos	Consider if <24 mos of age AND profoundly immunocompromised during the RSV season: AML, stem cell transplant, infant ALL, infant brain tumor intensive protocol, SCIDS, ICE protocol AND <24 mos	Consider if <24 mos of age AND profoundly immunocompromised during the RSV season.		To be adjudicated
Other immunocompromised children	PVZ should not routinely be offered to other diagnoses including most cancer patients		PVZ should not routinely be offered	To be adjudicated
Administration to multiple	Multiples of enrolled children approved for same number of doses	Not considered	Not in the CPS guideline	PVZ if <35w and discharged for first time
Breakthrough RSV infection.	Continuation of monthly PVZ is not recommended	Discontinue monthly PVZ	Continuation of moly PVZ is not recommended	Continuation of PVZ not funded

\* Hemodynamically insignificant CHD: secundum ASD, small VSD, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and PDA

## BC RSV Immunoprophylaxis Program

### Guidelines by Comparison - Miscellaneous


Circumstance	BC 2014	AAP 2014	CPS 2015	BC 2016 (same practice as 2015)
Teaching for parents	Education advocated, but not formalized in Program documentation		Young infants (and their siblings) should not be in contact with individuals with respiratory tract infections whenever practical. A Cochrane review suggests that hand hygiene in the home decreases the spread of respiratory tract infections in children. Breastfeeding and avoidance of cigarette smoke are also presumed to decrease the incidence and/or severity of viral respiratory tract infections.	While PVZ is beneficial in reducing RSV risks, very important measures for relieving and lowering the risk of viral respiratory tract infections include the following: <ul style="list-style-type: none"> <li>* Whenever possible, keep your child (and their siblings) away from people who have respiratory tract infections.</li> <li>* Frequent handwashing or use of alcohol hand sanitizer.</li> <li>* Breast milk.</li> <li>* Avoidance of cigarette smoke.</li> <li>* Discouraging daycare, especially &lt;1yo</li> </ul>
Maximum number of doses per season	4 doses, except for pump after which an extra dose is given	Up to 5; last dose in March	Programs should administer a maximum of 3-5 doses, with 4 doses probably being sufficient in all risk groups if PVZ is started only when there is RSV activity in the community, especially if doses 2, 3, and 4 are given 38 days apart.	4 doses, except post pump after which an extra dose is given
When first dose	For eligible infants being discharged home for the first time during RSV season, start just before discharge.	48-72 hours prior to discharge	For eligible infants being discharged home for the first time during RSV season, start just before discharge.	For eligible infants being discharged home for the first time during RSV season, start just before discharge.
Greater than 5 doses	Not funded	Not considered	No evidence to support giving >5 doses in one RSV season	Not funded
Use to prevent nosocomial infection	Not funded	Not recommended	Expensive strategy that is not recommended.	Not funded
PVZ as RSV therapy	Not funded	Not effective; not approved	PVZ as RSV therapy is no indicated	Not funded
>24 mos	Not funded	Not considered	No evidence to support administration to any child >24mo age	Not funded
Use of Risk Score system	BC RSV Risk Score used for >29w without CLD	Not discussed	Not discussed	BC RSV Risk Score will remain in place
Cluster administration	PVZ wastage should be minimized by cluster administration to the largest number of patients possible			PVZ wastage should be minimized by cluster administration to the largest number of patients possible



## BC RSV Immunoprophylaxis Program

### Guidelines by Comparison - Miscellaneous

Circumstance	BC 2014	AAP 2014	CPS 2015	BC 2016 (same practice as 2015)
Infants in remote communities who would require air transportation for hospitalization	10 pts per BC risk score; otherwise not a factor	RSV disease and costs associated with transport from remote locations may result in a broader use in special populations	If born before 36 + 0 weeks' GA and <6 mos of age at start of RSV season should be offered PVZ. Not clear if this should apply only to Inuit infants, to all Aboriginal infants or to all infants in remote communities. However, first priority should be to provide PVZ to infants with prematurity, CLD or CHD.	10 pts per BC risk score; otherwise not a factor
Program Review	Arms length program with no funding or participation by vendor.		A panel of experts should be convened in each province or territory to review annually the PVZ program guidelines and outcomes. People serving on these panels should not have COI, including research funding, participation in a speaker's bureau or financial links, with the pharmaceutical firm that makes PVZ.	No member of advisory committee or adjudicator panel to have a COI (real or perceived). Adjudication is conducted by a panel of 3. No adjudication of one's own patients.

 <p><b>STANDARD WORK</b></p>	Title: <b><u>Palivizumab Preparation / Reconstitution</u></b> Role performing Activity: Nurse/physician/nurse practitioner	
	Location: Established clinics and doctors' offices	Department: <b>BC RSV Immunoprophylaxis Program</b>
	Document Owner: Cheryl Christopherson	
	Date Prepared: July 1, 2014	Last Revision: September 15, 2015

**Note the following:**

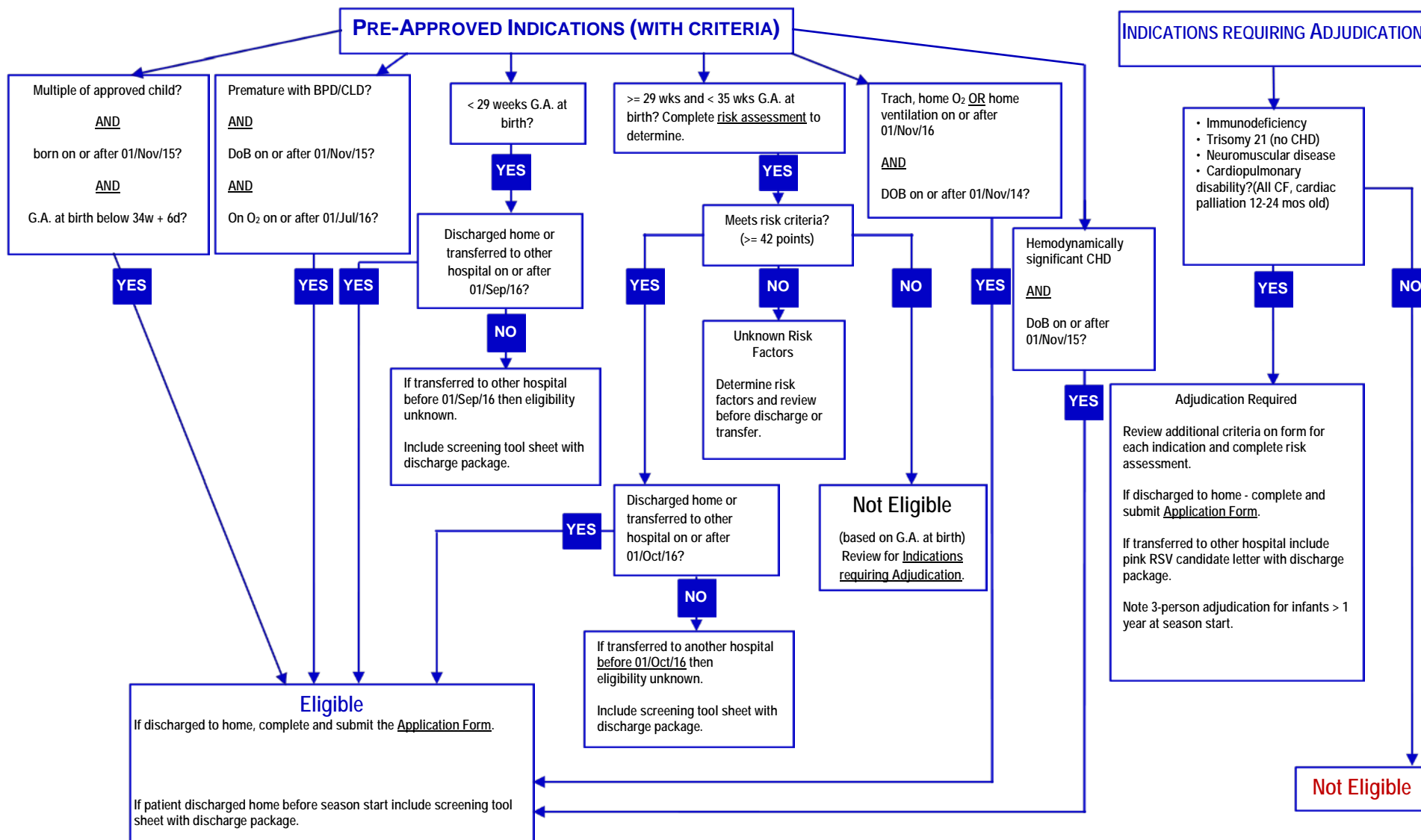
- Vials of palivizumab may contain a small overfill.
- Barring the use of controlled and validated aseptic conditions, palivizumab should be used within 3 hours of reconstitution.

**Items needed:**

- Alcohol swabs
- Dry gauze pads (or equivalent)
- Small syringe
- Needles

Task Sequence	Essential Tasks
1	Place the contents of the package on a clean surface.
2	Wash your hands thoroughly.
3	Using antiseptic technique, remove tab portion on the vial cap and clean rubber stopper with 70% ethanol (or equivalent).
4	Prepare small syringe for withdrawal of sterile water.
5	Carefully tap top of ampoule of sterile water for injection, until all droplets have fallen to bottom of the ampoule. In one hand, hold ampoule with red dot facing you.
6	With your other hand, hold the gauze pad (or equivalent) at the top, near the red dot, and snap off upper portion of ampoule away from you.
7	Hold the ampoule at an angle, so needle rests on upper part of ampoule, to facilitate easy withdrawal of all the sterile water (0.6 mL). Remove syringe from ampoule.
8	Carefully remove any excess sterile water from syringe and prepare palivizumab vial.
9	Insert needle carefully into the vial. To minimize foaming, slowly add 0.6 mL of sterile water for injection along inner side of vial. Water is best added by "dripping" along the inner side of the wall.
10	Rotate sides of vial after half the sterile water has been added to palivizumab powder, and add the balance of the sterile water down other side of the vial.
11	After removing syringe from the vial, gently turn vial between fingers for approximately 30 seconds, visually inspecting all palivizumab powder has been saturated by sterile water. Please <b>do not shake</b> or vigorously agitate vial, <b>nor invert the vial</b> during the reconstitution process.
12	Let the reconstituted solution stand at room temperature, undisturbed, for at least 20 minutes, until solution clarifies. If excessive foaming has occurred and a full dose of 0.5 mL is required, allow more time for the foam to dissipate (typically one hour or longer).
13	Prior to drawing any solution from the vial, invert for approximately 30 seconds.

# RSV Program Screening Decision Tree



**Northern Health Authority regions:**



**Other regions of BC:**



*NOTE: Although the RSV Season is extended in NHA regions, the maximum number of doses remains three or four per infant (depending on indication).*

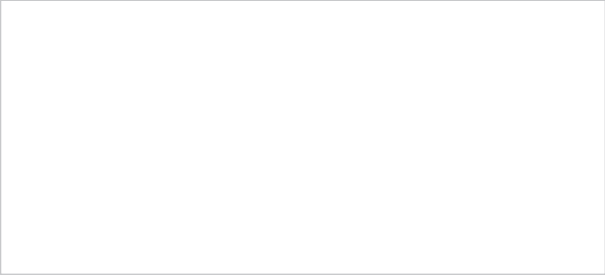
# BC RSV IMMUNOPROPHYLAXIS PROGRAM APPLICATION FORM

The BC RSV Immunoprophylaxis Program only covers high risk children who meet the risk criteria established by the Program.

No child > 2 years of age by 01 November, 2016 is eligible.

Please COMPLETE THIS FORM ONLINE, save it and submit it to [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca), as an attachment to an email, from a Health Authority (i.e., hospital) email account. Print a copy for your records.

To contact the RSV Program, please email [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca), telephone 1-877-625-7888, or fax 1-877-625-7555.



## Section 1 - PATIENT INFORMATION

Last Name:		First Name:		PHN:	
Date of birth: (dd/mmm/yyyy)	Gest age at birth (w + d):	Date first discharged home (dd/mmm/yyyy)	Age at time of request (mos):		
<input type="checkbox"/> Male <input type="checkbox"/> Female	Birth weight (g):	Birth weight percentile:	Current weight (g):		
Father's / Guardian's First & Last Name			Mother's / Guardian's First & Last Name		
Parent / Guardian phone number:			City of Residence:		

## Section 2 - REQUESTING PHYSICIAN

First and Last Name:		Person completing form (Name/Number):			
Physician Phone:		Physician Fax:		Physician Email:	

## Section 3 - COMMUNITY PHYSICIAN

First and Last Name:		Office Address or Institution Name			
Phone:		Fax:		email:	

## Section 4 - PRODUCT DELIVERY INFORMATION

Hospital name for initial dose:		Hospital name for subsequent doses:			
Number of 50 mg vials to be shipped now:		Number of 50 mg vials required for season:			

Note: Dose of palivizumab is 15 mg/kg, as per Product Monograph

## Approval

Approved for maximum 4 doses / season   
  Approved for maximum 3 doses / season   
  Not approved  
 Adjudicator Name & Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## [For Pharmacy Use Only]

AbbVie Ref. #:	Patient Initials:	PHSA / C&W PO #:	Provincial Ref. #:
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**Section 5 - PRE-APPROVED INDICATIONS**

- Prem with BPD/CLD (oxygen or CPAP for over 28d) **AND**  DoB on or after 01 Nov 2015 **AND**  on oxygen on or after 01 Jul 2016
- GA at birth below 29w + 0 days **AND**  discharged home on or after 01 Sep 2016
- GA at birth 29w + 0d to 34w + 6d **AND**  discharged home on or after 01 Oct 2016 **AND**  risk factors score greater than 41 points\*
- Tracheostomy / continuous home oxygen / ventilation on or after 01 Nov 2016 **AND**  born on or after 01 Nov 2014
- Multiple of approved child **AND**  GA at birth below 34w + 6d **AND**  discharged for first time
- Hemodynamically significant CHD **AND**  DoB on or after 01 Nov 2015 (clinical details/name of supporting cardiologist below)

**Section 6 - INDICATIONS REQUIRING ADJUDICATION**

- Trisomy 21 without significant CHD **AND**  discharged home on or after 01 Sept 2016 **AND**  risk factors\*
- Progressive neuromuscular disease with inability to clear secretions **AND** DoB on or after 01 Nov 2014 (clinical details below)
- \*\*Severe immunodeficiency (e.g., stem cell transplantation) **AND**  DoB on or after 01 Nov 2014
- \*\*Significant cardiopulmonary disability (pulmonary hypertension, pulmonary malformations, severe BPD, symptomatic CF, cardiac palliation, other) **AND**  DoB on or after 01 Nov 2014 (clinical details below)

\* The risk factors below will be important to facilitate adjudication in all borderline cases  
 \*\* Summarize clinical course and level of disability in the space below or in separate sheet

**Section 7 - ADDITIONAL CLINICAL INFORMATION REQUIRED (to be completed for ALL requests)**

**Risk factors present in this child at discharge:**

Yes	No		
<input type="checkbox"/>	<input type="checkbox"/>	Will attend daycare regularly during first three months after discharge	22 pts
<input type="checkbox"/>	<input type="checkbox"/>	Discharged home in Dec or Jan or Feb	20 pts
<input type="checkbox"/>	<input type="checkbox"/>	Discharged home in Nov or Mar	10 pts
<input type="checkbox"/>	<input type="checkbox"/>	Gestational age at birth 29 weeks + 0 days to 30 weeks + 6 days	10 pts
<input type="checkbox"/>	<input type="checkbox"/>	Other child younger than 5 years living at home (not including multiples of applicant)	14 pts
<input type="checkbox"/>	<input type="checkbox"/>	6 or more people at home (including applicant and multiples of applicant)	12 pts
<input type="checkbox"/>	<input type="checkbox"/>	Remote residence (Over 1 hour travel time or >100 km in Google maps to the nearest hospital)	10 pts
<input type="checkbox"/>	<input type="checkbox"/>	Girl not receiving breastmilk, or Boy (any)	8 pts
<input type="checkbox"/>	<input type="checkbox"/>	SGA (BW less than 10th percentile)	8 pts
<input type="checkbox"/>	<input type="checkbox"/>	2 or more smokers living at home	8 pts
			TOTAL:

Summarize clinical course to date with current/proposed Rx in the space below or on a separate sheet

**ADJUDICATOR'S COMMENTS**



Patient Name: \_\_\_\_\_ DOB (dd/mmm/yyyy): \_\_\_\_\_

Prov. Health #: \_\_\_\_\_ Registration #: \_\_\_\_\_

Parent / Legal Guardian Name (Print): \_\_\_\_\_

Phone: \_\_\_\_\_ Other Phone / Contact: \_\_\_\_\_

**Authorization for Administration of Palivizumab and Follow-Up**

The benefits and risks of this medication have been explained to me and I have received information on reducing the risk of respiratory infections. I consent to my child receiving Palivizumab as per the BC RSV Immunoprophylaxis Program Guidelines and to contact for follow-up.

