Passive immunization against RSV using either RespiGam® (RSV-IGIV {Human}), or Synagis™ (palivizumab) has been available in Canada for the past two years RSV seasons. The goal is to minimize the severity of a RSV-infection in high risk young infants, although the cost-benefit issue remains unclear and probably varies from region to region. Available data (from Abbott Laboratories, Ltd.) so far have indicated that, for eligible infants who have been treated, the vast majority have opted for Synagis™ because of its relative ease of administration and lack of any serious side effects. It is well tolerated and compliance in completing the full course of injections is high. Physician awareness has also increased, with the number of physicians administering Synagis™ in London increasing 4-fold over the two RSV seasons, 1998-99 and 1999-2000. In Southwestern Ontario the number of physicians requesting the product has doubled over the two seasons.

Infants Eligible to Receive RSV Immunoprophylaxis

For the upcoming RSV season (winter months 2000 - 2001), Canadian Blood Services (CBS) will continue to make available the two products to eligible infants through the Special Access Program. The categories for CBS funding have not changed and are based on recommendations of the Canadian Paediatric Society:

1. Children under 2 years of age with bronchopulmonary dysplasia and who have required oxygen therapy within the 6 months preceding the RSV season (deemed to start late November each year).
2. Infants born ≤32 weeks gestation and aged ≤6 months as of the start of the RSV season.

Note: Product requests not meeting the funding criteria described above require a letter of support for medical review before funding by CBS can be considered.

Other preventive measures remain important and should be emphasized:

- Hand washing
- Eliminating exposure to tobacco smoke
- Minimizing exposure to contagious settings such as childcare centres

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To Request RespiGam® or Synagis™

The requesting physician should complete a Respiratory Syncytial Virus Prophylaxis Request Form for each patient and FAX it to the appropriate agent listed below:

Completed Request Forms for Synagis™ must be faxed to:
Abbott Laboratories: (514) 832-7251

Completed Request Forms for RespiGam® must be faxed to:
Special Access Program: (613) 941-3194

The RSV season typically lasts up to five months. The beginning of the season in any year varies across Canada, and clinicians should check with local infectious diseases specialists or microbiologists to determine when the RSV season begins in their communities. The NICU at St. Joseph’s Health Care, London, will start to offer RSV Immunoprophylaxis to eligible preterm infants on November 15, 2000.

Information for Parents

The majority of eligible infants would have been graduates of Neonatal Intensive Care Units. An information pamphlet on prevention of RSV infection will be sent to the parents of eligible infants who have been admitted to the NICU at St. Joseph’s Health Care, London. The parents are encouraged to discuss the available options with their physicians.

Additional Information

The administration of RespiGam®, a blood product, may require a 3 to 4 hour-admission to a hospital. In the London region this can be arranged through the Paediatric Medical Day Unit of the Children’s Hospital of Western Ontario by calling (519) 685-8434. This product will be maintained at most CBS Blood Centres. It is advisable to contact the local Blood Centre to confirm availability.

RespiGam®, but not Synagis™, interferes with the response to measles, mumps and rubella (MMR) vaccine. Hence, the first dose of MMR vaccine should be deferred for ten months after the last dose of RespiGam®. If MMR vaccine had been administered within ten months after the last RespiGam® infusion, the child should be revaccinated. Schedules for other childhood immunizations are not affected.

Product Information

<table>
<thead>
<tr>
<th>Antibodies Source</th>
<th>Synagis™</th>
<th>RespiGam®</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Monoclonal antibody effective only against RSV (humanized murine antibody produced by recombinant DNA technology)</td>
<td>Polyclonal antibodies, enriched in RSV-neutralizing antibodies and antibodies to other viruses (from pooled human plasma)</td>
</tr>
<tr>
<td>Licensing</td>
<td>Not licensed currently in Canada but licensed by FDA, USA (1988)</td>
<td>Licensed by Health Canada in 1997 and FDA, USA</td>
</tr>
<tr>
<td>Available by Approval</td>
<td>Funded by CBS only with approval of the Special Access Program</td>
<td></td>
</tr>
<tr>
<td>For Medical and Scientific Information Contact:</td>
<td>Abbott Laboratories Ltd., St. Laurent, Quebec 1-888-832-7755</td>
<td>Genesis Bio-Pharmaceuticals Inc., Hackensack, New Jersey 1-800-828-6941</td>
</tr>
<tr>
<td>Route of administration</td>
<td>Intramuscular (IM) injection</td>
<td>Intravenous (IV) infusion</td>
</tr>
<tr>
<td>Dose</td>
<td>15 mg (0.15 ml)/kg</td>
<td>750 mg (15 ml)/kg</td>
</tr>
<tr>
<td>Frequency</td>
<td>Monthly for 5 months during the RSV season</td>
<td></td>
</tr>
<tr>
<td>Interference with MMR vaccine</td>
<td>No</td>
<td>Yes*</td>
</tr>
</tbody>
</table>
RSV Passive Immunization: The Owen Sound Experience, 1999 - 2000

