As another NCE approaches, we not only look back at an incredibly successful year for SOATT, but we look with excitement to the future. Our Section has grown to over 500 members from diverse backgrounds who share a common passion and interest in pediatric innovation. In this issue of the SOATT Newsletter, you will read about innovative concepts in Texas, Massachusetts, and Minnesota, a new International Neonatal Consortium, the launch of the International Children’s Advisory Network, and important upcoming conferences. We hope to see many of you at the NCE in Washington, DC, at our Research & Award presentation, Dr. Dianne Murphy’s (US FDA) presentation, or Dr. Andy Schuman’s Gadgets and Gizmos workshops. In the near-term, we are exploring ways to encourage communication and collaboration both within and outside of the Section. Please continue to share with us your ideas and suggestions and, as always, thank you for your passion and dedication to the pediatric community.
From the Editor's Desk
“More Pediatric Innovation Meetings of Interest”

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“Innovation” continues to be THE buzzword in the healthcare field and especially in the areas of digital health, therapeutics, and medical devices.

This edition of the SOATT newsletter features innovation activities in Texas and Minnesota, and Dr. Natan Noviski describes the long history of telemedicine at MGH and how it has impacted the pediatric care that they deliver both locally and afar.

In this edition, we also welcome our colleagues at the newly formed International Neonatal Consortium (INC) that is spearheading efforts to increase collaborations among neonatal caregivers, governmental agencies, patient advocacy groups and industry partners to advance neonatal therapeutics.

We look forward to seeing you at this fall’s NCE meeting in Washington DC 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 an avenue of communication for our Section, and 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.

Further details can be found in the previous editions of the newsletter at:


(AAP login information required)
or

www2.aap.org/sections/pedsadvances/Newsletters/SOATT_Newsletter_Spring_2014.pdf

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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

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)
www.PhillyPediatricMedDevice.org

Southern California Consortium 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)
http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/PediatricDeviceConsortiaGrantsProgram/default.htm
Texas-sized Pediatric Innovation at SXSW

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On Monday, March 16, 2015, the nation's four largest pediatric hospitals collaborated together to produce the “Impact Pediatric Health Pitch Competition”, the first of its kind pediatric pitch event at South by Southwest (SXSW) Interactive in Austin, Texas. Sponsored by Cincinnati Children's, Boston Children's, Texas Children's Hospital, and Children's Hospital of Philadelphia, the event was focused on finding new products that uniquely affect pediatric health and that challenged innovators to think about the pediatric population when creating their products.

For those not familiar with SXSW, it is Texas's most well-known event that draws attendees and startup companies from across the globe. While its core interests have been in Music, Film, and Interactive technologies that value creativity, innovation and inspiration, Health has achieved recent attention as a SXSW core interest, where Impact Pediatric Health was an official part of the 1st ever SXSW Health and MedTech Expo. Of note, SXSW showcases both up-and-coming technologies as well as industry leaders. More information on the event can be found at http://impactpediatrichealth.com.

Internet pioneer, billionaire, angel investor, NBA team owner, Shark Tank member, and father of three Mark Cuban served as emcee for the Impact Pediatric Health Pitch Competition event. Hospital leaders and Investor / venture capital (VC) leaders served as judges for the event. Since there are 75 million children in USA accounting for 24% of the total U.S. population, it was no surprise that over 200 start-ups applied to the pediatric competition, from which 12 finalists were selected.

The awardees for the Pediatric Pitch event were:

VC Awards:
1. CareAline - www.carealine.com
2. Medical Informatics - www.medicalinformaticscorp.com
3. Lully - www.lullysleep.com

Hospital Awards:
1. CareAline - www.carealine.com
2. Medical Informatics - www.medicalinformaticscorp.com

AARP Award:
CareMonster - www.caremonster.com

Congratulations to the winners!