Signature of Parent/Guardian: \_\_\_\_\_ Date: \_\_\_\_\_

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**This section for Physician/Nurse providing care**

The application form's details and contact information have been confirmed above and the patient is eligible for funded prophylaxis. I have provided information on the RSV program and have answered questions. I confirm that consent for treatment and follow-up has been obtained (*telephone consent is acceptable*).

\_\_\_\_\_  
Signature of Physician/Nurse obtaining consent

\_\_\_\_\_  
Signed on [this date]: [dd/mmm/yyyy]

\_\_\_\_\_  
Printed name of Physician/Nurse

\_\_\_\_\_  
Contact telephone number of Physician/Nurse

## (For use by clinic / point of care as an individual administration record)

Patient Name: \_\_\_\_\_ DoB (dd/mmm/yyyy): \_\_\_\_\_

Parent / Legal Guardian Name: \_\_\_\_\_ Provincial Health #: \_\_\_\_\_

Phone: \_\_\_\_\_ Provincial Reference #: \_\_\_\_\_

Other Phone / Contact: \_\_\_\_\_

Consent obtained?  NO  YES

Course complete?  NO  YES

### Eligibility Criteria:

Dose #	When Taken	Where Dose Was Administered	Date (dd/mmm/yy)	Lot Number	Weight (kg)	Expiry Date	Dose (mg)	Admitted with any respiratory infection in previous month?	Admitted with RSV+ infection in previous month?	Clinic for next dose?
1		<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____
2	3-4 weeks after Dose 1	<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____
3	4-5 weeks after Dose 2	<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____
<i>*NOTE: the standard administration is three to four doses; a fifth dose may only be given to patients who have undergone cardiac bypass surgery.</i>										
4 <sup>th</sup> ?	4-5 weeks after Dose 3	<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____
5 <sup>th</sup> ?		<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____
Final f/up		<input type="checkbox"/> No <input type="checkbox"/> Yes, at: _____						<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	<input type="checkbox"/> No <input type="checkbox"/> Yes, to: _____

At the end of each day, fax this page to the RSV Program and to any clinic that the patient attends.

If the patient has been hospitalized for any respiratory infection, then please fill out a Hospitalization Data form and send to [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca).





***This form to precede all RSV Forms submitted via fax***

This facsimile communication is intended only for the use of the addressee and may contain information that is privileged and confidential. Any dissemination, distribution, or copying of this communication by unauthorized individuals or for unauthorized purposes are strictly prohibited.

If you received this communication in error, please notify us immediately via telephone at 604-875-2867 or toll free at 1-877-625-7888, and return to the original to us by regular mail.

Date: \_\_\_\_\_

To:

...at Fax Number: \_\_\_\_\_

From:

Contact Information: \_\_\_\_\_

Number of pages (including this page): \_\_\_\_\_

Notes:



## For Respiratory Infection in Infants approved for Palivizumab and admitted for Respiratory Illness until April 30, 2017

Name of Patient: \_\_\_\_\_ DoB: \_\_\_\_\_

Provincial Reference #: \_\_\_\_\_ PHN: \_\_\_\_\_

Admitting Hospital: \_\_\_\_\_ Attending Physician: \_\_\_\_\_

Admitted (dd/mmm/yyyy): \_\_\_\_\_ Discharged (dd/mmm/yyyy): \_\_\_\_\_

If Transferred:

Name of Hospital: \_\_\_\_\_ Attending Physician: \_\_\_\_\_

Admitted (dd/mmm/yyyy): \_\_\_\_\_ Discharged (dd/mmm/yyyy): \_\_\_\_\_

Reason(s) for Hospitalization (e.g., apnea, respiratory distress): \_\_\_\_\_

Final RSV test result:  Negative  Positive  Unknown

Other significant viruses/bacteria isolated: \_\_\_\_\_

### **Medical support while in hospital**

Supplemental O2:  No  Yes: Number of days: \_\_\_\_\_

NG feeding:  No  Yes: Number of days: \_\_\_\_\_

IV fluids:  No  Yes: Number of days: \_\_\_\_\_

PICU admission:  No  Yes: Number of days: \_\_\_\_\_

CPAP:  No  Yes: Number of days: \_\_\_\_\_

Intubated/Ventilated:  No  Yes: Number of days: \_\_\_\_\_

Other treatments? Please specify: \_\_\_\_\_

*Please complete as much information as possible, then fax to 604-875-2879, or toll-free 1-877-625-7555.*

# RSV Program – Tracking and Screening Tool



NOTE: This form is a tool to track eligible infants during the off season, with particular attention to infants <35 weeks gestational age or with chronic lung disease or who may qualify under the "Indications Requiring Adjudication" category below.

### Patient Information

Discharge to home (dd/mmm/yy): \_\_\_\_\_

Last Name: \_\_\_\_\_

First Name: \_\_\_\_\_

Date of Birth (dd/mmm/yy): \_\_\_\_\_

PHN: \_\_\_\_\_

Gender: \_\_\_\_\_ Gestational Age at Birth (weeks + days): \_\_\_\_\_

Birth Weight: \_\_\_\_\_ grams

Transfer to other Hospital? If yes, name: \_\_\_\_\_ on (dd/mmm/yy) \_\_\_\_\_

Parent/Guardian Name: \_\_\_\_\_ Parent/Guardian Telephone: \_\_\_\_\_

Accepting Physician Name: \_\_\_\_\_ Accepting Physician Telephone: \_\_\_\_\_

### Pre-Approved Indications

- Premature with BPD/CLD (O<sub>2</sub> or CPAP for >28 days) and DoB on or after 01-Nov-15 and continuous O<sub>2</sub> requirements on or after 01-Jul-15
- Premature (<29w) discharge home on or after 01-Sep-16
- Premature (29w–34w+6days) without BPD discharged home on or after 01-Oct-16 and Risk Factor Score ≥ 42 points
- Home respiratory support (e.g., home oxygen, CPAP, tracheostomy) on or after 01-Nov-16 and born on or after 01-Nov-14
- Multiple of approved child and under 35 weeks gestation at birth and DoB on or after 01-Nov-15
- Hemodynamically significant CHD and born on or after 01-Nov-15

### Risk Factor Assessment

- Discharged home Dec, Jan, or Feb .....+20 points
  - Discharged home Nov or Mar .....+10 points
  - Female infant not receiving breastmilk .....+8 points
  - GA at birth 29w or 30w + 6 days .....+10 points
  - ≥2 smokers in household .....+8 points
  - Male infant .....+8 points
  - Other <5 year old in home (not including multiples) .....+14 points
  - Regular daycare in first 3 mos after discharge\* .....+22 points
  - Remote residence (>1hr or 100 km to hospital able to provide paediatric care) .....+10 points
  - 6+ people in household (including multiples) .....+12 points
  - SGA (birth weight <10<sup>th</sup> percentile) .....+8 points
- Total Points: \_\_\_\_\_

### Indications Requiring Adjudication (Note: also complete risk factor assessment above.)

- Trisomy 21 without significant CHD and discharged on or after 01-Sep-16 and risk factors
- Significant cardiopulmonary disability\*\* and DoB on or after 01 Nov 2014
- Severe immunodeficiency and DoB on or after 01-Nov-15
- Progressive neuromuscular disease and inability to clear secretions and DoB on or after 01-Nov-14
- Other: \_\_\_\_\_

### Additional Relevant Information:

\* i.e., home or facility-based group daycare with 4 or more children

\*\* i.e., pulmonary hypertension, pulmonary malformation, severe BPD, progressive neuromuscular disease, other diagnosis

***This form is for clinicians.***

- Begin a conversation using consent language, such as, “Do you have a few minutes?”
- *Tell them who you are* (e.g., that you work with Cardiology, or another program); and that you work with BC’s RSV (Prevention) Program.
- Ask the parent/guardian *whether they have heard of RSV*; if not, reassure them that *most people haven’t*. Tell them that it *stands for Respiratory Syncytial Virus* and that it is a respiratory virus.
- Explain the following:
  - RSV is one of many viruses that become more common in winter months, and the majority of babies have had it by age 1, and almost all by age 2.
  - For adults and older children it’s like a cold; but that some few can get quite sick from RSV, especially if born prematurely, have heart or lung problems, or have trouble clearing their airways.
  - Because it’s a virus treatments like antibiotics do not work, though oxygen and IV hydration have been used as supportive therapies.
- Introduce the reason for the conversation, such as by saying: “One of the reasons I’m calling you is because there is a medicine that can help prevent RSV. This medicine, called palivizumab, is for a select group of babies and your baby has qualified because of their heart defect/prematurity/etc.”
- Explain that because palivizumab is an antibody and not a vaccine, it doesn’t prevent RSV, but helps support their immune system so they don’t get as sick from it, keeping the virus away from the lower airway, where it can cause more problems.
- Explain that sometimes babies who have had palivizumab still come to the hospital with RSV, but the hope is that palivizumab makes it less severe.
- Quote studies that determine a 55% reduction in hospitalizations in premature babies and a 45% reduction in cardiac patients after receipt of palivizumab.
- Address other ways to prevent RSV, such as hand-washing around the baby, and avoiding:
  - Large crowds (e.g., malls, buses)
  - Second-hand smoke
  - Sick people
  - Kissing your baby on the face, particularly when parent is experiencing symptoms
 Express that these measures are the best ways to prevent the spread of RSV infection.
- Explain that it is an injection that goes into the baby’s muscle in their thigh and it can be a total of 3 injections (4 where applicable). It takes one injection every month during the cold season which is from November to March/April. The first two doses are given three weeks apart; subsequent doses are administered thereafter up to the limit prescribed by the guidelines of BC’s RSV Program.
- Palivizumab is generally well tolerated. There are usually no side effects, but like any medication there may be some side effects linked to the immune response, most commonly:
  - ↳ The baby seems “a bit off”;
  - ↳ Not feeding well;
  - ↳ Runny nose and other cold-like symptoms (with or without a fever);
  - ↳ An ear infection; and
  - ↳ A rash.
 There is always a risk of serious reaction, like any medicine that someone has not had (in studies, less than 1 in 100,000 cases of serious reaction to palivizumab have been identified.) If a fever lasts more than 24 hours, it is recommended that a doctor see the baby, in case something else is going on.

- Gently explain that RSV gets worse before it gets better (usually around day 3-5). Watch the baby closely at this time because babies do not have a lot of reserve. The baby should be seen by a doctor if you are concerned, especially if the baby appears to be having difficulty breathing. This gives the doctor a chance to assess the baby and also get a baseline of what the baby looked like in case he/she gets worse.
- Tell the family that their baby has already been approved by Cardiology/their physician/etc. for palivizumab, and ask whether they are interested. (Spell out any unrecognized terms if they wish to research the subject.)
- If they agree to proceed, explain the follow-up portion of the authorization:
  - The details of each dose given will be sent to the program (date, dosage, and weight).
  - A final follow-up telephone call will be made in April or May to ask how the patient has done for the remainder of the winter / early spring.
  - If the patient is hospitalized with RSV-related illness, we may contact the family to ask permission to access information from the hospitalization record (at which point no further doses will be administered).

### FREQUENTLY ASKED QUESTIONS

“Can I have my baby’s four-month immunizations done there in the clinic?”

Unfortunately not. Babies’ immunizations can be arranged through the public health nurse. Paediatricians often do not administer immunizations, as public health nurses are very informed on the latest in immunization policies, and their capacity to document is much more consistent.

“Can my baby have his/her RSV shot on the same day as his/her immunizations?”

There is no contraindication to administering them at the same time, but it is recommended to give them separately, especially on the first dose; that way, if there’s an adverse reaction, it’s clear which one caused it.

“Should I give my baby Tylenol before or after? How much?”

Giving your baby Tylenol is really by the discretion of the parent or caregiver. Dosage is based on age/weight group, as detailed on the bottle. We do not have Tylenol to provide you; it can be found at your local pharmacy.

“Does *Emla* help decrease the pain of the injection?”

While *Emla* helps to decrease the surface pain associated with needles, it doesn’t really make a difference deep in the muscle where the medication is being injected. It’s your choice.

“My child’s application was denied; who can I talk to about this?”

If you and your doctor strongly feel that s/he should have been approved, then it is recommended that your doctor fill out another request form giving even more detailed information as to why s/he believes your child is a candidate.

“Can my baby feed immediately after the shot?”

Absolutely. In fact, many moms breastfeed while the baby receives their shot to help comfort them.

“Can my baby get their RSV shot at the same time they see their paediatrician in the Medical Day Unit?”

If an RSV Clinic is running on the same day, then the RSV nurse can easily administer the dose with the paediatrician’s permission; if there isn’t, this will have to be coordinated with the MDU charge nurse and is up to their discretion.

“Can someone other than the RSV nurse give a shot of palivizumab?”

Yes. While it is suggested that the RSV nurse give the dose when possible (to keep the left-over palivizumab in their clinic), a bedside nurse can also administer a dose when necessary.

