Home-Based Interventions to Improve Outcomes in Respiratory Syncytial Virus (RSV) Prevention in Pre-term Infants: A Case Study

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Prevention in Pre-term Infants: A Case Study

Michelle. L. Cooney, PT Date

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This manuscript is dedicated to all those persons dear to me in my life who provided so much support and encouragement to me along this journey. My deepest love and thanks to all of you.

Michelle

Home-Based Interventions to Improve Outcomes in Respiratory Syncytial Virus (RSV) Prevention in Pre-term Infants: A Case Report

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Abstract

Background and Purpose. Respiratory syncytial virus (RSV) affects the lungs and is the leading cause of hospitalization for infants below age one. Babies born pre-term, with congenital heart or lung disease, with low birth weight or from multiple births are at high risk to develop RSV. Studies show the effectiveness of pharmacological management of RSV using a series Palivizumab (trade name Synagis) vaccine. Research examining the use of Synagis in conjunction with a home-based education program of risk reduction is limited. The purpose of this case report is to describe the addition of a home-education program for risk reduction to a current prevention program using Synagis for pre-term infants. **Case Description.** The cases for this report were four infants born prematurely and diagnosed with disorders of the lung. All received physical therapy services at home, received the Synagis vaccine, and were instructed in a home program for risk reduction of RSV. **Outcomes.** The infant with the most comorbities had the most office visits and hospitalizations. The infants whose caregivers reduced the most risk factors had less physician visits and no hospitalizations. **Discussion.** Premature infants are at high risk to contract RSV which can lead to respiratory compromise later in life. As professionals working in homes, we have a unique opportunity to take a proactive approach to prevention of this disease by expanding and emphasizing our role as educators. Further research to investigate the link between outcomes and adherence to a home education program for RSV prevention is needed.

Key Words. Respiratory syncytial virus, Synagis, prematurity, early intervention.

Introduction

Respiratory Syncytial Virus (RSV), a virus affecting the lungs, is the most common cause of bronchiolitis and pneumonia among infants under one year of age. RSV is the number one cause of hospitalization in babies under one year of age.[1] The RSV virus causes narrowing of the small airways in the lungs (bronchioles) leading to wheezing and bronchiolitis.[2] About 125,000 children are hospitalized in the United States with RSV infection each year and approximately 500 (1-2%) of these children will die.[1] RSV can also cause croup, ear infection and pneumonia.[3] There is no permanent immunity to this virus which means people can be effected many times over.[2] RSV tends to occur seasonally, with the most infections occurring between October and April.

Symptoms of RSV begin like those of a common cold and may escalate to include wheezing, tachycardia, tight breathing, persistent cough (mucus producing), fever greater than 100.4 degrees and runny nose.[2] Other signs of RSV may include irritability and restlessness.[1] In severe cases, apnea and respiratory failure may result.[3] In the most severe situations death may result.[3]

RSV is diagnosed through by method of a rapid test performed by healthcare professionals on fluid obtained from the nose.[3] This virus is a strong concern for small children because of the possibility of long-term side effects. Over time, 30% of children who develop bronchiolitis from RSV later develop asthma.[2] Studies show that this virus can damage the lungs and lead to respiratory compromise in the future.[2]

At particularly high risk for RSV are babies born pre-term (<32 weeks gestation), those with chronic lung disease, those with low birth weight or babies of multiple births.[4] The number of premature births has risen over the last 10 years and some estimates project a

pre-term baby is born somewhere in the world every 60 seconds.[2] Pre-term infants have fewer maternal antibodies to help ward off infection making them highly susceptible to this virus.[2] The ability to identify signs and symptoms of this virus for early detection and treatment has been a focal point of recent pediatric literature.

Figueras-Aloy et al[5] discuss the risk factors for RSV in their research. Research conducted by the this group and referred to as the "FLIP Study" led to identifiable independent risk factors linked to RSV in premature infants. This prospective cohort study was conducted during 2005-2006 (October-April) and 2006-2007(October-April) RSV seasons. It included 5,441 children from 37 Spanish hospitals. The authors were able to isolate 3 independent risk factors found to significantly increase the risk of RSV related hospitalization including: absolute chronological age, presences of school-aged siblings or day car attendance, and smoking during pregnancy.[5] The authors used logistic regression analysis to demonstrate that the risk of RSV-related respiratory infection requiring hospital admission in pre-term infants was associated with the following factors:

- Absolute chronological age of 10 weeks at the onset of RSV season (odds ratio: 2.99; 95% confidence interval: 2.23-4.01)
- Presence of school-aged siblings or day care attendance (odds ratio 2.04, 95% confidence interval: 1.53-2.74)
- Smoking during pregnancy (odds ratio 1.61; 95% confidence interval 1.16-2.25).[5]

Additional studies to support evidence of these distinct and identifiable risk factors for RSV include a birth cohort study of 469 children in rural Kenya. In this study by Okiro et al[6] a COX regression was used to determine the relative risk of disease for a range of cofactors. Factors associated with RSV were severe stunting (z score<-2, RR 1.7 95% CI 1.1-2.8),

crowding (RR2.6, 95%CI 1.0-6.5), number of siblings under 6 years (RR 2.0, 95% CI1.2-3.4)[6]

An additional observation in this study was "higher education level of the primary caregiver was associated with protection."[6] This may indicate caregivers who are more educated may be more compliant with prevention measures. Once these risk factors are identified, the focus of treatment can move toward methods of prevention of infection with the RSV virus.

Methods to reduce risk of RSV advocated by the American Pediatric Association include the following:

- Toy washing
- Limiting exposure to school-aged children
- Limiting exposure to persons with colds
- Removal of household lung irritants
- Cessation of smoking in the household[2,3,4]

Recent literature not only confirms evidence of identifiable risk factors for RSV and advocates for methods of risk reduction but also supports the effectiveness of medicinal management of RSV. Since its approval by the Food and Drug Administration in 1998, the use of Palivizumab (trade name Synagis) through monthly intramuscular injection during the regionally determined RSV season has been the gold standard for RSV prevention.[7] The injection is administered seasonally, typically October through April and each dose gives infants only enough RSV fighting antibodies to last about 28-30 days.[7] Multiple published studies have provided evidence supporting the effectiveness of the prophylactic use of Synagis for RSV prevention.[7] One of these studies that strongly supported the use of Synagis

was the IM pact-RSV trial. In this study, 1502 infants were enrolled in a well constructed multicenter, double blind, randomized clinical trial of Synagis. Prophylaxis with this vaccine resulted in a 55% overall decrease in the rate of RSV-related hospitalization.[7] The rate of hospitalization with oxygen therapy was decreased by 55% with the use of Synagis and the overall number of days in the hospital for the infants with RSV using the vaccine was decreased by 40% overall. This study found that the use of Synagis with these infants resulted in an overall 27% decreased in the rate of hospitalization.[7]

