

Rare “EXIT” Procedure Performed by Maternal Child Health Team

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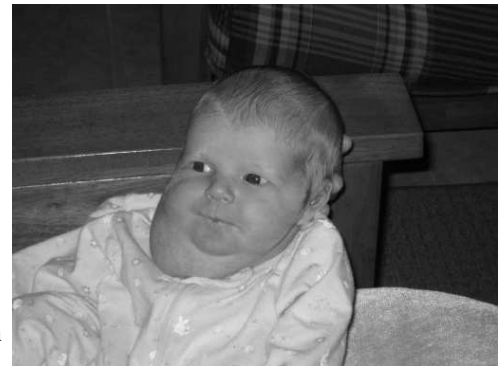
From left: Parents Susan and Josh Robinson, & Nurse Patricia Bornick with baby Anna.

Susan Robinson, a 31 year-old mother with 2 healthy children was expecting her third child in October 2009. An ultrasound examination in May revealed that Susan’s baby had a right anterior neck mass consistent with a cystic hygroma.

The patient was informed of the findings and was advised of all clinical management alternatives, which included the “EXIT” procedure. The EXIT procedure is used for obstetric patients whose fetus has been diagnosed with a mass or other birth defect in the neck and chest that may obstruct the baby’s trachea and cause asphyxiation upon birth. Ex Utero Intrapartum Treatment, or EXIT, is a procedure that takes advantage of the intact umbilical cord and placenta to provide oxygen to

the baby during the delivery process until the clinician is assured the baby can receive oxygen either on its own or by intubation/ventilation. Before birth, the masses or birth defects do not reduce the fetal oxygen supply because of placental oxygenation. However after birth, lacking placental oxygenation, a mass on the neck may cause hypoxia and ultimate demise of the neonate. The focus of the EXIT procedure is to provide a secure airway so that the newborn can continue to receive oxygen and thrive.

The first successful intubation with this technique was reported in 1992, however, the acronym EXIT was introduced in 1997 by Mychaliska, et al, who standardized the technique as it is now known. The EXIT procedure is rarely performed. There have been just over 100 reported cases in the United States. Performing this procedure requires an extensive health care team of Obstetricians, Neonatologists, Pediatric Surgeons, Anesthesia providers, specialized nurses and ancillary support staff all working in concert. Few hospitals have the resources and specially trained staff to safely provide these services.



Baby Anna Greets The World!

The EXIT procedure is done as follows: A cesarean section is performed with the abdomen opened in the usual manner. At this point, the management changes completely. Normally the baby is delivered as quickly as possible and handed off to a waiting Pediatrician. With an EXIT procedure, the Obstetrician (usually a maternal fetal medicine specialist trained in managing difficult pregnancies and deliveries) uses a different instrument to make the incision on the

(Continued on page 2)

1st “EXIT” Procedure at TGH (cont.)

(Continued from page 1)

uterus to prevent maternal blood loss. Then, only the infant's head is delivered. To prevent any contractions, the Anesthesia team provides medication not normally administered at a cesarean section to make certain the uterus doesn't contract. A Neonatologist is scrubbed in and, while the rest of the baby is still inside the uterus and receiving oxygen through the placenta, performs the intubation securing the airway. In the event that the intubation is difficult, a Pediatric Surgeon is present to operatively secure an airway by dissecting the mass or performing a tracheostomy. The baby's heart rate is continually checked by ultrasound. The rest of the baby is delivered, medications provided to the mother to contract her uterus, and the rest of the surgery is completed like a routine cesarean section.

In Susan Robinson's case, an ultrasound in June 2009 confirmed her pregnancy at 22 weeks and noted a neck mass with solid and cystic components measuring 5.6 cm x 5.0 cm x 3.9 cm with an extension to the anterior chest measuring 2.4 x 1.5 cm. The fetal heart appeared deviated and a small pericardial effusion was noted. A fetal echocardiogram was performed revealing normal cardiac structure. The patient was seen by pediatric surgery who determined that resection of the mass after birth was feasible. MRI findings were most consistent with a cystic hygroma.