# Information for Parents about Respiratory Syncytial Virus or RSV



**The Pharmacy Department**  
4480 Oak Street, Vancouver, BC V6H 3V4  
604-875-2867 • 1-877-625-7888  
[www.bcchildrens.ca](http://www.bcchildrens.ca)

## Is RSV serious?

Most children that get RSV will experience a minor cold which will go away in 1 to 2 weeks. In a small number of children, RSV can develop into a more severe infection, especially in children who:

- Are born premature
- Have chronic lung disease
- Have heart disease
- Are less than 6 months old

## What is Respiratory Syncytial Virus (RSV)?

RSV is a virus that affects the lungs and airways. It is one of the most common viruses in infancy and childhood. Researchers say that almost all children have had RSV by the time they are three. It is the most frequent cause of lower respiratory tract infection in children. You can learn more about the lungs and the respiratory system at: [www.aboutkidshealth.ca/BCCH/En/HowTheBodyWorks](http://www.aboutkidshealth.ca/BCCH/En/HowTheBodyWorks)

## How do you catch RSV?

RSV is very easy to catch. It is spread by contact such as touching, kissing, or shaking hands with a person infected with RSV. It can also be spread by touching countertops, toys, Kleenex or any other surfaces. RSV viruses can last for hours on these objects after an infected person has touched them. You can catch the infection when infectious material touches your mouth, nose or eyes. You can also catch it by inhaling droplets from a sneeze or cough from an infected person. RSV is around all year but is most active from November to April.

There is an increased chance of catching RSV if your child:

- Attends day care.
- Has a sibling who attends day care.
- Lives in a household with 5 or more people.
- Is exposed to second hand smoke.
- Is exposed to crowded environments.

## What are the symptoms of RSV?

The symptoms of RSV are often like that of the common cold:

- Runny or stuffy nose
- Cough
- Low grade fever (less than 38.5° C or 101° F)
- Not feeling hungry

The symptoms can get worse if the virus moves lower and causes inflammation of the lungs. Symptoms could include:

- Difficulty breathing or rapid breathing
- Unusual or long pauses of breathing
- Wheezing
- Difficulty feeding

## When should I take my child to the doctor?

If your child seems to be getting sicker, with more rapid breathing, a wheezy sound, high temperature or is having a harder time feeding they should be seen by a doctor. If they are having a lot of trouble breathing they should be taken to emergency as soon as possible.

## How do I protect my child against RSV?

- **Clean your hands** each time before touching your baby and ask others to do the same. You can use warm water and soap or an alcohol based cleanser. More information about good hand washing is available at: [http://www.cw.bc.ca/library/pdf/pamphlets/PHSA311\\_HowToHandRubWash\\_2010\\_Dec17.pdf](http://www.cw.bc.ca/library/pdf/pamphlets/PHSA311_HowToHandRubWash_2010_Dec17.pdf)
- Keep your child away from people who have colds or who are sick. **This includes saying “No visiting” to family and friends if they are ill.**
- Try to avoid crowded places such as church, daycare centres, and shopping malls during the RSV season (from November to April).
- Keep your child away from second hand smoke, smokers who have recently smoked, and clothes that smell of smoke.
- Do not share personal items such as cups, washcloths, and towels with people who are ill.
- Breastfeed your child. It may help protect your child from catching RSV.

# Information for Parents about Synagis



**The Pharmacy Department**  
4480 Oak Street, Vancouver, BC V6H 3V4  
604-875-2867 • 1-877-625-7888  
[www.bcchildrens.ca](http://www.bcchildrens.ca)

## What is Synagis®?

It is a medication that helps a child's body fight off a serious respiratory syncytial virus also called RSV. It is given every month for 3 to 5 months during the RSV season. In BC the RSV season is November to April.

## Why has my child been prescribed Synagis®?

Your child has more risk of developing a severe RSV infection. Your doctor has asked that your child receive Synagis®.

## How is Synagis® given?

It is given by needle into the thigh muscles. If your child needs more than 1 ml of Synagis® the amount is split and your child will receive a shot in each thigh.

## Is Synagis® a vaccine like the other immunizations my child receives?

No. There is no vaccine available for RSV. Synagis® is a type of antibody. It works like antibodies that your child's body makes naturally to fight an infection. The antibodies from Synagis® help your child for about one month.

## Is Synagis® a blood product?

No. There is also no chance of your child getting an infection from Synagis®.

## Does my child need to receive all of the monthly injections?

**Yes!** It is very important that your child get all of the injections. Each injection protects your child from a serious RSV infection for about 30 days. It is very important that you bring your child to her or his appointment every month during the RSV season. If you miss an appointment then contact your clinic to reschedule as soon as possible.

## What are the side effects of Synagis®?

Synagis® has few side effects. If side effects develop they are usually mild and do not last very long. Side effects may include:

- a mild fever
- a rash
- redness and soreness at the injection site.

Severe side effects are very rare.

## Can my child still receive their other immunizations?

Yes, Synagis® does not interfere with other immunizations. It can be given on the same day.

## If my child is sick can they still receive their Synagis®?

Usually yes. If your child is very sick with a high fever you should contact your doctor. Your doctor may want to wait until your child is well. On the other hand your doctor may feel that waiting to give the Synagis® may be a greater risk for your child. A mild fever or cold is usually not a reason to wait.

## Can my child still get RSV even if they are receiving Synagis®?

Yes, but the chance of getting so sick that she or he needs to be admitted to hospital is reduced. It is also important to know that Synagis® will not prevent other viral infections.

**Remember** – it is very important that your child receive all of her or his injections **on time** to be protected for the entire RSV season.

**Protect your child by coming every month for her or his Synagis injection.**

## 呼吸道合胞病毒嚴重嗎？

大部分感染了呼吸道合胞病毒（本文簡稱合胞病毒）的兒童都會在1至2周內出現輕微傷風的病徵。少數兒童則會出現較嚴重感染。這些兒童包括：

- 早產者
- 有長期肺病
- 有心臟病
- 未滿6個月大

## 何謂呼吸道合胞病毒（合胞病毒）？

合胞病毒是一種影響肺部和氣道的病毒，是嬰兒和兒童期間最常見的病毒之一。研究人員表示，幾乎所有兒童在屆滿3歲前均曾感染合胞病毒。這種病毒是引致兒童下呼吸道感染的最普遍成因。如要更詳盡了解肺部和呼吸道，可上網至：

[www.aboutkidshealth.ca/BCCH/En/HowTheBodyWorks](http://www.aboutkidshealth.ca/BCCH/En/HowTheBodyWorks)（英文網站）。

## 如何感染合胞病毒？

合胞病毒十分容易傳染。只要觸摸、親吻合胞病毒感染者，或與他們握手，病毒便會透過這些接觸傳播。另外，接觸工作枱、玩具、紙巾或任何其他表面，亦可以是傳播病毒的途徑。感染者接觸過的物件，便有合胞病毒在表面停留數小時。如果你的口、鼻或眼睛接觸到帶病毒的物件，或者你吸入患者打噴嚏或咳嗽濺出的飛沫，亦有機會受感染。合胞病毒全年均有，但在十一月至四月期間最為活躍。

如果你的子女屬於以下情況，便有較大機會感染合胞病毒：

- 上日託中心。
- 有兄弟姐妹上日託中心。
- 家中有5名或以上成員。
- 會接觸二手煙。
- 處身於稠密的環境。

## 呼吸道合胞病毒有何病徵？

呼吸道合胞病毒的病徵與普通傷風類似：

- 流鼻水或鼻塞
- 咳嗽
- 發低燒（低於38.5°C（攝氏）或101°F（華氏））
- 不會感到飢餓

如果病毒向下蔓延，引致肺部發炎，病徵便會惡化。徵

狀包括：

- 呼吸困難或急速
- 呼吸異常或間歇很長
- 發出喘聲
- 難於餵食

## 我何時要帶小孩看醫生？

如果小孩病情惡化，例如呼吸更急速、發出喘聲、發高燒或更難於餵食，你便須要帶小孩看醫生。如果小孩呼吸十分困難，你便要盡快帶他／她到急救部門。

## 我如何保障子女避免呼吸道合胞病毒？

- 清潔雙手然後才觸摸嬰兒，其他接觸嬰兒的人亦須要先洗手。你可以用溫水加肥皂，或者用含酒精的清潔劑。要了解如何能徹底清潔雙手，可上網至：[http://www.cw.bc.ca/library/pdf/pamphlets/PHSA311\\_HowToHandRubWash\\_2010\\_Dec17.pdf](http://www.cw.bc.ca/library/pdf/pamphlets/PHSA311_HowToHandRubWash_2010_Dec17.pdf)（英文網站）。
- 小孩要與傷風病患或感到不適者保持距離。換言之，如有家人或親友不適，請他們“不要到訪”。
- 合胞病毒高峰期間（十一月至四月）盡量避開人多聚集的地方，例如教會、日託中心及商場。
- 小孩應避開二手煙、剛剛吸煙或衣物仍有煙味的人士。
- 不要與患病不適者共用個人物品，例如杯、洗滌布及毛巾等。
- 母乳餵哺小孩有助保護他／她免受呼吸道合胞病毒感染。



## 甚麼是Synagis®？

Synagis®是一種藥物，專門幫助兒童身體抵抗一種名為呼吸道合胞病毒（簡稱合胞病毒）的嚴重病毒。在合胞病毒高峰期間，兒童每個月接受這種藥物一次，為期3至5個月。卑詩省的合胞病毒高峰期為十一月至四月。

## 為何我的子女需要接受Synagis®？

你的子女有較大機會出現嚴重的呼吸道合胞病毒感染。你的子女需要接受Synagis®，是出於醫生的指示。

## Synagis®如何服用？

Synagis®以針筒注射在大腿上。如果你的子女需要的Synagis®劑量多於1 ml（毫升），藥物會分成兩份，分別注射在兩邊大腿上。

## Synagis®是否類似子女接受的其他免疫注射？

**不是。**現在並無疫苗預防合胞病毒。Synagis®是一種抗體，功能類似兒童抵抗感染時天然製造的抗體。Synagis®的抗體可幫助兒童抵抗病毒約一個月。

## Synagis®是血液產品嗎？

**不是。**你的子女不會因接受Synagis®而受感染。

## 我的子女需要在整個高峰期每月接受一次注射嗎？

**是！**你的子女接受所有注射是很重要的。每次注射能保障小孩在約為30天內不至感染嚴重的呼吸道合胞病毒。在合胞病毒高峰期間，你必須帶小孩每個月接受注射。如果你未能按時赴約，請盡快聯絡診所重新預約時間。

## Synagis®有甚麼副作用？

Synagis®的副作用很少。如果有，一般也很輕微，而且不會持續長久。副作用或包括：

- 輕微發燒
- 出疹
- 注射部位發紅和疼痛。

嚴重的副作用非常罕見。

## 我的子女仍能接受其他免疫注射嗎？

**可以。**Synagis®不會干擾其他免疫注射。小孩可以同日接受疫苗。

## 如果我的子女感到不適，仍能接受Synagis®嗎？

**一般均可以。**如果子女感到非常不適，並發高燒，你便要帶她／他看醫生。醫生或要求小孩痊癒後才接受注射。但另一方面，醫生亦可能覺得拖延注射Synagis®對小孩構成更大風險。一般來說，輕微發燒或傷風，都不足以構成延遲注射的理由。

## 子女接受Synagis®後仍會感染呼吸道合胞病毒嗎？

**可以，**但嚴重不適以至需要入院治理的機會便可減低。家長須要知道，Synagis®不能預防其他病毒感染。

請緊記—子女在整個呼吸道合胞病毒高峰期，均需**按時**接受所有注射，才能獲得保障。

**保障子女，每月安排他們接受Synagis注射。**

## ਕੀ ਆਰ.ਐੱਸ.ਵੀ. ਗੰਭੀਰ ਹੈ?

ਆਰ.ਐੱਸ.ਵੀ. ਵਾਲਿਆਂ ਜ਼ਿਆਦਾਤਰ ਬੱਚਿਆਂ ਨੂੰ ਮਾਮੂਲੀ ਜਿਹਾ ਸਰਦੀ ਜ਼ੁਕਾਮ ਹੋ ਸਕਦਾ ਹੈ ਜੋ 1 ਤੋਂ 2 ਹਫ਼ਤਿਆਂ ਵਿੱਚ ਚਲਾ ਜਾਂਦਾ ਹੈ। ਕੁੱਝ ਬੱਚੇ ਜਿਹੇ ਬੱਚਿਆਂ ਵਿੱਚ ਆਰ.ਐੱਸ.ਵੀ. ਜ਼ਿਆਦਾ ਗੰਭੀਰ ਇਨਫੈਕਸ਼ਨ ਬਣ ਸਕਦੀ ਹੈ ਖਾਸ ਕਰ ਉਹ ਬੱਚੇ:

- ਜੋ ਸਮੇਂ ਤੋਂ ਪਹਿਲਾਂ ਪੈਦਾ ਹੋਏ ਹੋਣ
- ਜਿਨ੍ਹਾਂ ਨੂੰ ਫੇਫੜਿਆਂ ਦੀ ਪੱਕੀ ਬਿਮਾਰੀ ਹੈ
- ਜਿਨ੍ਹਾਂ ਨੂੰ ਦਿਲ ਦਾ ਰੋਗ ਹੈ
- ਜੋ 6 ਮਹੀਨਿਆਂ ਤੋਂ ਘੱਟ ਉਮਰ ਦੇ ਹਨ

## ਰੈਸਪੀਰੇਟਰੀ ਸਿੰਸੀਸ਼ੀਅਲ ਵਾਇਰਸ (ਆਰ.ਐੱਸ.ਵੀ.) ਕੀ ਹੈ?

ਆਰ.ਐੱਸ.ਵੀ. ਇੱਕ ਵਾਇਰਸ ਹੈ ਜੋ ਫੇਫੜਿਆਂ ਅਤੇ ਸਾਹ ਨਲੀ ਤੇ ਅਸਰ ਕਰਦਾ ਹੈ। ਬਚਪਨ ਦੀ ਉਮਰ ਵਿੱਚ ਇਹ ਇੱਕ ਆਮ ਵਾਇਰਸ ਹੈ। ਅਨੁਸੰਧਾਨ ਕਰਨ ਵਾਲਿਆਂ ਦਾ ਕਹਿਣਾ ਹੈ ਕਿ 3 ਸਾਲ ਦੀ ਉਮਰ ਤੱਕ ਤਕਰੀਬਨ ਸਾਰੇ ਬੱਚਿਆਂ ਨੂੰ ਆਰ.ਐੱਸ.ਵੀ. ਦਾ ਅਸਰ ਹੁੰਦਾ ਹੀ ਹੈ। ਬੱਚਿਆਂ ਦੀ ਸਾਹ ਨਲੀ ਦੇ ਹੇਠਲੇ ਹਿੱਸੇ ਵਿੱਚ ਇਨਫੈਕਸ਼ਨ ਦਾ ਕਾਰਨ ਜ਼ਿਆਦਾਤਰ ਇਹੀ ਵਾਇਰਸ ਹੁੰਦਾ ਹੈ। ਤੁਸੀਂ ਫੇਫੜਿਆਂ ਅਤੇ ਸਾਹ ਪ੍ਰਣਾਲੀ ਬਾਰੇ ਹੋਰ ਜ਼ਿਆਦਾ ਜਾਣਕਾਰੀ [www.aboutkidshealth.ca/BCCH/En/HowTheBodyWorks](http://www.aboutkidshealth.ca/BCCH/En/HowTheBodyWorks) ਵੈੱਬਸਾਈਟ ਤੋਂ ਲੈ ਸਕਦੇ ਹੋ।