Introduction

Following the initiation of RSV immunoprophylaxis program for premature infants in London, Ontario, the Department of Paediatrics at the Grey Bruce Health Services (GBHS), Owen Sound decided in October 1999 to organize a follow-up immunization against RSV for all returning and other eligible preterm infants in this region. The GBHS provides services to a regional population of approximately 150,000. In the RSV season from December 1999 to April 2000 there were 8 families who had preterm infants who met the eligibility criteria for RSV immunization.

Organization

Although the Canadian Paediatric Society has recently published guidelines on the use of Synagis™ (palivizumab) and RespiGarm® (RSV-IGIV) for the passive immunization against RSV infection for high risk infants (1), there has been no recommendation on the organizing of any RSV immunization clinics. Since these products were new and expensive we felt that it would be beneficial to coordinate the administration of these products to eligible infants in our region. Furthermore, in order to monitor for any potential or untoward adverse effects it would be prudent to administer these in a hospital setting, with supervision of nursing and medical staff. We believed this to be advantageous to the patients and the health care system.

The Nurse Clinician

With only two full-time paediatricians in the hospital, a Nurse Clinician, from the Women and Child Care Unit, joined the team to oversee the organization of a RSV Clinic. Her role included:
- To meet with all stakeholders to implement the RSV outpatient clinic;
- To develop documentation tools;
- To organize and monitor patient scheduling;
- To incorporate the Intensive Care Nursery (ICN) nursing staff and facilities into the Clinic;
- To provide feedback to “London’s research team after parent signed release of information form.

She was responsible for patient scheduling, the proper documentation for each patient and the collection of work-related statistics. Patient documentation was based on the London “schedule form” which included information on patient demographics, date, weight, site of injection, dose ordered, nurses’s signature, follow-up clinic dates and any adverse reactions.

The Pharmacy

For the 1999-2000 RSV season only one product, namely Synagis™, was chosen, at the discretion of families, for passive immunization. This medication was not listed on the hospital formulary. The Pharmacy provided vital support to this program by assisting with the storage of this product at the proper temperature. This was helpful to the nursing unit, as the refrigerators in the ICN were not insured for product replacement.

The Level II Intensive Care Nursery (ICN)

The ICN conveniently provided nursing assistance and space for a trial of this program. A vacant area of the ICN was set aside to run the RSV Outpatient Clinic on a monthly basis. The ICN nurse on duty would weigh the infant and check the vital signs before and after the injection. She was responsible for reconstituting the Synagis™ product, its administration and infant assessment. The IM injection was given in the vastus lateralis of the thigh, using an appropriate length needle (16mm-25mm) to enter the muscle, and the site was recorded.

Since the primary responsibility of the ICN nurse was in the nursery she was only able to attend to the on-site Clinic in the afternoons and only one infant at a time. Each session took approximately 30 minutes. She was simultaneously responsible for the babies in the ICN. Backup was available as necessary.

The Paediatrician

An on-call Paediatrician was available to do an infant assessment before ordering the weight-based dose. He was responsible for the prescription and for any medical issues relating to the immunization.
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Other Stakeholders

Ambulatory Care

Each visit constitutes an outpatient visit. An ambulatory registration form was used to document the visit appropriately and permitted the detailing of vital signs, physician assessment and orders and nursing comments. The registration clerk received notification from the Nurse Clinician of the booked appointments in order to prepare the documentation in advance.

Nursing Information Co-ordinator

A workload measurement tool (Medicus) was developed and completed for each clinic visit. It logged the actual time taken for each visit and the number of infants attended. This tracking helped to determine the actual number of hours of nursing time required to run the clinic. The tool helped to demonstrate a need to reorganize the Clinic to an area that is more suitable for ambulatory care.