Plans are underway for the 2016 “Impact Pediatric Health” event at SXSW Interactive, so save the date for Monday March 14, 2016 (the www.impactpediatrichealth.com webpage will be updated soon).
If you walk down the health technology aisle of a major retailer you’ll observe a tremendous variety of activity tracking devices—Fitbit, Jawbone, Garmin, Misfit, and others. But look closer and you’ll see the emergence of the next generation of devices that address more specialized areas: Kinsa, a smart thermometer; Mimo, a smart onesie; Sproutling, a “Fitbit” for babies; and the iHealth suite of products including blood pressure cuffs, scales, and glucometers. Online you’ll find products like AliveCor, a smartphone connected ECG or CellScope, a smartphone connected otoscope. All of these products can be alluring for the tech-savvy parent. But all of the data from these devices can be overwhelming to a health care provider.

Until recently the data from these sensors had little use in a clinical setting. The data lived in a proprietary app and cloud with little connectivity to any clinical setting. Advances in secure integration are turning that disconnected data into actionable information when coupled with proper clinical oversight.

Pediatrics and Health Technology
As these emerging health management tools gain greater traction, they will impact clinical interactions across the patient spectrum—none more so than for pediatrics. As parents adopt these technologies with their children, particularly those with chronic conditions such as diabetes and asthma, clinicians will need to become adept at using these new sources of information. Through this persistent connectivity, we can improve health outcomes and lower costs for many patients.

Three years ago, fitness trackers were primarily for “early adopters.” Now fitness trackers are everywhere, including the type you wear on your wrist to those built directly into other devices, such as your smartphone, watch, and even your car. Consumer-grade pediatric health devices will likely follow a similar path. As we think of innovation in health devices, who better than kids and young parents to lead the charge? Kids love technology, as do many young parents. Neither group has a fear of technology, in fact, they embrace technology more than any other generation. Plus, they give honest feedback. Mobile technology is firmly entrenched in their everyday lives.

It’s entirely possible that a baby born today could have every heartbeat in their lifetime monitored and digitized. From a baby’s smart onesie to wearable heart rate monitors to integrated sensors in mattresses, automobiles, and other everyday items, every aspect of their life might be quantified, and available to their health care team at the touch of a button.

The Challenges
Creating meaningful action from this onslaught of data is a tremendous challenge. Text alerts for sports scores, online posts, and weather are ubiquitous, but you are a passive recipient of that type of information. Parents, kids, and providers will need to become engaged and responsive users of health care data. Systems to alert the parent of a chronically ill child of a meaningful health event are not readily available. The parents of a diabetic children until just recently had to “hack” into their children’s glucose monitor to access the information in real time. Providing this relevant health information (glucose levels, pollen count, etc.) at the right time and in a format that achieves the greatest engagement for parents and health care providers is a top priority for many digital health companies today, however this is not without challenges. Four primary challenges exist in the pediatric health monitoring space: regulation; market size; data security; and connectivity to the care team.

Regulation
Most connected health devices are making only general wellness claims, thus avoiding FDA regulation. This results in marketing the devices that track a baby's respiration, heart rate, O2 saturations, and sleep position as “smart baby monitors.” Just as a medication can be used off label, devices are also used off label. There are stories of parents removing the motion sensors from the smart onesie and sewing them into larger pajamas as a means of notification that their nine or 10 year old is having a seizure during the night. Parents have learned how to “hack” a product or system and create

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something that better fits their needs. Nightscout is a widely used data sharing cloud-based system that came out of parents “hacking” an FDA approved continuous glucose monitor (CGM). Parents are clamoring for ways to better manage their kids with chronic conditions.

**Market size**

The pediatric market for health management tools is small in comparison to the adult market. Since kids are not simply small adults, tightening the strap on an adult Fitbit doesn't make it work for kids. Dedicated design of a health device for infants and children is crucial for accuracy and ease of use. Given that the market is small (and the regulations more complex), major manufacturers have made the pediatric market a lower priority but we now starting to see products come to market.

**Data security**

Physicians must address and prioritize the privacy of patient data from remote sources. Having secure transfer and integration methods into the medical record are important factors when choosing the health management partners. Validic, and companies like it, make secure integration of data in the patient record possible. As we consider remote monitoring in pediatrics, many complex issues must be addressed: security on the monitoring device; security in the transmission of data to the cloud; rights and controls in accessing the data in the clinic and by parents/guardians. Parents and caregivers can't act on data if it isn't available or communicated.