## ਆਰ.ਐੱਸ.ਵੀ. ਕਿਵੇਂ ਹੋ ਜਾਂਦਾ ਹੈ?

ਆਰ.ਐੱਸ.ਵੀ. ਬੜੀ ਆਸਾਨੀ ਨਾਲ ਲੱਗ ਜਾਂਦਾ ਹੈ। ਇਹ ਆਰ.ਐੱਸ.ਵੀ. ਦੀ ਇਨਫੈਕਸ਼ਨ ਵਾਲੇ ਵਿਅਕਤੀ ਨੂੰ ਛੂਹਣ, ਚੁੰਮਣ ਜਾਂ ਹੱਥ ਮਿਲਾਉਣ ਨਾਲ ਫੈਲਦਾ ਹੈ। ਇਹ ਕਾਊਂਟਰਟਾਪ, ਖਿਡਾਉਣੇ, ਕਲੀਨੈਕਸ ਜਾਂ ਕਿਸੇ ਵੀ ਹੋਰ ਸਤਹ ਨੂੰ ਛੂਹਣ ਨਾਲ ਫੈਲ ਸਕਦਾ ਹੈ। ਕਿਉਂਕਿ ਇਨਫੈਕਸ਼ਨ ਵਾਲੇ ਵਿਅਕਤੀ ਦੁਆਰਾ ਇਹ ਚੀਜ਼ਾਂ ਛੂਹਣ ਤੋਂ ਬਾਅਦ ਆਰ.ਐੱਸ.ਵੀ. ਵਾਇਰਸ ਇਨ੍ਹਾਂ ਤੇ ਕਈ ਘੰਟਿਆਂ ਤੱਕ ਰਹਿ ਸਕਦਾ ਹੈ। ਜਦੋਂ ਦੂਸ਼ਿਤ ਚੀਜ਼ਾਂ ਤੁਹਾਡੇ ਮੂੰਹ, ਨੱਕ ਜਾਂ ਅੱਖਾਂ ਨੂੰ ਛੂੰਹਦੀਆਂ ਹਨ ਤਾਂ ਇਨਫੈਕਸ਼ਨ ਤੁਹਾਨੂੰ ਹੋ ਸਕਦੀ ਹੈ। ਇਨਫੈਕਸ਼ਨ ਵਾਲੇ ਵਿਅਕਤੀ ਦੁਆਰਾ ਨਿੱਛ ਮਾਰਨ ਜਾਂ ਖੰਘਣ ਨਾਲ ਹਵਾ ਵਿੱਚ ਫੈਲੀਆਂ ਬੂੰਦਾਂ ਸਾਹ ਨਾਲ ਅੰਦਰ ਜਾ ਕੇ ਵੀ ਤੁਹਾਨੂੰ ਇਨਫੈਕਟ ਕਰ ਸਕਦੀਆਂ ਹਨ। ਆਰ.ਐੱਸ.ਵੀ. ਤਕਰੀਬਨ ਸਾਰਾ ਸਾਲ ਹੀ ਰਹਿੰਦਾ ਹੈ ਪਰ ਨਵੰਬਰ ਤੋਂ ਅਪ੍ਰੈਲ ਤੱਕ ਜ਼ਿਆਦਾ ਸਰਗਰਮ ਹੁੰਦਾ ਹੈ।

ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ ਆਰ.ਐੱਸ.ਵੀ. ਹੋਣ ਦੇ ਜ਼ਿਆਦਾ ਚਾਂਸ ਹਨ ਜੇ:

- ਉਹ ਡੇ ਕੇਅਰ ਵਿੱਚ ਜਾਂਦਾ ਹੈ।
- ਉਸ ਦਾ ਛੋਟਾ ਭਰਾ/ਭੈਣ ਡੇ ਕੇਅਰ ਜਾਂਦਾ ਹੈ।
- ਉਹ 5 ਜਾਂ ਇਸ ਤੋਂ ਵੱਧ ਜੀਆਂ ਵਾਲੇ ਪਰਵਾਰ ਵਿੱਚ ਰਹਿੰਦਾ ਹੈ।
- ਉਸ ਨੂੰ ਤਮਾਕੂ ਦੇ ਪੁੱਠੇ ਵਿੱਚ ਸਾਹ ਲੈਂਦਾ ਹੈ।
- ਉਸ ਨੂੰ ਭੀੜ ਵਾਲੇ ਵਾਤਾਵਰਨ ਵਿੱਚ ਰਹਿੰਦਾ ਹੈ।

## ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਰੋਗ ਲੱਛਣ ਕੀ ਹਨ?

ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਰੋਗ ਲੱਛਣ ਆਮ ਤੌਰ ਤੇ ਸਰਦੀ ਜ਼ੁਕਾਮ ਜਿਹੇ ਹੀ ਹੁੰਦੇ ਹਨ:

- ਨੱਕ ਵਗਣਾ ਜਾਂ ਬੰਦ ਹੋਣਾ
- ਖੰਘ
- ਹਲਕਾ ਜਿਹਾ ਬੁਖਾਰ (38.5° C ਜਾਂ 101° F ਤੋਂ ਘੱਟ)
- ਭੁੱਖ ਨਾ ਲੱਗਣੀ

ਜੇ ਵਾਇਰਸ ਕਾਫੀ ਹੇਠਾਂ ਜਾ ਕੇ ਫੇਫੜਿਆਂ ਵਿੱਚ ਸੋਜਸ਼ ਪੈਦਾ ਕਰ ਦੇਵੇ ਤਾਂ ਇਹ ਲੱਛਣ ਗੰਭੀਰ ਹੋ ਸਕਦੇ ਹਨ। ਇਸ ਦੀਆਂ ਨਿਸ਼ਾਨੀਆਂ ਵਿੱਚ ਇਹ ਸ਼ਾਮਲ ਹੋ ਸਕਦੇ ਹਨ:

- ਸਾਹ ਲੈਣ ਵਿੱਚ ਤਕਲੀਫ਼ ਜਾਂ ਸਾਹ ਤੇਜ਼ ਆਉਣਾ
- ਅਸਾਧਾਰਨ ਜਾਂ ਸਾਹ ਕਾਫੀ ਦੇਰ ਬਾਅਦ ਆਉਣਾ
- ਸਾਹ ਵਿੱਚ ਘਰਰ ਘਰਰ ਦੀ ਅਵਾਜ਼ ਹੋਣਾ
- ਖਾਣ ਪੀਣ ਵਿੱਚ ਤਕਲੀਫ਼

## ਮੈਂ ਆਪਣੇ ਬੱਚੇ ਨੂੰ ਡਾਕਟਰ ਕੋਲ ਕਦੋਂ ਲੈ ਕੇ ਜਾਵਾਂ?

ਜੇ ਤੁਹਾਡਾ ਬੱਚਾ ਤੇਜ਼ ਸਾਹ, ਸਾਹ ਵਿੱਚ ਘਰਰ ਘਰਰ ਦੀ ਅਵਾਜ਼ ਜਾਂ ਤੇਜ਼ ਟੈਂਪਰੇਚਰ ਨਾਲ ਬਿਮਾਰ ਹੁੰਦਾ ਨਜ਼ਰ ਆਉਂਦਾ ਹੈ ਅਤੇ ਖਾਣ ਪੀਣ ਵਿੱਚ ਬਹੁਤ ਤਕਲੀਫ਼ ਮਹਿਸੂਸ ਕਰਦਾ ਹੈ ਤਾਂ ਬੱਚਾ ਡਾਕਟਰ ਨੂੰ ਦਿਖਾਉਣਾ ਚਾਹੀਦਾ ਹੈ। ਜੇ ਸਾਹ ਲੈਣ ਵਿੱਚ ਜ਼ਿਆਦਾ ਤਕਲੀਫ਼ ਹੋ ਰਹੀ ਹੋਵੇ ਤਾਂ ਜਿੰਨੀ ਜਲਦੀ ਹੋ ਸਕੇ ਅਮਰਜੈਸੀ ਵਿੱਚ ਲੈ ਜਾਣਾ ਚਾਹੀਦਾ ਹੈ।

## ਮੈਂ ਆਪਣੇ ਬੱਚੇ ਨੂੰ ਆਰ.ਐੱਸ.ਵੀ. ਤੋਂ ਕਿਵੇਂ ਬਚਾਵਾਂ?

- ਬੱਚੇ ਨੂੰ ਹੱਥ ਲਗਾਉਣ ਤੋਂ ਪਹਿਲਾਂ ਹਰ ਵਾਰ **ਆਪਣੇ ਹੱਥ ਧੋਣੇ** ਅਤੇ ਬਾਕੀਆਂ ਨੂੰ ਵੀ ਇਸ ਤਰ੍ਹਾਂ ਕਰਨ ਲਈ ਕਹੋ। ਇਸ ਲਈ ਤੁਸੀਂ ਗਰਮ ਪਾਣੀ ਅਤੇ ਸਾਬਣ ਜਾਂ ਅਲਕੋਹਲ ਆਧਾਰਤ ਪਦਾਰਥ ਵਰਤੋ। ਚੰਗੀ ਤਰ੍ਹਾਂ ਹੱਥ ਧੋਣ ਲਈ ਹੋਰ ਜ਼ਿਆਦਾ ਜਾਣਕਾਰੀ [http://www.cw.bc.ca/library/pdf/pamphlets/PHSA311\\_HowToHandRubWash\\_2010\\_Dec17.pdf](http://www.cw.bc.ca/library/pdf/pamphlets/PHSA311_HowToHandRubWash_2010_Dec17.pdf) ਵੈੱਬਸਾਈਟ ਤੇ ਉਪਲਬਧ ਹੈ।
- ਸਰਦੀ ਜ਼ੁਕਾਮ ਵਾਲੇ ਜਾਂ ਬਿਮਾਰ ਲੋਕਾਂ ਤੋਂ ਆਪਣੇ ਬੱਚੇ ਨੂੰ ਦੂਰ ਰੱਖੋ। **ਇਸ ਵਿੱਚ ਇਹ ਕਹਿਣਾ ਵੀ ਸ਼ਾਮਲ ਹੈ ਕਿ ਉਨ੍ਹਾਂ ਪਰਵਾਰਾਂ ਅਤੇ ਦੋਸਤਾਂ ਨੂੰ ਵੀ “ਮਿਲਨ ਨਹੀਂ ਜਾਣਾ” ਜੋ ਬਿਮਾਰ ਹਨ।**
- ਨਵੰਬਰ ਤੋਂ ਅਪ੍ਰੈਲ ਦੇ ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਮੌਸਮ ਵਿੱਚ ਭੀੜ ਵਾਲੀਆਂ ਜਗ੍ਹਾਂ ਜਿਵੇਂ ਕਿ ਗੁਰਦੁਆਰਾ/ਮੰਦਰ/ਚਰਚ, ਡੇ ਕੇਅਰ ਸੈਂਟਰ ਅਤੇ ਚੀਜ਼ਾਂ ਖ਼ੀਦਣ ਲਈ ਮਾਲਜ਼ ਵਿੱਚ ਜਾਣ ਤੋਂ ਪਰਹੇਜ਼ ਕਰੋ।
- ਆਪਣੇ ਬੱਚੇ ਨੂੰ ਤਮਾਕੂ ਦੇ ਪੁੱਠੇ, ਜਿਨ੍ਹਾਂ ਨੇ ਹੁਣੇ ਸਿਗਰਟ ਪੀਤੀ ਹੋਵੇ ਅਤੇ ਉਹ ਕੱਪੜੇ ਜਿਨ੍ਹਾਂ ਵਿੱਚੋਂ ਤਮਾਕੂ ਦੇ ਪੁੱਠੇ ਦੀ ਗੰਧ ਆਉਂਦੀ ਹੋਵੇ ਤੋਂ ਦੂਰ ਰੱਖੋ।
- ਬਿਮਾਰ ਲੋਕਾਂ ਨਾਲ ਆਪਣੀਆਂ ਚੀਜ਼ਾਂ ਜਿਵੇਂ ਕਿ ਕੱਪ, ਨਹਾਉਣ ਵਾਲੇ ਕੱਪੜੇ ਅਤੇ ਤੌਲੀਏ ਸਾਂਝੇ ਨਾ ਕਰੋ। ਬੱਚੇ ਨੂੰ ਆਪਣਾ ਦੁੱਧ ਚੁੰਘਾਓ। ਇਸ ਨਾਲ ਤੁਹਾਡੇ ਬੱਚੇ ਦਾ ਆਰ.ਐੱਸ.ਵੀ. ਹੋਣ ਤੋਂ ਬਚਾਅ ਹੋ ਸਕਦਾ ਹੈ।

## ਸਾਈਨੇਜਿਸ (Synagis®) ਕੀ ਹੈ?

ਇਹ ਇੱਕ ਦਵਾਈ ਹੈ ਜੋ ਗੰਭੀਰ ਰੈਸਪੀਰੇਟਰੀ ਸਿੰਸੀਸੀਅਲ ਵਾਇਰਸ ਜਿਸ ਨੂੰ ਆਰ.ਐੱਸ.ਵੀ. ਵੀ ਕਹਿੰਦੇ ਹਨ ਦੇ ਵਿਰੁੱਧ ਲੜਨ ਲਈ ਬੱਚੇ ਦੇ ਸਰੀਰ ਦੀ ਮਦਦ ਕਰਦੀ ਹੈ। ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਮੌਸਮ ਦੌਰਾਨ 3 ਤੋਂ 5 ਮਹੀਨਿਆਂ ਲਈ ਹਰ ਮਹੀਨੇ ਦਿੱਤੀ ਜਾਂਦੀ ਹੈ। ਬੀ.ਸੀ. ਵਿਚ ਨਵੰਬਰ ਤੋਂ ਅਪ੍ਰੈਲ ਤੱਕ ਆਰ.ਐੱਸ.ਵੀ. ਦਾ ਮੌਸਮ ਹੁੰਦਾ ਹੈ।

## ਮੇਰੇ ਬੱਚੇ ਨੂੰ ਸਾਈਨੇਜਿਸ ਕਿਉਂ ਤਜਵੀਜ਼ ਕੀਤੀ ਗਈ ਹੈ?

ਕਿਉਂਕਿ ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ ਗੰਭੀਰ ਆਰ.ਐੱਸ.ਵੀ. ਇਨਫੈਕਸ਼ਨ ਹੋਣ ਦਾ ਜ਼ਿਆਦਾ ਖਤਰਾ ਹੈ। ਇਸ ਲਈ ਤੁਹਾਡੇ ਡਾਕਟਰ ਨੇ ਬੱਚੇ ਨੂੰ ਸਾਈਨੇਜਿਸ ਲੈਣ ਲਈ ਕਿਹਾ ਹੈ।

## ਸਾਈਨੇਜਿਸ ਕਿਵੇਂ ਦਿੱਤੀ ਜਾਂਦੀ ਹੈ?

ਇਹ ਸੂਈ ਨਾਲ ਪੱਟ ਦੇ ਪੱਠਿਆਂ ਵਿਚ ਦਿੱਤੀ ਜਾਂਦੀ ਹੈ। ਜੇ ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ 1 ਮਿ.ਲੀ. ਤੋਂ ਜ਼ਿਆਦਾ ਸਾਈਨੇਜਿਸ ਦੇਣ ਦੀ ਲੋੜ ਹੋਵੇ ਤਾਂ ਦਵਾਈ ਨੂੰ ਵੱਡੇ ਕੇ ਦੋਹਾਂ ਪੱਟਾਂ ਵਿਚ ਇਸ ਦਾ ਟੀਕਾ ਲਗਾਇਆ ਜਾਂਦਾ ਹੈ।

