Greetings from the SO ATT Leadership Team. The change in the New England weather is a reminder that the AAP National Conference & Exhibition in sunny Orlando is rapidly approaching! We hope that all SO ATT members and interested non-members will join our Section program entitled Partners in Progress: Pediatricians Bringing Medical Advances to Patients on Monday, October 28th, from 1:30-4:30PM in the Orlando Ballroom North at the Hyatt Regency Orlando (formerly the Peabody Hotel). The program will include discussions on the challenges and resources of pediatric medical device development, the challenges of conducting clinical trials in the newborn, and our first-ever research session with 20 poster & podium presentations on a variety of topics. We hope that you are able to join us in Orlando!

In this month’s newsletter, we cover a variety of diverse topics related to research and medical innovation for children. From transitioning to a nonclinical career and working within a Clinical
Research Organization to explaining and participating in clinical trials, our contributing authors expand on a number of topics that highlight the breadth of our Section's interests and expertise.

2013 is proving to be an important year for SOATT. We were approved as a Full Section by the AAP Board of Directors in May (i.e., we lost that “Provisional” designation), Dr. Andrew Schuman led our first SA TT Webinar “Gadgets and Gizmos: Best tech for pediatric practice 2013” in May, and we launched KIDS (Kids and Families Impacting Disease Through Science) in September as a pilot program in Connecticut. We’re looking forward to carrying this momentum into 2014.

Finally, I’d like to welcome the new members of the SOATT Leadership Team: Drs. Mitch Goldstein, Lisa Mathis, Eric Ng, and Stephen Spielberg. Following this edition, we are looking for someone to replace Seth Toback as Newsletter Editor. Seth will remain on the Leadership Team as Chair of the Membership and Communication Subcommittee. Seth’s herculean and creative efforts in putting these Newsletters together are greatly appreciated and he has played a significant role in the early success of our Section. Thank you, Seth! If you are interested in serving as our Newsletter Editor, please let us know!

We hope you find this newsletter interesting and informative. As always, the SOATT Leadership Team encourages your suggestions and involvement in Section activities. Thanks for your continued support and passion for innovation and child health.
I again spent many long hours walking up and down the beach thinking up a theme for this newsletter. Then it occurred to me that the perfect theme would be “anuria”. Why anuria you ask, well our section, the SOATT, has “No P” in front of it any more (what’s the use of being a pediatrician without a little potty humor?). Yet much to my chagrin I was unable to find any urologists or nephrologists to write a series of interesting and entertaining articles on this topic so we are left theme-less again. If this newsletter had a theme it would be children in research. Our newsletter has touched on this subject in the past and it is touching on it again with a dive into the ethics of children being involved in phase 1 studies and teaching children (and having children teach us) about clinical trials. We also touch on another non-clinical career option for pediatricians which I neglected to cover in our newsletter on careers. Anyway, as our chair noted above we have some great articles in this newsletter, which came from our devoted membership, leadership team and invited guests.

I sincerely hope you enjoy reading this newsletter. If you have learned something new, share that information with a colleague, patient or friend. Feel free to share this newsletter as well.

Happy reading,

Seth

Announcements from the AAP

AAP Section on Advances in Therapeutics and Technology is Looking for Members to Serve on The Leadership Team!

Your Section will conduct its first Section election from March 1- March 31, 2014. The Section has two open positions for the Executive Committee. The term is three years and is renewable once, if desired. The term begins November 1, 2014. The leadership team oversees the business of the Section.

If you are interested in talking with a member of the nominations committee about the openings, please contact either Mitchell Goldstein, MD, FAAP (mgoldstein@llu.edu) or Lisa Mathis, MD, FAAP (lmathis@amgen.com) no later than December 1, 2013.
KIDS
(Kids and Families Impacting Disease through Science)

In September, SOATT launched KIDS as a pilot program in Connecticut. KIDS is an advisory group of children, adolescents and families focused on understanding, communicating and improving the process of medical innovation for children. KIDS/CT is sponsored by SOATT as a collaboration between the Connecticut Chapter of the AAP, Connecticut Children's Medical Center, Yale-New Haven Children's Hospital, and local schools. The objectives for the KIDS participants are as follows:

- Learn, teach and advocate for the research process that creates medical innovation to improve the health and well-being of children
- Engage in the research process through projects and consultation activities with hospitals, researchers, and the public and private sectors
- Provide input on research ideas, unmet pediatric needs and priorities
- Contribute to the design and implementation of clinical studies for children (e.g., assent, monitoring tools, schedules, etc.)
- Serve as a vital link between medical innovators and those in need of innovation
- Serve as a critical voice for children and families in the medical innovation process

If you'd like to learn more about the KIDS program, please see the related press release http://www.connecticutchildrens.org/resources/newsroom/latest-news/13-kids-advisory-group/ and/or contact Charlie Thompson at charles.a.thompson@pfizer.com.

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e-mail tcoletta@aap.org
In 1997, the United States Congress enacted a law (the Best Pharmaceuticals for Children Act – BPCA) creating an incentive for the pharmaceutical industry to develop drug products in children in exchange for an extension of the drug's market exclusivity by 6 months. In 2003, the US Congress enacted another law called the Pediatric Research Equity Act (PREA) that authorizes the Food and Drug Administration (FDA) to require pediatric studies from drug sponsors. These two laws work in tandem generating pediatric information necessary for the drug label to advise physician on the safe and effective use of medications in the pediatric population. Under BPCA, manufacturers receive additional 6-months of exclusivity for all drug products in which the active moiety is present as long as the drug sponsor conducts FDA-required pediatric studies of approved or unapproved indications. PREA allows the FDA to require pediatric studies for a labeled indication in adults or for unapproved indications that the drug sponsor is actively pursuing through research. Under PREA, the drug sponsor may receive a waiver or deferral of the requirement to conduct pediatric studies under certain circumstances. In the US, Orphan indications are exempted from the PREA requirement. These laws have been very successful in achieving their goal of generating information promoting the safe and effective use of drugs in children. Because the laws demonstrated a remarkable success in the US, the European Community enacted a similar law in 2007, with incentives and requirements for drug sponsor to produce appropriate pediatric information.

The FDA and the European Medicines Agency (EMA) have created an internal infrastructure to implement their respective laws. The FDA has a Pediatric Office in the Office of the Commissioner to address international and policy issues pertaining to pediatric drug development. The FDA also has a Pediatric and Maternal Health office in the Center of Drug Evaluation and Research (CDER) and an Internal Pediatric Review Committee mandated by Congress. This office and committee work alongside the reviewing CDER Divisions at the FDA to prepare Written Requests listing the required studies, number of patients and timeline for execution of the pediatric program. Based on completion of the studies described in the Written Request, the FDA grants the additional 6-months of exclusivity. The EMA also has dedicated staff working on pediatric drug development and a large pediatric committee (PDCO) in which all European member states are represented. The PDCO approves the Pediatric Investigational Plans (PIPs) that drug sponsors must execute. The PIP is analogous to the Written Request although often there are major differences in FDA and EMA requirements. The Pediatric Center of Excellence helps the clinical teams bridge those differences to achieve a single global development program.