**Connectivity to a Care Team**

Diseases that require daily management; diabetes, asthma, heart disease; eating disorders – all lend themselves to daily remote monitoring and care team connectivity. In most existing care models, intervention happens between clinic visits only. With emerging connected technology, healthcare providers can access to data between scheduled clinic visits. In the case of a type 1 diabetic child, connected glucose monitors (intermittent and continuous) allow real-time transmission of blood glucose data to both parents and the clinic. When paired with a connected insulin pump or “smart insulin pen,” caregivers can start to see a more complete picture. Through smartphones and secure cloud-based portals, real-time management of our patients will become a viable reality in the coming years.

When connected devices can securely transmit data to a connected care team, the model of care starts to shift dramatically. Interesting emerging models include Glooko and Marucci.

Glooko is a connected diabetes management system allowing for near real-time remote management of patients with diabetes. When a patient performs a glucose test using their standard glucose meter, they connect and sync through the Glooko device and transmit their results to a secure patient-management platform. In addition to glucose data fitness, activity data also syncs to the management tool. A clinician (or parent) can log in and review the glucose and activity data. Parents can now inquire about a test or practice instead of opening every conversation with “what were your numbers? “.And clinicians can manage patients between scheduled quarterly visits. Glooko is adding CGM and insulin pump data in future versions of their software, which will enhance the functionality and usefulness of the service. Research is underway to start creating data sets that may eventually enable more advanced machine-based, real-time disease management.

Marucci is a sporting goods manufacturer. Their BodiTrak system integrates in-helmet concussion sensing, locker room baseline testing and virtual clinical care. Many helmets are now incorporating impact detection, but the true innovation at Marucci comes after the player is pulled from the field of play. Once a hit of significant force is detected, and the player is removed from the game, a diagnostic assessment via a tablet can take place in the locker room. An immediate, virtual connection, with impact and baseline data, will be made to a concussion specialist through the MDLive care platform. By the time the child leaves the locker room, they've been evaluated by a concussion specialist, have a care plan in place, and an appropriate follow-up scheduled.

**Conclusion**

Technology is moving forward at an increasingly rapid rate. Dramatic changes to care models will emerge as these advances in health monitoring become more engrained in pediatrics. As hardware and software merge with smart systems, physicians will have access to information not previously available. For children with chronic conditions,
these tools could be game-changers. Smart connected systems could alert the patient, the parent and the provider to potentially harmful health events such as an abnormally low glucose reading. For otherwise healthy kids, connected technology could quantify an impact to the head that needs ongoing treatment and allow that child to recover and return to school more quickly. The technology, in all cases, can be seen simply as another tool to keep children healthy and safe.

AAP Section
on
ADVANCES IN THERAPEUTICS & TECHNOLOGY
is Looking for Members to Serve
on EXECUTIVE COMMITTEE

The AAP Section on Advances in Therapeutics & Technology (SOATT) has one opening for an executive committee member beginning November 1, 2016. Executive Committee members help to steer the current and future activities of the SOATT. If you are a member of the AAP and the SOATT and are interested in a 3-year executive committee position, please forward your letter of interest and a biographical sketch to our staff at jburke@aap.org, who will forward to the SOATT Nominations Committee.

Also, the position of Chairperson for the SOATT will also be open beginning November 1, 2016. If you have served on the executive committee of the SOATT in the past and are interested in serving as Chairperson, please forward your letter of interest and a biographical sketch to our staff at jburke@aap.org

DEADLINE: December 1, 2015

Thank you!

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.
Global Efforts to Accelerate the Development of Safe and Efficacious Therapies for Newborns

Jonathan M. Davis, MD, FAAP
Co-Director, International Neonatal Consortium
Professor of Pediatrics, Tufts University School of Medicine
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There are daunting challenges routinely facing neonatologists caring for critically ill newborns due to limited evidence available to guide most treatment decisions. Most drugs administered in the NICU have not been approved for use in newborns by the regulatory agencies. This has stimulated passage of important legislation in the US and Europe and helped motivate the global community to join forces in order to break down barriers and facilitate the development of safe and effective therapies for neonates (McCune, 2014). Launched on May 18, 2015 at the European Medicines Agency (EMA), the International Neonatal Consortium (INC) is a unique organization that includes regulators from FDA, EMA, and Health Canada and the Japanese regulatory authorities, funding agencies such as NIH, members of the academic community (from many different countries), practicing neonatologists, industry scientists, neonatal nurses, patient advocacy organizations, and the non-profit Critical Path Institute (http://c-path.org/programs/inc/).