Another current study by Singleton et al[8] involving the prophylactic use of Synagis was conducted with premature Alaska Native children. This population has historically demonstrated extremely high rates of hospitalization for RSV. Evidence from this cohort study demonstrated the efficacy of this prevention by reduction in rates of hospitalization from 439 per 1000 births to 150 per 1000 births (relative rate 0.34; 95%confidence interval, 0.17 to 0.68).[8]

A major drawback of the use of Synagis is its high cost. The Synagis injection costs about $900 or more a month. Most insurance companies are willing to pay for this type of RSV prophylaxis provided the patient meets the established criteria for a high-risk group.[9] To assist with establishing an eligibility criterion, the American Academy of pediatrics has developed guidelines for the indication of Synagis therapy. (Please refer to Table 1). The American Academy of Pediatrics advocates this guideline for Synagis when used in conjunction with programs of risk reduction for at risk infants.[3]

Physical therapists and other healthcare professionals working in the home bear a responsibility for educating caregivers about RSV as well as providing discipline specific techniques for early detection as part of their comprehensive management of these delicate

patients. Early Intervention programs provide a unique avenue for physical therapists to work closely with families in their home for improved outcomes in RSV prevention. A study by Golombek[10] compared compliance with prophylaxis for RSV in a home setting as compared to a physician's office. Results showed that there was a 98% compliance with dosage schedule in the home setting as compared to the 89% compliance in the office setting.[10] According to a survey conducted by the National Perinatal Association (NPA) "90% of parents whose babies have been hospitalized with RSV say that parents need better information about RSV".[11] Over half of all survey respondents rated the information they received about RSV as "fair" or "poor".[11]

Although prevention of RSV using the Synagis series of vaccines has proven effective in evidences-based research, there is limited research that has investigated the relationship of medicinal intervention in conjunction with a home education program of risk reduction and skilled diagnostic physical therapy techniques for early detection of RSV. The purpose of this case report is to describe the addition of a home- based caregiver education program for risk reduction and physical therapy management, including diagnostic screening techniques, to current RSV prevention programs for preterm infants.

Case Description

The focus for this in case report was infants born prematurely (at less than 32 weeks gestation), chronologically aged 2 or younger that were diagnosed with a disorder of the lung. These infants all received physical therapy services and were enrolled in the Early Intervention Program in Cayuga County. All subjects received the Synagis shots at monthly intervals prescribed by their pediatrician and were instructed by home healthcare providers in risk reduction for RSV.

Infant 1 was a female twin delivered at 28 weeks gestation via emergency c-section. Birth weight was 1215 grams (2.7 lbs). She was transported to another local hospital shortly after birth for neonatal intensive care unit (NICU) services. She was intebated and ventilated immediately after birth and underwent surgical repair of a hole in her heart at 7 days of age. The infant remained hospitalized in the NICU for 2 months and was discharged home with apnea monitor and continuous oxygen. She was diagnosed with prematurity, chronic lung disease and bradycardia. Infant 1 was referred to the Cayuga County Early Intervention Program at 3 months of age and began physical therapy services twice weekly at home at 4 months of age. She began Synagis shots at 4 months of age. Infant 1 resided in the same home as Infant 2 and had two other siblings under age 5. She resided primarily with her mother and grandmother who are smokers and spent additional time with her father whom also smokes.

Infant 2 was a male twin delivered at 28 weeks gestation via emergency c-section. Birth weight was 1300 grams (2.9 lbs). He was intebated and ventilated immediately and transported to another hospital for NICU services. This infant experienced a pneumothorax and had a chest tube inserted. Surgical repair of a hole in his heart was performed at 8 days. While hospitalized, he experienced massive pulmonary hemorrhage with acute deterioration. Infant 2 was discharged home at 2 months of age with an apnea monitor and a continuous oxygen machine. He was diagnosed with prematurity, hydrocephalus, pulmonary dysplasia and was referred to the Cayuga County Early Intervention Program at 3 months of age. Infant 2 began receiving physical therapy services twice weekly in his home at 4 months of age. He began Synagis shots at 4 months of age. Infant 2 resided in the same home as Infant 1 and

resided with two other siblings under the age 5. He resided primarily with his mother and grandmother who are smokers and spent additional time with his father who is a smoker.

Infant 3 was a female born at 28 weeks gestation that stayed in the NICU for 2 months. Her birth weight was 985 grams (2.2 lbs). She experienced respiratory difficulties at birth and was placed on continuous passive airway pressure (CPAP). In addition, she suffered a right germinal matrix hemorrhage and left grade 2 hemorrhage. While hospitalized, case 3 was eventually transitioned to a nasal canula for 12 hours per day. She received phototherapy to treat increased bilirubin levels. Upon discharge at 8 weeks, she continued with an apnea and heart monitor and oxygen at home. Infant 3 was diagnosed with prematurity, apnea, and brain bleed. She received her first Synagis shot at her pediatrician's office at 3 months of age and entered the Cayuga County Early Intervention program at 4 months of age, receiving physical therapy services in her home one time per week. She resided initially with her father in a home with multiple adults and school-aged children but was placed with her maternal grandmother at age 6 months when her mother died and father was incarcerated. Her maternal grandmother was a non-smoker and there were 4 other school aged children in the home.

Infant 4 was a male born at approximately 25 weeks gestation to an 18-year-old mother who received limited prenatal care. His birth weight was 645 grams (1.4 lbs) and he was delivered vaginally. Infant 4 was intebated and immediately transferred to the NICU. As per his medical record, he suffered from oligohydramnios (too little amniotic fluid) in utero. At birth, he had a swollen and bruised left hand and foot, mal-rotated left great toe, facial bruising, and contractures of the hips and elbows. He was diagnosed with pulmonary dysplasia, bronchopulmonary disease and chronic lung disease. Infant 4 underwent several

surgeries during his hospitalization including bilateral inguinal hernia repair, laser eye surgery, and g-tube insertion. He experienced severe gastro-intestinal reflux, had multiple infections, sustained an intracranial bleed and received several blood transfusions during his 226-day hospitalization. He was discharged with breathing and apnea monitors, continuous oxygen and multiple medications including steroid therapy. Infant 4 was discharged to a foster home where no one smoked and had bi-weekly supervised visitation with his biological mother. Infant 4 was referred to Cayuga County Early Intervention at age 7.5 months and began physical therapy services twice weekly. He began his Synagis shots at 8 months of age.