## ਕੀ ਸਾਈਨੇਜਿਸ ਉਹੋ ਜਿਹਾ ਵੈਕਸੀਨ ਹੈ ਜੋ ਮੇਰਾ ਬੱਚੇ ਇਮਿਊਨਾਈਜ਼ੇਸ਼ਨ ਲਈ ਲੈਂਦਾ ਹੈ?

**ਨਹੀਂ।** ਆਰ.ਐੱਸ.ਵੀ. ਲਈ ਕੋਈ ਵੈਕਸੀਨ ਉਪਲਬਧ ਨਹੀਂ। ਸਾਈਨੇਜਿਸ ਇੱਕ ਕਿਸਮ ਦੀ ਐਂਟੀਬਾਡੀ (Antibody) ਹੈ। ਇਹ ਉਨ੍ਹਾਂ ਐਂਟੀਬਾਡੀ ਦੀ ਤਰ੍ਹਾਂ ਹੀ ਕੰਮ ਕਰਦੀ ਹੈ ਜੋ ਤੁਹਾਡੇ ਬੱਚੇ ਦਾ ਸਰੀਰ ਇਨਫੈਕਸ਼ਨ ਨਾਲ ਲੜਣ ਲਈ ਕੁਦਰਤੀ ਬਣਾਉਂਦਾ ਹੈ। ਸਾਈਨੇਜਿਸ ਵਿਚਲੀਆਂ ਐਂਟੀਬਾਡੀ ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ ਤਕਰੀਬਨ 1 ਮਹੀਨੇ ਲਈ ਮਦਦ ਕਰਦੀਆਂ ਹਨ।

## ਕੀ ਸਾਈਨੇਜਿਸ ਖੂਨ ਤੋਂ ਬਣਦਾ ਹੈ?

**ਨਹੀਂ।** ਸਾਈਨੇਜਿਸ ਤੋਂ ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ ਇਨਫੈਕਸ਼ਨ ਹੋਣ ਦਾ ਕੋਈ ਚਾਂਸ ਨਹੀਂ।

## ਕੀ ਮੇਰੇ ਬੱਚੇ ਨੂੰ ਮਹੀਨੇ ਵਾਰ ਸਾਰੇ ਟੀਕੇ ਲਵਾਉਣੇ ਪੈਣਗੇ?

**ਹਾਂ ਜੀ।** ਇਹ ਬੜਾ ਜ਼ਰੂਰੀ ਹੈ ਕਿ ਤੁਹਾਡਾ ਬੱਚਾ ਸਾਰੇ ਟੀਕੇ ਲਵਾਏ। ਹਰ ਇੱਕ ਟੀਕਾ ਆਰ.ਐੱਸ.ਵੀ. ਦੀ ਗੰਭੀਰ ਇਨਫੈਕਸ਼ਨ ਤੋਂ ਤੁਹਾਡੇ ਬੱਚੇ ਨੂੰ ਤਕਰੀਬਨ 30 ਦਿਨਾਂ ਲਈ ਬਚਾਉਂਦਾ ਹੈ। ਇਸ ਲਈ ਇਹ ਬੜਾ ਜ਼ਰੂਰੀ ਹੈ ਕਿ ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਮੌਸਮ ਵਿਚ ਹਰ ਮਹੀਨੇ ਬੱਚੇ ਦੀ ਐਪੁਆਇੰਟਮੈਂਟ ਤੇ ਤੁਸੀਂ ਬੱਚੇ ਨੂੰ ਲੈ ਕੇ ਆਓ। ਜੇ ਤੁਸੀਂ ਇੱਕ ਵਾਰ ਨਾ ਆ ਸਕੋ ਤਾਂ ਆਪਣੇ ਕਲੀਨਿਕ ਨੂੰ ਸੰਪਰਕ ਕਰ ਕੇ ਜਿੰਨੀ ਜਲਦੀ ਹੋ ਸਕੇ ਦੁਬਾਰਾ ਐਪੁਆਇੰਟਮੈਂਟ ਬਣਾਓ।

## ਸਾਈਨੇਜਿਸ ਦੇ ਗੋਣ ਪ੍ਰਭਾਵ ਕੀ ਹਨ?

ਸਾਈਨੇਜਿਸ ਦੇ ਕੁੱਝ ਕੁ ਗੋਣ ਪ੍ਰਭਾਵ ਹਨ। ਜੇ ਗੋਣ ਪ੍ਰਭਾਵ ਪੈਦਾ ਹੋਣ ਤਾਂ ਬਹੁਤ ਮਮੂਲੀ ਹੁੰਦੇ ਹਨ ਅਤੇ ਜ਼ਿਆਦਾ ਦੇਰ ਨਹੀਂ ਰਹਿੰਦੇ। ਗੋਣ ਪ੍ਰਭਾਵਾਂ ਵਿਚ ਇਹ ਸ਼ਾਮਲ ਹੋ ਸਕਦੇ ਹਨ:

- ਹਲਕਾ ਜਿਹਾ ਬੁਖਾਰ
- ਧੱਫੜ (ਰੈਸ)
- ਟੀਕੇ ਵਾਲੀ ਜਗ੍ਹਾ ਲਾਲ ਹੋਣੀ ਅਤੇ ਦੁਖਣੀ।

ਗੰਭੀਰ ਗੋਣ ਪ੍ਰਭਾਵ ਬਹੁਤ ਹੀ ਘੱਟ ਹੁੰਦੇ ਹਨ।

## ਕੀ ਮੇਰਾ ਬੱਚਾ ਹੋਰ ਇਮਿਊਨਾਈਜ਼ੇਸ਼ਨ ਵੀ ਲੈ ਸਕਦਾ ਹੈ?

**ਹਾਂ ਜੀ।** ਸਾਈਨੇਜਿਸ ਹੋਰ ਇਮਿਊਨਾਈਜ਼ੇਸ਼ਨ ਵਿਚ ਰੁਕਾਵਟ ਨਹੀਂ ਪਾਉਂਦਾ। ਇਹ ਉਸੇ ਦਿਨ ਦਿੱਤਾ ਜਾ ਸਕਦਾ ਹੈ।

## ਜੇ ਮੇਰਾ ਬੱਚਾ ਬਿਮਾਰ ਹੈ ਤਾਂ ਕੀ ਉਹ ਫਿਰ ਵੀ ਸਾਈਨੇਜਿਸ ਲੈ ਸਕਦਾ ਹੈ?

**ਆਮ ਤੌਰ ਤੇ ਹਾਂ।** ਜੇ ਤੁਹਾਡਾ ਬੱਚਾ ਤੇਜ਼ ਬੁਖਾਰ ਕਰ ਕੇ ਬਹੁਤ ਬਿਮਾਰ ਹੈ ਤਾਂ ਆਪਣੇ ਡਾਕਟਰ ਨੂੰ ਸੰਪਰਕ ਕਰੋ। ਜਦ ਤੱਕ ਤੁਹਾਡਾ ਬੱਚਾ ਠੀਕ ਨਹੀਂ ਹੋ ਜਾਂਦਾ ਤੁਹਾਡਾ ਡਾਕਟਰ ਸ਼ਾਇਦ ਠਹਿਰਨ ਲਈ ਕਹੇ। ਇਹ ਵੀ ਹੋ ਸਕਦਾ ਹੈ ਕਿ ਡਾਕਟਰ ਮਹਿਸੂਸ ਕਰੇ ਕਿ ਸਾਈਨੇਜਿਸ ਲੈਣ ਲਈ ਠਹਿਰਨਾ ਬੱਚੇ ਲਈ ਜ਼ਿਆਦਾ ਖਤਰਨਾਕ ਹੈ। ਮਮੂਲੀ ਬੁਖਾਰ ਜਾਂ ਠੰਢ ਠਹਿਰਨ ਲਈ ਕੋਈ ਕਾਰਨ ਨਹੀਂ ਹਨ।

## ਜੇ ਮੇਰਾ ਬੱਚਾ ਸਾਈਨੇਜਿਸ ਲੈ ਰਿਹਾ ਹੈ ਤਾਂ ਕੀ ਉਹ ਫਿਰ ਵੀ ਆਰ.ਐੱਸ.ਵੀ. ਲੈ ਸਕਦਾ ਹੈ?

**ਹਾਂ ਜੀ।** ਪਰ ਉਸ ਦੇ ਇਤਨਾ ਬਿਮਾਰ ਹੋਣ ਦੇ ਚਾਂਸ ਬਹੁਤ ਘੱਟ ਜਾਂਦੇ ਹਨ ਕਿ ਉਸ ਨੂੰ ਹਸਪਤਾਲ ਦਾਖਲ ਹੋਣਾ ਪਵੇ। ਇਹ ਜਾਣਨਾ ਵੀ ਬੜਾ ਜ਼ਰੂਰੀ ਹੈ ਕਿ ਸਾਈਨੇਜਿਸ ਕਿਸੇ ਹੋਰ ਵਾਇਰਲ ਇਨਫੈਕਸ਼ਨ ਨੂੰ ਨਹੀਂ ਚੋਕੇਗਾ।

ਯਾਦ ਰੱਖੋ - ਇਹ ਬੜਾ ਜ਼ਰੂਰੀ ਹੈ ਕਿ ਆਰ.ਐੱਸ.ਵੀ. ਦੇ ਸਾਰੇ ਮੌਸਮ ਦੌਰਾਨ ਸੁਰੱਖਿਆ ਲਈ ਤੁਹਾਡਾ ਬੱਚਾ ਸਾਰੇ ਟੀਕੇ **ਸਮੇਂ ਸਿਰ** ਲਵਾ ਲਵੇ।

**ਹਰ ਮਹੀਨੇ ਬੱਚੇ ਦੇ ਸਾਈਨੇਜਿਸ ਦੇ ਟੀਕੇ ਲਈ ਆ ਕੇ ਆਪਣੇ ਬੱਚੇ ਨੂੰ ਸੁਰੱਖਿਅਤ ਕਰੋ।**



As part of BC's RSV Program your child will receive up to 4 doses of palivizumab (brand name Synagis®). Palivizumab is given by intramuscular injection into your child's leg muscle. Depending on your child's weight they may receive 1 or 2 injections with each visit.

Any of these pain management measures may help your child during the injection.

### BREASTFEEDING

- The combined aspects of holding your child, skin-to-skin contact, the sweet-tasting milk, and the act of sucking helps to reduce discomfort.
- If possible, start breastfeeding your child a few minutes before the injection and continue to breastfeed during the injection and a few minutes after the injection.

### HOLD YOUR CHILD UPRIGHT

- Infants and young children are best held upright, unless breastfeeding (i.e., bear hug on your lap.) Hugging feels comfortable and helps your child stay still.
- Hold and support your child but without using excessive force or restraint.

### DISTRACTION

- Distraction can be provided by a parent or health care professional.
- Directing your child's attention away from the procedure can help discomfort, such as to something in the room or something you can show them.
- Choose something that will work for the age of your child. For instance:
  - Babies: toys, bubbles, singing
  - Toddlers: toys, bubbles, pop-up books, songs, party blowers

### SUCROSE THERAPY

- This therapy works through activation of sweet taste receptors and distraction.
- It is recommended as an option for children under 12 months old who are not breastfeeding.
- Sucrose therapy should be only used for the management of painful procedures, not for general comfort or as food.
- Please discuss with a member of the RSV team as to where sucrose preparations may be purchased and how they are used.

Please remember these measures are intended to **reduce** or manage your child's discomfort. Measures typically work best when used in combinations. After each injection, watch for your child's response and assess if the measures used are helping your child cope with the discomfort of intramuscular injections. Discuss any concerns with your health care provider.

### WHAT IS AN INFECTION?

- An infection is caused by germs (bacteria, viruses or fungi).
- Some germs on or in your body are helpful and some germs are harmful.
- An infection occurs when harmful germs get into body tissues or fluids and grow.

### WHAT ARE COMMON SITES OF INFECTION?

Common sites of infection are:

- The bowel;
- The top of the head;
- The lungs;
- The nose;
- The skin;
- The stomach;
- The throat; or
- Inside the middle ear.

### BEST WAYS TO AVOID INFECTION

Cleaning your hands and your children's hands is the best way to stop the spread of germs. A thorough, careful wash is even more effective. For best results:

1. Wet hands first.
2. Lather with soap and rub hands for 10 to 15 seconds – about the same amount of time as singing the alphabet. Wash all areas, including between your fingers/thumbs and the backs of your hands.
3. Rinse hands well.
4. Dry with a clean towel.

When water and soap are not available, use a hand sanitizer. Keep hand sanitizer out of reach of young children because they may be harmful if swallowed. To apply hand sanitizer:

1. Put hand sanitizer on the palm of one hand.
2. Rub hands together, covering all surfaces of hands and fingers with the hand sanitizer.
3. Rub until dry.

### HOW TO PREVENT AND INFECTION IN THE NOSE, THROAT OR LUNGS

Germs that grow in the nose, throat or lungs are spread:

- in the droplets from a cough
- in the mucus from the lungs or nose

An infection spreads when the droplets or mucus from a person with an infection get in the lining of your child's nose, throat or lungs. An infection can spread to your child when:

- the sick person coughs right into your child's face
- germs from the sick person get onto the hands of someone who then touches your child
- germs from the sick person get onto cups, toys or other objects that your child then touches

*[continued on following page]*

**TO PREVENT YOUR CHILD FROM GETTING AN INFECTION IN THE NOSE, THROAT OR LUNGS:**

**IN HOSPITAL:**

- clean your hands with soap and water or a hand sanitizer before and after caring for your baby
- keep your baby in your hospital room with you as much as possible
- do not allow visitors with colds or flu to visit your baby
- breast feeding helps protect your baby from infections, including RSV

**AT HOME:**

- Keep baby away from places where there are people with colds such as shopping malls or schools
- Teach children to **cover their coughs**. Turn away and cough into a tissue (or their sleeve if a tissue cannot be found) when they cough or sneeze. Teach them not give baby toys or other objects that have been used by a sick person and to teach them to **clean their hands**.
- **Clean your hands** after blowing your nose/coughing/sneezing/wiping or blowing your child's nose
- Use a tissue (only once)
- Clean your hands after being with a sick person

The best way to prevent your baby from getting an infection are to clean your hands & to keep baby away from people with colds or flu!

**IF YOU HAVE ANY QUESTIONS CALL:**

- Your doctor
- A nurse or nursing station [BC's nurse line can be reached by phoning 811]

*Based on "How to Prevent your Child from Getting or Spreading an Infection",  
by the Children's Hospital Patient Education Committee of the Winnipeg Regional Health Authority, ©2011.*

*These guidelines are applicable to the BC RSV Immunoprophylaxis Program as well.*



# Adverse Event Following Immunization (AEFI) Case Report Form

### INSTRUCTIONS

- Complete this reporting form for AEFIs which have a temporal association with a vaccine and which cannot be clearly attributed to other causes. For Temporal Reporting Criteria by Event see Page 4 of this form.
- Enter into Panorama or PARIS.
- When completed, submit form to your local health unit. See the AEFI reporting map [here](#).
- Additional information on reporting criteria, clinical management and interpretation of AEFIs and implications for subsequent immunization, please refer to [Immunizations Program Manual, Section IX - Adverse Events Following Immunization](#).