What conditions will INC focus on?
INC will concentrate on therapeutic areas most commonly encountered in neonatal care: neonatal lung, brain, and gastrointestinal injury, retinopathy of prematurity, sepsis, and neonatal abstinence syndrome (Figure 1). Affecting both preterm and term neonates, these disease processes are associated with significant short- and long-term morbidity and mortality. The consortium is also interested in accelerating the development of drugs to prevent preterm labor.

What will INC deliver?
Participants of the initial October 2014 Workshop at the FDA and the May 2015 Workshop at the EMA discussed and prioritized both approaches and deliverables that would have the most impact on neonatal therapeutics. These included the following:

- Standardized methods and consensus-derived standards-of-care, which could include draft master protocols, general guidance on standardizing assessment and collection methods for the conduct of clinical trials in neonates, and consensus-derived optimal short and longer term clinical endpoints. Innovative trial designs tailored to this population as well as trial designs for a particular class of drugs could also be developed.

- Draft position papers on the appropriateness of extrapolation of research results from other populations (adults and older children) to the neonatal population.

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• Revised definition of neonates to take into account physiology and the unique need for pharmacokinetic and pharmacodynamic modeling (complicated by the vast differences in caring for infants ranging at birth from 22 to 42 weeks gestation and weighing 400 to 5000g at birth).

• Draft decision criteria for conducting clinical trials of new and existing therapies, including prioritizing which pharmacologic agents are best suited for intervention trials in the neonate.

• Drug Development Tools endorsed or qualified by the regulatory agencies for a specific context of use. Such tools can also be used to evaluate a variety of interventions designed to prevent pre-term birth.

• Safety and Efficacy Biomarkers

• Clinical Outcome Assessments (COA)

• Modeling approaches such as physiologically based pharmacokinetic and disease progression models, as well as clinical trial simulation tools.

• Guidance on the development of safer formulations designed specifically for neonates.

Four INC workgroups have been recently formed. Two of the workgroups are focused on indications/symptoms commonly encountered in neonatal care, namely seizures (secondary to brain injury) and bronchopulmonary dysplasia. The other two workgroups are addressing cross-cutting needs: 1) The clinical pharmacology workgroup will draft a position paper on the special pharmacologic considerations for the neonatal population, and 2) The data workgroup will begin with a landscape analysis of neonatal data available from participating countries (i.e. Canada, Europe, Japan, South Korea, and the US). Additional work streams will be considered as the consortium grows.

Collaborating to Advance Neonatal Therapeutics

In order for this approach to be successful, it is essential that Neonatologists have sufficient equipoise to question existing standards and be open to studying therapies that have been in routine use for many years. Protocols must be designed using “team science”, based on “best practice”, and implemented in the US, Europe, Canada, and Asia simultaneously (since much of Neonatology involves rare diseases). If the therapy is safe and beneficial, product approval can occur in multiple countries simultaneously, saving significant time and money. This will only be possible if agreement can be reached by physician-scientists and Regulators worldwide. The INC can catalyze these efforts since the greatest strength of the organization is the integration of global expertise from so many disciplines. This will provide unprecedented opportunities to better understand the unique needs of this population and the appropriate processes that must be instituted in order to begin to meet these needs. The prospects of participating in this process do exist and more information about INC can be obtained by contacting the Critical Path Institute in Tucson, AZ (LHudson@c-path.org).

