Greetings from the SOATT Leadership Team!

We hope that you have all enjoyed the summer of 2014, and are recharged and energized for a very busy fall season. Dr. Koh has quickly immersed himself in the creation of the SOATT Newsletter and we are grateful for his efforts and passion. In this issue, we will extend the focus on the importance of medical devices for the pediatric population and the current efforts that are underway to improve that innovation process. In addition, we have included a number of important updates on Section and Academy activities.

In October, we will convene in San Diego for the National Conference and Exhibition. This year's meeting will mark some significant milestones for our young Section as we move from an H program format to a plenary format and the potential larger audience that it provides (see details of our activities in this newsletter). We are honored that Dr. Stephen Spielberg will be delivering a plenary session on our behalf to be followed by a session with Ms. Lindsey.
Elsaesser, a wonderful patient advocate who presented at our H program in New Orleans. Dr. Andy Schuman will be leading an exciting session on the important gadgets and gizmos for the pediatric office and we will be hosting our second research poster session in the Exhibit Hall. Please make note of our Section programs on your calendar and help us to make them a wonderful success.

On behalf of the Leadership Team, thank you for your continued commitment to understanding and improving the medical innovation process for children. As always, please let us know if you have ideas or would like to get involved in some of our activities. See you in San Diego!

We welcome contributions to the newsletter on any topic of interest to the pediatric community.

Please submit your idea or article to:

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“Pediatric Innovation”

Innovation can be challenging in the pediatric world, but not impossible. As I have experienced, one only needs to survey their local children's hospital, university, and business community to locate examples of successful and innovative small companies who have dedicated themselves to improving children's health.

Yet, the pathway to success can be challenging, and only through the sharing of the lessons learned (both successes and failures) such as via this newsletter will pediatric innovation thrive.

This edition of the newsletter continues the descriptive series on the FDA-funded Pediatric Device Consortia, which can provide consulting, project management, and bridge funding for pediatric device projects. Below is a summary of the consortia.

We also continue the Pediatric Device Spotlight section with devices from the Boston Pediatric Device Consortium and the Philadelphia Regional Pediatric Medical Device Consortium that share their experiences with the pediatric device development pathway.

In addition, updates are provided on two important Section initiatives: the Kids and Families Impacting Disease Through Science (KIDS) program, and the upcoming Stakeholder Forum on Improving Pediatric Clinical Trials that is scheduled for early November which is focused on improving the availability of novel pediatric drugs, biological products, and medical devices.

We look forward to seeing you at this fall’s NCE meeting and especially at the Section's program on pediatric innovation.

We hope that you enjoy reading this edition of the newsletter, and please share it with a colleague, patient, or friend. We welcome all suggestions for articles. It is meant to be an avenue of communication for our Section, and also for those who share the passion of caring for children and improving our care for children.

Pediatric Medical Device Resource List:

FDA-funded Pediatric Device Consortia (PDC) – a resource for pediatricians, pediatric caregivers, and pediatric specialists in developing their innovative pediatric medical device projects. Available assistance can include consulting, project management, and bridge funding.

Continued on Page 4
FDA’s Pediatric Device Consortia Grant Program  Continued from Page 3

Further details can be found in the Spring 2014 edition of the newsletter at:
www2.aap.org/sections/pedsadvances/Newsletters/SOATT_Newsletter_Spring_2014.pdf

Atlantic Pediatric Device Consortium
(Georgia Institute of Technology / Emory University / Children's Healthcare of Atlanta / Virginia Commonwealth University Institute for Engineering and Medicine)
pediatricdevicesatlanta.org

Boston Pediatric Device Consortium
(Boston Children's Hospital / Harvard Medical School)
childrenshospital.org/research-and-innovation/research-initiatives/innovation-acceleration-program

Multidisciplinary Initiative for Surgical Technology Research-Advanced Laboratory (MISTRAL)
(Stanford University / Lucile Packard Children's Hospital / SRI)
mistralpediatric.org

National Capital Consortium for Pediatric Device Innovation
(Children's National Health System / University of Maryland)
innovate4kids.org

New England Pediatric Device Consortium
(Simbex / CIMIT / IPI / Mass General Hospital for Children / Dartmouth University)
nepdc.org

Philadelphia Regional Pediatric Medical Device Consortium
(Children's Hospital of Philadelphia / University of Pennsylvania / Drexel University)
linkedin.com/groups/Philadelphia-Pediatric-Medical-Device-Consortium-8113221

Southern California Center for Technology and Innovation in Pediatrics
(Children's Hospital Los Angeles / University of Southern California)
scctip.com

University of California San Francisco Pediatric Device Consortium
(University of California San Francisco)
pediatricdeviceconsortium.org

University of Michigan Pediatric Device Consortium
(University of Michigan)
peddev.org

FDA Pediatric Device Consortia Grants Program
(Office of Orphan Products Development)
fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/PediatricDeviceConsortiaGrantsProgram/
Overview

Every invention starts with a problem. For Jim Geiger, M.D., a young pediatric surgeon at the University of Michigan Health System in the late 1990s, it was an unwieldy surgical clamp. Geiger often operated on infants with pyloric stenosis — an obstruction in the pyloric muscle that connects the stomach to the small intestine. The surgery was challenging, but to make it even more cumbersome, the surgical instruments used for the procedure were made for adults.

The more Geiger tried to fit adult-sized instruments through a tiny incision in a newborn baby to stabilize the pylorus, the more he thought there must be a better way to do this.