Interventions

A review of the medical record for all cases revealed that each infant received their initial Synagis shot from their physician. Twenty-eight to thirty days later, all infants began their series of Synagis vaccines in their home. A home health nurse delivered these shots after the infants were screened for any illnesses present on that day that would be contraindicated for administration of the medication. Caregivers in each of the cases were provided with educational materials regarding RSV and methods to be used for its prevention by the nurse administering the medication. This material was verbally reviewed with their caregivers and left in each home in written form (see Appendix). This packet of information explained the virus itself and who should receive prophylaxis Synagis in addition to suggestions for risk reduction in the home. The goal of this teaching intervention was to prevent each infant from contracting RSV.

Weekly physical therapy services were provided in the home for each infant. During these sessions, pulmonary status was monitored by method of caregiver interview, clinical

observation and auscultation of the lungs as needed. If lung congestion was detected, postural drainage techniques were employed to help the child mobilize secretions. Standard methods for reduction for the risk and spread of RSV were reinforced verbally with all caregivers by both the nursing staff and physical therapist on an ongoing basis.

To obtain information for this case report, a retrospective medical chart review for all cases, from birth through to age two, was performed at the Cayuga County Health Department after obtaining consent from all legal caregivers and the Cayuga County Health Department Administration. A single examiner conducted data collection in a single session. This data collection included the following information:

- Adherence to Synagis schedule
- Attendance to physical therapy sessions
- Number of office visits with positive respiratory infection
- Number of hospitalizations
- Reduction of risk factors in the home including: hand washing, washing toys, limiting exposure to school-aged children, limiting exposure to persons with illness, and removal of tobacco smoke from the household.

The data collection included all information described above and the infants were numbered 1-4 for the purpose of data collection in order to maintain confidentiality of the personal health record. Outcomes of this data collection are summarized in Figure 1. Review of the medical records demonstrated that upon discharge from the hospital to home, all infants began a monthly regime of Synagis shots as per orders from their primary physician. For infants 1, 2, and 3 this began at age 4 months. For infant 4 this began at 7.5 months due to his prolonged hospitalization and compromised health status. A physician, either in the

hospital or at the pediatrician's office, administered the first shot. After initial vaccination, a maternal health nurse from the county agency administered the rest of the shots at home. Each shot was given 28-30 days apart during the local RSV season of October through April until the children turned 2 years of age. Caregivers were given initial information regarding Synagis and reduction of risk factors as well as signs and symptoms of RSV. These materials were in written form that was left in each home after being reviewed verbally with each caregiver. In addition, weekly physical therapy services were initiated in the home to monitor gross motor skills and medical status. These sessions included developmental activities and respiratory assessment including auscultation of the lungs as well as postural drainage treatment as needed. Auscultation of lungs for detection of lung congestion was performed by the physical therapist based on the clinical observation and interview of caregivers regarding signs and symptoms of respiratory compromise. Clinical decisions for interventions were based on clinical assessment, observation of the child, and caregiver interview. If congestion, wheezing or increased respiratory rate was detected upon auscultation, the patient was referred to their primary care physician for further evaluation. Follow- up with recommendation for further evaluation by primary physician was excellent with infants 3 and 4 however limited with infants 1, 2. The limitations in follow up recommendations with infants 1, 2 were not only based on adherence by the caregiver but also limitations in resources including transportation to office visits and social dynamics in the home.

Throughout the time of treatment, the suggestions for risk reduction were reinforced verbally with all caregivers by the early intervention staff. Adherence to factors for risk

reduction was monitored throughout the episode of treatment and was recorded in the medical record for each infant. These outcomes are summarized in Figure 2.

Outcomes

Adherence to risk factor reduction in the home of infants 1, 2 was poor. Caregivers continued to smoke in the home, had poor compliance with hand and toy washing, and attempts to keep the infants away from persons with illness was minimal. In addition, caregiver compliance with preventative use of breathing treatments of albuterol was questionable. On several occasions caregivers reported being out of the medications, not having a workable machine or not having the machine in the home at all. Contributing factors of older siblings in the home with close interaction to the infants was also observed. Attendance to scheduled physical therapy sessions was 80.3% and 78.7% of sessions respectively. Carry through with the instructed home program of risk factor reduction and preventative breathing treatments was minimal.

In the case of infant 3, caregiver adherence to risk factor reduction was better than in cases 1 and 2. Although persons in the home smoked, they did so outdoors and toys were cleaned regularly and not shared with older siblings. Attendance to scheduled physical therapy sessions was 85% as calculated from the review of records and carry through with home risk reduction program was good.

Infant 4 was the most medically fragile and had multiple outings to specialist as well as and multiple therapists into and out of the foster home. Caregivers were excellent with instructed reduction of risk factors. They were diligent with hand washing, toy washing, and limiting exposure to illness and did not smoke. There were no other children in the home.

Attendance to scheduled physical therapy sessions was 95.3% of all scheduled sessions and carry through with home program of risk reduction was excellent.

All infants in this report followed the prescribed protocol for Synagis shots and rates of hospitalization were relatively low. Infant 1 was seen by her pediatrician for pulmonary complications 10 times in a 20-month period. The pediatrician diagnosed her with “lung infection” as opposed to RSV and treatment included an antibiotic and breathing treatments with albuterol. This infant was hospitalized once during this time frame of this case review (from 0-2 years old) for treatment of a lung infection. Risk reduction adherence in the home was poor and did not include cessation of smoking, washing of toys, washing of hands and limitation of exposure to persons with illness. In addition, infant 1 shared a crib frequently with her twin. During the time period covered by this case report, the infant was found to be ill more frequently than other infants as noted in the record. At age 2 ½, she was weaned from supplemental oxygen, all monitors and routine medications. At that time, she was released from the care of her pulmonary specialist.

Infant 2 was seen by his pediatrician for respiratory infection 8 times in a 20-month period. Although he was never hospitalized, frequent illness led to more absences from scheduled physical therapy sessions. This infant attended the least number of scheduled physical therapy sessions of all the infants in this case report. He lived in a home with multiple smokers. Risk reduction was poor and did not include toy or hand washing, or limitation of contact with illness and small children. In addition, he shared a crib with his twin sister frequently. One variance in treatment for this infant as noted in the record was that he more frequently than the other subjects required postural drainage techniques as part of his physical therapy program to maintain clearance of secretions in his lungs. This infant was

weaned from supplemental oxygen and his apnea monitor at age 2. At 2 ½ he was released by his pulmonary specialist and currently takes no routine medications. This infant does use albuterol treatments as needed due to ongoing respiratory compromise.