To respond to the legal and regulatory demands, drug sponsors have created their own infrastructures for pediatric drug development. At Janssen (a Johnson & Johnson company), we created the Pediatric Center of Excellence (CoE). The Pediatric CoE is formed by one clinician from each of the therapeutic areas and a representative of each of a number of functional groups

Continued on Page 6
that participate in the development of drugs. We have six clinicians with expertise in their respective specialties. In addition, we have representation from pre-clinical toxicology, clinical pharmacology, pediatric formulation development, regulatory affairs, global clinical operations, and global medical safety. J&J has extensive expertise in pediatric formulations in its consumer sector. Therefore, we have invited an expert in pediatric formulation development from McNeil Consumers to be part of our CoE. Our Mission is to serve the drug development needs of all the therapeutic areas by: 1) providing guidance, education and expertise in pediatric program development, 2) driving alignment of pediatric drug development strategies across functions, 3) advocating for children and pediatric drug development across the company, 4) engaging external stakeholders with a similar mission in order to improve our performance and advocacy on behalf of children.

We work alongside the therapeutic areas developing pediatric strategies and feasible pediatric programs that fulfill the medical needs of children. We believe that by responding to the medical needs of children, we will be meeting the spirit of the pediatric laws and fulfilling the regulatory demands. In addition to the high level strategic aspects, we collaborate with the therapeutic areas on the extensive internal and external consultations that occur before we even develop the first pediatric protocol. Consultations with practicing pediatricians and lead clinical investigators inform us on the validity of our ideas. These experts shape our approach and guide us in the process of pediatric protocol development. This approach is not only needed because of their expertise but because many of them become our investigators. They have the best interest of their patients in mind when advising us what to do and what not to do. It is only after these extensive consultations that we develop the initial program that we submit for evaluation to regulators. Regulators in turn provide their perspectives which we convey to our consultants. Through this interactive process, we formulate our pediatric program.

Another benefit of such a matrix organization is that best practices can be shared across therapeutic areas and across functions. The functions represented in the pediatric CoE work within their own disciplines to gather new knowledge that can be applied to ongoing pediatric programs. Here is a description of how the different functions work in their own space and how they interact with the CoE.

The Preclinical Pediatric Team (PPT) serves as a single resource and point of contact in evaluating the nonclinical needs to support pediatric drug development. The PTT advises the nonclinical project team representative working on compounds for pediatric use by providing strategic, scientific and regulatory guidance as it relates to the nonclinical area. A primary philosophy of the PPT is to avoid generating preclinical data that fail to provide a relevant contribution to assessing potential clinical risks, while meeting regulatory guidelines for global pediatric development. Members of the PPT are well recognized internally and externally as key experts in the area of nonclinical testing to support pediatric drug development. The team organizes an external symposium approximately every 18 months, which is focused on cutting edge science in the field of juvenile toxicology assessments. These symposia are attended by both

*Continued on Page 7*
internal Janssen scientists as well as external participants from Industry, CROs and global Health Authorities. In addition to giving many invited lectures, members of the PPT have written numerous peer review papers and chapters for books in this area.

The Johnson & Johnson “Pediatric Formulations Network” is formed by technical experts working on various aspects of pediatric product development, including formulation development for prescription and over the counter products, packaging and device development, manufacturing of clinical supplies and commercial products, CMC regulatory affairs, and others. The Network also addresses particular topics, such as taste masking or acceptance testing, and plays an important role in evaluating emerging technologies and new dosage forms. The main mission of the Pediatric Formulations Network is to provide guidance, education and expertise in pediatric product development across J&J, advocate for pediatric development within J&J technical units, and interact with external stakeholders in the area of CMC.

The Global Clinical Operations Pediatric Working Group is comprised of GCO operations members and a representative from each Therapeutic Area and Ad hoc members representing regulatory and grants and contracts. The group provides support from the first concept of planning a Pediatric Program, development of protocols, operational support including tools for informed consent and assent forms, recruitment and retention planning tools, workshops and general guidance on Pediatric Programs. Training on pediatric clinical operations is available in one of our educational intranet sites.

Our regulatory group focuses on pediatric policies and requirements from global health authorities. This group facilitates the relationship between Janssen and health authorities. This group also drives the development of regulatory strategies for our pediatric programs for all therapeutic areas. This group provides guidance on understanding and interpreting the pediatric regulatory environment as well as resources available at FDA or EMA in advancing the company pediatric programs.

Physicians in Global Medical Safety (GMS) provide analysis of adult and pediatric patient safety data from a number of sources including clinical trials, post-marketing consumer or health care professional reports, literature, health authorities, or any other sources through which we become aware of potential safety concerns. In addition, GMS physicians are major contributors to pediatric regulatory initiatives such as the European Union Article 45 – Pediatric Work Sharing Procedure. The challenge of pediatric pharmacovigilance is to not only address physiologic difference between children and adults but to also be mindful of the continuous states of growth and development within the pediatric population.

The aim of the pediatric experts within Clinical Pharmacology is to develop highly differentiated products more effectively and to optimize benefit-risk by delivering the right dose to the right patient. Clinical Pharmacology closely collaborates with the recently established department of Model Based Drug Development. These groups jointly drive decisions during pediatric

Continued on Page 8
development and for the label by applying the expert knowledge on empirical (e.g., population pharmacokinetics) and mechanistic (physiologically-based pharmacokinetic) modeling techniques to guide pediatric trial design and dosing regimen.

The clinicians, clinical pharmacologists, safety physicians, global trial managers, statisticians, and epidemiologist affiliated with the Pediatric Center of Excellence are continually researching and investigating new and innovative ways to redesign pediatric clinical trials in order to insure safety, ethical conduct, and efficient and viable evaluations of efficacy. The unique challenges of clinical pharmaceutical research in vulnerable infants and childhood populations mandates that we constantly re-evaluate our study designs so that we minimize risk and exposure and maximize potential benefit. The Pediatric Center of Excellence is currently focused on such important issues as aspects of adaptive design; ethical conduct of phase I trials; revision of informed consent and assent documents; maximizing recruitment and retention; and reimbursement and compensation.

It is important that all drug sponsors develop internal expertise to respond to the medical needs of children. In the history of therapeutics, most misadventures affected children when the drugs were given to them in the absence of appropriate data. It has been said that “we should not protect children from research but rather protect them through research.” We in the pharmaceutical industry have the expertise and knowledge to create the necessary information for our products to be used by the most vulnerable members of our society in a way that is safe and effective.