In July, a team consisting of Maternal-Fetal Medicine, Neonatology, Pediatric Cardiology, Pediatric Surgery and nursing representatives met to formulate a plan of care. The plan included repeat MRI, weekly ultrasounds, monthly fetal echocardiograms, and delivery as close to term as possible via cesarean section with the EXIT procedure.

An EXIT Procedure Planning Meeting took place in August that included Respiratory Therapy, Ultrasonography, Anesthesia, Operating Room staff, Labor & Delivery staff, and hospital administration. The meeting resulted in the development of a protocol for the scheduled procedure and a plan for emergency delivery. Two dry-run procedures were scheduled. The first dry-run involved all participants and occurred on 8/19/09. A two-phase dry-run took place 9/23/09. The first hour was devoted to nursing roles and the second hour to physician roles. Neonatology conducted a separate simulation lab in September, as did Maternal-Fetal Medicine.

The procedure was planned for 37 weeks gestation due the mother's history of two prior deliveries at 38 weeks with rapid labors. On October 1, little Anna Robinson made a safe EXIT from her mother. General Anesthesia was induced by Dr. Devanand Mangar and Dr. Amrat Anand. The C-section was performed by Dr. Valerie Whiteman, assisted by Dr. Aaron Deutsch. Anna's head was delivered through the incision at 0808. Dr. Terri Ashmeade had Anna intubated by 0809. Continuous sonography showed Anna's heart rate remained steady throughout the procedure. Anna was completely delivered by 0815 and the umbilical cord was cut. She was taken to a special infant bed and examined by Pediatric Surgeon Dr. Charles Paidas, and Neonatologists Dr. Lewis Rubin and Dr. Ashmeade. On the way to the NICU the transport team stopped in the hallway so that her father, Josh, and both of her grandmothers and grandfathers could take a peek at their very special little girl. Anna weighed 7 pounds and 11 ounces.

Though Anna's hospital course was a bit bumpy in the beginning, her condition improved and she was able to go home 11 days later. Originally, Dr. Paidas planned to see her in about a month and perform the surgery to remove the hygroma in 3 to 6 months. However, the neck mass began growing and her surgery was done on Friday, October 30th.

Ms. Robinson is a stay at home mom. Her husband Josh is a physicist. Both her father and her brother are physicians. Her father said he had never seen such coordinated teamwork in his entire career. Josh, Anna's father, said it was amazing. When they met with the different doctors, they were all “on the same sheet of music”. Each doctor knew what the other doctors were doing and it was very reassuring.

Congratulations to all physicians and staff involved in this “first” for Tampa General.

A Therapeutic Interchange:

Making the Switch from Regular Insulin to Insulin Aspart (Novolog®)

John Allen, PharmD, PGY1 Pharmacy Resident

In September, the Pharmacy and Therapeutics Committee (P&T) approved the automatic therapeutic interchange of subcutaneous regular insulin (Novolin R Innolet Pen®) sliding/correction scale to insulin aspart (Novolog FlexPen®). In addition to maintenance of patient safety, the interchange is being implemented secondary to unavailability of regular insulin in a pen delivery system. This change does not impact scheduled doses of subcutaneous regular insulin or intravenous doses of insulin including insulin drips. **The effective date for this change is December 1, 2009.**