Infant 3 was seen twice by her physician in a 16-month period for respiratory infection. She received all Synagis shots at home through the Maternal Children's Health Program and her caregiver's adherence to the program of risk reduction good. Risk reduction factors that were complied within her home included: toy washing, hand washing, and limitation of exposure to persons with illness. Risk factors not eliminated from the home included limiting her exposure to multiple school-aged children in the home and cessation of smoking. The smoking was however restricted to the back porch of the home. This infant was quickly weaned from apnea monitor and heart rate monitor once she moved to her second home placement at the age of 6 months and was discharged from physical therapy services at age 22 months. This child now three years old, attends daycare, takes no routine medications and she no longer receives related services as her gross motor skills are at an age appropriate level and her health status is stable.

Infant 4, the most medically fragile of all cases, was seen by his physician for 8 respiratory infections in the 16-month period of treatment. This child was hospitalized on 3 separate occasions for lung infection and had multiple visits with specialist while in Early Intervention. He received all Synagis vaccines as scheduled and reduction of risk factors was excellent. His foster patents washed all toys, insisted on hand washing and use of anti-bacterial soap, limited visitation, did not allow those with illness around the child and never smoked according to the record review. This infant was unable to be weaned from oxygen or his breathing monitor but continued to make good strides in his growth and development. At

age 2 ½, infant 4 was placed in an adoptive home and continues with follow-up with a pulmonary specialist. This child continues on steroid therapy and continuous oxygen therapy as well as several other medications to maintain his health.

Discussion

In this case report, the infant who was the most medically fragile (infant 3) and had the most comorbities had the most visits to his pediatrician and most hospitalizations but missed the fewest scheduled physical therapy sessions. The twins (infants 1 and 2) whose caregivers had minimal adherence to an instructed home program for risk reduction demonstrated reduced attendance to scheduled therapy sessions and were ill more often than the other two infants (infants 3 and 4). Infant 3 whose caregiver reduced multiple risk factors, had the least office visits and no hospitalizations. Superior reduction of risk factors in the homes of infants 3 and infant 4 could possibly prevented illness but this requires more formal investigation in a structured study.

In addition to an education program of risk reduction for RSV, early detection of signs and symptoms of RSV by healthcare providers in needed to make timely medical referral for follow up care with primary care providers. Physical therapists as well as home health nurses are trained to screen for respiratory issues. In a study by Durani et al[12] the authors developed a clinical prediction model for lung sounds that identifies RSV infection in infants and young children. “The study included 197 patients and identified the combination of cough, wheezing, and retractions as predictors of RSV”.[12] Statistical analysis of data included backward stepwise logistic regression analysis: cough p=0.000, wheezing p=0.002 and retractions p=0.008 as independent predictive variables of RSV. This model had a sensitivity of 80% (95%CI, 71-87%), specificity of 68% (95%CI 54-79%), positive

predictive value of 82% (95%CI 74-89%), negative predictive value of 68% (95%CI 52-77), positive likelihood ratio 2.5 (95%CI 1.8-3.7) and post-test probability of 82%. [12] However, the identification of lung sounds through auscultation is only as good as our instrumentation. A study by Elphick et al[13] refuted the validity and reliability of acoustical analysis of respiratory sounds in infants using a stethoscope. They concluded that the stethoscope is unreliable for assessing respiratory sounds in infants. This has important implications for its use as a diagnostic tool for lung disorders in infants and confirms that it cannot be used as a gold standard.[13] Data analysis shows "Convergent validity for agreement between stethoscope examination and acoustic analysis was poor for wheeze (k=0.07, 95%CI –0.13 to 0.26), and rattles (k=0.11 95%CI, -0.05-0.27) and fair for crackles (k=0.36, 95%CI0.18-0.54). It was further suggested by this study that healthcare providers working in pediatrics use stethoscopes specific to the pediatric population (i.e. smaller drum) for improved accuracy when auscultating lungs of infants.[13] This evidence indicates that the accuracy of diagnosis through lung auscultation may be questionable due to issues with the reliability of the instrumentation used. Therefore this method to assess lung congestion and the need for further medical referral may be questionable.

As healthcare professionals, we bear a responsibility as primary educators of caregivers about RSV as well as providers of discipline specific techniques for early detection. Early Intervention programs provide a unique avenue for physical therapist to work closely with families in their home for improved outcomes in RSV prevention. Golomek et al [10] performed a study that compared compliance with prophylaxis for RSV in a home setting as compared to a physician's office. Results showed that there was a 98% compliance with dosage schedule in the home setting as compared to the 89% compliance in

the office setting.[10] According to a survey conducted by the National Perinatal Association "90% of parents whose babies have been hospitalized with RSV say that parents need better information about RSV".[11] Over half of all survey respondents rated the information they received about RSV as "fair" or "poor".[11] Clearly, more effective education of caregivers is needed.

The review of records for infants 1 and 2 indicates an increased number of visits to the physician for illness related to respiratory compromise. Although education regarding reduction in risk factors was provided on an ongoing basis, adherence to suggestions was minimal. These subjects also frequently shared a crib and dates of illnesses coincided indicating the virus may have been transmitted back and forth. This assumption is supported by the research of Okiro et al[6] who found shunting to be a contributing factor to spread of the virus. In addition, research shows the virus can live for up to 7 hours on surfaces so the failure to disinfect toys, wash hands and keep mucus contained may also have contributed to illness.[4]

Infant 3 remained relatively healthy with few visits to the physician for respiratory illness and no hospitalizations. Caregivers were receptive to suggestions to reduce risk in the home and compliant with suggestions for follow up when respiratory illness was suspected. She made steady improvement in her respiratory status and had the most positive outcomes of all 4 subjects. This subject was weaned from supplemental oxygen and apnea monitor more quickly than the other cases and had the least number of visits for illness to her physician as well as no hospitalizations. She is now a healthy 3 year old and enrolled in a typical preschool. Infant 3 no longer receives physical therapy services.

Infant 4 presented with multiple comorbities and had fragile health status throughout the time period for record review. Although his caregivers were diligent with reduction of risk factors in the home and compliance with referral to physician as indicated by diagnostic pulmonary screen in the home, he had the most visits to the physician for respiratory infection and the highest number of hospitalizations of all cases. The multiple medical complications as well as his dependence on steroid therapy may have influenced his degree of illness. Steroid use tends to suppress the immune system making this client more susceptible to the virus.[6]In addition, this subject received the most related service support from outside the home (physical therapy, occupational therapy, nursing, speech therapy and special education teacher, social services and adoption workers). These persons coming into the home may have carried more viruses as well. In addition, the influence of limited prenatal care is unable to be determined.