Acknowledgment: All the members of Janssen's Pediatric Center of Excellence for their contributions to this article.
In the last three decades since the first Clinical Research Organization (CROs) was founded, CROs have become important partners in the drug development process along with traditional Biopharmaceutical companies. CROs today provide full services for clinical development of a drug or device on a regional or global basis.

Historically, most biopharmaceutical companies both sponsored and managed all aspects of their clinical trials from protocol development to delivery of a final clinical study report to a regulatory agency. With increasing complex drug development programs and the need for staff in certain regions as well as financial pressures, many biopharmaceutical companies are finding it prudent to outsource some or all drug development duties to Clinical Research Organizations (CROs). This increased rate of outsourcing has had a dramatic impact on the growth of the CRO industry and subsequent increases in opportunities for clinically adept Pediatricians.

For the past 20 years, the Food and Drug administration has encouraged the inclusion of pediatric age groups in clinical trials. By the early 2000s, specific laws had been passed in the US requiring inclusion of children in many clinical trials ( Pediatric Research Equity Act ) and financial incentives for doing trials requested by the FDA ( Best Pharmaceuticals for Children Act ). The European Union enacted legislation in 2007 requiring a Pediatric Investigational Plan accompany each application to the European Medicines Agency. Finally, the permanent reauthorization of BPCA and PREA by Congress as the Food and Drug Administration Safety and Innovation Act (FDASIA) in July 2012, continues to encourage and require the testing of drug products in neonates, infants, children, and adolescents solidifying the need for Pediatricians to provide guidance on the treatment and care [within the context of a clinical trial] in this special population.

CROs provide support services related to drug and device development for the biopharmaceutical and medical device industries including regulatory consultation and support, managing pre-clinical research, Phase 1 and Bioequivalence studies, Phase 2-4 clinical trial management, and commercialization (marketing drugs and devices). Within a CRO, pediatricians have the opportunity to experience the excitement and challenges of working in several therapeutic areas cutting across the entire biopharmaceutical industry. Experience can be obtained in designing and reviewing protocols, serving as advisors to investigators conducting the clinical trials, safety monitoring (pharmacovigilance), teaching non-medical CRO staff, and evaluating the regulatory approval processes for drugs and devices in different stages of development. In addition, because CROs have to bid for business from the biopharmaceutical companies, there are opportunities to participate in sales presentation to potential clients. This business experience would be ideal for pediatricians who have a great interest in sales and dream of closing business deals worth millions of dollars.

Continued on Page 10
For a variety of reasons, many pediatricians decide to leave the world of clinical practice and continue their careers in non-clinical sectors such as the biopharmaceutical and medical device industry. The CRO environment provides an alternative career path for pediatricians who are ready to learn something new while using the knowledge and expertise they have gained in clinical or academic practice. These companies need the expertise of physicians with good clinical and communication skills to perform a variety of tasks. CRO pediatricians serve as the bridge between their pharmaceutical counterpart who is generally a physician and the CRO project team. CRO pediatricians can be expected to review and analyze protocols for adherence to standard of care and any clinical or medical considerations. They may also present the protocol at meetings of physician investigators, train the project teams, review data for safety trends or issues, and communicate with the physician investigators regarding patient eligibility and safety. Additionally, as drug development for Pediatric populations’ increases, many biopharmaceutical companies do not have internal pediatric resources instead relying on the pediatric expertise housed within the CRO to assist in their development design and development.

Within our organization, pediatricians are required to be Board Eligible or Board Certified, licensed in the country of residence and most are trained in a subspecialty area. We hire pediatricians with experience ranging from extensive knowledge of clinical research and pharmaceutical development to minimal experience in either area.

Although pediatricians who work within CROs and biopharmaceutical companies do not provide hands-on patient care, the research they do and the decisions they make impacts the health of the millions of children. It is exciting to be involved in the development of new drugs, devices and technologies several years before they become available to other physicians and the public.

Although CRO Pediatricians are one small step away from the bedside they are one giant leap towards improving the health of children through research.

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**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.
In speaking with people about working in pharmaceutical drug development I am often asked how I got started. From our previous newsletters which have looked at various non-clinical careers that are open to pediatricians I have found that there are about as many paths into non-clinical careers as paths into medicine in general. So perhaps a more tangible question should be “what should I do if I am considering a non-clinical career, such as one in pharmaceuticals?”. To that question, I respond with another question: “What do you want to do?” This then leads to me ask for a list of questions you need to ask yourself. So here they are.

1. What clinical topics (called therapeutic areas or disease areas by those in the know) are you interested or knowledgeable in?
2. What additional skills do you have? Can you write well, speak in public, use Excel?
3. What additional competencies do you have? Do you have a PhD, an MPH, an MBA or a great skill in epidemiology?
4. Are you willing to move?
5. Do you like to travel for work?
6. How well do you work on a team?

The answer to these questions can often point you in a general direction such as working in clinical research or as a field-based medical director. (See the SOATT Fall 2011 Newsletter for further descriptions of these careers) At this point, people tend to ask me, what do I do next. Typically I tell them to begin the search for more information. For those not willing to move, look for research companies that are within driving distance of your home. For those who like to travel look for jobs that are field based in your general area such as the mid-Atlantic region. For those without a clue, it might be helpful to look at pharmaceutical job posting sites such as www.medzilla.com.

Once you have found a company that looks promising (with an interesting existing product or therapeutic area) visit that company’s website and look over their careers section. Perhaps there is job description that is appealing to you. Now might be a good time to look at networking sites such as www.linkedin.com. Look that company up and see if there is anyone there that you know, perhaps an old friend from medical school or residency. Often a personal referral from an inside person can help you tremendously and potentially earn your friend a company sponsored referral bonus (a win-win if there ever was one!)

If you have gotten this far and you are truly interested in applying for a non-clinical position, now might be a good time to consult someone in a similar position such as a friend or colleague in our Section. Advice on a specific company, a written job description or general tips on how to prepare

Continued on Page 12
for the interview from someone with a similar existing job can be a great asset. Feel free to explore the vast area of expertise and experience that exists within our Section. Don't hesitate to use the listserv (insert email address) to ask questions and start conversations. Now might also be a good time to consult with a professional career counseling service or at least a service that can help craft your resume into the style which pharmaceutical companies are more accustom to.

Best of luck to you and if you have any questions you can always ask me….happy to help.

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**Commentary: Making the Transition . . . Continued from Page 11**

**Did You Know?**

The Academy Travel Office is here to serve your travel needs Monday thru Friday from 8:00am till 4:30pm CST. Receive air discounts to AAP meetings and car discounts through Avis and Hertz.