Geiger sketched out some designs for new pyloric clamps to use on his tiny patients. He shopped them around, but his ideas went nowhere. Then, in 2004, Geiger met Albert Shih, Ph.D., a professor of mechanical engineering who was making a career transition to biomedical engineering. It was a fortuitous match: Shih wanted to collaborate with Medical School faculty who were interested in new medical devices; Geiger needed engineering expertise to develop his pyloric clamp.

Shih assigned the project to a team of senior engineering students enrolled in his design and manufacturing class. Geiger spent a lot of time working with the students to perfect the design for the clamp. He invited them into the operating room to see the surgery. And he came up with money to cover the cost of making a prototype.

With a working prototype and engineering specifications in hand, Shih and Geiger were able to interest executives at a medical device company. The University licensed the device to the firm in 2008, and now the device is available to pediatric surgeons around the world.

The experience inspired Geiger and Shih to help other U-M faculty negotiate the challenges inherent in the medical innovation process, and they established the Medical Innovation Center (MIC), in 2008. A truly multidisciplinary partnership, the MIC brought together the Medical School

Continued on Page 6
and Department of Surgery, the College of Engineering, School of Dentistry, Ross School of Business, and School of Art & Design. From that foundation, Geiger was awarded funding from the FDA in 2009 to launch the Michigan Pediatric Device Consortium (M-PED), a non-profit organization for innovation and advancement in the field of pediatric healthcare devices.

The MIC's activities spurred the development of the Fast Forward Medical Innovation initiative, the U-M Medical School's new innovation program. Geiger and his team now focus specifically on pediatric device innovation with the M-PED. Its goal is to advance innovative ideas into near-market pediatric devices for commercialization.

M-PED actively supports faculty inventors and external entrepreneurs; has helped launch several spinoff companies; and serves as a hub for biomedical innovation, both within the University and externally. Its Pediatric Innovation Fellowship attracts postgraduate applicants nationally, and serves as a crucible for innovation process education.

**Fellowship**
The M-PED Pediatric Innovation Fellowship is a multidisciplinary team training program for post-graduate professionals with medical or engineering advanced degrees, who are committed to addressing real healthcare issues through innovation excellence. This program draws on the strengths of Michigan's renowned schools and colleges to develop a new type of medical innovator, one with the integrated skills and knowledge necessary to transform complex problems into practical solutions.

Physicians and engineers are paired on innovation team, blurring the boundaries of their respective disciplines, and immersed in a specific pediatric domain. Through a structured innovation process over the course of one year, teams create a medical product or service addressing an unmet need and advance it towards commercialization.

**Commercialization Support**
M-PED maintains a creative environment and supports team members from engineering, business and medical backgrounds. Through its commercialization support program, project concepts are evaluated and assistance is provided to innovators who are seeking to address issues in the healthcare of children. M-PED helps innovators nationwide find collaborators, make prototypes, assess intellectual property, determine the regulatory path, determine the reimbursement landscape, identify licensees, manage their project and find funding for all of the above.

M-PED also provides commercialization “gap funding” in amounts up to $50,000 to specific projects. This funding helps accelerate the commercialization of pediatric medical devices, including mobile medical apps.

**Successes**
Selective Laser Sintering (SLS) offers the potential for making geometrically complex scaffolds for human tissue engineering directly from computer models or digital imagery such as computed tomography (CT) or magnetic resonance imaging (MRI) scans. SLS processes can bypass labor intensive, time-consuming conventional manufacturing processes that often require the use of

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toxic solvents while providing little control over geometry and the types of scaffold materials that can be used.

In SLS, a three-dimensional digital model of the scaffold is mathematically sliced into a number of thin layers. The scaffold is then created by selectively laser sintering the ‘sliced’ patterns into sequentially deposited layers of a biopolymer powder. Polycaprolactone (PCL) is an FDA approved bioresorbable polymer that has been found suitable for the repair of craniofacial defects and is suitable for SLS modeling. These scaffolds were created directly from computationally-optimized digital designs developed by U-M Associate Professor Scott Hollister.

Using an optimized model based on nonlinear programming techniques, the scaffolds incorporated complex internal geometries and porous architectures. Through the use of optical microscopy, they were found to be structurally sound, dimensionally accurate and more than 99 percent dense, attesting to SLS process capability. The scaffold design and fabrication process combines computationally optimized scaffold designs and solid freeform fabrication techniques. It has the potential to offer scaffolds and other bioimplants that are custom-made to individual patients’ needs in a variety of biomaterials.

Kaiba Gionfriddo

Every day, their baby stopped breathing, his collapsed bronchus blocking the crucial flow of air to his lungs. April and Bryan Gionfriddo watched helplessly, just praying that somehow the dire predictions weren't true.

“Quite a few doctors said he had a good chance of not leaving the hospital alive,” says April Gionfriddo, about her now 3 year old son, Kaiba. “At that point, we were desperate. Anything that would work, we would take it and run with it.”

They found hope at the University of Michigan, where a new, bioresorbable device that could help Kaiba was under development. Kaiba’s doctors contacted Glenn Green, M.D., associate professor of pediatric otolaryngology at the University of Michigan.

Green and his colleague, Scott Hollister, Ph.D., professor of biomedical engineering and mechanical engineering and associate professor of surgery at U-M, went right into action. With help from the M-PED experts, they obtained emergency clearance from the Food and Drug Administration to create and implant a tracheal splint for Kaiba made from a biopolymer called polycaprolactone.