These infants demonstrate that multiple factors have an influence on the health status of premature babies receiving Early Intervention services in the home. This case report supports the assertion in the literature that the series of Synagis vaccine are an effective way to mange RSV under specific conditions. The specific conditions met by each infant include:

- Administration at appropriate age
- Application during appropriate regional RSV season
- Compliance to risk reduction techniques
- Providing this intervention during a full season cycle of the virus.[7]

Although this treatment strategy of using Synagis management of RSV has demonstrated efficacy in the literature, the cost–effectiveness for this strategy is debated in the medical community.[9] Providing this prophylaxis in the home setting was supported as

best practice by current literature as it eliminates barriers to compliance including transportation and caregiver motivation.[14] The physical therapist working in the home is in a unique position as primary educator for compliance as well as risk reduction.[14] In addition, they are available as diagnosticians for early detection of the signs and symptoms of RSV. Their established relationship with parents can make compliance with medical referral in these cases more viable.

There were several limitations to this case report. The infants included in this case report were not an exact match diagnostically and the inclusion criterion was broad. Although similar in diagnoses, Infant 4 had several co morbidities that influenced his health status and may have led to his increased number of hospitalizations. In addition, a subject group of four is a small number to draw data from and to generalize information about. Furthermore, service delivery in other Early Intervention Programs may be variable and yield different outcomes. A sampling from several Early Intervention programs may yield information that is more easily generalized. Another factor which warrants further examination regarding its influence in this case report is the examination of barriers to adherence including; literacy of caregivers, transportation to physician, mental issues of caregivers, social and economic factors. An additional influence on compliance was the belief system of the primary care physician. (i.e. whether or not he/she valued the opinions of the Early Intervention provider or gave credence to reports of respiratory compromise provided by the caregiver). This may or may not have led to having patient come to the office for a sick child visit or having the child continue to be treated at home.

An additional confine of the case report relates to interrater reliability. Although the same therapist treated all patients, the determination of adherence with the reduction of risk factors documented in the record was subjective.

Although limitations to this case report exist, information yielded may be supportive of a possible positive relationship between caregiver adherence to risk reduction strategies in the home and improving outcomes for RSV prophylaxis. The extent of that relationship requires further research with a larger patient population. As providers we need to be diligent about continually improving our outcomes even though we have a medicinal treatment from which the evidence demonstrates positive outcomes. Small adjustments like adding a home education program to our treatment protocol could possibly lead to even better outcomes for our patients.

This case report described the addition of a home education program for risk reduction to an ongoing program of RSV prevention using Synagis vaccine injections along with physical therapist management of pre-term infants. Whether risk reduction will influence long term effects of RSV on respiratory compromise later in life cannot be determined. Nor can we determine how many respiratory infections were prevented by reduction of risk factors at home. A home based intervention that combined caregiver education and diagnostic physical therapy techniques, in addition to medical management of RSV, may have produced a better outcome for these pre-term infants.

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Table 1: American Academy of Pediatrics Indication for Palivizumab Therapy for RSV Prevention

Children less then two years of age with chronic lung disease
Premature infants who were born less than 28 weeks and who are less than 12 months old at the start of RSV season
Premature infants who were born between 29-32 weeks and who are less than 6 months old at the start of RSV season
Premature infants who were born between 32-35 weeks and who are less than 6 months old at the start of RSV season and have 2 or more risk factors including; attending daycare, having school aged siblings, exposure to environmental pollutants, congenital airway abnormalities and /or severe neuromuscular disease
Certain children who are younger than 2 years of age with congenital heart disease, including congestive heart failure, pulmonary hypertension, and cyanotic heart disease