We also offer reservations through Concur on line, for those who prefer to book their own travel. If taking a vacation is what you are looking for then contact Elizabeth Harrison for air, cruises or land packages.

Our toll free number is 888-227-1772.

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

Please submit your idea or article to:

Jackie Burke at jburke@aap.org
Clinical trials in children have resulted in significant improvements in their health care. For example, 5-year survivals of childhood cancers improved significantly as a result of multicenter trials. Consequently, the need for pediatric clinical trials has been increasingly recognized by the scientific community and broader public, leading to new legislations. In 1998, the National Institute of Health (NIH) issued a policy requiring inclusion of children in all human subject research conducted or supported by the NIH unless there are scientific or ethical reasons to exclude them. The Food and Drug Administration (FDA) passed the Modernization Act (FDAMA) Pediatric Exclusivity Provision, which was reauthorized as the Best Pharmaceuticals for Children Act (BPCA) in 2002. This legislation offered financial incentive for pharmaceutical companies to develop drugs for use in children. In 2003, the US House of Representatives approved the Pediatric Research Equity Act or PREA (Bill S.650), giving the FDA the authority to mandate pediatric studies in specific defined conditions, and most recently, on July 9, 2012, the FDA Safety and Innovation Act (FDASIA) was signed into the law and made the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) permanent, supporting the generation of pediatric drug information for patients and providers.

Despite these legislative developments, there exists a shortage of institutional review boards and investigators experienced in pediatric clinical trials and a smaller pool of pediatric patients available for trials. Concerns over discomfort, inconvenience, pain, fear, separation from parents or familiar surroundings is also present. In addition, the potential effects on growing/developing organs, size or volume of biological samples, and the higher costs of pediatric clinical trials combined with the smaller market size for the pharmaceutical industry has limited the number of pediatric clinical trials and lead to extrapolation of data from adult studies and the use of ineffective and even harmful treatments which have not been tested in randomized trials in children. Consequently, this resulted in a delay in the availability of effective interventions for pediatric use.

In addition to these logistical challenges, there are ethical concerns over pediatric research. Some critiques consider Phase 1 safety studies in healthy volunteers and placebo controlled trials where the child is not getting direct benefit from participating in the study as unethical because children are not competent to consent and their involvement provides benefit only to the society.

Children are not small adults. The diseases that affect them, drug metabolism, treatment responses and adverse effects are different from those in adults. In the study Wendler and colleagues from the Department of Bioethics at the NIH entitled “A new justification for pediatric research without the potential for clinical benefit.” (Am J of Bioeth. 2012; 12(1):23-31.) the impact of clinical research without benefit among adolescents enrolled in a research study as assessed. Children 13 to 17 years of age who were involved in a clinical trial in the previous 6 months for any

Continued on Page 14
disorder or as healthy controls at the NIH Clinical Center or Seattle Children’s Hospital were evaluated.

The investigators developed and pretested (cognitive and behavioral pretesting) two survey instruments at the NIH Clinical Center, one for adolescents and one for their parents. The final surveys were used to assess consent/assent, motivations, decision-making, and attitudes. In this paper the investigators presented their findings on the attitudes of adolescents and parents regarding pediatric research. The surveys were conducted in person by interviewers who were specifically trained for this study and who were independent of the clinical trials in which the adolescent respondents were enrolled. The adolescents and their parents were interviewed concurrently and separately; interviews lasted approximately 30 minutes. The interviewers read the questions and recorded respondents’ verbatim answers while the respondents could read along with a copy of the survey as the questions were being read aloud to them.

Overall, 177 of 186 adolescent-parent pairs who were approached completed the survey. 147 adolescent-parent pairs were at the NIH Clinical Center and 30 were at the Seattle Children’s Hospital. Of the adolescents, 51.4% were girls; 72.3% had a significant illness, and 20.9% were healthy. Mean age was 15.1 years. Based on self-report, 69.5% of the adolescents were white 14.7% were African American, and 12.4% were Hispanic. Of the adults, 76.3% were women, with a mean age of 45.3 years. 173 were parents and 4 were legal guardians. Overall, 59.9% of the adolescents were participating in a study that did not offer the prospect of clinical benefit and included non-beneficial research procedures. 33.3% were participating in a study that offered the prospect of clinical benefit but included non-beneficial procedures, such as purely research biopsies, imagining scans, or blood draws.

84.7% of the adolescents and 87.1% of their parents indicated that “helping find better treatments for others who are ill” was “pretty important” or “very important” to their decision to participate in research. 68.9% of the adolescents and 78.0% of the parents felt the adolescent was “helping a moderate amount” or “helping a lot”. 80.8% of the adolescents indicated that they felt “proud,” 5.7% indicated that they felt like a “guinea pig,” and 8.5% indicated that they felt both ways. Adolescents whose parents earned >$50,000 per year were significantly more likely to report feeling like a guinea pig compared with children whose parents earned <$50,000 per year. Similarly, adolescents who lived in urban or suburban area were significantly more likely to report feeling like a guinea pig compared with children who lived in a town or rural area. Many of the adolescents did not regard feeling like a guinea pig as necessarily problematic.

Overall, 90.4% of the adolescents and 91.6% of the parents were “definitely” or “probably” willing to allow the research staff to perform extra blood draws in order to learn something that might help others. Similarly, 64.4% of the adolescents and 65.5% of the parents were “definitely” or “probably” willing to allow the adolescent to undergo an extra skin biopsy. Adolescents who had been diagnosed >6 months prior to the survey were significantly more likely to be willing to undergo the skin biopsy compared with adolescents who had been diagnosed within the previous 6 months. Interestingly there was a discrepancy between adolescents and their parents in terms of willingness to participate in charity vs. research activities. Overall, 67.2% of the adolescents and 80.2% of their parents were equally willing to have the adolescent participate in

Continued on Page 15
charity or research activities; 14.7% of the adolescents and 5.5% of their parents preferred participation in research, and 11.9% of the adolescents and 3.4% of the parents preferred that the adolescent participate in a charitable activity.

These data suggest that adolescents older than 13 years of age and their parents value participating in research where there may not be any direct benefit to them, and that the perception of contributing to the society outweighs the risks encountered. In this study only 39 (22%) of the adolescent participants were healthy and the majority of the adolescents had already been enrolled in a clinical trial. It would be valuable to repeat this study in a larger cohort of healthy adolescents to better understand their motivation to participate in clinical trials.