References


“Pediatric Urgent Care from a Distance: the MGH Experience”

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Historical Background

The first telemedicine program in the nation was founded and directed by Dr. Kenneth T. Bird of Mass. General Hospital (MGH) in 1967, and it established a link between the hospital and Logan Airport, 2.7 miles away. The Logan International Airport Medical Station of the Mass. General Hospital provided occupational health services to airport employees and delivered emergency care and medical direction to travelers. It was staffed around-the-clock by nurses, with a physician in attendance for 4 peak hours each day. If needed, the nurses could consult with a physician via telephone. Using a two-way closed circuit television system, Dr. Bird created an audio-visual link allowing the on-site nurse, remote physician, and the patient to consult face-to-face (Fig. 1). A study done on this system over the course of 16 months found over 1,000 patients were treated using telemedicine, with over 60% stating the experience “about as satisfactory” as seeing a physician in person, and 7% that it was “more satisfactory.”

Following this first success, the use of telemedicine grew rapidly. In 1968, a link was established with the Veterans Hospital in Bedford, MA, and from 1968 – 1975, technical reports were published regarding various aspects of telemedicine e.g. telediagnosis in psychiatry, radiology, otolaryngology, dermatology, etc.). In 1993 and 1994, live demonstrations of the use of telemedicine were given between MGH and United Arab Emirates and Saudi Arabia, respectively. In 1996, MGH created a Telemedicine Center.

Managing Patients in Distant Hospitals

In 1998, the Department of Pediatrics at MGH (later known as MassGeneral Hospital for Children) created links between the Pediatric Intensive Care Unit (PICU) and Emergency Departments at area community hospitals such as Newton-Wellesley Hospital in Newton, MA (13 miles), North Shore Medical Center, Salem, MA (16 miles), and, more recently, Nantucket Cottage Hospital in Nantucket, MA (101 miles). These links were used for pediatric emergency consultation and medical simulation. The program was presented in 1999 at the AAP meeting in San Francisco, “Telemedicine as an aid in simulated management of critically ill patients during transport. In 2001, MGHfC further expanded their telemedicine program to the remote and underserved Good Samaritan Hospital in Aguadilla, Puerto Rico, to the best of our knowledge, the first such program to cross state lines. With funding from the Carlos Delgado Foundation, under the leadership of Dr. Elliot Melendez, the project provided telemedicine advice/service between the Division of Pediatric Critical Care Medicine at Massachusetts General Hospital and the Department of Pediatrics at Good Samaritan Hospital. It also provided emergency consultation, advice on Good Samaritan's current pediatric inpatients, and didactic medical education. This program was presented at the 4th Pediatric Intensive Care World Congress, Boston, MA in 2003, and was also highlighted on WCBV, TV Channel 5, Chronicle, “Above and Beyond”.

Management of Patients in our PICU

A slightly different use for telemedicine was instituted by the MGHfC PICU in 2009, with their home-to-hospital program, which featured real-time video communication, enabling the on-call attending physician, when at home, to personally examine the hospitalized patient and communicate directly with the PICU staff (residents, fellows, nurses, respiratory

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The remote examination involved the use of a mobile, high-definition videoconferencing unit with cameras and scopes located in the PICU and linked to small videoconferencing units in each PICU attending's home. We showed, in a study on the program (Yager et al, CCM 2012), that important information was obtained via telemedicine that would not have been possible by telephone alone, such as physical assessment, multidisciplinary communication, communication with parents, and review of ventilator, pumps, and monitor. During the study period, the ability of the on-call attendings to view the study patients allowed them to provide better recommendations for patient care than would have been available from the information provided by telephone only: e.g., two intubations advised and supervised, two intubations averted, one head CT cancelled, and one I/O needle removed, and others. The attending physicians felt that the use of telemedicine caused significant changes in patient care decisions in 32% of the cases, and in 39%, current care decisions were reinforced. This initiative was recognized by the Agency for Healthcare Research and Quality – U.S. Dept. of Health as an innovation. [https://innovations.ahrq.gov/profiles/call-attending-physicians-consult-onsite-care-team-home-based-videoconferencing-improving](https://innovations.ahrq.gov/profiles/call-attending-physicians-consult-onsite-care-team-home-based-videoconferencing-improving)

We then investigated the reliability of telemedicine compared to face-to-face for many aspects of circulatory and neurologic examinations of children admitted to a PICU. (Yager et al. J Peds 2014). In a study of 55 patients, our findings indicated that many aspects of the circulatory examination are reliable when compared with face-to-face exams, and that on nearly every element of the neurologic examination, there was substantial to perfect agreement.