On February 9, 2012, the specially-designed splint was placed in Kaiba at C.S. Mott Children's Hospital. The splint was sewn around Kaiba's airway to expand the bronchus and give it a skeleton to aid proper growth. Over about three years, the splint will be reabsorbed by the body. The case was featured in the New England Journal of Medicine.

“It was amazing. As soon as the splint was put in, the lungs started going up and down for the first time and we knew he was going to be OK,” says Green.

Green and Hollister were able to make the custom-designed, custom-fabricated device using
high-resolution imaging and computer-aided design. The device was created directly from a CT
scan of Kaiba's trachea/bronchus, integrating an image-based computer model with laser-based
3D printing to produce the splint.

Kaiba was off ventilator support 21 days after the procedure, and has not had breathing trouble
since then.

“The material we used is a nice choice for this. It takes about two to three years for the trachea to
remodel and grow into a healthy state, and that's about how long this material will take to dissolve
into the body,” says Hollister. “Kaiba's case is definitely the highlight of my career so far. To actu-
ally build something that a surgeon can use to save a person's life? It's a tremendous feeling.”

Severe tracheobronchomalacia is rare. About 1 in 2,200 babies are born with tracheomalacia and
most children grow out of it by age 2 or 3, although it often is misdiagnosed as asthma that does-
n't respond to treatment. Severe cases, like Kaiba's, are about 10 percent of that number.

And they are frightening, says Green. A normal cold can cause a baby to stop breathing. In Kaiba's
case, the family was out at a restaurant when he was six weeks old and he turned blue.

“Severe tracheobronchomalacia has been a condition that has bothered me for years,” says Green.
“I've seen children die from it. To see this device work, it's a major accomplishment and offers hope
for these children.”

Before the device was placed, Kaiba continued to stop breathing on a regular basis and required
resuscitation daily.

“Even with the best treatments available, he continued to have these episodes. He was imminently
going to die. The physician treating him in Ohio knew there was no other option, other than our
device in development here,” Green says.

Kaiba is doing well and he and his family, including an older brother and sister, live in Ohio.

“He has not had another episode of turning blue,” says April. “We are so thankful that something
could be done for him. It means the world to us.”

The University of Michigan is becoming a leader in pediatric device manufacturing, as is the case
with the manufacturing process device used to save this baby's life. The FDA-funded University
of Michigan Pediatric Device Consortium (M-PED) offers product development guidance and
strategic support for advancing devices to market. In a new medical product manufacturing video
released by M-PED, Green, Hollister and other U-M and industry experts share their experiences
and advice: https://vimeo.com/64302665

The Future
With the national emphasis on patient impact from academic discovery, and acting at the inter-
section of engineering, medicine, business and design, the M-PED is ideally positioned to con-

Continued on Page 9
continue its early success across the medical realms of devices, diagnostics and health information technology for pediatric applications. “M-PED has reached a turning point,” notes Geiger. “With the increasing University attention and resources surrounding health innovation, the Consortium is engaging more meaningfully with its partners outside of the University.”

Recent project support has borne this out. Seventy-five percent of new projects in the past six months have come from inventors outside of the University, from locations as far away as Utah and Louisiana. “The challenges facing pediatric device development necessitate that we partner early and broadly,” states Geiger. “To de-risk devices for the pediatric market in a cost effective way is definitely a team sport.”

But as Kaiba Gionfriddo’s family knows, it is well worth it.

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**We’re New and Need You!**

**How to Join . . .**

It's easy! There are NO DUES to join the SOATT.

Send an e-mail to Jackie Burke at jburke@aap.org to request to be added to the Section.

Also, please see the Message from the Membership Committee on page 24 for more information.
Editor's note: This new section will spotlight the development and commercialization of new pediatric medical devices and hopefully serve as a resource and inspiration.

**Heat Retention Head Wrap: A Novel, Noninvasive Method for Rewarming Infants Following Cardiopulmonary Bypass**

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In this report we describe the development of a heat retention head wrap designed to facilitate normalization of an infant’s body temperature during the rewarming phase of cardiopulmonary bypass surgery (CPB).

As a protective mechanism infants placed on cardiopulmonary bypass for surgical procedures are routinely cooled to a core body temperature of 28 degrees Celsius (~82 degrees Fahrenheit). Once repair of the heart is complete, the rewarming phase of surgery begins. Rewarming an infant to normal body temperature after surgery is currently accomplished using a forced-air warming system, water-heated mattress, warmed IV and irrigation fluids, humidified gases, adjustments to the cardiopulmonary bypass equipment and by increasing operating room temperature.

However, achieving and maintaining normal body temperature is challenging, especially during transfer from the operating room to cardiac intensive care. Thus there is a need for improved methods for rewarming infants post-operatively.

**Innovation**

Our goal was to develop a simple, noninvasive method to reduce the time needed to rewarm an infant while allowing some element of control over body temperature, thereby avoiding the risks of both hypothermia and hyperthermia during the rewarming and immediate post-operative periods.

We took as inspiration for this novel device:

- the knowledge that as much as 60 percent of an infant's body heat escapes through the scalp
- the practice of using cold packs placed around an infant's head, sometimes utilized for cooling infants

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Further it was recognized that caregivers were not routinely using hats or other head coverings to assist with thermoregulation during cardiopulmonary bypass surgery. Review of the relevant literature revealed that the use of head coverings could result in significant heat conservation with no hazard or inconvenience, and minimal cost.