A. CLIENT INFORMATION							
First name:		Last name:			PHN:		
Address:							
Province:			Postal code:			Phone: (    )	
Date of birth (YYYY/MM/DD):						Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other	
ADVERSE EVENT ID:				IMPACT LIN:			
PATIENT'S PHYSICIAN (OR PRIMARY CARE PROVIDER)							
First name:				Last name:			
Address:				Phone: (    )		Fax: (    )	
REPORTER INFORMATION							
Setting: <input type="checkbox"/> Physician office <input type="checkbox"/> Public health <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify:							
Name:		Phone: (    )			ext.	Fax: (    )	
Address:					Branch Office:		
Province/Territory:			Postal code:		Date reported (YYYY/MM/DD):		
Signature:				<input type="checkbox"/> MD <input type="checkbox"/> RN <input type="checkbox"/> IMPACT <input type="checkbox"/> Other, specify:			
B. IMMUNIZATION DATA							
Immunizing agent	Trade name	Manufacturer	Lot number	Dose #	Dosage/unit	Route	Site
C. INFORMATION AT TIME OF IMMUNIZATION AND AEFI ONSET							
Province/Territory of immunization:					Age at onset:		
Date vaccine administered (YYYY/MM/DD):					(hr: <input type="checkbox"/> am/ <input type="checkbox"/> pm)		
Health Care Provider who administered the vaccine:					Phone: (    )		
Address:							
<b>Did an AEFI follow a previous dose of any of the above immunizing agents listed in section B?</b>							
<input type="checkbox"/> No <input type="checkbox"/> Not applicable (no prior doses) <input type="checkbox"/> Unknown <input type="checkbox"/> Yes (If <b>yes</b> , provide details in section G.)							
<b>Did this AEFI follow an incorrect immunization?</b>							
<input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Yes (If <b>yes</b> , choose all that apply and provide details in section 10.):							
<input type="checkbox"/> Given outside the recommended age limits		<input type="checkbox"/> Product expired		<input type="checkbox"/> Dose exceeded that recommended for age			
<input type="checkbox"/> Wrong vaccine given		<input type="checkbox"/> Incorrect route		<input type="checkbox"/> Other, specify:			
<b>Medical history</b> (up to time of AEFI onset). Check all that apply and provide details in section G.							
<input type="checkbox"/> Concomitant medication(s)		<input type="checkbox"/> Known medical conditions/allergies			<input type="checkbox"/> Acute illness/injury		



# Adverse Event Following Immunization (AEFI) Case Report Form

<b>D. AEFI DETAILS:</b> Complete all section as appropriate. For each check all signs/symptoms that apply. Item(s) with asterisk (*) should be diagnosed by a physician. If not, provide sufficient information to support the selected item(s). Use Section G for additional information including clinical details and test results.					
<b>Local reaction at or near injection site</b>					
<b>Onset:</b>	Min.	Hrs.	Days from immunization to onset of 1 <sup>st</sup> symptom/sign		
<b>Duration:</b>	Min.	Hrs.	Days from 1 <sup>st</sup> symptom/sign to resolution of all symptoms/signs		<input type="checkbox"/> Unresolved
<input type="checkbox"/> Infected abscess* <input type="checkbox"/> Sterile abscess* <input type="checkbox"/> Cellulitis* <input type="checkbox"/> Nodule <input type="checkbox"/> Reaction crosses joint <input type="checkbox"/> Lymphadenitis*					
<input type="checkbox"/> Other, specify:					
<b>For any injection site reaction indicated above, check all that apply and provide details in section G:</b>					
<input type="checkbox"/> Swelling <input type="checkbox"/> Pain <input type="checkbox"/> Tenderness <input type="checkbox"/> Erythema <input type="checkbox"/> Warmth <input type="checkbox"/> Induration <input type="checkbox"/> Rash					
Specify largest diameter of vaccination site reaction (cm):			Site(s) of reaction (e.g., LA, RA):		
<input type="checkbox"/> Palpable fluctuance <input type="checkbox"/> Fluid collection shown by imaging technique (e.g., MRI, CT, ultrasound)					
<input type="checkbox"/> Spontaneous/surgical drainage <input type="checkbox"/> Microbial results <input type="checkbox"/> Lymphangitic streaking <input type="checkbox"/> Regional lymphadenopathy					
<b>Anaphylaxis and other allergic events</b>					
<input type="checkbox"/> Anaphylaxis <input type="checkbox"/> Other allergic events					
<b>Onset:</b>	Min.	Hrs.	Days from immunization to onset of 1 <sup>st</sup> symptom/sign		
<b>Duration:</b>	Min.	Hrs.	Days from 1 <sup>st</sup> symptom/sign to resolution of all symptoms/signs		<input type="checkbox"/> Unresolved
<b>For the event indicated above, select all symptoms/signs that apply.</b>					
<b>Skin/mucosal:</b>	<input type="checkbox"/> <b>Generalized:</b> <input type="checkbox"/> At Injection Site <input type="checkbox"/> Non-Injection Site <input type="checkbox"/> Urticaria <input type="checkbox"/> Erythema <input type="checkbox"/> Pruritus <input type="checkbox"/> Prickly sensation				
	<input type="checkbox"/> <b>Localized:</b> <input type="checkbox"/> Injection site <input type="checkbox"/> Non-injection site <input type="checkbox"/> Urticaria <input type="checkbox"/> Erythema <input type="checkbox"/> Pruritus <input type="checkbox"/> Prickly sensation				
	<b>Eye(s):</b> <input type="checkbox"/> Red <input type="checkbox"/> Itchy				
	<b>Angioedema:</b> <input type="checkbox"/> Tongue <input type="checkbox"/> Throat <input type="checkbox"/> Uvula <input type="checkbox"/> Larynx <input type="checkbox"/> Lip <input type="checkbox"/> Eyelids <input type="checkbox"/> Limbs <input type="checkbox"/> Other, specify:				
<b>Cardiovascular:</b>	<input type="checkbox"/> Measured hypotension <input type="checkbox"/> ↓ central pulse volume <input type="checkbox"/> Capillary refill time >3 sec <input type="checkbox"/> Tachycardia <input type="checkbox"/> ↓ or loss of consciousness:				
<b>Respiratory:</b>	<input type="checkbox"/> Sneezing <input type="checkbox"/> Rhinorrhea <input type="checkbox"/> Hoarse voice <input type="checkbox"/> Sensation of throat closure <input type="checkbox"/> Stridor <input type="checkbox"/> Dry cough <input type="checkbox"/> Tachypnea <input type="checkbox"/> Wheezing <input type="checkbox"/> Indrawing/retractions <input type="checkbox"/> Grunting <input type="checkbox"/> Cyanosis				
<b>Gastrointestinal:</b>	<input type="checkbox"/> Diarrhea <input type="checkbox"/> Abdominal pain <input type="checkbox"/> Nausea <input type="checkbox"/> Vomiting				
<b>Neurologic event</b>					
<b>Onset:</b>	Min.	Hrs.	Days from immunization to onset of 1 <sup>st</sup> symptom/sign		
<b>Duration:</b>	Min.	Hrs.	Days from 1 <sup>st</sup> symptom/sign to resolution of all symptoms/signs		<input type="checkbox"/> Unresolved
<input type="checkbox"/> <b>Seizure(s) (Check all that apply):</b>					
<input type="checkbox"/> Witnessed by health care professional <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Sudden loss of consciousness <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Focal: <input type="checkbox"/> Tonic <input type="checkbox"/> Clonic <input type="checkbox"/> Tonic-clonic <input type="checkbox"/> Atonic <input type="checkbox"/> Generalized: <input type="checkbox"/> Tonic <input type="checkbox"/> Clonic <input type="checkbox"/> Tonic-clonic <input type="checkbox"/> Atonic <input type="checkbox"/> Previous history of seizures: <input type="checkbox"/> Febrile <input type="checkbox"/> Afebrile <input type="checkbox"/> Unknown types					
<input type="checkbox"/> Meningitis* <input type="checkbox"/> Encephalopathy/Encephalitis* <input type="checkbox"/> Guillain-Barre Syndrome (GBS)* <input type="checkbox"/> Bell's Palsy*					
<input type="checkbox"/> Other paralysis <input type="checkbox"/> Other neurological diagnosis, specify:					
<b>For any neurological event indicated above, check all that apply and provide details in section G.</b>					
<input type="checkbox"/> Depressed/altered level of consciousness/Lethargy/ Personality change lasting ≥24 hrs <input type="checkbox"/> Focal or multifocal neurologic sign(s)					
<input type="checkbox"/> Fever (≥38°C) <input type="checkbox"/> CSF abnormality <input type="checkbox"/> EEG abnormality <input type="checkbox"/> EMG abnormality					
<input type="checkbox"/> Neuroimaging abnormality <input type="checkbox"/> Brain/spinal cord histopathologic abnormality					





# Adverse Event Following Immunization (AEFI) Case Report Form

Other defined events of interest			
<b>Onset:</b>	Min.	Hrs.	Days from immunization to onset of 1 <sup>st</sup> symptom/sign
<b>Duration:</b>	Min.	Hrs.	Days from 1 <sup>st</sup> symptom/sign to resolution of all symptoms/signs <input type="checkbox"/> Unresolved
<input type="checkbox"/> <b>Hypotonic-Hyporesponsive Episode* (age &lt;2 years):</b>			
<input type="checkbox"/> Limpness <input type="checkbox"/> Pallor/cyanosis <input type="checkbox"/> Reduced responsiveness/unresponsiveness			
<input type="checkbox"/> <b>Persistent crying</b> (continuous and unaltered crying for ≥3 hours)			
<input type="checkbox"/> <b>Rash</b> (For rash at injection site or rash in allergic reaction, use other section.):			
<input type="checkbox"/> Generalized <input type="checkbox"/> Localized at non-injection site			
<input type="checkbox"/> <b>Intussusception*</b>			
<input type="checkbox"/> <b>Arthritis*:</b> <input type="checkbox"/> Joint redness <input type="checkbox"/> Joint warm to touch <input type="checkbox"/> Joint swelling <input type="checkbox"/> Inflammatory changes in synovial fluid			
<input type="checkbox"/> <b>Parotitis*</b> (Parotid gland swelling with pain and/or tenderness)			
<input type="checkbox"/> <b>Thrombocytopenia*:</b> <input type="checkbox"/> Platelet count <150×10 <sup>9</sup> /L <input type="checkbox"/> Other clinical evidence of bleeding			
<b>Oculo-Respiratory Syndrome (ORS)</b> (Note: This is different from allergic/respiratory symptoms):			
<input type="checkbox"/> Bilateral red eyes <input type="checkbox"/> Cough <input type="checkbox"/> Wheeze <input type="checkbox"/> Sore throat <input type="checkbox"/> Difficulty swallowing			
<input type="checkbox"/> Difficulty breathing <input type="checkbox"/> Chest tightness <input type="checkbox"/> Hoarseness <input type="checkbox"/> Facial swelling			
<input type="checkbox"/> <b>Fever ≥38°C</b> (Report <b>only</b> if fever occurs in conjunction with reportable event. For a neurological event use section above.)			
<input type="checkbox"/> <b>Other serious or unexpected event(s) not listed above</b> (Specify and provide details in section G):			
E. Impact of AEFI, outcome, and level of care obtained			
<b>Highest impact of AEFI</b> (Choose one of the following):		<b>Outcome at time of report</b> (Choose one of the following):	
<input type="checkbox"/> Did not interfere with daily activities		<input type="checkbox"/> Death    Date (YYYY/MM/DD):	
<input type="checkbox"/> Interfered but did not prevent daily activities		<input type="checkbox"/> Permanent disability/incapacity <input type="checkbox"/> Fully recovered	
<input type="checkbox"/> Prevented daily activities		<input type="checkbox"/> Not yet recovered <input type="checkbox"/> Unknown	
<b>Highest level of care obtained</b> (Choose one of the following):			
<input type="checkbox"/> Emergency visit <input type="checkbox"/> Non-urgent visit <input type="checkbox"/> Telephone advice from a health professional <input type="checkbox"/> None			
<input type="checkbox"/> Admitted to Hospital (    days) <b>OR</b> <input type="checkbox"/> Resulted in prolongation of existing hospitalization (by    days)			
Hospital name:			
Hospital admission date (YYYY/MM/DD):		Hospital discharge date (YYYY/MM/DD):	
<b>Treatment received:</b> <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Yes (If <b>yes</b> , provide details of treatment, including self treatments, in section G.)			
F. Public health recommendations for further information (Provide comments. Use section G if extra space is required.)			
<input type="checkbox"/> No change to immunization schedule		<input type="checkbox"/> Expert referral, specify:	
<input type="checkbox"/> Determine protective antibody level, specify:		<input type="checkbox"/> Controlled setting for next immunization, specify:	
<input type="checkbox"/> No further immunizations, specify:		<input type="checkbox"/> Active follow up for AEFI recurrent after next vaccine, specify:	
<input type="checkbox"/> Other, specify:		<input type="checkbox"/> No recommendations	
Name:	Professional status:	<input type="checkbox"/> MOH/MHO <input type="checkbox"/> MD <input type="checkbox"/> RN <input type="checkbox"/> Other, specify:	
Comments:			
Phone: (    )    ext.		Date (YYYY/MM/DD):	<b>Signature:</b>
<b>Send a copy to:</b> <input type="checkbox"/> BCCDC <input type="checkbox"/> Client's Physician <input type="checkbox"/> Other _____			
G. SUPPLEMENTARY INFORMATION			
<b>Please indicate the section number when providing details. In Panorama enter the comments into the AEFI details section of the reaction type, ie. Local, Allergic, etc.</b> Provide details of any investigation or treatment for the recorded AEFI. If not, provide sufficient information to support the selected item(s). Append information on additional pages if required.			