More recently, we have conducted two studies in relation to the assessment of the respiratory system in critically ill children. The first study (accepted for publication, J Med Internet Research ms #4661), investigated the reliability of telemedicine compared to face-to-face assessment in many aspects of the respiratory system. We found that, in some aspects, which are extremely important to intensivists (airway maintenance and clearance), telemedicine was very sensitive and very specific. However, we found that with the currently available technology, we could not detect abnormal breath sounds well. This leaves the field open for more studies on this topic.

The second study (accepted for publication Respir Care RC-04080) investigated telemedicine vs face-to-face assessment in mechanically-ventilated children and neonates by respiratory therapists. In 20 assessments on 11 patients (6 Pediatric ICU and 5 Neonatal ICU), tidal volume, minute ventilation, mean airway pressure, and oxygen saturation were highly correlated, with r ranging from 0.84 to 0.97 (all p<0.01). For the I:E ration, r=0.47 (p=0.04). Respiratory assessments were perfectly correlated for the presence of an end-tidal CO2 monitor and the need for increased ventilatory support (k=1).

Following this, we addressed the needs of the parents by enhancing communication with the care team and increased face-to-face time with their child via teleconnection linking them from home or work to the PICU (Figs. 3 and 4). Parents of children admitted to the PICU for prolonged hospitalizations often face barriers preventing them from spending time at the bedside and from maintaining communication with the care team which can contribute to increased stress. In the study, parents were provided with an iPad to enable them to virtually join morning rounds or to virtually visit with their child. Connectivity was established in 100% of encounters. Parents reported excellent audio and visual quality for all encounters. Parents reported a high level of satisfaction following each encounter, citing increased confidence that they understood the daily care plan for their child and had had all of their questions answered. Parents reported an overall sense of relief at being able to see and communicate with their child.

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This study was accepted as a poster presentation at the Society of Critical Care Medicine Annual Conference, San Francisco, January 2014.

**Conclusion and Looking Forward**

Although much research remains to be done, Mass. General Hospital's experience with telemedicine, particularly in the Division of Pediatric Critical Care Medicine, has demonstrated the adaptability of the technology to many different settings and applications. It has been used successfully between medical centers from 2.7 to 1800 miles apart, as a way for on-call attendings to stay better connected to a busy PICU during the overnight hours, and as a way for parents to stay in touch with their critically ill child and his/her medical team when they are not able to be at the bedside. It has been used to assess children in emergency rooms, to consult with physicians on complex cases, to evaluate patient circulatory, respiratory, and neurologic symptoms, and as a teaching tool for medical simulation and didactic teaching.

Looking forward, in the near future we would like to see better digital auscultation equipment for breath sounds and cardiac sounds; the ability to intubate from a distance by potentially combining video-assisted laryngoscopy with telemedicine equipment; and some type of “head cam” giving supervising attendings the ability to examine patients through the eyes of a resident or fellow for improved teaching.

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* One day before The American Academy of Pediatrics National Conference in Washington, DC
Kids and Families Impacting Disease through Science (KIDS) Update:
The 2015 International Children's Advisory Network (iCAN) Launch & Research Summit Brings Together Youth From Around the World

Nick Frederico
iCAN Coordinator
nick.icanresearch@gmail.com

Washington DC - The 2015 iCAN Launch and Research Summit was a unique four-day conference that took place from June 22 - 26, 2015 and was attended by 130 children, parents, and group leaders representing 14 iCAN chapters from 8 different countries. As part of this first annual event, iCAN officially launched its global network of youth advisors to pediatric health, medicine, research, and innovation. iCAN is composed of 15 member organizations who work at the local level with hospitals, researchers, AAP Chapters, and other partners, and they all share the same objective:

Continued on Page 15
to improve pediatric health, medicine, research, and innovation by sharing children's voices in an impactful way.

