HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Neonatal Intensive Care Unit (NICU)		
Document:	Departmental Policy and Procedure		
Title:	Respiratory Syncytial Virus Prophylaxis		
Applies To:	All NICU Staff		
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1. PURPOSE:

1.1 Prevention of RSV lower respiratory tract disease and reducing hospitalization attributable to RSV infection in susceptible infants.

2. DEFINITIONS:

2.1 **Respiratory Syncytial Virus (RSV)** is a single stranded, non-segmented RNA negative-sense virus belonging to the Pneumovirinea subfamily of the Paramyxoviridae family. It has two subtypes, A and B, which are distinguished largely by differences in the viral attachment (G) protein and the nuclear (N) protein. During epidemics, either subtype may predominate or both subtypes may circulate concurrently.

2.2 **RSV** is unstable in the environment and is readily inactivated by soap and water. The virus spreads through close contact with infected carriers or contaminated surfaces. Infection occurs when contaminated materials come in contact with the mucous membranes of the eyes, nose or mouth. It can remain infectious on surfaces or fomites for 4-7 hours and can survive on unwashed hands.

2.3 **RSV** is a leading cause of serious seasonal lower respiratory tract infections (LRTI) in high-risk infants and children, with epidemics occurring annually. In Saudi Arabia the onset usually occurs in middle to late October and ends in early to mid-March.

2.4 **RSV** causes acute upper respiratory tract infection in patients of all ages. However, premature infants born at less than 29 weeks gestation with chronic lung disease or those with significant congenital heart disease who have RSV infection are more likely to be hospitalized and have increased morbidity and mortality.

2.5 **Palivizumab**, is a humanized murine monoclonal immunoglobulin G-I directed against an epitope on the F glycoprotein of RSV, is produced by recombinant DNA technology, and has 95% human and 5% murine amino acid sequences. It is used for the prevention of severe LRTI by RSV in high-risk children.

2.6 Abbreviations:

RSV: Respiratory Syncytial Virus	CLD: Chronic Lung Disease
GA: Gestational Age	O_2: Oxygen
CHD: Congenital Heart Disease	ASD: Atrial Septal Defect

3. POLICY:

3.1 RSV prophylaxis team is formed of the head of neonatology department, head of pediatric cardiology, two neonatology/ Consultants, one pediatric cardiology Consultant and two nurses (one pediatric cardiology and one neonatology nurse). All work in collaboration with pediatric infectious diseases Consultant.

3.2 Palivizumab is administered by assigned neonatology/ pediatric cardiology nurse, to the eligible patients in the RSV prophylaxis clinic during the RSV season; Middle of October to middle of March each year. The clinic is supervised by the RSV prophylaxis team Consultants.

3.3 Parent/caregivers education about RSV prevention at home is mandatory because Palivizumab is not completely protective: emphasis on scrupulous hand hygiene at home, breastfeeding precautions if contacts at home have respiratory tract infection, avoid crowds, never expose infant to tobacco, smoking.

3.4 Palivizumab is not approved or recommended for the treatment of RSV disease.
3.5 Palivizumab prophylaxis use is not recommended for controlling outbreaks or preventing healthcare associated RSV disease.
3.6 Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV Hospitalization.

4. PROCEDURE:

4.1 Administration of RSV prophylaxis (Palivizumab) begins with the onset of RSV season (middle of October) and concludes at the end of the RSV season (middle of March).
4.2 Indications: Palivizumab injection is indicated for the following susceptible groups of infants during the RSV season for a maximum of 5 doses.
- 4.2.1 Infants born before 29 weeks gestation who are younger than 12 months at the start of the RSV Season.
  Palivizumab prophylaxis is not recommended for otherwise healthy preterm infants born at or after 29 weeks gestation.
- 4.2.2 Preterm infants with Chronic Lung Disease (CLD) of prematurity, in the first year of life.
- 4.2.3 Palivizumab prophylaxis should not be administered in the second year of life except for children who required supplemental oxygen at 36 weeks corrected gestational age, who also continue to require medical intervention (supplemental oxygen, chronic corticosteroid treatment, or diuretic therapy) in the six months prior to the second season.
- 4.2.4 Infants with certain hemodynamically significant heart diseases during their 1st year of life e.g.
  - 4.2.4.1 Infants receiving medications for severe congestive heart failure.
  - 4.2.4.2 Infants with moderate to severe pulmonary hypertension.
  - 4.2.4.3 Infants with cyanotic heart disease.
  - 4.2.4.4 Children under medical treatment for cardiomyopathies with severely impaired cardiac function.
  - 4.2.4.5 Children with heart diseases and scheduled hospitalization for a diagnostic catheterization or therapeutic procedure during the risk season who have one or more of the above mentioned criteria.

4.3 The following groups of infants with CHD are not at increased risk of RSV infection and generally should not receive immune-prophylaxis.
- 4.3.1 Infants with hemodynamically insignificant heart disease e.g. a small VSD, secundum ASD, pulmonary stenosis, uncomplicated aortic stenosis, coarctation of the aorta and patent ductus arteriosus.
- 4.3.2 Children with lesions adequately corrected by surgery generally unless they continue to require medication e.g. for heart failure.
- 4.3.3 Infants with mild cardiomyopathy who are not receiving medical therapy for the condition.
- 4.3.4 Children in the second year of life.

