International Journal of Pediatrics and Adolescent Medicine (2016) 3, 38—42

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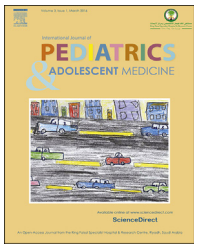

CLINICAL PRACTICE GUIDELINES

# Guidelines for palivizumab prophylaxis in infants and young children at increased risk for respiratory syncytial virus infection in Saudi Arabia

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Received 20 October 2015; received in revised form 1 November 2015; accepted 12 November 2015
Available online 13 January 2016

**KEYWORDS**
Palivizumab;
Guidelines;
RSV;
LRTI;
Saudi;
Prematurity

**Abstract** Respiratory syncytial virus (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 from October to March.

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. Palivizumab (Synagis®, Medimmune) is a humanized monoclonal antibody for the prevention of severe LRTI by RSV in high-risk children. The current use of Palivizumab in Saudi Arabia is not regulated and does not meet approved standards.

This clinical practice policy statement was developed by the Ministry of Health and is supported by the National Immunization Technical Advisory Group (NITAG) in Saudi Arabia. It is based on available national and international data on the use of Palivizumab for the prevention of severe LRTI caused by RSV in high-risk pediatric patients. These guidelines were solicited and endorsed by two Saudi societies: The Neonatology and the Pediatric Infectious Diseases Societies.

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Peer review under responsibility of King Faisal Specialist Hospital & Research Centre (General Organization), Saudi Arabia.

http://dx.doi.org/10.1016/j.ijpam.2015.11.005

## 1. Introduction

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 [1].

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 h and can survive on unwashed hands [2,3].

The main therapy for RSV in infants is supportive. Palivizumab (Synagis®), a human monoclonal antibody directed against the fusion protein F of RSV (conserved among isolates), is produced by recombinant DNA technology and was licensed for use in RSV prophylaxis in June 1998 by the United States Food and Drug Administration for the reduction of serious lower respiratory tract infection caused by RSV in children at increased risk of severe disease [4–6].

This clinical practice policy statement was developed by the Ministry of Health and supported by the National Immunization Technical Advisory Group (NITAG) in Saudi Arabia based on all available national and recent international data for the use of Palivizumab for the prevention of severe LRTI caused by RSV in high-risk pediatric patients.

The Saudi Pediatrics Infectious Diseases Society (SPIDS) and the Saudi Neonatology Society (SNS) have endorsed these RSV prophylaxis guidelines. These guidelines shall be reviewed and updated every 2 years as needed. The Ministry of Health laboratories will monitor changes in RSV seasons (see Table 1).

## 2. Purpose of the guidelines

1. Implement national guidelines on RSV immunoprophylaxis to reduce variations across the country and limit Palivizumab to a specific high-risk population on the basis of available evidence, as well as expert opinion.
2. To be a resource for healthcare professionals (HCPs) involved in the management of an RSV Immunoprophylaxis Program.
3. Improve the utilization of resources and enhance cost-effective practices.

## 3. Epidemiology

RSV is a highly contagious virus that causes serious global outbreaks. The virus results in significant morbidity and mortality in infants during the first year of life, and nearly all infants experience one or more RSV infections by the end of their second year [2]. The disease severity ranges from a mild upper respiratory tract infection (URTI) to a severe lower respiratory tract infections (LRTI). Globally, RSV is estimated to have caused 66,000 to 199,000 pneumonia deaths in children younger than 5 years in 2005. In the United States, the hospitalization rate is 2345 per 100,000 person-years for RSV compared to 151 for influenza, consistent with reports that RSV hospitalizes 1–2% of infants each winter [7,8].

In Saudi Arabia, RSV was reported to be the main cause of LRTI in infants in more than one study [1,9–13], accounting for up to 40% of all LRTIs in children aged <1 year and up to 83% in children aged <5 years. Most cases occur from November through March, but infections have been reported in other months in Saudi Arabia [6,11]. Most RSV infections are mild and require minimal hospital stays; however, some children are severely affected, requiring pediatric ICU admission and a longer hospital stay. Risk factors for serious infection with RSV include prematurity; bronchopulmonary dysplasia (BPD); cyanotic congenital heart disease; and immunodeficiency diseases or immunosuppression caused by therapy [12].

**Table 1** Summary of studies conducted in Saudi Arabia [14].

| Year | City/province | Hospital | No of samples | Detection test | HRSV positive No. (%) | Type | Ref. |
|---|---|---|---|---|---|---|---|
| 1993 | Riyadh | KKUH[a] | 127 | IFA[g] | 69 (54)[k] | — | Jamjoom et al |
| 1998 | Riyadh | KFSHRC[b] | 256 | ND | 73(28.5) | — | Al-Hajjar et al [9] |
| 1998 | Riyadh | KKUH | 1429 | ND | 412 (79) | — | Bakir et al [11] |
| 2002 | Riyadh | KKUH | 20 | ND[h] | 8 (40) | — | Kilani |
| 2004 | Mecca-Hajj | KAUH-Jeddah[c] | 500 | IFA | 4 (7.4) | — | Bakhly et al |
| 2005 | Abha | ACH[d] | 51 | ELISA[i]/IFA | 20 (40) | — | Al-shehri et al [10] |
| 2005 | Riyadh | KKUH | 4575 | IFA | 884 (19) | — | Sheir and Mona |
| 2006 | Al-Qassim | BMPH[e] | 282 | IFA | 128 (45) | — | Meqdam and Sobaih |

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