Figure 1 - Outcomes

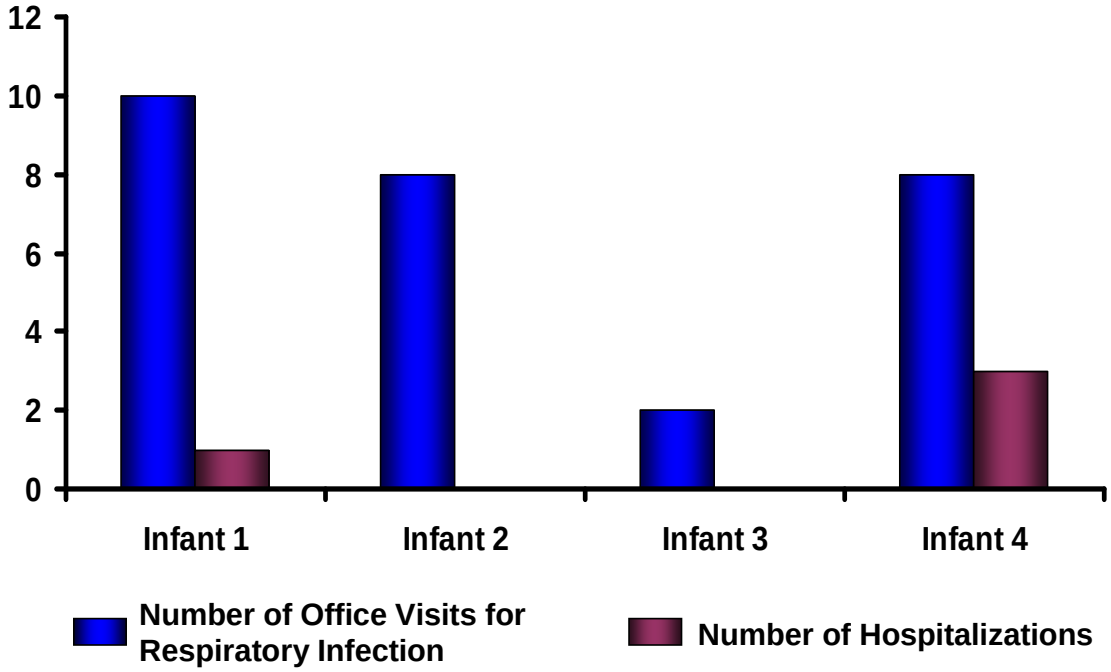
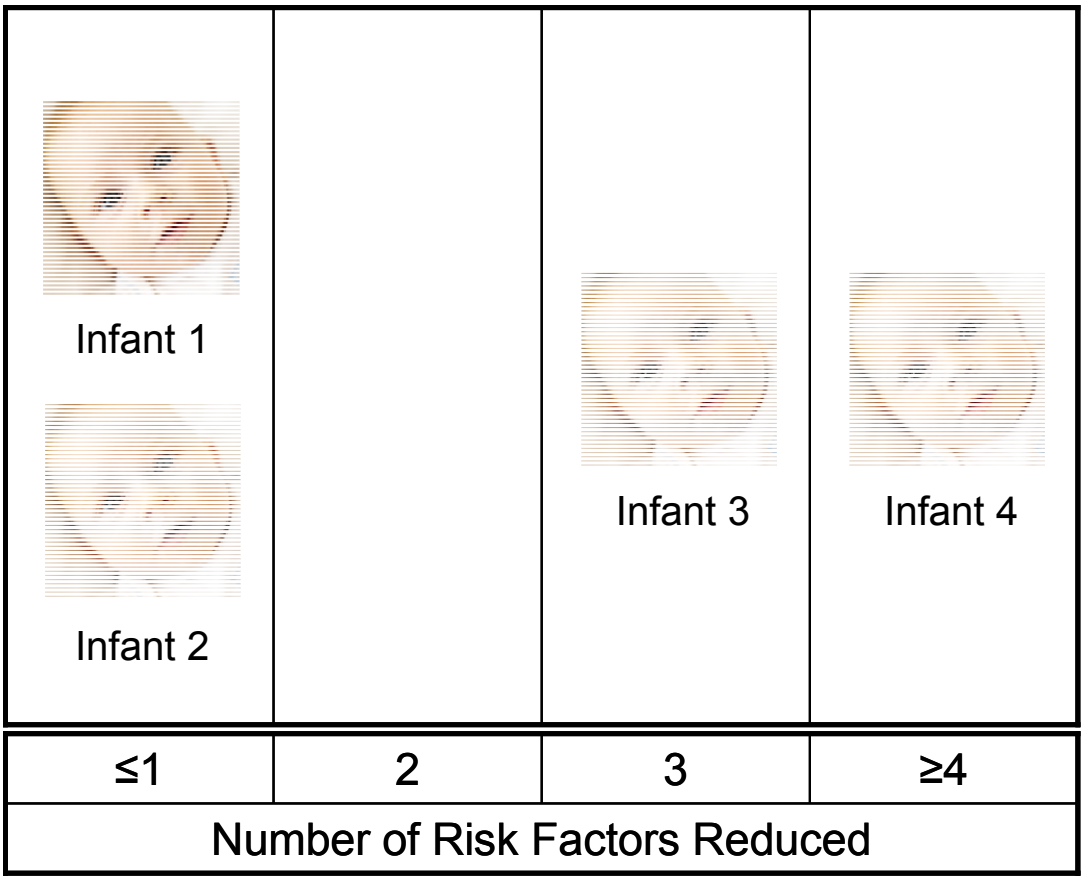
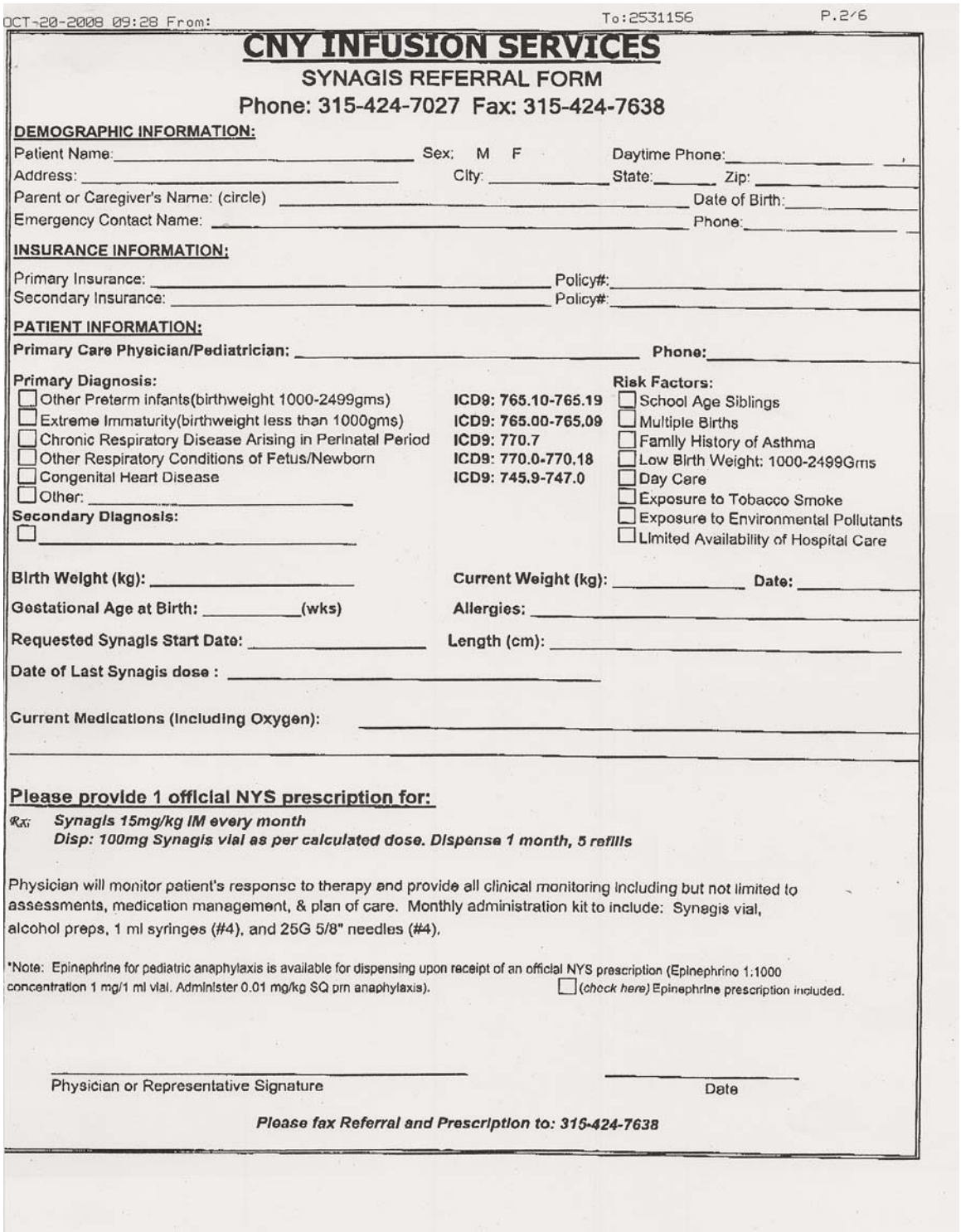


Figure 2: **Risk Factor Reduction Adherence**



Appendix: Cayuga County Health Department Early Intervention Program Handouts for RSV Referral and Prevention



OCT-20-2008 09:28 From: To:2531156 P.2/6

CNY INFUSION SERVICES

SYNAGIS REFERRAL FORM

Phone: 315-424-7027 Fax: 315-424-7638

DEMOGRAPHIC INFORMATION:

Patient Name:_____ Sex: M F Daytime Phone:_____

Address: _____ City: _____ State:_____ Zip: _____

Parent or Caregiver's Name: (circle) _____ Date of Birth:_____

Emergency Contact Name: _____ Phone:_____

INSURANCE INFORMATION:

Primary Insurance: _____ Policy#:_____

Secondary Insurance: _____ Policy#:_____

PATIENT INFORMATION:

Primary Care Physician/Pediatrician: _____ **Phone:**_____

Primary Diagnosis:

- ☐ Other Preterm infants(birthweight 1000-2499gms) — **ICD9: 765.10-765.19**
- ☐ Extreme Immaturity(birthweight less than 1000gms) — **ICD9: 765.00-765.09**
- ☐ Chronic Respiratory Disease Arising in Perinatal Period — **ICD9: 770.7**
- ☐ Other Respiratory Conditions of Fetus/Newborn — **ICD9: 770.0-770.18**
- ☐ Congenital Heart Disease — **ICD9: 745.9-747.0**
- ☐ Other: _____

Secondary Diagnosis:

☐ _____

Risk Factors:

- ☐ School Age Siblings
- ☐ Multiple Births
- ☐ Family History of Asthma
- ☐ Low Birth Weight: 1000-2499Gms
- ☐ Day Care
- ☐ Exposure to Tobacco Smoke
- ☐ Exposure to Environmental Pollutants
- ☐ Limited Availability of Hospital Care

Birth Weight (kg): _____ **Current Weight (kg):** _____ **Date:** _____

Gestational Age at Birth: _____(wks) **Allergies:** _____

Requested Synagis Start Date: _____ **Length (cm):** _____

Date of Last Synagis dose : _____

Current Medications (Including Oxygen): _____

Please provide 1 official NYS prescription for:

℞: ***Synagis 15mg/kg IM every month***
Disp: 100mg Synagis vial as per calculated dose. Dispense 1 month, 5 refills

Physician will monitor patient's response to therapy and provide all clinical monitoring including but not limited to assessments, medication management, & plan of care. Monthly administration kit to include: Synagis vial, alcohol preps, 1 ml syringes (#4), and 25G 5/8" needles (#4).

*Note: Epinephrine for pediatric anaphylaxis is available for dispensing upon receipt of an official NYS prescription (Epinephrine 1:1000 concentration 1 mg/1 ml vial. Administer 0.01 mg/kg SQ prn anaphylaxis). ☐ *(check here)* Epinephrine prescription included.

_____ _____

Physician or Representative Signature Date

Please fax Referral and Prescription to: 315-424-7638

333 Butternut Drive
Dewitt, NY 13214
315-424-7027

Patient Education Monograph

Monograph For SYNAGIS

Patient:

Issue Date: July 30, 2008

The information in this monograph is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. This information is generalized and is not intended as specific medical advice. If you have questions about the medicines you are taking or would like more information, check with your doctor, pharmacist, or nurse.

GENERIC NAME: PALIVIZUMAB(pah-lih-VIH-zyou-mab)

COMMON USES: This medicine is a monoclonal antibody used to prevent serious lower respiratory disease caused by Respiratory Syncytial Virus (RSV) in certain children.

HOW TO USE THIS MEDICINE: This medicine is usually administered as an injection into the muscle at your doctor's office, hospital, or clinic. Ask your doctor, nurse, or pharmacist any questions that you may have about this medicine. IF YOU ARE USING THIS MEDICINE AT HOME, a healthcare professional will provide detailed instructions for its appropriate use. Ask them any questions that you may have about your medicine or giving injections. If the medicine is discolored, contains particles, or if the vial is cracked or damaged in any way, do not use it. WHEN DRAWING A DOSE INTO A SYRINGE, be sure to follow the procedure demonstrated to you to prevent contamination of the vial, syringe, or medicine. Never touch the rubber stopper of the vial or the needle of the syringe with your fingers. CAREFULLY CHECK that you have drawn the correct dose before administration. DO NOT SHAKE the vial before using. STORE THIS MEDICINE in the refrigerator between 36 and 46 degrees F (2 and 8 degrees C) in its original container. Do not freeze. This vial is intended for a single use only. Throw away any medicine left in the vial after the first use. Do not use this medication past the expiration date on the container. Use this medicine regularly as directed by your doctor to receive the most benefit from it. Continue using this medicine for the full course of treatment. Do not miss any doses. IF YOU MISS A DOSE OF THIS MEDICINE, contact your doctor as soon as possible.

CAUTIONS: DO NOT USE THIS MEDICINE if you have had an allergic reaction to it or are allergic to any ingredient in this product. IF YOU EXPERIENCE difficulty breathing; tightness of chest; swelling of eyelids, face, or lips; or if you develop a rash or hives, tell your doctor immediately. Do not take any more of this medicine unless your doctor tells you to do so. DO NOT EXCEED THE RECOMMENDED DOSE or use this medicine for longer than prescribed without checking with your doctor. KEEP ALL DOCTOR AND LABORATORY APPOINTMENTS while you are using this medicine. BEFORE YOU BEGIN TAKING ANY NEW MEDICINE, either prescription or over-the-counter, check with your doctor or pharmacist.

POSSIBLE SIDE EFFECTS: SIDE EFFECTS that may occur while using this medicine include stuffy nose; diarrhea; cough; vomiting; upset stomach; or pain, swelling, or redness at the injection site. If they continue or are bothersome, check with your doctor. CHECK WITH YOUR DOCTOR AS SOON AS POSSIBLE if you experience ear pain or fever. CONTACT YOUR DOCTOR IMMEDIATELY if you experience swelling of your hands, legs, face, lips, eyes, throat, or tongue; difficulty swallowing or breathing; wheezing; or hoarseness. An allergic reaction to this medicine is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include rash, itching, dizziness, swelling other than the injection site, or trouble breathing. If you notice other effects not listed above, contact your doctor, nurse, or pharmacist.

Date Printed: 10/07/2008

333 Buttornut Drive
Dewitt, NY 13214
315-424-7027

Patient Education Monograph

Monograph For SYNAGIS

Patient:

BEFORE USING THIS MEDICINE: INFORM YOUR DOCTOR OR PHARMACIST of all prescription and over-the-counter medicine that you are taking. DO NOT START OR STOP any medicine without doctor or pharmacist approval. Inform your doctor of any other medical conditions, including blood or bleeding problems (such as hemophilia or thrombocytopenia), certain heart surgery (such as cardio-pulmonary bypass), or allergies. Contact your doctor or pharmacist if you have any questions or concerns about taking this medicine.

OVERDOSE: IF OVERDOSE IS SUSPECTED, contact your local poison control center or emergency room immediately.

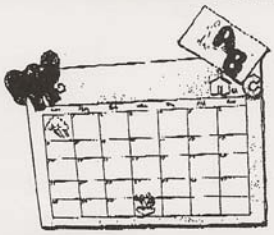
ADDITIONAL INFORMATION: DO NOT SHARE THIS MEDICINE with others for whom it was not prescribed. DO NOT USE THIS MEDICINE for other health conditions. KEEP THIS MEDICINE out of the reach of children. KEEP THIS PRODUCT, as well as syringes and needles, out of the reach of children. Do not reuse needles, syringes, or other materials. Dispose of properly after use. Ask your doctor, nurse, or pharmacist to explain local regulations for selecting an appropriate container and properly disposing of the container when it is full. KEEP THIS MEDICINE out of the reach of children.