Children and families took part in engaging, interactive sessions with representatives from Children's National Medical Center, Pfizer, the US Food and Drug Administration, Health Canada, European Medicines Agency, National Institutes of Health, Nuffield Council on Bioethics, National Organization for Rare Disorders, Non-Communicable Disease Child, and the American Academy of Pediatrics Division of Federal Affairs. Young people also visited with their senators and congressmen, and a select group of youth participants were invited to the Pharmaceutical Researchers and Manufacturers of America headquarters to deliver a stakeholder advocacy briefing. “This was truly a landmark event bringing youth from around the world to interact with leaders from the pediatric medical community and unify around the common cause of providing a voice to children and families,” said Dr. Charles Thompson, a pediatrician and founder/chairman of the iCAN Board of Directors.

This event was a great opportunity for youth advisors from all over the world to network with one another, and it also provided an opportunity for the scientific community to engage children and learn their perspectives on the important work that they do. iCAN is hopeful that each successive Research Summit proves to be more successful than the last. For more information, visit www.icanresearch.org.

A highlights video of the summit can be seen at https://youtu.be/MgUeEXM4_w0
A Message from the Membership Committee

Seth Toback, MD, MMM, SOATT Membership Committee Chair

Our section has seen some very impressive growth in 2015. Since our last newsletter update, our section has gone from 346 members to 508 members! Our members continue to discuss the section with their coworkers, colleagues and friends, and we greatly appreciate your help in getting the word out. Our number of affiliated members also continues to grow with 11 members from diverse backgrounds such as non-AAP medical doctors, PhDs, and PharmDs. As always thank you for discussing the section with your colleagues and sharing our newsletter 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. Also any Affiliate Member can join. Affiliates are those 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](http://www.aap.org/moc/memberservices/sectionform.cfm)

Affiliates: [https://fs25.formsite.com/aapmembership/affiliate/secure_index.html](https://fs25.formsite.com/aapmembership/affiliate/secure_index.html)

If you have any questions about membership please contact Seth Toback, MD, FAAP at Seth.Toback@gilead.com or staff at jburke@aap.org.
Welcome New Members
(April 2015 to August 2015)

Abdelazim Abdalla MD
Essam Abdel Bary, MD
Kamal Abdelfatah, MD
Mazen Abou-Chaabab, MD
Yasser Al-Kahf, MD
Hassan Alsabea, MD
Lofty Aly, MD
Paul Ambush Jr., MD, FAAP
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Evelyn Berman, MD
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Valeria Defaz, MD
Cynthia Diaz Galeano, MD
Mohamed El Nadoury, MD
Nevine El-Kabbany, MD
Nesrin El-Kabbany, MD
Tarek El-Sayed, MD
Shahid Gauhar, MD
Katherine Griswold, MD, FAAP
Fayez Hafez, MD
Qais Hameed, MD
Khaled Hamzeh, MD
Peter Haney, MD, PhD, FAAP
Ahmed Ibrahim, MD
Harith Ibrahim, MBChB
Valeriy Ivanov, MD
Bushra Jaafar, MD
Ayman Jabbar, MD
Jason Kane, MD, FAAP
Hoda Karbalivand MD
Imran Khares, MD
Tarek Koth, MD
Nemishh Mehta, MD, FAAP
Mohamed Mostafa, MD
Anwar Mousa, MD
Ahmed Nassef, MD
Sydney Nichols, MD, FAAP
Sireesha Palkamsetti, MD, FAAP
Eric Perez, MD, FAAP
Alicia Rapson, MD, FAAP
Srikanth Ravisankar, MD, FAAP
Hima Reddy, MD, FAAP
Khalil Rehman, MD, FAAP
Kiersten Ricci, MD
Toni Richards-Rowley, MD, FAAP
Robert Rosenberg, MD, FAAP
Mohammed Sadik, MD
Soewira Sastra, MD
Ashraf Sayed, MD, MRCPCH
Deborah Schein, MD, FAAP
Sloane Sevran, MD, FAAP
Bassil Shaaban, MD
Annu Sharma, MD, FAAP
Janice Sullivan, MD, FAAP
Eslam Tawfik, MD
Maria Tesin, MD
Kiran Upadhyay, MD, FAAP
Emily Webber, MD, FAAP
Chang-Yo Yang, MD
Nancy Zeidan, MD
Dear Colleagues,