In developing a possible solution, several considerations precluded the use of a typical hat, including:

- intravenous (IV) lines are commonly placed in the scalp veins of infants,
- putting a hat on an infant in the operating room would require moving the infant, which could disrupt the surgical field

In developing a new solution, we settled on the following requirements:

- construction using a heat-reflective material to help retain body heat
- a physical design that could be laid flat on the operating table before surgery and folded over the infant’s head at the appropriate time

The resulting prototype head wrap, developed with the support of an internal Innovation Grant from Boston Children’s Hospital’s Innovation Acceleration Program, is a five-sided piece of cotton-reinforced Mylar® with flaps that can be folded over an infant’s scalp and forehead and held fast with Velcro closures. This design offers several potential advantages over a typical hat:

- ready access to IV lines placed in the scalp
- regulation of body temperature support; should the infant’s body temperature rise too high, a flap can be folded back to allow some heat to escape
- complements other rewarming methods
- simplicity in manufacturing
- low-cost through the use of readily available, off-the-shelf materials; the initial prototype was designed and produced in a seamstress shop

**Heat Retention Head Wrap In The Operating Room**

In order to assess the safety and feasibility of this heat retention head wrap, our team of physician and nurse scientist co-investigators—Jean A. Connor, PhD, RN, CPNP; Pedro Del Nido, MD; Kirsten Odegard, MD; and Michele DeGrazia, PhD, RN, NNP-BC—undertook a descriptive Phase I clinical study. With Institutional Review Board approval, the study enrolled 10 infants placed on cardiopulmonary bypass for cardiac surgery.

Each infant was placed on an unfolded wrap prior to surgery. The wrap was applied at the onset of rewarming and removed following admission to cardiac intensive care. Core body temperature was measured at four defined time points in the peri and immediate post-operative period, and each infant’s scalp was assessed before and up to 72 hours after surgery for any signs of skin reaction. To assess feasibility, each infant’s medical team was asked to complete an ease-of-use questionnaire. As this was a safety and feasibility study only, no control group was included.

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Infant participants experienced a steady increase in temperature across the four defined time points and no adverse skin reactions were noted in any of the infants. The infants’ medical teams reported that the wrap was easily applied and removed.

**Steps Toward Market Entry**
In November 2013 Boston Children’s Technology and Innovation Development Office granted a non-exclusive commercial license for further development of the wrap for applications in an adult population. Opportunities to partner with industry are also being explored to continue developing and refining the wrap for additional pediatric applications where temperature regulation is a concern, with a particular interest in:

- critical care newborns and infants during transport and specialized procedures
- transport of newborns and infants following non-cardiac surgery
- post-delivery care of newborns

Despite its simplicity, as with any innovation the development of the heat retention head wrap has been a team effort, drawing on people with a broad range of resources and expertise, including members of the following offices, departments and programs at Boston Children’s:

- Academy for Clinical Scholarship and Innovation in Pediatric Nursing Science
- Department of Cardiac Surgery
- Department of Perioperative Services
- Division of Cardiac Anesthesia
- Innovation Acceleration Program
- Technology and Innovation Development Office
- Translational Research Program

In particular, mentorship by nurses and physicians with experience in clinical research has been crucial to the success of this endeavor thus far. The hospital’s willingness to provide institutional financial, logistical, developmental and marketing support has also proved critical at every step of the development path.

In summary, we have developed this novel heat retention head wrap that, in a Phase I clinical study, was found to be a safe and a feasible solution in the rewarming process for infants placed on CPB. We continue to explore the application of the head wrap in other settings as well as potential opportunities for industry partnerships that would enable broader development, evaluation and adoption.

**Reference:**
Oct. 2009 – May 2010: Evidence-based Practice Internship Program; initial head cover idea

April 2010: Filed disclosure with Boston Children’s Hospital’s Technology and innovation Development Office

June 2010: Manufacturers’ interest confirmed; provisional patent filed

Dec. 2010: Awarded Innovement Grant from Boston Children’s Innovation Acceleration Program

Jan. 2011: Nurse science mentorship secured; Phase I protocol development

Feb. 2014: Manuscript accepted by the American Journal of Critical Care

May 2011: IRB approval; prototype produced

Nov. 2013: Licensing agreement executed

June 2011 – May 2012: Phase I trial

Timeline of the development of the heat retention head wrap
Editor’s note: This new section will spotlight the development and commercialization of new pediatric medical devices and hopefully serve as a resource and inspiration.

**Real World Challenges Taking a Device from Adults to Pediatrics**

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Actuated Medical, Inc. is a medical device development and manufacturing company that is in the process of adapting an FDA cleared adult medical device for the pediatric market. This article outlines some of the regulatory, economic, and engineering challenges that we have encountered and lessons learned along the way.

About Actuated Medical®

Actuated Medical, founded in 2006, is located in Central Pennsylvania. Our vision is to Improve Patient Outcomes by developing medical devices that move in such a way to enhance the intervention. Our innovations enable healthcare practitioners to perform faster, easier, and safer procedures by integrating electronically controlled Innovative Motion® technologies.

As a business, we constantly look for new opportunities that fit our scientific and technological skill set. We continually engage with our company’s Medical Advisory Board, Board of Directors, and healthcare practitioners to explore potential devices that are both clinically important and commercially viable. When we discover the right opportunity, we often seek R&D funding in the form of Small Business Innovation Research (SBIR) grants from agencies such as the National Science Foundation (NSF) and National Institutes of Health (NIH). In fact in 2014, Actuated Medical received a Small Business Administration (SBA) Tibbetts Award for SBIR Excellence.