References

2. Caldwell PH, Murphy SB, Butow PN, Craig JC. Clinical Trials in Children. The Lancet. 2004; 364:803-11
substantial number of newborns are exposed to “illicit” drugs prenatally, including cocaine, amphetamines, and heroin. Considerably more are exposed to “legal” drugs, including nicotine, alcohol, and prescribed psychotropic medications or narcotics, during pregnancy. Exposure to these drugs may impact the course of a woman’s pregnancy and profoundly affect a newborn once delivered. Some pediatricians routinely deal with babies who undergo drug withdrawal while others have the luxury of practicing in an area where neonatologists manage these newborns. Regardless of your own situation, every pediatrician needs to be familiar with the problem of prenatal drug exposure, as we will all manage these infants post discharge and may be asked counsel parents regarding this issue. This article will present a brief overview of the spectrum of neonatal drug withdrawal syndromes, focusing on detection, management, and follow-up.

An Unfortunate Problem
The department of Health & Human services, Substance Abuse and Mental Health Services Administration (SAMHSA), reported in 2006 that among pregnant women, aged 15 to 44 years, 4.0% used illicit drugs in the past month, 11.8% reported current alcohol use, 2.9% reported binge drinking, and 16.5% of pregnant women used tobacco in the month prior to delivery. Furthermore the agency reported that nearly 90% of drug-abusing women are of reproductive age and that substances most commonly abused during pregnancy include cocaine, amphetamines, opioids, marijuana, ethanol, and tobacco.¹

A common presentation
While rounding in the newborn nursery pediatricians often encounter the following scenario:

A nurse is concerned that a baby born the previous afternoon is becoming increasingly fussy, sleeping and feeding poorly, and is somewhat tremulous. The baby's blood sugar and complete blood count (CBC) are normal. A urine drug screen is currently pending. She asks you what to do next…

Astute pediatricians will review the prenatal record to determine if the newborn was exposed to drugs or medications prenatally and then interview the mother regarding possible prenatal drug exposure. However colic, sepsis, meningitis, hypoglycemia, hypomagnesemia, and hypocalcemia may present similarly to neonatal drug withdrawal. To avoid missing non-drug related medical problems, it is prudent to perform a CBC, and obtain a calcium, glucose, and magnesium level on such infants, and when sepsis is suspected to start antibiotics pending culture results.

Getting the History
It is routine obstetrical practice to query patients during pregnancy regarding tobacco, alcohol and prescription drug use, as well as illicit drug use - but some obstetrical providers may be less aggressive when it comes to questioning their patients regarding these sensitive issues. It is

Continued on Page 17
recommended that mothers considered “at risk” be screened with urine tests for drugs of abuse. Those that test positive should be referred for abuse counseling and management as continued use put women at risk for fetal loss, prematurity, in utero growth retardation, and birth asphyxia. Not surprisingly women using illicit drugs may be reticent to volunteer their drug use history, even when aware that it may affect their newborn. There are several common characteristics of substance abusers that should alert experienced obstetricians to the possibility of drug use. These include, enrollment late in pregnancy, missed appointments, and switching providers during pregnancy - and any of these may prompt an obstetrician to request a drug screen. In addition, a history of placental abruption, small for dates or premature babies in previous pregnancies are red flags as well.²

In some communities clinics provide methadone or suboxone to mothers with a history of opiate addiction and will continue treatment during pregnancy. These mothers are made aware that these drugs put their baby at risk for postnatal withdrawal (over 50% of babies exposed to methadone require pharmacologic management³).

Maternal drug screening is voluntary and needs to be done with a women's consent. Refusal to comply with a request is yet another red flag that should make an obstetrician suspicious of illicit drug abuse. Despite screening, substance abusers are notoriously good at concealing their drug use, and a clean obstetrical drug history or a negative maternal drug screen early in pregnancy should not prevent a pediatrician from querying the mother about drug use when suspicious symptoms arise in a newborn. While maternal drug screening requires maternal permission, it is a pediatrician's prerogative to screen a newborn for drugs of abuse when a newborn presents with symptoms that raise suspicions of drug use during pregnancy. Additionally placental abruption, precipitous labor, as well as unexplained premature delivery or growth retardation are reasons to screen a newborn maternal substance abuse. Unfortunately newborn urine tests for drug use can produce false negative results as their ability to detect illicit drugs will vary with the timing of last use, and whether the newborn's first void can be collected for testing. In general newborn urine tests will be positive if a mother used cocaine within 3-4 days of delivery, opiates within 2 to 4 days, methadone within 10 days, and marijuana within 5 days and oxycodone for 4 days. If possible, mothers with a history of suspected illicit drug use should be screened during pregnancy and prior to delivery to document drug exposure. In some states a positive maternal drug screen prior to delivery is reason enough to report the situation to Child Protective Services, while in others, even if a mother has a positive screen, urine must be collected on the baby as well in order to substantiate a report. It is also possible to send samples of the baby's meconium or umbilical cord tissue to testing labs; results can reflect drug use up to 90 days prior to delivery. Unlike urine tests, these are both send out test with results taking several days, and will not be helpful in assisting physicians in determining the immediate cause of a baby’s symptoms, when a mother denies use and the urine test was not done or is negative.

The plot thickens…..

Screening CBC, glucose, magnesium, and calcium all return normal. Exam of the infant shows a jittery baby, with slight hypertonia. The baby has been spitty, with an occasional loose stool. Upon questioning, the baby's mother admits to illicit oxycodone use daily for a chronic back injury and once weekly marijuana use to relieve stress. Both items were not documented in the obstetrical

Continued on Page 18
You also discover that the mother continued to smoke 1 pack per day during the pregnancy and she was on Paxil for chronic depression during the pregnancy. The urine test returns positive for opiates and tetrahydrocannabinol (THC).

Neonatal Drug Withdrawal Syndromes
A variety of drugs and medications can be associated with postnatal drug symptoms, so it is important to recognize that there is range of neonatal drug withdrawal “syndromes” associated with maternal use of nicotine, prescribed SSRIs or opiates, alcohol, as well as illicit drugs including cocaine, amphetamines, and opiates. Most pediatricians are aware that newborn opiate withdrawal is frequently associated with a constellation of symptoms described below and is called the Neonatal Narcotic Abstinence Syndrome (NNAS). As in this scenario, many pregnancies are complicated by polydrug use.

In general, babies born to heavy smokers are at risk for in utero growth retardation from the vasoconstrictive effects of nicotine. Many pediatricians report babies born to mothers to smokers sometimes have fine tremors and increase tone, symptoms which usually resolve within the first day following birth. Those babies born to mother with excessive alcohol consumption are at risk for babies with characteristic features of the fetal alcohol syndrome (FAH), while those without FAH have been reported to frequently experience diaphoresis, excessive crying, tremors or seizures, and poor suck. SSRI medications, especially Paxil (Paroxetine) are similarly associated with tremors and or seizures, extreme fussiness, and change in a baby’s tone. There is no withdrawal syndrome associated with cocaine or amphetamine use prior to delivery; rather symptoms in newborns are the direct effects of the drugs themselves that can include tremors, apnea, tachycardia, excessive crying and fussiness. Symptoms abate within a few day of delivery and rarely require drug therapy. Mothers who use illicit opiates (ie heroin) or prescribed opiates (methadone, oxycontin, suboxone) place their infants at risk for Neonatal Narcotic Abstinence Syndrome (NNAS). Symptoms of NNAS may include tremors and seizures, increased tone, vomiting and loose stools, poor feeding, nasal stuffiness, yawning, and diaphoresis. NNAS is the most drug withdrawal complex encountered by pediatricians and neonatologists, and one that often requires both non-pharmacologic and pharmacologic treatment.