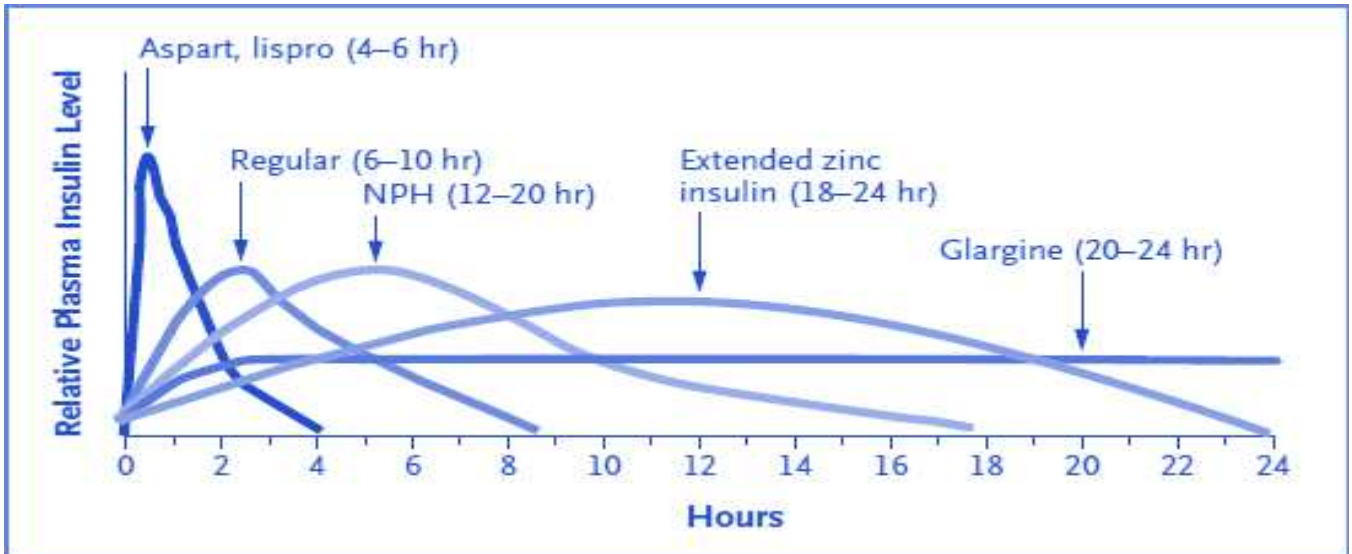
Insulin aspart (Novolog®) is a rapid-acting synthetic insulin analogue. It is similar to regular insulin but not identical. Benefits of insulin aspart include its quicker onset, higher relative plasma concentration and shorter duration of action compared to regular insulin. Dosing of insulin aspart is similar to regular insulin with the usual total insulin requirement of 0.5 to 1 units/kg/day.

An advantage of using insulin aspart for correctional scales compared to regular insulin is that it can be administered up to 15 minutes before, during, or at the end of meals. This change in timing will eliminate the often difficult task of timing pre-meal administration of insulin and may also reduce hypoglycemic events. When coupled with insulin aspart's shorter duration of action, adjustment of sliding/correctional scale regimens may be required in patients who are at risk for hyperglycemia who were euglycemic on a regular insulin regimen (e.g. switching from Accuchecks every six hours to every four hours). The pharmacokinetic and pharmacodynamic differences of regular insulin and insulin aspart have been highlighted in Table 1 below. Figure 2 offers an overall comparative illustration of the activity profile of commonly prescribed insulin.

Figure 1: Pharmacokinetic Profiles of Human Insulin and Insulin Analogues

	Insulin aspart (Novolog®)	Regular insulin (Novolin®)
Onset	5 to 15 minutes	30 minutes to 1 hour
Peak	1 to 3 hours	2 to 3 hours
Duration	3 to 5 hours	3 to 6 hours
Meal Timing	Up to 15 minutes before, during, or immediately after meals	30 - 60 minutes before meals
Appearance	Clear	Clear

Insulin to Insulin Aspart (cont.)



Hirsch IB. NEJM 2005; 352:174-83.

In summary, insulin aspart has a faster onset, quicker time to peak, and shorter duration of action than regular insulin. As a result, frequency of insulin administration for correctional scale may need to be monitored more closely to ensure euglycemia in patients. To accommodate a seamless transition, the subcutaneous insulin order set has been updated to reflect the approval of this therapeutic interchange. Prescribers must be mindful of this interchange at discharge to ensure that the proper insulin is prescribed. If you have any questions about the interchange, contact Shacreyett Burton, PharmD, BCPS (sburton@tgh.org/844-4996) or Renee Meehan, RN, CDE (rmeehan@tgh.org/844-7091) for more details.

Key Points to Remember about the switch to Novolog®

Therapeutic Interchange	No Impact
Sliding Scale regular insulin → Novolog Sliding Scale Insulin	Scheduled subcutaneous doses of regular insulin
	IV doses of insulin

References

- Novolog Prescribing Information. Novo Nordisk Inc., Princeton, NJ; July 2009. <http://www.novomedlink.com/pdf/pi/NovoLog-Prescribing-Info.pdf>. Accessed October 18, 2009.
- Hirsch IB. Insulin Analogues. *New Engl J Med*. 2005; 352:174-83.
- American Diabetes Association. Insulin administration. *Diabetes Care* 2004; 27 (suppl 1):S106-S107.
- Mudaliar S, Lindberg FA, Joyce M, et al. Insulin aspart (B28 Asp-insulin): a fast-acting analog of human insulin: absorption kinetics and action profile compared with regular human insulin in healthy nondiabetic subjects. *Diabetes Care* 1999; 22:1501-6.