The Initial Opportunity – Feeding Tubes Clog

On his first visit to Actuated Medical, Paul L. Frankhouser, a former Executive Vice President of Arrow International, said, “You know where you need to use your technology? Feeding tube clearing. There is nothing on the market that reliably clears clogged tubes.” That conversation was the genesis of the TubeClear product line.

Feeding tubes are required when critically ill or severely compromised patients are unable to swallow food or medication. Patients requiring long-term feeding assistance typically use a surgically placed gastrostomy (G), jejunostomy (J) or a gastrostomy-jejunostomy (GJ) tube. For short term feeding assistance, nasoenteral (NE) tubes are normally used. In the United States (USA), approximately 7 million feeding tubes are placed each year. The problem is that these tubes often

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become clogged at reported rates from 12.5% to >35%1-6. This results in millions of clogged tubes each year. When tubes remain clogged, patients can go without nutrition and medication for hours or even days. The interruption in nutrition and medication negatively impacts recovery. Healthcare practitioners spend significant time trying to clear clogged tubes. Our healthcare practitioner focus groups concluded practitioners spend more than 20 minutes clearing clogged tubes.

We set out to develop a device that would:
+ Reduce interruptions to feeding and medication regimens.
+ Help healthcare practitioners stay focused on patient care, not hardware issues.
+ Demonstrate significant savings of time and money.

R&D Funded by NSF SBIR Program

We carefully defined the clinical need and identified the state of practice. Then we assembled a team of engineers and clinical consultants who brought the right mix of medical expertise, real-world experience, and engineering talent.

We needed a way to finance our initial R&D so we submitted a Phase I SBIR grant application to NSF in December 2007. It was awarded in July 2008. During Phase I, our device was investigated and proven feasible. In July 2009, a Phase II SBIR grant was awarded. During the Phase II, we took TubeClear from concept to verification-and-validation testing and 510(k) FDA market approval. We then sought investors and found some wonderful Angels which enable us to receive a Phase IIB SBIR match from NSF. During Phase IIB, we conducted market awareness, evaluations and clinical in-human uses. Actuated Medical was also issued patents from the USPTO.

Throughout the project, we used our seven-stage development process to ensure our tube-clearing device would solve the clinical challenge identified by Paul Frankhouser and clarified by our clinical consultants. In fact, over 50 nurses and doctors were surveyed during the device's development to ensure that the final device would be effective and easy to use.

**Adult Product – TubeClear®**

TubeClear is comprised of a reusable Control Box paired with a single use Clearing Stem. The healthcare practitioner attaches a Clearing Stem to the Control Box and inserts the Stem a few centimeters into the tube. Then the healthcare practitioner turns on the Control Box and manually directs the Clearing Stem further into the tube. The Clearing Stem has a specially designed tip that moves in a forward and backward motion that chips away at the clog to restore patency.

TubeClear helps the healthcare practitioners to rapidly clear the tube without the expense and risk of tube replacement. The system is FDA cleared and CE Marked specific to NE, NG, G and J feeding and decompression tubes for adult patients.

**The Pediatric Challenge**

For the pediatric market, clogged feeding tubes can occur more often due to the narrow diameters. The lack of nutrition and medication quickly exhausts the patient’s energy reserves and the
patient may develop dehydration with electrolyte abnormalities more quickly than in adults. When a tube cannot be cleared by standard practice, it is replaced which then puts the patient at risk for surgical intervention, tube misplacement and dislodgement.

But, as commonly found, there were challenges to successfully transitioning an adult device to the pediatric market. Often the adult device is too big, too strong or simply inappropriate for pediatrics. In our case, even though TubeClear is considered by the FDA to be “a non-significant risk device” there was still concern with moving TubeClear into the pediatric market.

We saw the challenge as threefold:
+ The first was scale. Pediatric tubes are inherently smaller and our Clearing Stems now had to work in a much smaller tube. This is largely an engineering challenge we were sure that we could be overcome.
+ The second is regulatory. Rightly so, the bar is higher for pediatric medical devices. We needed to comply with FDA requirements for pediatrics, which in some aspects can be more stringent than for the adult population.
+ Third is market size. While there is certainly a medical need, the market is relatively small. Because developing a medical device is expensive, medical device firms typically look for a large market to offset their up-front R&D investment. Sadly, this combined with the regulatory burden often keeps larger firms out of the pediatric market.

Additional SBIR Funding

As with the adult version of TubeClear, we sought out SBIR funding to develop the pediatric Clearing Stem models. And again, it came in the form of Phase I and II grants this time from NIH. It’s interesting to note that we see using SBIR grants to support pediatric R&D as the perfect solution for the up-front R&D investment. It keeps our financial development risk low letting us focus on the engineering and regulatory aspects of the challenge.

The NIH Phase I grant research successfully demonstrated that the prototype was 100% effective in clearing occluded GJ tubes (tested using 9 Fr tubes). Patency was restored in an average time of 3 minutes without causing dislodgement or damage to tubes in anatomical models. The Phase II NIH SBIR project is currently underway for pediatric GJ feeding tubes.

FDA’s High Bar

As we mentioned earlier, the bar can be set much higher, in some aspects, to enter the pediatric market. To receive FDA clearance, we needed to, among other factors, investigate the behavioral response in a pediatric clinical study setting – clearly a more stringent process than we went through for the adult indication.

Finding the Right Research Team

We needed a top-notch research partner at a recognized children's hospital. Unfortunately, finding a partner for pediatric clinical research is no easy task. We approached several children's...
Pediatric Medical Device Spotlight  Continued from Page 16

hospitals, but nearly all declined to work on the study. We believe the challenge was less in the study design and more that the high risk target population.