The November 2014 Pediatric Clinical Trials Stakeholder Forum brought together an unprecedented number of diverse stakeholders resolved to establish a Global Pediatric Clinical Trials Network. This meeting, hosted by the American Academy of Pediatrics (AAP) and funded by an unrestricted grant from the Pharmaceutical Research and Manufacturers of America (PhRMA), resulted in a goal to set out a “pre-launch” consortium that would serve as the home to launch a global pediatric clinical trials network as an independent, non-profit entity.

Since the meeting in DC, several important milestones have occurred, including:

• Formation of a working group to explore the mechanisms to implement a “pre-launch” consortium and identification of the Critical Path Institute as an ideal home for the consortium.
• Review of the proposal and agreement by Critical Path Institute to establish the “pre-launch” consortium.
• Creation of the Consortium within the Critical Path Institute (See attached Press Release), formation of its initial coordinating committee, and establishment of key work streams and timelines.
• Initiation of the work of the “pre-launch” consortium.

We are quite enthusiastic about the progress thus far and all of us are dedicated to seeing the vision and mission established at the Forum come to reality. There is still much to do and we are working under tight timelines as the clock has now started in earnest. Nevertheless, this is now an achievable task, with your help and that of others committed to high-quality product development for children.

We wanted to keep you all in the loop of activities that resulted from your work with the 2014 Forum. Thanks for all of your ongoing support and collaboration. We look forward to continuing to work with you as the work moves ahead.

Sincerely,
Ed Connor, MD, MBE, FAAP Executive Director Pre-Launch Consortium
Pam Simpkins, MBA, Co-Director Pre-Launch Consortium
Martha Brumfield, PhD, President and CEO Critical Path Institute
If you are attending the 2015 AAP National Conference (NCE), the Section on Advances in Therapeutics & Technology has several exciting and interesting programs sponsored by SOATT during the conference:

SOATT Research and Award Presentation for Outstanding Research

Session Description/Objectives: This abstract and research session will cover research topics in the areas of pediatric innovation, therapeutics and technology. The program will also include the inaugural Section Award for Innovations in Pediatrics.

Monday, October 26, 2015 • Noon – 2 PM • Marriott, Marquis Ballroom Salon 14

Noon – 2 PM Section on Advances in Therapeutics & Technology Research

Noon – 12:05 PM Welcome
Top Three Abstract Podium Presentations:

12:05 – 1:00 PM Top Three Research Paper Presentations (podium) plus Q & A
Capnography Monitoring to Reduce Adverse Events in the Pediatric Post-Anesthesia Care Unit
Compliance Rate of PPSV23 Vaccination Among High Risk Persons Aged 2-19 Years
Immunogenicity and Safety of an Investigational Hexavalent Vaccine Against Diphtheria, Tetanus, Pertussis (DTaP5), Polio (IPV), H. Influenzae Type b (Hib; PRP-OMPC), and Hepatitis B (HepB) Administered Concomitantly with RV5 and PCV-13 in US Infants

1:00 – 1:30 PM Section Award Presentation
Award for Pediatric Innovation (2015 Recipient: Natan Noviski, MD, FCCM, FAAP)

1:30 - 2 PM Reception

Monday, October 26, 2015 • 2-3:30 PM, repeat at 4 – 5:30 PM • Convention Center, 143 BC

Gadgets and Gizmo’s for the Pediatric Office Workshops (2)
Andrew Schuman, MD, FAAP

Tuesday, October 27, 2015 • 2-2:40 PM • Convention Center, 201

Role of the FDA in Issues Facing Practicing Pediatricians
Dianne Murphy, MD, FAAP

The Section on Advances in Therapeutics and Technology (SOATT) research posters on pediatric innovation will be located in the Walter E Washington Convention Center. The posters will be set up in the walk way (concourse) by meeting rooms 150-152 from Friday, October 23 after 1 PM through Monday, October 26 until 5 PM. Stop by and check out the remarkable research that is being highlighted by the Section!
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.