4.4 Children with immune deficiencies, Down syndrome, cystic fibrosis, upper airway obstruction or a chronic pulmonary disease other than CLD of prematurity or neuromuscular disease should not routinely receive Palivizumab because of limited and in conclusive data. However, prophylaxis may be considered for children less than 24 months of age who are on home oxygen, have had a prolonged hospitalization for severe pulmonary disease or are severely immune compromised.
4.5 **Selection of cases:**
- 4.5.1 Admitted Neonates:
  - 4.5.1.1 During admission, eligible patients are selected for RSV prophylaxis by the assigned Neonatology Consultants and/or the RSV prophylaxis team.
  - 4.5.1.2 Updated list of selected patients is made by the RSV team neonatal nurse and kept in the Neonatal RSV prophylaxis log book.
- 4.5.2 Patients with congenital heart disease:
  - 4.5.2.1 Selected by pediatric cardiologist through organization with the RSV team pediatric cardiac Consultant.

4.5.2.2 Decision to administer Palivizumab to neonates with hemodynamically significant CHD is decided by RSV team pediatric Cardiologist.

4.5.3 Eligible patients from pediatric department who qualified for prophylaxis are selected by assigned pediatric Consultant and referred to the team for approval.

4.6 Before Discharge of selected patients:

4.6.1 Parent/patient guardian are informed and educated about RSV, its potential severity, and the indications for Palivizumab.

4.6.2 It includes the necessity of hand hygiene, breastfeeding, avoiding crowded places and contact with ill people and of exposure, to smoke.

4.6.3 Parents are advised that household members should be immunized against influenza and practice good hand and cough hygiene.

4.6.4 They are given a card indicating the dates for prophylaxis injections during the current season.

4.6.5 The assigned physician includes the recommendation for RSV prophylaxis when indicated in the patient's discharge summary year-round.

4.7 Records:

4.7.1 All patients assigned to receive RSV prophylaxis are registered in two log books, one for preterm infants and the second for patients with CHD. It includes patient's information name, age, sex & diagnosis, medical record number, current weight and any remarks.

4.7.2 The assigned RSV prophylaxis team nurse documents all given doses in the RSV log book and the RSV prophylaxis card.

4.7.3 The planned dates of next dose are registered on the patient's RSV prophylaxis card.

4.8 Palivizumab administration, preparation and storage:

4.8.1 Administration:

4.8.1.1 The drug is given intramuscularly in the anterolateral aspect of the thigh, at a dose of **15mg/kg** (on the patient current weight), once every 4 weeks.

4.8.1.2 It is given for a maximum of five doses. Qualified infants' born during the RSV season must receive fewer doses according to their month of birth. For example, infants' born in January would receive their last dose in March.

4.1.8.3 Palivizumab does not contain preservative and should be administered within 3 hours of preparation.

4.1.8.4 To minimize loss of the opened vials, eligible neonatology patients who are ready for discharge may share opened vials within the 3 hours limited time. The RSV team neonatology Consultant selects the admitted patients who can receive Palivizumab on the RSV clinic day.

4.8.2 Preparation:

4.8.2.1 SLOWLY add 0.6 ml of water for injections for the 50 mg vial or 1.0 ml of water for injections for the 100 mg vial. The final concentration is 100 mg/ml.

4.8.2.2 Slowly add the water along the inside wall of the vial to minimize foaming. Tilt the vial slightly and gently rotate the vial for 30 seconds. DO NOT SHAKE THE VIAL.

4.8.2.3 Let the solution stand at room temperature for a minimum of 20 minutes until the solution clarifies.

4.8.2.4 It is prepared under complete aseptic technique.

4.9 Palivizumab injection does not interfere with response to vaccines or routine childhood immunizations

5. MATERIAL AND EQUIPMENT:

5.1 Palivizumab injection
5.2 Appropriate syringe and needle
5.3 Alcohol swab
5.4 Cotton ball
5.5 RSV prophylaxis card

6. RESPONSIBILITIES:

6.1 Physician
6.2 Nurse

7. APPENDICES:

N/A

8. REFERENCES:

8.1 American Academy of Pediatrics. Policy Statement: Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus. Committee on Infectious Diseases and Bronchiolitis. Guidelines Committee. Pediatrics; 2014; 134:415420

8.2 Canadian Pediatric Society. Position Statement. Infectious Diseases and Immunization Committee. Paediatric Child Health 2015;20 (6):321-26. Updated: May 12,2016

8.3 Fahad Al Aql et al. Guidelines for palivizumab prophylaxis in infants and young children at increased risk for respiratory syncytial virus infection in Saudi Arabia. Clinical Practice Guidelines. International Journal of Pediatrics and Adolescent Medicine 2016; 3,3E42.

9. APPROVALS:

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