Fortunately, the Children's Hospital of Philadelphia (CHOP) was willing to partner with us. CHOP is an innovative hospital whose investigators had a clear understanding of the clinical need and potential benefits addressed by a pediatric model of TubeClear. We are quite honored to be working with them.

The process of engaging CHOP seemed to be fate, if you can believe that. All within two days, we read a paper by a UPENN/CHOP nurse about pediatric feeding tubes and a press release by the FDA sponsored Philadelphia Regional Pediatric Medical Device Consortium. We arranged an introductory meeting then a technology demonstration meeting at CHOP with Drs. Irving, Srinivasan, and Maltese. They were enthusiastic on the technology and we began working on the research protocol for IRB submission.

The objective of our Study is to evaluate the safety and efficacy of TubeClear in patients between 8 and 21 years of age in the Pediatric Intensive Care Unit (PICU) or the Progressive Care Unit (PCU) at CHOP. We will examine efficacy in a variety of tubes including GJ (9-18 Fr, 10-140 cm) as well as J, ND, NG, NJ, and NE (6-10 Fr, 10-140 cm). Our protocol will be submitted to CHOP IRB in August 2014 and we hope to get approval for the study by October 2014.

Lessons Learned

We know that adult devices may not easily translate into their pediatric equivalent. The key message here is that you must plan for the inevitable engineering, regulatory, and market challenges.

Here are a few takeaways from our experience:
+ There are unique regulatory challenges with the pediatric market including a much higher bar for FDA clearance.
+ Smaller market size makes it financially difficult to invest heavily into up-front R&D. Finding outside funding sources is critical to commercializing a pediatric device.
+ Finding the right clinical research team is critical to your success. Start the process early.

If you are interested in more information about TubeClear please visit TubeClear.com. In addition to the Tibbetts Award, TubeClear was also a 2013 PA BIO Patient Impact Technology finalist. If you are interested in TubeClear for adult patients, it is being distributed by Corpak Medical Systems (Buffalo Grove, IL) worldwide.

References


Continued on Page 18
KIDS Update

Charles A. Thompson, MD, FAAP

Kids and Families Impacting Disease Through Science (KIDS) is an advisory group of children, adolescents and families focused on understanding, communicating and improving medicine, research and innovation for children. KIDS is a collaboration between SOATT, local AAP Chapters, children’s hospitals, local schools and other partners. Since our last newsletter, the program has been quite busy:

- Published an invited blog on the program for Real World Health Care (http://www.realworld-healthcare.org/2014/04/kids/)
- Delivered CHES Rounds at Toronto SickKids Research Institute
- KIDS Connecticut Team attended the Pediatric Academic Societies Meeting in Vancouver
  - Jointly staffed an exhibit booth with KidsCan (an advisory group based in Vancouver) highlighting their work and the importance of research and innovation for children
  - Conducted survey-based research by collecting >400 responses with a focus on participant’s opinions of the importance of research in their lives and the role of children in research
  - Held a brainstorming session with KidsCan about building an international network of advisory groups called iCAN (International Children’s Advisory Network) and began planning a path forward

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KIDS Update  Continued from Page 18

- Interacted with hundreds of researchers from around the world and advocated for the voice of children in this process

- KIDS Connecticut Team President (age 17 yo) met with Dr. Paolo Rossi in Rome, Italy, to discuss the KIDS project and the possible creation of a team in Italy

- KIDS Connecticut Team incoming President (age 16 yo) and Vice President (age 15 yo) delivered invited presentation on KIDS concept at the Institute for Pediatric Innovation Annual Meeting in Cambridge, MA

- KIDS Leadership delivered an invited presentation on the concept at the European Network of Pediatric Research at the European Medicines Agency Pediatric Workshop in London

- KIDS abstract entitled “Listen to KIDS” was accepted for poster presentation at the 2014 AAP NCE in San Diego

- Planning underway for expansion of program in the US (Utah, New Jersey, Georgia, Missouri/Kansas, Ohio) and the creation of the International Children’s Advisory Network (iCAN)

If you would like more information on the KIDS program or the iCAN, please feel free to contact Charlie Thompson at charles.a.thompson@pfizer.com.
Section on Advances in Therapeutics & Technology Brings Grant to the AAP to Hold Stakeholder Forum to Improve Pediatric Clinical Trials

Background
The Food and Drug Administration Safety and Innovation Act (FDASIA) was enacted in 2012 and renews and strengthens laws designed to improve the safety and efficacy of pediatric drugs, biological products, and medical devices used in children: the Best Pharmaceuticals for Children Act (BPCA), the Pediatric Research Equity Act (PREA), and the Pediatric Medical Device Safety and Improvement Act. The law makes BPCA and PREA permanent – no longer subject to reauthorization every five years – and now ensures that children will have a permanent seat at the table for drug and device research and development. It is expected that these improvements will increase pediatric drug and device development; however, implementation will also depend on pediatric study plans. To achieve this, an improved approach to planning studies and commensurate pediatric clinical trial infrastructure is needed. Integrative work across multiple stakeholders is needed to achieve a common goal of better health, faster, and safer, for children. Making this future a reality will require all stakeholders in children’s health to come together to share ideas, map out a new vision, and share it across children’s health organizations to build commitment for implementation.

Project Description
The Pediatric Clinical Trials Stakeholder Forum, tentatively scheduled for Tuesday and Wednesday, November 4 and 5, 2014 will discuss the feasibility and logistical challenges for the potential creation of a global pediatric clinical trials network. AAP will have complete discretion over the attendees, agenda and outcomes reporting of the meeting. The AAP’s Corporate Relationship Guidelines will be in force throughout the process.