# Adverse Event Following Immunization (AEFI) Case Report Form

## Adverse Events Following Immunization – Temporal Criteria

The length of time between vaccine administration and onset of symptoms is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

Reaction Type	Adverse Event Following Immunization	Temporal Criteria	
		Inactivated Vaccines	Live Attenuated Vaccines
Local Reactions at Injection Site	Infected Abscess	0-7 days	
	Sterile Abscess	0-7 days	
	Cellulitis	0-7 days	
	Nodule	0-7 days	
	Pain or Redness or Swelling	0-48 hours	
Systemic Reactions	Adenopathy/Lymphadenopathy	0-7 days	MMR: 5 - 30 days Varicella: 5 - 42 days
	Fever	Timing in conjunction with other reportable adverse events	
	Hypotonic-Hyporesponsive Episode (HHE)	0-48 hours	
	Parotitis	Not applicable	MMR: 5-30 days
	Orchitis	Not applicable	MMR: 5-30 days
	Rash	0-7 days	MMR: 0 - 30 days Varicella: 0 - 42 days
	Screaming/Persistent crying	0-72 hours	
	Severe Vomiting/Diarrhea	0-72 hours	Rotavirus: 0-7 days
Allergic Reactions	Anaphylaxis	0-24 hours	
	Oculo-respiratory Syndrome (ORS)	0-24 hours	
	Other Allergic Reactions	0-48 hours	
Neurological Events	Anaesthesia/Paraesthesia	0-15 days	MMR: 0 - 30 days Varicella: 0 - 42 days
	Bell's Palsy	0-3 months	
	Convulsion/Seizure	0-72 hours	MMR: 5 - 30 days Varicella: 5 - 42 days
	Encephalopathy or Encephalitis or Acute Disseminated Encephalomyelitis (ADEM)	0-42 days	MMR: 5 - 30 days Varicella: 5 - 42 days
	Guillain-Barré syndrome (GBS)	0-8 weeks	
	Meningitis	0-15 days	MMR: 5 - 30 days Varicella: 5 - 42 days
	Subacute sclerosing panencephalitis (SSPE)	Not applicable	Up to 10 years following a measles-containing vaccine
	Paralysis	0-15 days	OPV: 5 - 30 days Varicella: 5-42 days
Other Events of Interest	Arthritis	0-30 days	MMR: 5 - 30 days Varicella: 0 - 42 days
	Intussusception	Not applicable	Rotavirus: 0-42 days
	Syncope with injury	0-30 minutes	
	Thrombocytopenia	0-30 days	
	Other severe or unusual	A temporal association to immunization and for which there is no other known cause and not covered under the other categories	

## STORAGE & HANDLING

- Store vaccine on the middle shelves of the fridge; never on the doors or in the crispers.
- Keep vaccines in their original packaging to protect from light.
- Use a separate tray in the refrigerator for opened vaccines and keep them in the original packaging. Use the opened ones before opening new vials/packages.
- Clearly print the date opened on the label of a multi-dose vial. Use a multi-dose vial within 30 days of opening, unless there are specific directions in the product insert for using/discarding sooner.
- Do not reconstitute vaccines or pre-fill syringes until ready to administer.
- Use the correct diluent to reconstitute lyophilized vaccines.

## TEMPERATURE

- Maintain a refrigerator temperature of between **2.0° C to 8.0° C**.
- Check refrigerator temperature twice daily (am & pm) and record on a temperature form.
- Store bottles of water (if space allows) on the empty refrigerator shelves and in the door.
- Store ice packs in the freezer.
- Open the refrigerator door only when necessary.
- Do not store food, beverages or lab specimens in the refrigerator.
- Have a refrigerator maintenance check done, at minimum, annually.

## TRANSPORTING VACCINES

- Keep vaccines in their original packaging and maintain the packing configuration when removing vaccines from – or returning vaccines to – the cooler.
- Use large coolers for large quantities of vaccine. Either a hard-sided or soft-sided insulated cooler can be used with a tight-fitting lid along with frozen ice packs and insulating material to transport vaccines at all times.
- If the vaccine is in a large cooler for more than 4 hours, monitor cooler temperatures with a minimum-maximum thermometer.
- Use all vaccines in one large cooler before opening the next large cooler.
- Transport vaccines directly from the Health Unit refrigerator to the clinic setting.
- Refrigerate vaccines as soon as transportation is complete.
- Transport diluents separately, unless they have been cooled in the refrigerator for 24 hours prior to transport.

## AT THE CLINIC SETTING

- Use small insulated coolers at each work station.
- Maintain the appropriate packing configuration when removing or returning vaccines to the small cooler.
- Avoid pre-loading syringes.
- Mark the date/time of opening on all multi-dose vials.

*[continued on following page]*

## INVENTORY MANAGEMENT

- Rotate vaccines according to their expiry date; place those with the longest expiry date at the back.
- Check for expired products every month.
- Never use expired vaccine; always return them to the public health unit/office.
- Keep vaccine stock at a minimum.
- Order only the quantity of vaccine required for one month until the next scheduled pick-up of vaccines.
- For more information, see Section VI, Management of Biologicals, at: <http://www.bccdc.ca/dis-cond/comm-manual/CDManualChapt2.htm>

## KEY PRINCIPLES

- The insulated coolers used for transport is the “refrigerator” in the clinic setting.
- Open these coolers only when necessary.
- Monitor the temperature in these large coolers.

*Based on “Mass Clinics”, by the BC Centre for Disease Control, at:*  
<http://www.bccdc.ca/NR/rdonlyres/3F7DE213-BB20-4324-AD8B-E2E3A83D0349/0/MassClinics.pdf>.

*and*

*“Handle vaccines with care”, by the BC Centre for Disease Control, at:*  
<http://www.bccdc.ca/NR/rdonlyres/BEF4EA99-0B9A-417C-9B67-58428833139B/0/HandleVaccineswithCare.pdf>.  
*These guidelines are applicable to RSV Immunoprophylaxis as well.*

**IMMUNIZATION SKILLS CHECKLIST**

Name: \_\_\_\_\_

Registration No.: \_\_\_\_\_

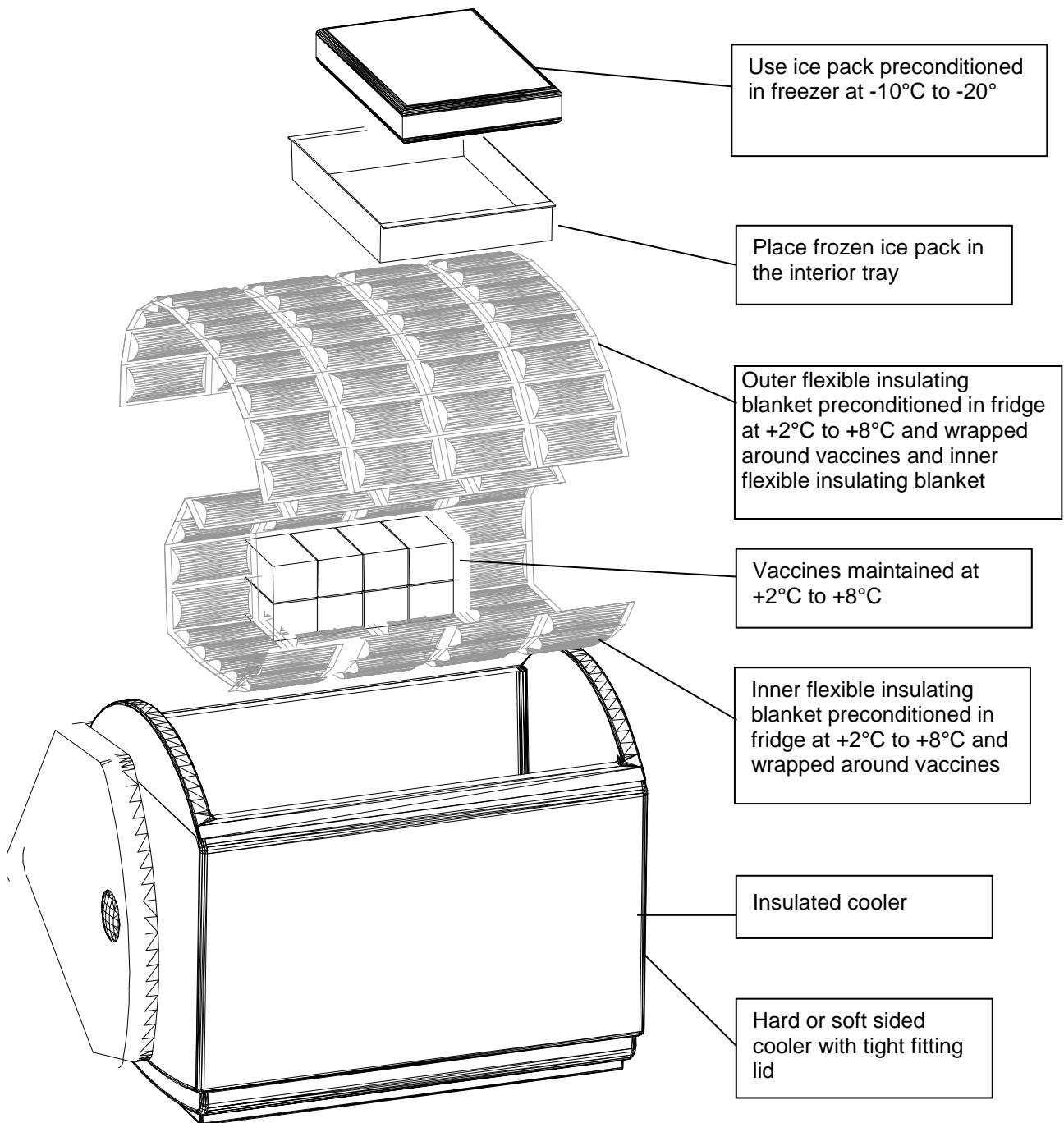
ACTIVITY	DATE
<b>CLINIC SETUP</b>	
<input type="checkbox"/> Ensures anaphylaxis kit is complete and accessible	
<input type="checkbox"/> Sets up supplies and equipment to promote proper body mechanics and OHS standards	
<input type="checkbox"/> Follows provincial guidelines when storing, handling or transporting vaccines	
<b>PERFORMS APPROPRIATE CLIENT ASSESSMENT PRIOR TO IMMUNIZATION</b>	
<input type="checkbox"/> Health status	
<input type="checkbox"/> Contraindications and adverse event history	
<input type="checkbox"/> Vaccine history from client/agency record	
<input type="checkbox"/> Determines high risk eligibility for additional vaccines (e.g. influenza)	
<input type="checkbox"/> Recognizes and responds to the unique immunization needs of certain population groups	
<b>VACCINE(S) TO BE ADMINISTERED</b>	
<input type="checkbox"/> Determines vaccine(s) to be administered according to guidelines of the BCCDC Immunization Program	
<b>OBTAINS INFORMED CONSENT</b>	
<input type="checkbox"/> Discusses the implications of the individual's rights, confidentiality, privacy, informed consent and informed refusal	
<input type="checkbox"/> Explains that consent is obtained for a vaccine series and consent is valid until completion of the series	
<input type="checkbox"/> Refers to appropriate HealthLink File(s) and identifies credible sources of immunization information	
<input type="checkbox"/> Using scientific knowledge, delivers clear, concise messages about the risks of vaccine-preventable diseases and the benefits of vaccines	
<input type="checkbox"/> Describes the nature and purpose of the vaccine(s)	
<input type="checkbox"/> Describes the common and expected reactions following immunization	
<input type="checkbox"/> Reviews possible serious or severe adverse events and their frequency	
<input type="checkbox"/> Reviews contraindications and precautions related to vaccine(s) to be administered	
<input type="checkbox"/> Provides aftercare instructions	
<input type="checkbox"/> Ensures client has opportunity to ask questions	

PREPARES VACCINE CORRECTLY	DATE
<input type="checkbox"/> Cleanses hands	
<input type="checkbox"/> Maintains sterile and aseptic technique	
<input type="checkbox"/> Selects correct vaccine, checks vaccine, expiry date, and dosage X 3 prior to administration	
<input type="checkbox"/> Reconstitutes vaccine	
<input type="checkbox"/> Chooses the correct needle length and gauge for the age and size of the client	
DEMONSTRATES CORRECT VACCINE ADMINISTRATION	
<input type="checkbox"/> Instructs proper positioning either by showing parent to position and hold child appropriately or by instructing adult to sit and relax site of injection	
Demonstrates accurate injection technique and site location	
<input type="checkbox"/> Intramuscular	
<input type="checkbox"/> Subcutaneous	
<input type="checkbox"/> Intradermal	
<input type="checkbox"/> Safely handles and disposes of syringe	
<input type="checkbox"/> Assists parent to comfort child as needed	
<input type="checkbox"/> Demonstrates appropriate knowledge of protocol for the management of anaphylaxis, and describes emergency plan to manage anaphylactic event or a fainting episode	
DOCUMENTATION	
<input type="checkbox"/> Documents consent or refusal for immunization	
<input type="checkbox"/> Documents contraindications	
<input type="checkbox"/> Records an immunization encounter on the appropriate documentation instruments accurately and completely.	
<input type="checkbox"/> Records the reason for and planned follow-up action when a scheduled immunization is not given	
<input type="checkbox"/> Reports adverse events in the electronic registry OR submits adverse events via HLTH 2319 form to the appropriate agency	
<input type="checkbox"/> Provides immunization record to client	
CLIENT REMINDERS	
<input type="checkbox"/> Explains when next vaccines are due	
<input type="checkbox"/> Reminds client to report possible serious or adverse events	

Immunization Evaluator(s): \_\_\_\_\_ (NAME) \_\_\_\_\_ (SIGNATURE) \_\_\_\_\_ (DATE)

\_\_\_\_\_ (NAME) \_\_\_\_\_ (SIGNATURE) \_\_\_\_\_ (DATE)

## Packing an Insulated Cooler



**Protect the vaccines. Protect your patients.**

The BC RSV Immunoprophylaxis Program ('the RSV Program' / 'the Program') is a Provincial Health Services Authority Program administered at BC's Children's Hospital.

## 1. PURPOSE

- 1.1. To identify and coordinate RSV immunoprophylaxis for eligible infants and children residing in British Columbia;
- 1.2. To evaluate the outcomes of children in the Program;
- 1.3. To measure and track the burden of RSV illness in BC in both children in the Program and children not in the Program;
- 1.4. To make recommendations regarding the functioning and location of palivizumab (PVZ) clinics on the basis of burden of RSV illness and centre size; and
- 1.5. To participate in and encourage / support activities, other than immunoprophylaxis, that may decrease the burden of RSV illness in small children.

## 2. RESPONSIBILITIES

- 2.1 To develop the annual guidelines for eligibility to the Program;
- 2.2 To develop the educational materials, forms, and processes that will be used to maximize penetration of and compliance with the BC RSV Immunoprophylaxis Program Guidelines ('the Guidelines');
- 2.3 To develop a system of adjudication for admission to the Program of children with defined conditions that require secondary evaluation;
- 2.4 To ensure that the Guidelines are evidence based, including based on BC outcomes;
- 2.5 To retrieve complete Health Authority and practitioner outcome information for Program evaluation;
- 2.6 To communicate effectively regarding eligibility or non-eligibility, PVZ shipments and utilization, and Program policies and procedures; and
- 2.7 To facilitate the linking of families to locations where PVZ is administered.

## 3. GENERAL PRINCIPLES

- 3.1 Prophylaxis typically begins in November and continues through to April; the dates are determined by the Program Advisory Committee (see Item 6).
- 3.2 The referral process is initiated by completion and submission of the Program Application Form; only the Program can approve a patient for funded PVZ administration.
- 3.3 Applications that require adjudication will be adjudicated within five working days.
- 3.4 Confirmation of eligibility or non-eligibility is issued by the PHSA (C&W) Pharmacy to the referral source.
- 3.5 Reconsideration of non-eligibility requires submission of additional clinical information.
- 3.6 The Program only covers children < 2 years of age by November 01 of the season start.
- 3.7 In order to minimize drug wastage, PVZ is generally administered to patient clusters in PVZ clinics.

## 4. EXECUTIVE SPONSOR

The Executive Sponsor is the Chief Operating Officer, Patient Administration, Children's and Women's Health Centre of British Columbia, who is accountable to the PHSA and the Ministry of Health.