Treatment of Neonatal Withdrawal
The mainstay of treatment of all types of drug withdrawal is providing as comfortable and non-stressful an environment as possible for the affected newborn and soliciting the mother to assist whenever possible. Comfort measures include swaddling, providing a quiet environment, rocking the infant, and providing close body contact. These measures are usually successful for non opiate withdrawal symptoms. Hospitals use a variety of medications to treat babies with withdrawal from opiates or opiates in addition to other drugs of abuse when required. If it is know that a mother used opiates alone during pregnancy then morphine is administered to a baby to treat withdraw with doses based on the level of scores. When mothers have used opiates and other drugs of abuse, some nurseries have found morphine combined with phenobarbital most effective. This author prefers a three-hour dosing schedule, which coincides with a newborns normal feeding pattern. Once a baby’s scores fall below a score of 8 the symptoms are considered “captured” and medication should be continued for a minimum of 48 hours before consideration should be given to weaning medications. Mothers who have abstained from illicit drug use or are
on methadone may be permitted to nurse. Some institutions require mothers to submit urine tests to prove that they drug free before they are allowed either to nurse or provide pumped breast milk for their babies. The NNAS baby’s weight must be closely monitored during treatment, as the symptoms of drug withdrawal often require providing higher calorie formula or enhancing the caloric content of breast milk with breast milk fortifier.

Weaning
Not surprisingly it may take many weeks for a baby to be weaned off morphine, even given an involved family, and an experienced nursery staff. Usually the morphine dose is weaned by 10% (based on the maximum dose found to “capture” the symptoms) every 24 to 48 hours, until a subclinical dose is being administered -when the dose is less than or equal to 0.02 mg/kg/dose and NAS scores are less than 8 for 24 - 48 hours. If the baby is on phenobarbital in addition to Morphine, wean the morphine first and then the phenobarbital can be weaned as an outpatient.

Additional Details and Follow Up
When it has been documented that a baby has been exposed to a long acting opiate (suboxone or methodone), babies should be observed for 5 days before considering discharge. Short acting opiate exposure (heroin, oxycontin) usually requires 3 days of monitoring. It should be noted that withdrawal symptoms from narcotics may not present until 2 weeks of age, so close follow up with a pediatric care provider and home VNA visits are very important. In the hospital, social service needs to get involved, before delivery when possible, and a child protective report filed per state guidelines. Mothers and fathers should be encouraged to room in with their babies and nurses should assess parenting skills and ability to nurture their new baby. Upon discharge any baby treated for Neonatal Narcotic Abstinence Syndrome should have referrals made for early intervention and timely follow up with their pediatrician.

References

Clinical trials in children have led to significant improvements in healthcare and illness outcome.\(^1\) For childhood acute lymphoblastic leukemia, for example, 5-year survival increased from 25% to more than 70% as a result of multicentre trials.\(^2\) Despite this, there is significant lack of robust pediatric trials. As a result, clinicians are often forced to extrapolate data and treatment guidelines from adult studies, which is far from ideal as factors such as disease presentation and responses to medication vary between both populations.\(^3\) The recruitment of children into clinical trials can be more difficult that that for adults. The reasons are many, and include factors that relate to doctors, parents, children, and to the trials themselves.\(^3\) A feature common to all these factors appears to be limited awareness and understanding of pediatric clinical trials, how they are undertaken and the processes involved. A recent paper highlighted the key issues for families of children, in this case those with cancer, when considering entry into a clinical trial. The authors emphasise the importance of understanding what questions the trial is asking and what this means for the individual.\(^4\) The authors make a recommendation, as a means of improving recruitment, to ‘Provide easily understood information about clinical trials (eg, consider inclusion of graphics and magazine-style layout)’.

With this in mind, Medikidz, an international initiative that creates books for children on health and illness, have just published a new title, *Medikidz Explain Clinical Trials*. The aim of the book is to educate children and their families on clinical trials, what they are about, what is involved in the process, and why they are important. The goal of this title, as with all Medikidz books, is to empower children by providing them with medical information that they can understand, without overburdening them with difficult to comprehend medical language. Thus, *Medikidz Explain Clinical Trials* presents sufficient information to children at their level, and in their language, so that children have a greater understanding of what happens in clinical trials and why they are needed.

The Medikidz series of books features five superheroes, all of who have expert knowledge on a particular part of the human body. In each book, the superheroes whisk the child, the central protagonist, off to Mediland, a planet shaped like the human body, to explain all about a particular illness or health concern.

Thus, in *Medikidz Explain Clinical Trials*, Sara goes on an adventure through Mediland for some ‘meducation’. The first thing Sara learns, is why clinical trials are needed:

‘Sara, the first thing you need to know is that scientists and doctors are always coming up with ideas for new treatments for diseases.’ ‘All treatments are tested in a laboratory before people are allowed to use them.’ ‘Only treatments that pass can be treated on people, and that’s where a clinical trial comes in.’

*Continued on Page 21*
As Sara and the Medikidz journey through Mediland and an intergalactic laboratory where vibrant and dynamic visuals complement the sense of adventure and discovery for Sara, Medikidz Explain Clinical Trials demystifies the concept, and brings it alive. A clinical trial is itself enacted, which tests a new ray to make Mediland’s defense force (the immune system army) more deadly to germs!

The content includes sections on permission and assent, pre-trial investigations, as well as a detailed description of the different phases of a clinical trial.

Research suggests that children respond positively to the altruistic aspect of trial participation. This motivating factor is also referred to in Medikidz Explain Clinical Trials:

‘You help doctors and nurses study and maybe find possible treatments for the kind of illness you have.’ ‘You also help other people like you by helping doctors study ways to get better medicines!’

To ensure that children receive a balanced view of what clinical trials are all about, the Medikidz also acknowledge the potentially negative aspects of trials:

‘Trials can be tough for the people taking part.’ ‘Doing all the regular tests and seeing your doctors all the time takes up a lot of time, especially if you’re away from home for a while, which can get tiring.’

It is important that children’s concerns are identified and acknowledged. Interruption in their normal routine has been reported as a significant negative factor for children who have taken part in clinical trials.

It is also important for children to feel informed and involved in decision making when it comes to their health and illness. Thus, Medikidz Explain Clinical Trials seeks to reassure children that they have a choice:

‘You can stop whenever you want. Just tell your researchers that you want to. It can also be really helpful if you tell them why.’