Treated Infants and Family Feedback

A total of nine infants, including a set of twins, were eligible for immunization according to the CPS guidelines (1) published in the fall of 1999. These were:

1. Patients < 2 years of age with bronchopulmonary dysplasia and who have required oxygen within the 6 months preceding the RSV season.
2. Infants born ≤ 32 weeks gestation and ages ≤ 6 months as of the start of the RSV season.

During the RSV season an eligible infant received the first dose of Synagis™ shortly before discharge from hospital. If an injection schedule had already been started in London, the schedule was continued here. Follow-up injections were scheduled at intervals of no more than 30 days.

One family with twins lived 2 hours away from Owen Sound. After the 2nd injection, they chose to have follow-up with their family physician. Information was sent along with the next month’s supply of Synagis™ and the family physician became responsible for subsequent injections.

The other families have returned according to the scheduled appointments. The parents had felt that the relatively small inconvenience of a clinic visit was well worthwhile if it was protecting their baby from a severe RSV infection. Some parents had first hand knowledge of other infants who had become severely ill with RSV and who had required endotracheal intubation and mechanical ventilation prior to being airlifted to a tertiary centre for further intensive care. They believed this to be a good prevention program. Of the treated infants, two had reportedly been hospitalized for respiratory illness but the RSV cultures were negative.

Challenges

Within the constraints of limited resources, we felt that our team had pulled together to offer this service to infants in our region. The Clinic functioned well and was valued by our families.

One of the most valuable experiences was to figure out how to maximize the efficient use of a very expensive medication. By means of careful scheduling we were able to adhere to a recommendation from the Neofax: “Administer doses to 2 or more eligible patients within 6 hours of reconstitution to minimize wastage” (2).

Future:

We have identified a need to incorporate these infants into an appropriate Ambulatory Care setting. Proper resources have to be in place to ensure the success of such a program. Efforts are underway to form a partnership with the Ambulatory Care Department, so that a part-time RN and an on-call Paediatrician can staff an Outpatient RSV Clinic, in time for the 2000-2001 RSV season. We have also felt that there are other at risk infants, currently not meeting treatment criteria, who may well benefit from proper protection against RSV. Perhaps the current criteria for inclusion should be broadened to include the larger preterm infants who may also be at risk of severe RSV infection.

References:

(1) Canadian Paediatric Society Statement. Palivizumab and respiratory syncytial virus immune globulin intravenous for the prophylaxis of respiratory syncytial virus infection in high risk infants. Paediatrics & Child Health 1999;4(7); 474-80.

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Women & Child Care Unit, Grey Bruce Health Services
Owen Sound, Ontario

George Sanz; M.D., FRCP, Paediatrican
Grey Bruce Health Services, Owen Sound, Ontario

David S. C. Lee, MB, FRCP, Neonotologist
St. Joseph’s Health Care, London, Ontario

Introduction

The Perinatal Outreach Program of Southwestern Ontario has been surveying and providing educational support to the obstetrical units in the region since 1979 through hospital perinatal program reviews and in-services to nurses and nurse/physician teams.

In-services to nurses and nurse/physician teams have been based on National Guidelines from the Society of Obstetrics and Gynaecologists of Canada (SOGC), and the Canadian Paediatric Society (CPS), as well as the National Guidelines for Family-Centred Maternity Care. Guidelines have been disseminated to the community hospitals through newsletters, perinatal manual chapters, annual regional meetings, additional workshops and conferences, in services to nurses and nurse/physician team meetings and hospital perinatal program reviews.

When the Perinatal Outreach Program team has visited the community hospitals, they have done so in a collegial and collaborative manner, disseminating information rather than coming to the community as the university teaching centre (some people would say, “big brother”) coming to dictate care.

Indeed, the Perinatal Outreach Program team has found their visits always to be a mutual learning experience, and have brought back from the community many ideas that they have been able to share with the larger region.

One of the programs that the nurses have found to be particularly helpful has been the regular Regional Nurse Manager meetings. The nurse managers from the region meet annually in the fall in London, and three smaller groups meet in the Spring in various locations in the region. This networking group gives the managers an opportunity to share ideas and experiences. The Perinatal Outreach Program team has recognized that many changes have occurred in perinatal care in recent years, and wanted an opportunity to look at practice trends across the region. Prior to the nurse manager meetings in the spring of 1999, the regional nurse managers were asked to inform the perinatal nurse consultants as to what regional practice issues and trends they were interested in learning about from the region. A questionnaire was devised and disseminated at the three Spring Regional Nurse Manager meetings in 1999. Staff at each obstetrical unit in the southwest region of Ontario completed the questionnaire and returned it to the Perinatal Outreach Program office. This article presents the results of this questionnaire.