## 5. PROGRAM EXECUTIVE COMMITTEE

Comprises the Program Medical Director, Chair of the Program Advisory Committee, the Program Administrative Director, the Program Nurse Coordinator, and the Program Pharmacy Coordinator.



Each of these positions is appointed by PHSA, save the Chair of the Program Advisory Committee (see Item 6).

The Executive Committee:

- 5.1 Is chaired by the Program Medical Director;
- 5.2 Reports to the Program’s Executive Sponsor though the Medical Director, the Chair of the Program Advisory Committee, and/or the Program Administrative Director at least three times annually;
- 5.3 Ensures that the Program meets its obligations, such as cost, schedule, clinical, and technical;
- 5.4 Meets at least monthly throughout the year;
- 5.5 Builds the foundations of each Program phase, i.e., pre-season, intra-season, post-season;
- 5.6 Manages Program phases and transitions between phases;
- 5.7 Creates and disseminates the documentation required at the end of each phase or process;
- 5.8 Reviews and determines viability, and translates into action the recommendations of the Advisory Committee;
- 5.9 Facilitates the adoption and implementation, at the Health Authority level, of the mechanisms that will allow for the smooth functioning of the Program, including data retrieval for Program management purposes; and
- 5.10 Makes decisions on a consensus basis, but should consensus not be reached, decisions will be made by a majority vote. If necessary, the Program Medical Director will hold ultimate decision-making authority regarding clinical matters.

**6. ADVISORY COMMITTEE**

Comprising the Program Executive, and relevant Pediatric subspecialty representatives when available, i.e., neonatology, cardiology, pulmonology-CF, immunology, infectious diseases, two nursing representatives of the RSV Clinics, and representatives of each Health Authority: one medical and one administrative; and PHSA Performance Measurement and Reporting.

The Advisory Committee is chaired by one of the subspecialty representatives as elected by the Committee; and:

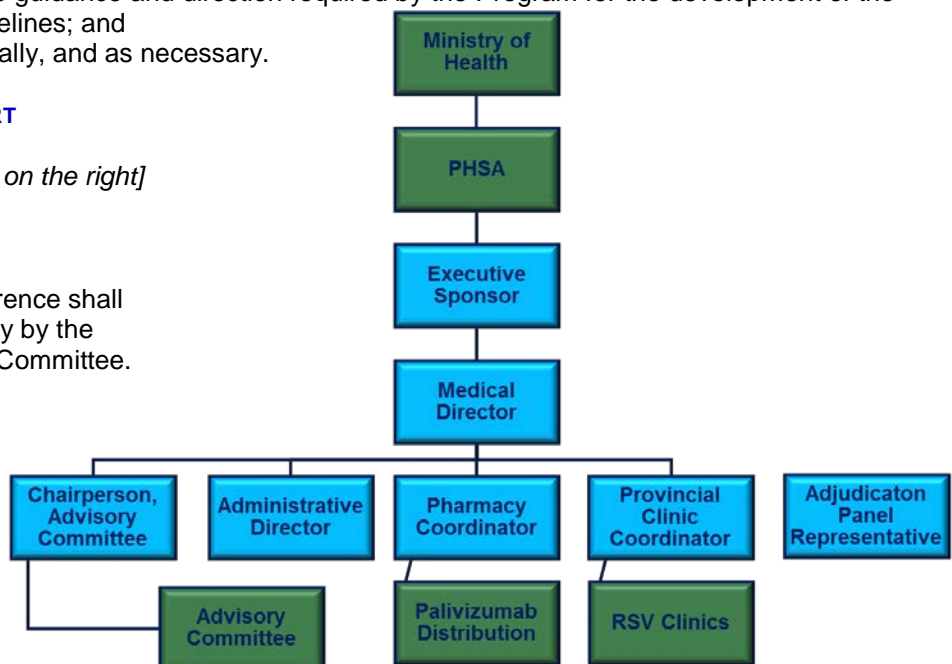
- 6.1 Supports the organizational structure of the Program;
- 6.2 Reviews the report on season outcomes and on new evidence that will inform the subsequent season guidelines;
- 6.3 Provides the guidance and direction required by the Program for the development of the annual guidelines; and
- 6.4 Meets annually, and as necessary.

**7. ORGANIZATION CHART**

*[As per the diagram on the right]*

**8. AMENDMENTS**

These terms of reference shall be reviewed annually by the Program Executive Committee.



**RSV Program Clinics – Contact List**  
as of the 2016/17 RSV Season

City	HA	RSV Clinic	Contact name	Email address	Telephone	Fax
100 Mile House	IHA	100 Mile House & District	Fay Martens	<a href="mailto:fay.martens@interiorhealth.ca">fay.martens@interiorhealth.ca</a>	250-395-7600, x5550	250-395-7640
Abbotsford	FH	Abbotsford Regional	Kim McLellan	<a href="mailto:kim.mclellan@fraserhealth.ca">kim.mclellan@fraserhealth.ca</a>	604-851-4700, x646267	604-851-4787
Abbotsford	FH	Abbotsford Regional	Katie Mattie	<a href="mailto:katie.mattie@fraserhealth.ca">katie.mattie@fraserhealth.ca</a>	604-851-4700, x642225	604-851-4787
Burnaby	FH	Burnaby NICU	Luba Kadnarova	<a href="mailto:lubomira.kadnarova@fraserhealth.ca">lubomira.kadnarova@fraserhealth.ca</a>	604-412-6296/604-412-6330	604-412-6541
Comox	VIHA	St. Joseph's	Kelly Phillips	<a href="mailto:kelly.phillips2@viha.ca">kelly.phillips2@viha.ca</a>	250-339-2242 x61076	250-339-1519
Duncan	VIHA	Cowichan District	Michaela Peet	<a href="mailto:michaela.peet@viha.ca">michaela.peet@viha.ca</a>	250-737-2030, x44277	250-709-3020
Kamloops	IHA	Royal Inland	Kerri MacKenzie	<a href="mailto:kerri.mackenzie@interiorhealth.ca">kerri.mackenzie@interiorhealth.ca</a>	250-314-2560	250-314-2369
Kelowna	IHA	Kelowna General	Laura-Lee Regnier	<a href="mailto:laura-lee.regnier@interiorhealth.ca">laura-lee.regnier@interiorhealth.ca</a>	250-862-4300, x4431	250-862-4146
Langley	FH	Langley Memorial	Shelley Krautsieder	<a href="mailto:shelley.krautsieder@fraserhealth.ca">shelley.krautsieder@fraserhealth.ca</a>	604-514-6139	604-539-4334
Nanaimo	VIHA	Nanaimo General	Roseanne Garcia	<a href="mailto:roseanne.garcia@viha.ca">roseanne.garcia@viha.ca</a>	250-739-5850	250-739-5855
New Westminster	FH	Royal Columbian	Jennifer Padley	<a href="mailto:jennifer.padley@fraserhealth.ca">jennifer.padley@fraserhealth.ca</a>	604-520-4558	604-520-4112
North Vancouver	VCH	Lion's Gate Peds/NICU	Gina Webb	<a href="mailto:gina.webb@vch.ca">gina.webb@vch.ca</a>	604-889-4602 (m)	604-984-5856
Penticton	IHA	Penticton Hosp	Mayee Loo	<a href="mailto:mayee.loo@interiorhealth.ca">mayee.loo@interiorhealth.ca</a>	250-492-9030	250-492-9046
Prince George	NHA	Univ Hosp N. BC	Beverly (Bev) Haight	<a href="mailto:Beverly.Haight@northernhealth.ca">Beverly.Haight@northernhealth.ca</a>	250-645-6164	250-565-5824
Prince George	NHA	Univ Hosp N. BC - NICU	Katherine Schemenauer	<a href="mailto:Katherine.Schemenauer2@northernhealth.ca">Katherine.Schemenauer2@northernhealth.ca</a>	250-565-2329	
Richmond	VCH	Richmond NICU	Joesphine Wong	<a href="mailto:joesphine.wong@vch.ca">joesphine.wong@vch.ca</a>	604-278-9711, x5293	604-244-5290
Surrey	FH	Surrey Memorial	Jennifer Watt	<a href="mailto:jennifer.watt@fraserhealth.ca">jennifer.watt@fraserhealth.ca</a>	604-585-5666, x774327	604-585-5641
Vancouver	PHS A	St. Paul's NICU	Liz Hennessey	<a href="mailto:ehennessey@providencehealth.bc.ca">ehennessey@providencehealth.bc.ca</a>	604-682-2344, x66029	604-806-9855
Vancouver / BC Coordinator	PHS A	Children's and Women's	Cheryl Christopherson	<a href="mailto:cchristop@cw.bc.ca">cchristop@cw.bc.ca</a>	604-875-2345, x7872	604-875-2703
Vernon	IHA	Vernon Jubilee	Michelle Rotenburger	<a href="mailto:michelle.rotenburger@interiorhealth.ca">michelle.rotenburger@interiorhealth.ca</a>	250-558-1200	250-558-1290
Victoria	VIHA	Victoria General	Margaret Baker	<a href="mailto:margaret.baker@viha.ca">margaret.baker@viha.ca</a>	250-727-4191	250-727-4042

RSV Desk: [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca); 604-875-2000 x2867



## Questions?

If you have any questions about the RSV Program guidelines, or anything else about the Program or administration of PVZ in BC, please contact one of the following members (depending on the nature of your query):

Laurence Bayzand: ..... **Administrative Director**, BC RSV Immunoprophylaxis Program  
BC Children's Hospital and BC Women's Hospital + Health Centre  
604-875-2337

Grace Burns: ..... **RSV Desk**, BC RSV Immunoprophylaxis Program  
Pharmacy Support, Children's & Women's Health Centre of BC  
604-875-2867 or toll-free 1-877-625-7888. Fax: 604-875-2879.

Cheryl Christopherson: ..... **Provincial Clinic Coordinator**, BC RSV Immunoprophylaxis Program  
Nurse Clinician, Children's & Women's Health Centre of BC  
604-875-2345 ext 7872

Alfonso Solimano: ..... **Medical Director**, BC RSV Immunoprophylaxis Program  
BC Children's Hospital and BC Women's Hospital + Health Centre  
604-875-2135

Richard Taylor: ..... **Chair**, BC RSV Immunoprophylaxis Advisory Committee  
Victoria General Hospital  
250-727-4531

## External Links

**Canadian Pediatric Society – Preventing Hospitalizations for Respiratory Syncytial Virus Infection**  
<http://www.cps.ca/en/documents/position/preventing-hospitalizations-for-rsv-infections>

**RSV Program Documents (including Decision Support Tool and Administrative Manual)**  
[http://childhealthbc.ca/?drawer=RSV%20Immuno-Prophylaxis%20Guidelines\\*RSV%20Immuno-Prophylaxis%20Guidelines](http://childhealthbc.ca/?drawer=RSV%20Immuno-Prophylaxis%20Guidelines*RSV%20Immuno-Prophylaxis%20Guidelines)

**RSV Program – Newsletter**  
[http://childhealthbc.ca/?drawer=RSV%20Immuno-Prophylaxis%20Guidelines\\*RSV%20Newsletters](http://childhealthbc.ca/?drawer=RSV%20Immuno-Prophylaxis%20Guidelines*RSV%20Newsletters)

**BC Centre for Disease Control – Vaccine Storage and Handling**  
<http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Immunization/Cold%20Chain/bccdccoldchainresourcescreen.pdf>

**BC Centre for Disease Control – Vaccine Management**  
<http://www.bccdc.ca/health-professionals/clinical-resources/immunization/vaccine-management>

- BC Centre of Disease Control  
[www.bccdc.ca](http://www.bccdc.ca)
- British Columbia RSV Immunoprophylaxis Program Information  
[www.childhealthbc.ca](http://www.childhealthbc.ca) under “RSV Immunoprophylaxis”
- Canadian Association of Neonatal Nurses:  
[www.neonatalcann.ca](http://www.neonatalcann.ca) (click on the “Respiratory Syncytial Virus (RSV) Information” found on the right hand side of the home page)
- College of Registered Nurses of British Columbia (CRNBC)  
Scope of Practice for Registered Nurses  
<https://crnbc.ca/Standards/Lists/StandardResources/433ScopeforRegisteredNurses.pdf>
- Manufacturer/distributor website for palivizumab:  
[www.rsvshield.ca](http://www.rsvshield.ca)  
PVZ monograph: [http://www.abbvie.ca/content/dam/abbviecorp/ca/english/docs/SYNAGIS\\_PM\\_EN.pdf](http://www.abbvie.ca/content/dam/abbviecorp/ca/english/docs/SYNAGIS_PM_EN.pdf)
- Position Statements: CPS:  
[www.CPS.ca](http://www.CPS.ca)
- The Public Health Agency of Canada outlines cold chain practices at:  
<http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php>

### Recommended Resources:

#### Pain Management

1. <http://www.cmaj.ca/content/182/18/1989/supp/DC1>
2. Taddio A, et al. *Reducing Pain of childhood vaccination: An evidence-based clinical practice guideline (summary)*. CMAJ. December 14, 2010, 182(18); 1989-95  
<http://www.cmaj.ca/content/182/18/1989.full.pdf+html>

#### Position Statements

1. Canadian Pediatric Society. *Preventing respiratory syncytial virus infections*. Paediatric & Child Health 2011;16(8):488-90
2. Fetus and Newborn Committee. *Palivizumab and Respiratory Syncytial Viruse Immune Globulin Intravenous for the Prophylaxis of Respiratory Syncytial Virus Infection in High Risk Infants*. Paediatric & Child Health 1999;4:474-480
3. Canadian Pediatric Society. *Use of Palivizumab in Children with Congenital Heart Disease*. Paediatric & Child Health 2003;8:631-633

#### Cost Effectiveness of Prophylaxis

1. Nuijten MJC, Wittenberg W, Lebmeier M. *Cost Effectiveness of Palivizumab for Respiratory Syncytial Virus Prophylaxis in High-Risk Children*. Pharmacoeconomics 2007;25:55-71

#### Related standards

1. CRNBC Standards of Practice: “Acting without an Order”

This Manual and Decision Support Tool is produced by:

- the **Executive Committee** to the BC RSV Immunoprophylaxis Program
- with the consultation and feedback from **the clinics of BC**.

and is collated and edited by

- **Cheryl Christopherson**  
and
- **Kyle Mallinson**.

The forms and content herein are reviewed annually and amended as appropriate. At times amendments must take place mid-season. Please consult the [RSV section](#) of the Child Health BC website for the latest version of each RSV Program Resource, including forms, guidelines, and protocols. If you have any questions, please contact [rsv@cw.bc.ca](mailto:rsv@cw.bc.ca) or an applicable member of the RSV team on Page 58.

The documents

- *How to Prevent Your Child from Getting or Spreading an Infection*  
and
- *Pain Management: Helping your Child Cope with the Discomfort of an Injection*  
are the intellectual property of the Children's Hospital Patient Education Committee of the Winnipeg Regional Health Authority.

The following documents are the intellectual property of the BC Centre for Disease Control:

- *How to Prevent your Child from Getting or Spreading an Infection*
- *Mass Clinics – Immunoprophylaxis-Handling Tips*
- *Handle vaccines with care*
- *Packing an Insulated Cooler*

Thank you all for your support and collaboration. We're always in touch.

cckm