Parents play a vital role in making decisions for pediatric trial participation. At such a stressful time, the concept of a clinical trial can be hugely challenging for many parents. All parents want the best treatment possible for their child, and also want to understand exactly what they might have to endure. Confusion for parents about what clinical trials entail appears to be a significant limiting factor in recruitment to clinical trials.

Medikidz Explain Clinical Trials is a response to the call for better education of the public about trials, and serves to inform both children and their parents about an often misunderstood concept, one which is essential for enhancing clinical care for children and furthering evidence-based pediatrics.
Medikidz Explain Clinical Trials  Continued from Page 21

References


Partners in Progress: Pediatricians Bringing Medical Advances to Patients

Monday, October 28, 2013
1:30 – 4:30 PM
Hyatt Regency Orlando – Orlando Ballroom N.

Program Description

The mission of the SATT is to advance pediatric health and well-being by collaboration, communication and education on the discovery and development of therapeutics and technology and their successful translation into practice. The program will target pediatric practitioners, researchers and others interested in new medicines and technology for children and the pediatric practice. The session will conclude with a one-hour poster session to present interesting and cutting edge pediatric data.

• Introduction to H-program (1:30-1:45PM)
  Gwen Levy, MD, FAAP (NCE Program Chair, P-SATT)
  ○ Introduction of Executive Committee
  ○ Review of mission, goals and objectives
  ○ Introduction of speakers and agenda

• New developments in Pediatric Medical Device Development: Challenges and Resources (1:45-2:15 PM) Priya Venkataraman-Rao, MD
  ○ Focus on medical device development
  ○ New developments and innovations

• Pediatric Medical Device Development: Challenges and Resources (2:15-2:45 PM)
  Linda Ulrich, CAPT, U.S. Public Health Service
  ○ Focus on Orphan product development
  ○ New developments and innovations

• Challenges of Clinical Trials in the Newborn (2:45-3:30 PM)
  Bob Ward, PhD
  ○ Focus on new neonatal research
  ○ Problems and pitfalls associated with this population

• P-SATT Poster Session/Snacks (3:30-4:30 PM)
Your Section is offering a research abstract program beginning with the 2013 NCE. Please stop by Hyatt Regency Orlando Orlando Ballroom N on Monday, October 28 from 3:30 – 4:30 PM to see the research on new innovations in pediatrics. A sneak preview is below:

<table>
<thead>
<tr>
<th>Abstract Title</th>
<th>Presenting Author LastName</th>
<th>Presenting Author FirstName</th>
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<tr>
<td>Efficacy of Live Attenuated Influenza Vaccine Against Moderate to Severe Versus Mild Influenza Illness in Children</td>
<td>Ambrose</td>
<td>Christopher S.</td>
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<td>Visual Freeze Indicators On Each Box of Vaccine Are An Early Warning Tool to Identify Potential for Freeze Damage</td>
<td>Angoff</td>
<td>Ronald</td>
<td>New Haven</td>
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<td>Randomized, Controlled, Phase 2 Trial of STX209 (Arbaclofen) for Social Function in ASD</td>
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<td>Carol</td>
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<td>Prospective Randomized Controlled Trial Assessing the Use of Nebulized Intraperitoneal Bupivacaine in Reducing Postoperative Pain in Children Undergoing Laparoscopic Surgery: Preliminary Results</td>
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<td>Constance S.</td>
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<td>Canines and Childhood Cancer: Measuring the Effects of Animal-Assisted Therapy for Pediatric Oncology Patients, Their Parents and Therapy Dogs</td>
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<td>Amy</td>
<td>Washington</td>
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<td>Use of An Ipad As a Distraction Technique to Reduce Pain During Immunizations and Improve Parent Satisfaction</td>
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<td>Ramzan</td>
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<td>Photoscreening for Refractive Error and Strabismus With a Smartphone App</td>
<td>Vaughan</td>
<td>Joannah</td>
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<td>Practical Validation Of Plusoptix, Iscreen, SPOT and Icheckkids Photoscreeners In Young and Developmentally Delayed Pediatric Patients</td>
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<td>Adherence to ACIP Recommended HPV Vaccine Dosing Intervals: Analysis of Privately Insured Female Cohort, 2006-2011</td>
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<td>A Survey of Patient Satisfaction With a Combined ‘Parent-Child’ Viral Hepatitis Clinic</td>
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<td>The Effect of Regulation On Drug Development and Clinical Research Within the Pediatric Population</td>
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<td>Baby Skin Surface Area Expansion and Possible Relation to Skin Barrier Integrity</td>
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<td>Russel</td>
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I am pleased to announce that as of September this year our section has grown to 313 members. Our number of affiliated members also continues to grow with 10 members from diverse backgrounds such as non-AAP medical doctors, PhDs and PharmDs. Our biggest method of growth continues to be “word of mouth” so please keep telling your friends, co-workers and associates about us.

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 now 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 SATT 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:


Affiliates: https://fs25.formsite.com/aapmembership/affiliate/secure_index.html

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.

Also new from the section is our e-mail newsletter update. The section is active on a number of fronts and we felt the best way to keep SATT members up to date was via e-mail updates. On the following page is an e-mail we most recently sent out to highlight the section’s activities.

Continued on Page 28
A Message from the Membership Committee  Continued from Page 27

AAP SATT UPDATES

Hello SATT! We are exploring this new electronic format to keep our members informed of the work of the Section. Please give us your feedback on this format and any suggestions you may have for content, projects and/or your involvement.

SATT 2013 NCE Program
October 28th (1:30-4:30PM)

- New developments in Pediatric Medical Device Development (Dr. Priya Rao)
- Pediatric Medical Device Development (Dr. Linda Ulrich)
- Challenges of Clinical Trials in the Newborn (Dr. Bob Ward)
- Research Session (Poster/Podium)

SATT KIDS project launching in September in Connecticut!

KIDS is an advisory group of children, adolescents and families focused on understanding, communicating and improving the process of medical innovation for children. KIDS/CT is a collaboration between SATT, the CT Chapter of the AAP, Connecticut Children’s Medical Center and Yale-New Haven Children’s Hospital.

Global Alliance for Pediatric Therapeutics

SATT is a partner in GAPT, pre-competitive public/private partnership between pharmaceutical industry leaders, key pediatric patient advocates, and federal authorities to advance the development of high-quality medicines for children. The results of GAPT’s first project on pediatric formulation palatability assessment will be published in the September issue of Therapeutic Innovation & Regulatory Science. A best practices document on the topic is under development.