TGH Pharmacy & Therapeutics (P & T) Committee UPDATE: October 2009

**Please visit Micromedex – FORMULARY ADVISOR for more details of the latest formulary decisions and access to the TGH Formulary. Micromedex – FORMULARY ADVISOR is available on any computer in the hospital with an internet browser!*

Prasugrel (Effient):

P & T Committee approved the addition of prasugrel (Effient) to formulary. The agent is a potent inhibitor of platelet activation and aggregation, similar to clopidogrel (Plavix) but with 10 times greater potency. Platelet recovery takes 48 hours to 7 days. FDA labeled indications include reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with unstable angina or non-ST segment elevation myocardial infarction (NSTEMI) and patients with ST-segment elevation myocardial infarction (STEMI) when managed with either primary or delayed PCI. The agent was added with a restriction to continuing therapy in patients admitted to the hospital previously taking prasugrel at home and initiation of therapy restricted to cardiology attending physicians and cardiology fellows.



Fluoxetine/olanzapine (Symbyax):

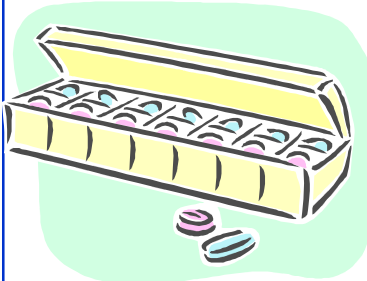
P & T Committee did not approve the addition of the combination product fluoxetine/olanzapine (Symbiax) to formulary. The combination product will remain non-formulary. It is a combination of olanzapine, an atypical antipsychotic, and fluoxetine, a selective serotonin reuptake inhibitor antidepressant. It is indicated for depression associated with bipolar disease and for treatment of resistant depression. The committee approved a therapeutic interchange for any orders for symbyax which involves conversion to the individual products (olanzapine and fluoxetine).

P & T Committee Process for Review and Management of Combination Products:

The process for reviewing and managing combination products (when individual component drugs are already on formulary) will be further discussed at future committee meetings along with assessing the implications of therapeutic interchange to the medication reconciliation process and continuity of care on discharge.

Pharmaceutical Shortage Update:

Current shortage information is listed on Micromedex Formulary Advisor and updated as necessary.



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WE'RE ON THE WEB
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TGH Welcomes our new Physicians

The physicians below were added to TGH staff September 30th

Salvador Bruno, MD	Hematology-Oncology
George F. Cohen, MD	Dermatology
Gitika Dham, MD	Internal Medicine
Alfred T. Frontera, MD	Neurology
James M. Galas, MD	Pediatrics
Ricardo J. Gonzalez, MD	General Surgery
Raquel G. Hernandez, MD, MPH	Pediatrics
Richard C. Karl, MD	General Surgery
Siva K. Kumar, MD	Cardiology
Christopher Maguire, MD	Emergency Medicine
Kathryn D. Nardell, MD	Pediatrics
Richard G. Picciocca, MD	General Surgery
Gilbert A. Postler, MD	Cardiology
Jeremy M. Ringwald, MD	Pediatrics
Shalin R. Shah, DO	Hematology-Oncology
Sabina Siddiqi, MD	Anesthesiology
William N. Upshaw, MD	Psychiatry

KUDOS TO OUR PHYSICIANS!

Congratulations to the following physicians who were recognized by their patients in the form of personal letters to TGH leadership.

This month's kudos go to: Dr. Daniel Greenwald, Dr. Albert Kabemba, Dr. Siviero Agazzi, Dr. Susan Smith, Dr. Robb Holley and Dr. Amir Ahmadian.



This newsletter is produced by Tampa General Hospital's Quality Improvement Department. All comments, responses or suggestions are welcome and should be directed to:

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