Funder
Pharmaceutical Research and Manufacturers of America (PhRMA). The Pharmaceutical Research and Manufacturers of America (PhRMA) represents innovative biopharmaceutical research and discovery companies. PhRMA is devoted to advancing public policies in the U.S. and around the world that support innovative medical research, yield progress for patients today and provide hope for the treatments and cures of tomorrow.

Child Health Goals
There are many stakeholders in the process of new drug development who would have a profound interest in the work of this project. Those invited to participate in the project will share common goals including:
  - Improved safety and efficacy for children by improving robust data to support pediatric labeling

Continued on Page 21
Deliverables and Timeframe

<table>
<thead>
<tr>
<th>Deliverable</th>
<th>Description</th>
<th>2014 Calendar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secure project</td>
<td>Develop letter of agreement, secure funds, agree upon program deliverables</td>
<td>Q1 DONE</td>
</tr>
<tr>
<td>Create an planning committee</td>
<td>Develop a well-rounded planning committee to direct the activities of the program</td>
<td>Q1 DONE</td>
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<tr>
<td>(Planning Committee roster below)</td>
<td></td>
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<tr>
<td>Identify stakeholders</td>
<td>Utilize the working group to plan the meeting and agenda</td>
<td>Q2</td>
</tr>
<tr>
<td>Plan meeting and agenda</td>
<td>Convene a meeting of 50 key stakeholders to talk about pediatric clinical trial issues and determine whether a network is desired and achievable.</td>
<td>Q4</td>
</tr>
<tr>
<td>Convene meeting</td>
<td>Write and distribute a formal paper summarizing the convening.</td>
<td>Q4</td>
</tr>
<tr>
<td>Public Documentation</td>
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</tbody>
</table>

Planning Committee MEMBERS:
Clifford Bogue, MD, FAAP, Chairman
Linda DiMeglio, MD, MPH, FAAP
Samuel Maldonado, MD, MPH, FAAP
Ronald Portman, MD, FAAP
Phillip (Brian) Smith, MD, FAAP
Janice Sullivan, MD, FAAP
Charles Thompson, MD, FAAP
Heide Woo, MD, FAAP

STAFF:
Jackie Burke
William Cull, PhD
Jonathan Klein, MD, FAAP
Raymond Koteras, MHA
Ken Slaw, PhD

Mr. Matt Hendricks of Pharmica Consulting and Susan Flinn have been retained as consultants for program facilitation and documentation.

For more information, contact Jackie Burke at the American Academy of Pediatrics Section on Advances in Therapeutics & Technology: (800) 433-9016 ext 4759 or jburke@aap.org
Section on Advances in Therapeutics and Technology Plenary:
The Future of Pediatric Clinical Trials: The Critical Role of Patients and Families

**Sunday, October 12, 2014**
10:50 AM – 12:15 PM
Convention Center, Ballroom 20

This plenary enhances knowledge for pediatricians in the importance of pediatric research, and how this affects daily practice.

*Stephen P. Spielberg, MD, PhD*

* * *

Section on Advances in Therapeutics and Technology Interactive Group Forum:
The Future of Pediatric Clinical Trials: The Critical Role of Patients and Families

**Sunday, October 12, 2014**
2:00 – 3:30 PM
Convention Center, 7A

This forum will explain the importance of and how physicians can promote clinical trials to their patients.

*Stephen P. Spielberg, MD, PhD*

*Lindsey Elsaesser*

* * *

Section on Advances in Therapeutics and Technology Program:
Research Abstracts Program and Award for Innovation

**Monday, October 13, 2014**
Noon – 2 PM
Hilton San Diego Bayfront, 202A

This abstract and research session will cover research topics in the area of pediatric innovation, therapeutics and technology. The program will also include the inaugural Section Award for innovations in pediatrics.

*Continued on Page 23*
2014 SOATT Section Programs at NCE  Continued from Page 22

Moderators: Charles Schubert, MD, MPH, FAAP and Paul Wang, MD, FAAP

Noon – 12:05 PM  Welcome
12:05 – 12:40 PM  Top Three Research Paper Presentations (podium)
12:40 – 1 PM  Section Award Presentation
1 – 2 PM  Research Poster Q&A and reception  
2 PM  Adjourn

*     *     *

Section on Advances in Therapeutics and Technology Program: Must-Have Gadgets, Gizmos and Technology For The Pediatric Office

Monday, October 13, 2014
4:00-5:30 PM
Convention Center, 7A

Informative session on new must have gadgets and technology available for the pediatric office. Andrew Schuman, MD, FAAP

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The AAP Section on Advances in Therapeutics & Technology would like to thank Pfizer for their Support of the Section’s New Award for Pediatric Innovation.
A Message from the Membership Committee

Seth Toback, MD, MMM, FAAP, SOATT Membership Committee Chair

I am pleased to announce that since our last newsletter of this year our section has grown to 346 members. We are one of the few sections in the AAP that are currently growing in size and we have you to thank for it. Our grass roots membership campaign is really getting the word out about our section. Our number of affiliated members also continues to grow with 10 members from diverse backgrounds such as non-AAP medical doctors, PhDs and PharmDs. Thank you for discussing the section with your colleagues and co-workers and sharing our newsletters with potential new members.