Results

Tables 1 to 4 break the results down according to annual birth rates in the hospitals offering obstetrical services in Southwestern Ontario. Table I looks at screening programs. Table II examines intrapartum issues (it is of note that there are two hospitals in the group with 0-99 annual births that do not have Caesarean section capability, although they offer obstetrical services). Table III addresses care of the newborn, and Table IV looks at the one question regarding postpartum management, and where there are obstetrical nurse clinicians in practice.

<table>
<thead>
<tr>
<th>ANNUAL BIRTH RATE</th>
<th>0 - 99 Births (2 Without C/S Capability)</th>
<th>100-249 Births N = 8</th>
<th>250-999 Births N = 6</th>
<th>1000 + Births N = 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy to Screen Women for Abuse During Hospital Stay</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triage in Birthing Area</td>
<td>1</td>
<td>5</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Pre-Registration</td>
<td>5</td>
<td>7</td>
<td>6</td>
<td>4</td>
</tr>
</tbody>
</table>
On receiving the results of this questionnaire, we recognized some pitfalls with the questions themselves. For instance, the question, “Is the baby routinely suctioned at birth” does not clarify whether the suctioning occurs at the birth of the head, or immediately following the birth of the baby. It also must be stated that in small communities there are surgeons who may serve several hospitals. For example, if the surgeon’s practice is to have the woman shaved for Caesarean birth; this practice will influence survey results in several hospitals.

We were interested to see that many former routines have been dispensed with for example, stirrups are no longer routinely used for a woman giving birth without an epidural. Intravenous lines are not started purely because a woman is in labour.

In addition, babies are now being tub bathed rather than sponge bathed. These changes have come about as practitioners have looked at their practices and questioned the continuance of practices that are strictly based on tradition. More and more hospitals are becoming woman-centred and family-centred.

There were also surprises as to practices that are continuing. For instance, there is still a significant number of institutions that do not routinely assess the mother’s Kleihauer if she is Rh negative, and has given birth to an Rh positive child. It has been recommended by the Southwest Ontario Rh Program, as well as other Rh Programs across the nation that a Kleihauer screening be routine in this instance. We were also surprised at the number of babies that are routinely suctioned at birth, in spite of the NRP training and the recommendations from the Canadian Institute of Child Health.

<table>
<thead>
<tr>
<th>Table II</th>
<th>ANNUAL BIRTH RATE</th>
<th>0 - 99 Births (2 Without C/S Capability) N = 8</th>
<th>100-249 Births N = 8</th>
<th>250-999 Births N = 6</th>
<th>1000 + Births N = 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile H₂O Injections for Back Labour</td>
<td>Nurses</td>
<td>1</td>
<td>5</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Physicians</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Stirrups Are Routine Without Epidural</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Routine IV Without Epidural</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Shave For Caesarean Section</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Have Electronic Fetal Monitoring</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Routine Electronic Fetal Monitoring Admission Strips</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermittent Intrapartum Auscultation of Fetal Heart</td>
<td>- Low Risk Women</td>
<td>8</td>
<td>8</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>- Induction of Labour</td>
<td>8</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Perineal Cleansing Prior To Birth</td>
<td>- Nothing</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
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<tr>
<td>- Betadine</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- Soap and H₂O</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Nurses Giving IV Push Oxytocin in Third Stage</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>2</td>
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</tbody>
</table>
The Perinatal Outreach team will be discussing this questionnaire at upcoming nurse manager meetings, as well as meetings with the Regional Perinatal Care Steering Committee to try to discern what the barriers to change are and receive from the region itself ideas for ways to affect change. The Perinatal Outreach Program believes that there needs to be a collaborative approach to change and to perinatal care. We look to the practitioners in the region to guide and continue to forge family-centred care in the southwestern region of Ontario.