SATT 2014 NCE Proposal

- Pediatric Innovation: A Call to Action (plenary)  
  Dr. Stephen Spielberg
- The Impact of Medical Innovation on Children and Families (seminar)  
  Dr. Stephen Spielberg & Ms. Lindsey Elsaesser
- Must-Have Gadgets, Gizmos and Technology For The Pediatric Office (interactive group forum)  
  Dr. Andrew Schuman

**program is pending approval**

SATT Webinars!

Dr. Andy Schuman delivered a very successful inaugural SATT Webinar on May 30th entitled “Gadgets and Gizmos: Best Tech for Pediatric Practice 2013.” Let us know if you have ideas for future Webinar topics.


If you would like to get involved, e-mail lburke@aap.org or visit our Web page at http://www2.aap.org/sections/pedsadvances/index.cfm.
Welcome New Members
(March 2013 to September, 2013)

| Joy B. Jackson                          | Priyanka Sherchan                          |
| Shellon Angela McAllister-Rogers       | Loai Akram Eid                              |
| Ameth Ariel Aguirre                    | Miriva Magar                                |
| Michael Osita Nwaneri                  | Holly Henderson Martin                      |
| Lukasz Witold Jagiello                 | Liliana Morales                             |
| Lidy Lopez                             | Pablo R Casaubon                            |
| Frank J. Steinberg                     | Marvin Camagay Callanta                     |
| Michael M Siegel                       | Zolina Baydid Cruz                          |
| Jeffrey Keith Burton                   | Lilia Fernandez                             |
| Daniel Arthur Goldstein                | Adriana Eva Pasqualini                      |
| Ruby Arline Raya-Morones               | Renato Augusto Zorzo                        |
| Sylvia Lopez                           | Douglas Nobrega Gomes                        |
| Alan Howard Cohen                      | Mayla Faria                                 |
| Irene A Burns                          | Temitope Adegboyega                         |
| Robert Albert Dracker                  | Renata Mazzotti Zampol                      |
| Venkataraman Balaraman                 | Betsabe Petit-Ortunez                       |
| Suzanne M Powell                       | Yury Yakubchyk                              |
| Gwenn S O'Keeffe                       | Deirdre Ita De Ranieri                      |
| Laura A Jana                           | Philip Zachariah                            |
| Deborah Wenkert                        | Lynn Palmer                                 |
| Lefkothea P. Karaviti                  | Birju Shah                                  |
| Mark Ransford Rigby                    | Andrei C Fodoreanu                          |
| Peter Hung-Ngo Vu                      | Manuel A Orta Cobo                          |
| Lou L Horvath                          | Nirbhay Parashar                            |
| Karl Li-Feng Yen                       | Elizabeth Bhoj                              |
| John Edgar Arnold                      | Arpit Kumar Agarwal                         |
| Jeniffer M Campo                       | Pearl Chang                                 |
| Lana Lynn Soylu                        | Adil H Zaidi                                |
| Ari Auron                              | Uma Kurugabti                               |
| Stacie Peacock Shepherd                | Robin Anne Huff                              |
| Sameeksha Meel                         | Mary Ann Short                              |
| Carrie Clement Kelly                   | Rachel E Sobel                               |
| Horacio Plotkin                        | Pirooz Eghetesady                            |
SOATT Member Highlights

Leaders of the World Pediatrics, from the United States and Mexico gathered at the American Academy of Pediatrics National Conference at New Orleans to strengthen ties and contribute to the exchange of information aimed at parents.

From Left to Right:

*Dr Jose Luis García* Past President of CONAPEME, México
*Dr Andreas Konstantopoulos* IPA President
*Dr Ignacio Vazquez* President of CONAPEME México
*Dr Jonathan Klein* MD, MPH, FAAP American Academy of Pediatrics Executive Director
*Dr Alfonso Rodríguez Jaramillo* Editor in Chief for Parents Guidance CONAPEME México

*Continued on Page 31*
Seyfullah Göekce, MD FAAP

Dr. Göekce is a graduate of the Charité Universitätsmedizin Berlin. He completed his pediatric residency at University Medical Center Mainz. He is German board certified by the district physician chamber Rheinhessen (Bezirksärztekammer Rheinhessen). He is a member of the German Society of Pediatrics and Adolescent Medicine and the American Academy of Pediatrics where he had been honored as a fellow.

He has clinical and research interests in numerous aspects of inborn metabolic diseases especially for lysosomal storage diseases and for orphan diseases. Dr. Göekce has participated in clinical trials and in multicenter research studies of treatments for glycogenosis type II (M. Pompe Disease) and Mucopolysaccharidosis type IV and VI as a co-investigator. Currently, he is working as study coordinator for Mucopolysaccharidosis type IV in the working group for Lysosomal Storage Disorders and as physician in the biochemical laboratory at the Center for Children and Adolescent Medicine Johannes Gutenberg University Medical Center Mainz.

Muhammad Waseem, MD, MS, FAAP, FACEP, FAHA

Dr. Muhammad Waseem has completed his pediatric residency training at Lincoln Medical & Mental Health Center Bronx New York in 1997. During his training, he became interested in the acute care of severely injured and critically ill children. He completed his fellowship training in Pediatric Emergency Medicine (PEM) in 2001. He believes that it is the responsibility of pediatricians to provide safe and effective drug therapy to children requiring acute care and resuscitation. During his fellowship, he became actively involved in departmental research activities. After completion of his PEM fellowship, he became the Research Director for the Department of Emergency Medicine at Lincoln Medical & Mental Health Center.

He has completed the Emergency Medicine Basic Research Skills Workshop (EMBRAS) and teaching Fellowship and Advanced Teaching Fellowship from the American College of Emergency Medicine (ACEP). In 2011, Dr. Waseem received a Master's Degree in Clinical Investigation at Cornell University. In 2013, he received an additional Master's Degree in Clinical Epidemiology and Health Services Research. He is an active member and Vice Chair of Intuitional Review and Ethics Board (IRB) at Lincoln Medical & Mental Health Center. He has been teaching and leading resuscitation courses including PALS, ACLS and ATLS at Lincoln Medical & Mental Health Center for many years. For his teaching, he received recognition when he was awarded “Teacher of the year” by ACEP and “Doctor of the year by Health & Hospital Corporation (HHC) in 2011.

Dr. Waseem is an active member of the American Academy of Pediatrics (AAP) participating in the Section of Emergency Medicine (SOEM) and Provisional Section on Advances in Therapeutics & Technology (PSATT). He is a Fellow of AAP, ACEP and the American Heart Association (AHA). He also serves on the pediatric emergency medicine and research committees of ACEP and is a Regional Faculty for AHA. Dr. Waseem is a member of the research committee of the New York Section of ACEP Currently, he is an Associate Professor of Emergency Medicine (Clinical Pediatrics) and Public Health at Well Medical College of Cornell University New York. He enjoys teaching and mentoring students, residents and junior faculty.