Who Can Join?
Membership in the section is open to Fellows, Specialty Fellows, Candidate Members, Post Residency Training Members, Honorary Fellows, Emeritus Fellows, and Corresponding Fellows with an interest in advances in therapeutics and technology. We also accept affiliate members, who are not eligible for membership in the AAP and hold a Masters degree or Doctorate (or equivalent) in pharmacy or other health science concentration. Affiliates must submit an application and have a signed letter of support from an AAP fellow in good standing. There is no fee to join the Section as a regular member and a $40 fee for affiliate members.

How To Join
If you are already a member of the AAP and would like to become a SOATT member, join online by:
1. Going to Member Center of the AAP website and use your AAP login and password.
2. Click on “Join a Section or Council” under Member Community
3. Choose “Advances in Therapeutics and Technology”, answer a few questions, and click “Submit”.

Membership applications can be found at:

Members:  http://www.aap.org/moc/memberservices/sectionform.cfm

Affiliates:  https://www.formrouter.net/forms01@AAPED/2010_AAP_Affiliate.pdf

If you have any questions about membership please contact Seth Toback, MD, MMM, FAAP at Seth.Toback@gilead.com or staff at jburke@aap.org.
## Welcome New Members
(April 2014 to July 2014)

<table>
<thead>
<tr>
<th>Oyinade Akinyede</th>
<th>Sajel Lala</th>
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<tr>
<td>Shally Awasthi</td>
<td>Todd McKenzie</td>
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<tr>
<td>Hamid Bassiri</td>
<td>Steven McSwain</td>
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<tr>
<td>Corrie Chumpitazi</td>
<td>Hasan Merali</td>
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<tr>
<td>Ritika Coelho</td>
<td>Hossam El Din Mostafa</td>
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<tr>
<td>Peggy DeFelice</td>
<td>Matthew Nestander</td>
</tr>
<tr>
<td>Danielle Ehret</td>
<td>Alisa Niksch</td>
</tr>
<tr>
<td>Alexander Fiks</td>
<td>Folake Olaosebikan</td>
</tr>
<tr>
<td>Lois Freisleben-Cook</td>
<td>Rohit Passi</td>
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<tr>
<td>Rebecca Frontz</td>
<td>Jewel Ponvelil</td>
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<tr>
<td>Balaji Govindaswami</td>
<td>Carmen Rivera-Velez</td>
</tr>
<tr>
<td>Marney Gundlach</td>
<td>Snehal Shah</td>
</tr>
<tr>
<td>Kyon Hood</td>
<td>Beena Sood</td>
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<tr>
<td>Viral Jain</td>
<td>Esther Speer</td>
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<tr>
<td>Mohammad Janjua</td>
<td>Jason Stoller</td>
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<tr>
<td>Hilda Kabali</td>
<td>Nancy Swigonski</td>
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<tr>
<td>Suhasini Kaushal</td>
<td>Brent Upchurch</td>
</tr>
<tr>
<td>Robert Koppel</td>
<td>Leticia Watanabe</td>
</tr>
<tr>
<td>Soo Hyun Kwon</td>
<td>Scott Wenderfer</td>
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</tbody>
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**Be Informed! Get Involved!**

Join the
Section on Advances in Therapeutics and Technology
Listserv® Today!
If you are interested in joining the Listserv,
e-mail tcoletta@aap.org
Section Produces Patient Education Brochure on Clinical Trials in Conjunction with the AAP Department of Marketing and Publications

Should My Child Join a Clinical Trial? Patient education brochure was finalized and published in February 2014. The brochure covers:

- Why are clinical trials for children needed?
- How are clinical trials done?
- What are the benefits and risks of a clinical trial?
- What do I need to know before I sign up my child for a clinical trial?
- What questions should I ask about a clinical trial?
- Words to Know
- For more information

For a free sample copy of the brochure, please contact AAP Customer Services at 866/843 -2271.

The Digital Navigator is Now Available!

The American Academy of Pediatrics Practice Excellence (APEX) program is proud to announce the release of the Digital Navigator. Designed to guide practices as they transition to a high-performing organization under the Patient and Family-Centered Medical Home (PCMH) model of care, the Digital Navigator is a web-based software application that can help any practice navigate the practice transformation process. The Digital Navigator can be accessed via any desktop computing or mobile device that has an internet connection. It is designed to be team-based, where both practicing physicians and office staff work together to achieve the practice's desired goals.

The Digital Navigator:

- Aligns with the 2011 NCQA Standards and empowers clinicians with the ability to scale their investment of time and resources into the Medical Home transformation process through a modular format that will allow them to implement each standard at their convenience.
- Provides a comprehensive methodology and set of procedures, tools, and resources that guide practices through each aspect of implementing the PCMH model of care.
- Consolidates best practices and industry expertise into a self-guided, modular format that breaks the PCMH implementation effort into manageable tasks to accelerate progress and ensure success.
- Guides implementation of an efficient front- and back-office operations through this effective practice management system.

The Digital Navigator is a powerful application that can help any practice or organization meet its needs as it transforms into the Patient and Family-Centered Medical Home model of care. Whether you are seeking formal recognition with the 2011 NCQA Standards, or simply trying to transform your practice to an effective and efficient organization, the Digital Navigator can help your practice lower costs and improve care.

To purchase the Digital Navigator or learn more about the tool, click on the "Get Started" button below. If you have any questions or are interested in seeing a demo of the software, contact the APEX team at dnsales@aap.org or 1-847-434-7010.

Click link to get started.

http://digitalnavigator.aap.org/Pages/Welcome.aspx

This message is sent to you by the American Academy of Pediatrics APEX Program