Date Printed: 10/07/2008

RSV is the #1 cause of hospitalization in babies under one year of age.

Is your baby at risk for RSV?

Respiratory syncytial virus (RSV) is a common, easily spread virus that almost all children catch at least once by the time they turn two. It usually causes moderate to severe cold-like symptoms. But for babies born at 35 weeks or less, or born with heart or lung problems, RSV can lead to serious lung infection, hospitalization, breathing problems and, in some cases, death. RSV has also been linked to asthma-like wheezing episodes during childhood.



Learn when RSV season starts in your area.

RSV season usually starts in the fall and runs into the spring, but can be different in certain parts of the country. Ask your baby's doctor about RSV season in your area.

Watch for these RSV symptoms.

If you see any of these common RSV warning signs, call your baby's doctor right away:

- **A fever above 100.4°F**
- **Bluish lips or fingertips**
- **Coughing**
- **Wheezing**
- **Trouble breathing**
- **Rapid breathing**
- **Gasping for breath**

Talk to your baby's doctor.

- Talk to your child's healthcare provider to find out if your child is at risk for severe RSV infection.
- And if the doctor says your child is at high risk, ask about ways you can help protect your baby from RSV.

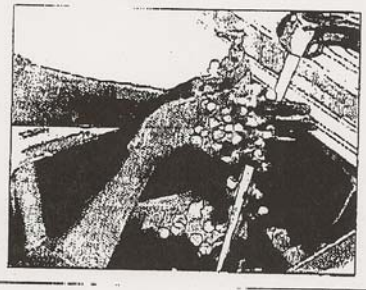
To get more information, call **1-866-441-9863** or visit **www.aboutRSV.com**

5YN07-050

Printed in USA

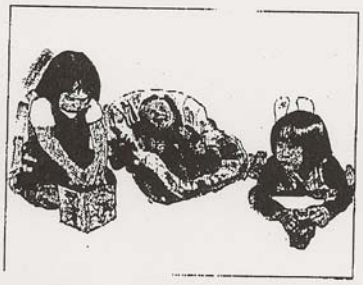
Tips to help keep your baby safe.

Everyone wants to see your baby. But RSV spreads just like a regular cold, so you have to take a few extra precautions around family and friends. Here are some ways to give your baby added protection during RSV season. For more information, call **1-866-441-9863** or visit **www.aboutRSV.com**.



Wash your hands before touching your child, and make sure others wash their hands, too.

Clean your baby's toys, crib rails and any other surfaces he or she might touch.



Avoid exposing your baby to crowds, like at daycare, family gatherings, or public places. Keep your baby away from anyone with a cold or fever.

Don't let anyone smoke near your baby. Tobacco smoke can increase the risk of severe RSV.

To get more information, call **1-866-441-9863** or visit **www.aboutRSV.com**

Palivizumab Solution for injection

Trade Names

Synagis

The list of names may not include all products that are available on the market.

What is this medicine?
PALIVIZUMAB is an antibody. It is used in high risk children to prevent severe cases of respiratory syncytial virus (RSV) infection. Children treated with this medicine may still get RSV but will not get as sick as if they were not treated at all. This medicine does protect against other infections.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

What should I tell my health care provider before I take this medicine?
They need to know if you have any of these conditions:
- blood or bleeding disorder
- immune system problem
- an unusual or allergic reaction to palivizumab, vaccines or antibodies, other medicines, foods, dyes, or preservatives
- pregnant or trying to get pregnant
- breast-feeding

How should I use this medicine?
This medicine is for injection into a muscle. It is given by a health care professional in a hospital or clinic setting.

Talk to your pediatrician regarding the use of this medicine in children. While this drug may be prescribed for selected conditions, precautions do apply.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?
It is important not to miss your dose. Call your doctor or health care professional if you are unable to keep an appointment.

What may interact with this medicine?
Interactions are not expected.

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?
Side effects that you should report to your doctor or health care professional as soon as possible:

- allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- blue color to lips, skin
- breathing problems
- loss of appetite
- ear pain
- fast, irregular heart beat
- fever
- less active
- less alert
- very irritable

Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome):

- cough
- pain at site where injected
- runny nose

This list may not describe all possible side effects.

What should I watch for while using this medicine?
See your health care provider for monthly injections of this medicine as directed.

Where should I keep my medicine?
This drug is given in a hospital or clinic and will not be stored at home.

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.

CDC Features

Learn about Respiratory Syncytial Virus

Respiratory syncytial virus (RSV) is a con viral disease that can lead to serious hea problems—especially for young children a older adults. There is no vaccine to preve However, there are simple ways you can your child or yourself from getting sick d RSV season.

Some quick facts about respiratory syncytial virus, or RSV:

- It is a contagious viral disease that infects a person's lungs and breathing passages.
- RSV mostly strikes younger children and older adults.
- Almost everyone gets RSV by age 2.
- People can get the disease more than once.
- Most people recover from the disease in a week or two, but RSV can be severe, most commonly for children 6 months of age and younger.
- The number of RSV cases typically rise in the fall, winter, and early spring, but the exact timing of RSV season varies by location.

Symptoms

RSV symptoms are like those of many other respiratory illnesses. Infants and young children may experience a fever, reduced appetite, runny nose, cough, and wheezing. Older children and adults may have a runny nose, sore throat, headache, cough, and a feeling of general sickness. RSV also can lead to more serious illnesses in both children and adults, including pneumonia and bronchiolitis.

Transmission

RSV spreads when an infected person coughs or sneezes, sending respiratory droplets into the air. These dropl contain RSV and can end up in other people's mouths or noses, causing an infection. The droplets can also lanc objects that people touch, such as toys or countertops. People can get infected by touching these objects and t touching their mouths or noses. Children often pass the virus to one another at their school or daycare center.

Prevention

To help prevent the spread of RSV, people who have cold-like symptoms sh

There is not yet a vaccine to protect against RSV. However, for high-risk chi
babies, monthly shots with a drug called palivizumab can help prevent serio
your healthcare provider if your child would be a good candidate for the dru

Care

If you think that you or your child might have an RSV infection that requires
appointment with a healthcare provider. Such visits are common for young
evaluate the severity of the illness and decide how best to treat it. RSV sym
adults clear up on their own in a week or two.

More Information

RSV

Respiratory Syncytial Virus (RSV) Surveillance (Seasonal and geographic pa

- RSV: A Respiratory Virus in Young and Old (🎧 4:37 mins)

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