Perinatal Outreach Program
Of Southwestern Ontario
St. Joseph’s Health Care
London, Ontario

<table>
<thead>
<tr>
<th>Table III</th>
<th>Care of the Newborn</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANNUAL BIRTH RATE</strong></td>
<td>0 - 99 Births (2 Without C/S Capability) N = 8</td>
</tr>
<tr>
<td>Bulb Syringes Used for Newborn Suctioning</td>
<td>2</td>
</tr>
<tr>
<td>Baby Routinely Suctioned At Birth</td>
<td>7</td>
</tr>
<tr>
<td>Baby Temperature - Axilla - Tympanic</td>
<td>7</td>
</tr>
<tr>
<td>Cord Care Alcohol H2O</td>
<td>1</td>
</tr>
<tr>
<td>Baby Tub Bathed</td>
<td>8</td>
</tr>
<tr>
<td>Routine Incubator/ Radiant Warmer - After Vaginal Birth</td>
<td>1 (15-60 M)</td>
</tr>
<tr>
<td>After C/S</td>
<td>2 (15 M-2H)</td>
</tr>
<tr>
<td>Circumcision Pain Relief - Nothing - EMLA - Block - Tylenol Post-Op - Other</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>3</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Table IV</th>
<th>Postpartum Management OBS Nurse Clinicians</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANNUAL BIRTH RATE</strong></td>
<td>0 - 99 Births (2 Without C/S Capability) N = 8</td>
</tr>
<tr>
<td>Postpartum Kleihauer Done (If Rh Negative Mother has Rh Positive Baby)</td>
<td>7</td>
</tr>
<tr>
<td>OBS Nurse Clinicians</td>
<td>1</td>
</tr>
</tbody>
</table>
For Your Information...

Term Breech Trial
An international study designed to compare the outcome of caesarean section and planned vaginal birth for selected breech at term was terminated prior to its completion in April 2000. After the second interim analysis of the first 1600 women enrolled, it became clear that the differences in perinatal mortality and complex neonatal morbidity were significant. In its interim position notice, dated September 27, 2000, the Society of Obstetricians and Gynaecologists (SOGC) have recommended:

1. Physicians should inform all patients with term breech presentations of the results of this interim analysis of the Term Breech Trial Study.
2. The individual physician should address their own expertise and skills in the management of term breech.
3. The method of delivery of the term breech should be made on an individual basis after full disclosure of the risk/benefits of caesarean and vaginal birth in the term breech presentation.

The final review of the term breech trial is summarized in:


NRP
The Canadian launch of the new Neonatal Resuscitation Program guidelines was hosted recently in Montreal. Those who attended were able to purchase the new neonatal resuscitation textbooks. The Perinatal Outreach Program was able to obtain some manuals for those hospitals who had placed an order with us. It is anticipated that by the end of this year the textbooks (which include a CD-ROM), instructor manuals, video, test package and other NRP products will be available through a Canadian distributor however, who this will be has not been determined yet. The Outreach Program will notify hospitals once this has been decided upon. The new NRP protocol is to be implemented by July 2001.

To facilitate this initiative, the Perinatal Outreach Program will be offering Instructor Update Programs in the new year for those who were not able to attend the “launch” in Montreal.

Updates are scheduled for:
January 10, 2001 - St. Joseph’s Health Care, London
February 21, 2001 - St. Joseph’s Health Care, London
March 29, 2001 - Chatham Public General Hospital
April 5, 2001 - Hanover District Hospital

A course for “New” NRP instructors will be hosted in London (St. Joseph’s Health Care) April 19, 2001.

For further information or to register contact:
Nancy Dodman, Perinatal Outreach Program
Phone: (519) 646-6100 ext. 65900
Fax: (519) 646-6172

Upcoming Events:

SOGC 18TH Ontario Continuing Medical Education (CME) Program
November 30, 2000 - December 2, 2000
Toronto Marriott Eaton Centre
525 Bay Street, Toronto, ON M5G 2L2
Phone: (416) 597-9200
Fax: (416) 597-9211
Contact: www.sogc.org

Obstetrical Nurse Education Program - 2001
Tuesdays: January 16 - February 27, 2001
St. Joseph’s Health Care, London
Contact: Gwen Peterek, Perinatal Outreach Program of Southwestern Ontario
Phone: (519) 646-6100 ext. 65901
Fax: (519) 646-6172
gwen.peterek@sjhc.london.on.ca

This newsletter is a publication of the Perinatal Outreach Program of Southwestern Ontario.

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Tel: (519) 646-6100, ext. 65901
E-mail: perinout@sjhc.london.on.ca
www.sjhc.london.on.ca/sjjs/profess/profess.htm